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Assessment of Impacts of a European Register of Products Containing Nanomaterials

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Assessment of Impacts of a European Register of Products Containing Nanomaterials

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Preliminary Remark by the Contracting Authority

In June 2012 the German Federal Environment Agency (in the following: UBA) published a "Concept for a European Register of Products Containing Nanomaterials"[1] (in the following: ENPR concept), which is build on the present substance-related regulations and particular product-related regulations, supplements and adapts such regulations where necessary, and consolidates the information in a register.

In order to estimate costs for notifiers and competent authorities as well as benefits for all actors and the environment that are associated with such an ENPR UBA commissioned a study for an impact assessment. One of the aims of the study was a comparison between the ENPR concept proposed by UBA, which foresees a horizontal register that is build on the present substance-related regulations and particular product-related regulations, and the alternative of a new, separate register which is structured independently from existing EU product- and substance-related regulations and therefore causes duplicate obligations.

While conducting the study various difficulties occurred, which resulted in a lower reliability of the determined figures than UBA had hoped to achieve. The determination of the figures was complicated due to various reasons. The companies were not interested or not able to substantiate the high burden that they allocate to such a register with reliable figures. In addition to the uncertainties regarding the nano-definition, quite a number of companies do not seem to have knowledge of the possible content of nanomaterials in their products. Due to the fact that the European Commission has still not put forward a proposal regarding the adaptation of REACH to nanomaterials, there are also uncertainties which information that would then already be available via chemicals legislation could be used for such a register.

Basically, the cost estimation for such a product register is difficult, because there are currently insufficient information on nanomaterials and their areas of application on the market. The information on the French national nanoproduct register[2] which is now published by France could not be considered within the duration of the project.

Because of the difficulties in data collection, the calculation of costs was problematic because much of the data is based on assumptions. Here, more comprehensive descriptions of the model assumptions and variance analysis of the input parameters would be desirable. This was no longer possible to accomplish in the context of this study. Despite the limited capacity, we decided to publish the study. We understand it as a basis for further reflection and discussion on the impact assessment. The necessary more detailed derivations will hopefully be analysed in the course of the project[3] commissioned by the European Commission.

[1] http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products

[2] http://www.developpement-durable.gouv.fr/IMG/pdf/Rapport_public_format_final_20131125.pdf

[3] https://infoeuropa.eurocid.pt/files/database/000053001-000054000/000053345_2.pdf

Nonetheless, from the perspective of UBA the results of the impact assessment show a clear trend. Nanomaterials are used in a variety of products that can be attributed to a wide variety of sectors. An ENPR, which is build on present substance- and product-related regulations, would cost the notifiers significantly less than an independent register which causes duplicate obligations. In general, the extent of additional costs differs depending on the economic sectors. Economic Sectors that are currently not subject to notification are inherently more affected than notifiers that have to generate the necessary data already now. The costs caused by such a register must be considered in relation to the economic strength of the sectors. This sector specific assessment, that would allow statements about the relative price effect on specific product groups, was not reliably possible on the basis of the collected information.

It was determined that in total 5-8% of the identified companies (766,600), whose main activity is in the surveyed sectors, would be obliged to notify. However, the extent of notification between the various sectors differs considerably. The analysis shows that in particular the product categories: "Coating & inks", “rubber products", " paper products", "cosmetics" and "health care" would be subject to notification. In addition to the use in pigments and paints the obligation to notify is attributed to the use of nanomaterials as fillers. This concerns, amongst others, substances such as calcium carbonate (paper and plastics), synthetic amorphous silica (paints, coatings, adhesives and sealants, plastics and rubber) or carbon black (rubber and to a lesser extent in plastics and paints).

For sectors with a low number of notifications the ratio of the implementation costs to the recurring costs, such as updating of information, is high. The costs result from the necessary adaptation of business processes, training of staff and the administrative start-up costs when submitting the data for notification. For sectors with a high number of notifications, the ratio of costs to the recurring cost is low because potentially hundreds of products have to be updated (checked). Overall, the implementation costs are 4 to 5 times higher than the recurring costs. In general, the costs for substances are an order of magnitude lower compared to the costs of mixtures and articles.

In case the ENPR is build on existing obligations in substance- or product-related regulations significant lower cost can be expected. Thus, for substances registered under REACH 90-95% savings are expected, 80% in the area of cosmetics, 95% for food (Novel Food Regulation), and 40% for cleaning & disinfection (partly Biocidal Products Regulation). For product groups where there are currently no notification obligations, no significant reduction of administrative costs is expected.

The estimation of costs for the competent authority was based on the existing experience of authorities that manage similar registers. The contractor estimates the hardware and software costs for an ENPR at approximately 500,000 €, if a self-sufficient system without interface with other databases from EU regulations (e.g. REACH, cosmetics regulation) is created. The transfer, modification and integration of data from databases of these other regulations into the ENPR-database would cause additional costs. Staff costs for the maintenance of the register have to be added.

Regarding the effects on innovation & competition it can be concluded that a single ENPR on the European level would cause far less market distortion than individually different registers at the national level.

Public authorities and governments, consumers and companies can benefit from an ENPR in many ways. Public authorities are provided with a comprehensive overview on the use of nanomaterials in various sectors, information on the possible exposure of humans and the environment to nanomaterials and support in the selection of possible risk management measures. In addition, it supports the competent authorities in charge of the permission and enforcement of environmental, consumer and workers' health protection rules by informing about the notifier and the nanomaterials used.

Companies, particularly manufacturers of a final product, benefit from the improved knowledge about the use of nanomaterials throughout the entire production chain. This improves traceability and plays an important role for companies and public agencies in taking the necessary risk management measures.

An advantage for consumers is the possibility of a choice between products containing nanomaterials and products without nanomaterials. This can be enabled to consumers by means of a notification number for the nanomaterials containing product. In connection with labelling a number of industry representatives fear that consumers will interpret this as a hazard warning. Nevertheless, notification numbers can also be interpreted as evidence of regulatory control. This transparency can create or retain trust in this technology.

The study provides important insights into factors that have a high impact on the cost-benefit ratio of a register. For example, it was found that information about the release in the waste phase is important in order to determine whether a product falls under the notification obligation. However, information on the possible release of nanomaterials in the waste phase is available only to a small extent so far. In this area, we hope to be able to close knowledge gaps in the course of various ongoing projects, inter alia by UBA[4].

From the results of the study UBA concludes that the creation of a horizontal European register of products containing nanomaterials, which is build on present substance- and product-related regulations, is preferable to a separate register.

[4] "Incineration of manufactured NM in a test facility and afterwards in two real waste incineration plants" (term 2012 - 2015). http://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology/research-development-projects.

Vorbemerkung des Auftraggebers

Im Juni 2012 veröffentlichte das Umweltbundesamt ein Konzept[5] über die mögliche Ausgestaltung eines europäischen Registers für nanomaterialhaltige Produkte (im Folgenden: ENPR), welches sektorübergreifend auf bestehende Stoff-und Produktregelungen aufsetzt, diese wo erforderlich anpasst, sowie die notwendigen ergänzenden Regelungen trifft und die daraus gewonnene Informationen in ein Register zusammenführt. Um die Kosten für Meldepflichtige und Behörden sowie den Nutzen für alle Akteure und die Umwelt, die ein solches Register mit sich bringt, abzuschätzen, hat das Umweltbundesamt ein Gutachten zur Folgenabschätzung in Auftrag gegeben. Ziel war dabei auch der Vergleich zwischen dem vom Umweltbundesamt vorgeschlagenen Konzept, welches ein horizontales Register, das mit stoff- und produktrechtlichen Regelungen abgestimmt wird, vorsieht und der Alternative eines neuen, eigenständigen Registers, welches neben den bereits bestehenden Regelungen steht und dadurch Doppelpflichten für Meldepflichtige verursachen würde.

Während der Durchführung des Gutachtens traten verschiedene Schwierigkeiten auf. Die Belastbarkeit der ermittelten Zahlen fiel dann nicht so hoch aus, wie vom Auftraggeber erhofft. Die Datenerhebung gestaltete sich aus verschiedenen Gründen kompliziert. Die Unternehmen waren nicht bereit oder in der Lage, die von ihnen abstrakt angeführten hohen Belastungen durch ein solches Register mit belastbaren Zahlen zu hinterlegen. Neben den Unsicherheiten im Umgang mit der Nanodefinition scheinen recht viele Unternehmen derzeitig kaum Kenntnisse darüber zu haben, ob Nanomaterialien in ihren Produkten enthalten sind. Aufgrund der Tatsache, dass die EU-Kommission noch immer keinen Vorschlag zur Anpassung der REACH-VO an Nanomaterialien vorgelegt hat, bestehen außerdem Unsicherheiten, welche chemikalienrechtlich dann bereits vorliegenden Informationen für ein solches Register genutzt werden könnten.

Grundsätzlich ist die Aufwandabschätzung für ein solches Produktregister schwierig, weil derzeit nur unzureichende Informationen über die auf dem Markt befindlichen Nanomaterialien und ihre Einsatzbereiche bestehen. Die inzwischen von Frankreich veröffentlichten Informationen zum nationalen Nanoproduktregister[6] konnten innerhalb der Laufzeit des Projektes nicht mehr berücksichtigt werden.

Wegen der Schwierigkeiten bei der Datenerhebung war auch die Berechnung der Kosten problematisch, da ein Großteil der Daten auf Annahmen beruht. Hier wären umfassendere Beschreibungen der Modellannahmen und Varianzanalysen der Eingangsparameter wünschenswert. Diese konnten im Rahmen des Gutachtens nicht mehr geleistet werden. Wir haben uns trotz der eingeschränkten Belastbarkeit dazu entschieden, das Gutachten zu veröffentlichen. Wir sehen es als eine Basis für weitere Betrachtungen und Diskussionen zur Folgenabschätzung. Die notwendigen detaillierteren Ableitungen werden hoffentlich durch das

[5] http://www.umweltbundesamt.de/publikationen/konzept-fuer-ein-europaeisches-register-fuer

[6] http://www.developpement-durable.gouv.fr/IMG/pdf/Rapport_public_format_final_20131125.pdf

von der EU-Kommission in Auftrag gegebene Projekt[7] „Study to assess the impact of possible legislation to increase transparency on nanomaterials on the market“ geleistet werden.

Nichtdestotrotz zeigen aus Sicht des Umweltbundesamtes die Ergebnisse der Folgenabschätzung einen klaren Trend. Nanomaterialien werden in einer Vielzahl von Produkten, die den verschiedensten Sektoren zugerechnet werden können, eingesetzt. Ein ENPR, welches auf bestehende stoff- und produktrechtliche Regelungen aufsetzt, würde deutlich weniger Kosten für den Meldepflichtigen versuchen als ein Register, welches Doppelpflichten auslöst. Generell unterscheidet sich der Umfang der zusätzlich entstehenden Kosten je nach Wirtschaftssektoren. Wirtschaftssektoren, die bisher keiner Meldepflicht unterliegen, sind naturgemäß stärker betroffen als Meldepflichtige, die notwendige Daten bereits jetzt generieren müssen. Die Kosten, die durch ein solches Register verursacht werden, müssen im Verhältnis der Wirtschaftskraft der Sektoren betrachtet werden. Diese sektorspezifische Bewertung, die Aussagen zu dem relativen Preiseffekt auf konkrete Produktgruppen erlauben würde, war auf der Basis der erhobenen Informationen nicht belastbar möglich.

Es wurde ermittelt, dass insgesamt 5-8% der ermittelten Unternehmen (766.600), deren Hauptaktivität in den untersuchten Sektoren liegt, notifizierungspflichtig wären. Allerdings unterscheidet sich das Ausmaß der Notifizierungspflicht zwischen den verschiedenen Sektoren erheblich. Die Analyse zeigt, dass insbesondere die Produktkategorien: „Lacke & Farben, “Gummierzeugnisse”, “Papiererzeugnisse”, “Kosmetika“ und “Gesundheitspflege” einer Notifizierungspflicht unterliegen würden. Insbesondere ist hier, neben der Verwendung in Farben und Lacken, die Notifizierungspflicht auf die Verwendung der Nanomaterialien als Füllstoffe zurückzuführen. Dies betrifft unter anderem Stoffe wie Kalziumkarbonat (Papier und Kunststoffe), Siliziumdioxid (Farben, Lacke, Klebstoffe und Abdichtungsmittel, Kunststoffe und Gummi) oder Carbon Black (Gummi und zu einem geringeren Anteil in Kunststoffen und Farben).

Für Sektoren mit einer geringen Anzahl von Notifizierungen ist das Verhältnis der Implementierungskosten zu den wiederkehrenden Kosten wie zum Beispiel Fortschreibung der Informationen hoch. Die Kosten werden durch die nötige Anpassung der Unternehmensabläufe, Schulung der Mitarbeiter und die administrativen Anfangskosten bei der Eingabe der meldepflichtigen Daten ausgelöst. Für Sektoren mit einer hohen Anzahl von Notifizierungen ist das Verhältnis der Kosten zu den wiederkehrenden Kosten niedrig, weil potenziell hunderte Produkte aktualisiert (geprüft) werden müssen. Insgesamt sind die Implementierungskosten 4 bis 5 Mal höher als die wiederkehrenden Kosten. Im Allgemeinen sind die Kosten für Stoffe eine Größenordnung niedriger im Vergleich zu den Kosten für Gemische und Erzeugnisse.

Greift ein ENPR auf bereits bestehende Pflichten in stoff-und produktrechtlichen Regelungen zurück, sind bedeutsame Einsparungen zu erwarten. So sind für Stoffe, die unter REACH registriert sind, 90-95% Ersparnisse zu erwarten, im Bereich der Kosmetika 80%, Lebensmittel

[7] https://infoeuropa.eurocid.pt/files/database/000053001-000054000/000053345_2.pdf

(Novel Food Verordnung) 95% und Reinigung & Desinfizierung (teilweise Biozid-Verordnung) 40%. Für Produktgruppen, bei denen es bisher keine Regelungen gibt, kommt es zu keiner signifikanten Reduzierung der administrativen Kosten.

Die Abschätzung der Kosten für die zuständige Behörde wurde basierend auf den bestehenden Erfahrungen bei Behörden erstellt, die ähnliche Register verwalten. Der Auftragnehmer schätzt die Hard- und Softwarekosten für ein ENPR auf ca. 500.000 €, wenn ein autarkes System ohne Schnittstelle mit anderen Datenbanken aus EU Regularien (z.B. REACH, Kosmetik-Verordnung) ausgebaut wird. Der Transfer, die Modifikation und die Integration von Daten aus Datenbanken anderer Regularien in die ENPR-Datenbank würden zusätzliche Kosten verursachen. Hinzu kommen Personalkosten für die Unterhaltung des Registers.

Hinsichtlich der Auswirkung auf Innovation und Wettbewerb lässt sich schließen, dass ein europaweites einheitliches NPR weit weniger Wettbewerbsverzerrung verursachen würde, als bereits existierende bzw. sich in Entwicklung befindliche individuell unterschiedliche Register auf nationaler Ebene.

Ein ENPR könnte Behörden und Regierungen, Konsumenten und Unternehmen auf vielfältige Weise Nutzen bringen. Den zuständigen Behörden liefert es einen umfassenden Überblick über die Verwendung von Nanomaterialien in verschiedenen Sektoren, Informationen über die mögliche Exposition von Menschen und der Umwelt durch Nanomaterialien und Unterstützung bei der Auswahl möglicher Risikomanagementmaßnahmen. Darüber hinaus unterstützt es die Genehmigungs- und Überwachungsbehörden im Bereich der Umwelt-, Arbeitsschutz- und Verbraucherschutzvorschriften durch Informationen zum Notifizierungspflichtigen und über die eingesetzten Nanomaterialien.

Unternehmen, insbesondere Hersteller eines Endproduktes, könnten durch eine verbesserte Kenntnis über die Verwendung von Nanomaterialien über die gesamte Herstellungskette eines Produktes profitieren. Dies verbessert die Rückverfolgbarkeit und spielt für Unternehmen und Behörden eine wichtige Rolle bei der Ergreifung von Risikomanagementmaßnahmen.

Ein Vorteil für Verbraucher ergibt sich durch die Möglichkeit einer Wahlfreiheit zwischen nanomaterialhaltigen Produkten und Produkten ohne Nanomaterialien. Dies kann den Konsumenten mit Hilfe einer Notifizierungsnummer für das Nanoprodukt ermöglicht werden. Im Zusammenhang mit einer Kennzeichnung befürchten einige Industrievertreter, dass diese von den Kunden als Gefahrenhinweis interpretiert wird. Gleichwohl können Notifizierungsnummern auch als Nachweis einer behördlichen Kontrolle interpretiert werden. Durch diese Transparenz kann Vertrauen in diese Technologie geschaffen werden bzw. erhalten bleiben.

Aus dem Gutachten konnten wichtige Erkenntnisse über Faktoren erlangt werden, die einen hohen Einfluss auf das Kosten-Nutzen-Verhältnis eines Registers haben. Zum Beispiel zeigte sich, dass Informationen über die Freisetzung in der Abfallphase wichtig sind, um zu bestimmen, ob ein Produkt unter die Meldepflicht fällt. Allerdings liegen Informationen zur möglichen Freisetzung von Nanomaterialien in der Abfallphase bisher nur in geringem Maße

vor. In diesem Bereich hoffen wir durch die laufenden Projekte, unter anderem des Umweltbundesamtes[8], Wissenslücken schließen zu können.

Aus den Ergebnissen des Gutachtens folgert das Umweltbundesamt, dass die Schaffung eines europäischen Registers für nanomaterialhaltige Produkte, welches sektorübergreifend auf bestehende Stoff-und Produktregelungen aufsetzt, dem einer gesonderten Regelung vorzuziehen ist.

[8] "Untersuchung möglicher Umweltauswirkungen bei der Entsorgung nanomaterialhaltiger Abfälle in Abfallbehandlungsanlagen" (Laufzeit 2012 - 2015).
http://www.umweltbundesamt.de/themen/chemikalien/nanotechnik/forschungs-entwicklungsvorhaben

Report Cover Sheet

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Abstract

The implementation of a nanoproduct register as an instrument to increase the transparency on the use of nanomaterials in the EU and to ensure the regulatory oversight on nanomaterials has been discussed for quite a time. Reasons to implement a register are the uncertainties concerning the evaluation of the possible risks of nanomaterials for human health and the environment and the lack of knowledge of consumers and authorities regarding the use and concentration of nanomaterials in products. In June 2012 the German Federal Environment Agency has published a “Concept of a European Register of Products Containing Nanomaterials” (ENPR). According to the concept the manufacturer and importer of nanomaterial containing products with a likely exposure of nanomaterials to human beings and the environment should notify them to a single European register. It is the aim of this study to analyze the impacts of such an ENPR. Therefore sectors and companies concerned by an ENPR were identified and the number of notifiers and notifications, categories of substances, concerned mixtures and articles were estimated. Based on that result the administrative costs for notifiers and the competent authority for an ENPR were quantified and the benefits of an ENPR for public authorities, consumers and notifiers described.

Kurzbeschreibung

Die Einführung eines Nanoproduktregisters als ein Instrument zur Verbesserung der Transparenz über die Verwendung von Nanomaterialien in der EU und zur Gewährleistung des regulatorischen Überblicks über Nanomaterialien wird schon seit einiger Zeit diskutiert. Gründe dafür sind die Unsicherheiten in der Bewertung möglicher Risiken für menschliche Gesundheit und die Umwelt und das Informationsdefizit der Behörden und Konsumenten im Hinblick auf die Konzentration von Nanomaterialien in Produkten. Im Juni 2012 hat das Umweltbundesamt ein „Konzept für ein europäisches Register für nanomaterialhaltige Produkte“ (ENPR) veröffentlicht. Das Konzept sieht vor, dass Hersteller und Importeure von bestimmten Nanoprodukten, bei denen eine Exposition von Menschen und der Umwelt mit Nanomaterialien möglich ist, diese in einem europäischen Register notifizieren. Es ist das Ziel dieser Studie, die Folgen eines solchen ENPR abzuschätzen. Dazu wurden die betroffenen Sektoren und Unternehmen ermittelt und die Anzahl der Notifizierer, Notifizierungen, Stoffkategorien, Gemische und Erzeugnisse bewertet. Basierend auf diesen Ergebnissen wurden die administrativen Kosten für die Notifizierer und der registerführenden Behörde quantifiziert sowie die Vorteile des ENPR für Behörden, Konsumenten und Notifizierer beschrieben.

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List of Abbreviations

a	annum
Ag	Argentum
A.I.S.E.	International Association for Soaps, Detergents and Maintenance Products
Art.	Article
Al_2O_3	Aluminium oxide
BET	BET theory, BET model (isotherm), named after its developers, Stephen Brunauer, Paul Hugh Emmett und Edward Teller
BEUC	The European Consumer Organisation
BfR	Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment)
BImSchG	Bundes-Immissionsschutzgesetz (Federal Immission Control Act)
BMU	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety)
BPD	Biocidal Product Directive
BPR	Biocidal Product Regulation
BUND	Bund für Umwelt und Naturschutz Deutschland e. V. (Friends of the Earth Germany)
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety)
Ce_2O	Cerium oxide
CAS	Chemical Abstracts Service
CASG	Competent Authority Subgroup
CB	Carbon Black
CE	CE mark(ing) (EU trade “passport”)
CEN	Comité Européen de Normalisation (European Committee for Standardisation)
CLP	EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures
CMP	Chemical mechanical polishing/planarization
CMR	Carcinogenic, mutagenic or toxic for reproduction
CNT	Carbon nanotubes
Com, COM	Commission of the European Union
Dv	median diameter
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DNA	Deoxyribonucleic acid

Doc	Document
DÖV	Die öffentliche Verwaltung (German journal of public administration)
e.V.	eingetragener Verein (registered association, legal status for a registered voluntary association in Germany and Austria)
EC	European Community
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EEC	European Economic Community
EFSA	European Food Safety Authority
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINC	European list of notified chemical substances
EMA	European Medicines Agency
EN	Europäische Norm (European Standard)
ENM	engineered nanomaterial
EP	European Parliament
ENPR	European Register of Products Containing Nanomaterials
ETAD	Ecological and Toxicological Association of the Dyes and Organic Pigments Manufacturers
et al.	and others
ETRMA	European Tyre & Rubber Manufacturers' Association
EU	European Union
ff.	and following pages
h/hrs	hour/hours
IEC	International Electrotechnical Commission
IEC/TC	International Electrotechnical Commission / Technical Committee
IED	Industrial Emissions Directive
IP	Intermediate Producer
ISO	International Organization for Standardization
ISO/TC	International Organization for Standardization / Technical Committee
IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre
LCA	Life Cycle Analysis
NGO	Non-governmental organization
NIHS	The National Institute of Health Sciences, Japan

NIA	Nanotechnology Industries Association
n.a.	not available
NM	manufactured nanomaterial
nm	nanometre
No	number
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal
PBT	Persistent, bioaccumulative and toxic (chemical)
PCC	Precipitated calcium carbonate (PCC)
PEN	The Project on Emerging Nanotechnologies
PET	Polyethylene terephthalate
QSAR	Quantitative Structure Activity Relationship
REACH	EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIP-oN	REACH Implementation Project Substance Identification of Nanomaterials
RPA	Risk and Policy Analysis Ltd (RPA)
SAS	Synthetic amorphous silica
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SME	Small and medium-sized enterprises
TiO_2	Titanium dioxide
t	tonne
TFEU	Treaty on the Functioning of the European Union
TS	Technical specification
UBA	Umweltbundesamt (Federal Environment Agency)
UV	ultraviolet
vPvB	Very persistent, very bioaccumulative
WPMN	Working Party on Manufactured Nanomaterials
yr	year
ZnO	Zinc oxide

Summary

Background and study objectives

Since the early days of the public debate on the possible benefits of nanomaterials for society and their possible risks for the environment and human health a register for products containing nanomaterials has been discussed as an instrument to facilitate transparency on the use of nanomaterials. Up to the year 2013 a number of approaches to report nanomaterials in Europe and other countries, either voluntary or mandatory, have been proposed and implemented. Several EU Member States support the introduction of databases or registries for gathering necessary information on (products with) nanomaterials to address current uncertainties surrounding health and environmental safety and regulatory shortcomings. France has become the first country to require manufacturers to identify uses of substances in nanoform in the frame of a mandatory reporting scheme. Denmark and Belgium have published legislative proposals for a mandatory reporting scheme for nanoproducts. In June 2012 the German Federal Environment Agency (UBA) published a "Concept for a European Register of Products Containing Nanomaterials"[9] (in the following: ENPR-concept). According to the concept manufacturers and importers of substances, mixtures which comprise or contain nanomaterials as well as articles that intentionally or unintentionally release nanomaterials should notify a limited set of data to a single European register.

Against that background the central task of this study was to assess impacts of the ENPR-concept. To this aim the the sectors and companies concerned by an ENPR were identified and the number of notifiers, categories of substances, concerned mixtures and articles as well as the number of notifications were estimated. It must be pointed out that the ENPR-concept is deliberately planned to encompass a wide scope of products containing nanomaterials in order to estimate the maximum costs of an ENPR in this preliminary stage. On the basis of this assessment the scope of an ENPR in the implementation phase can be tailored according to several aspects, for example the focus of nanomaterials according to the precautionary principle and the proportionality principle taking into account the cost-benefit ratio of an ENPR. Based on the estimated number of notifications the costs for the affected industry and for the implementing authority were quantified. This is followed by a qualitative assessment of the ENPR-concept concerning the effects on innovation and competition as well as the benefits for public authorities, consumers and notifiers. Finally, a summary of the overall impacts of the ENPR-concept is presented.

Concept of a European Register of Products Containing Nanomaterials (ENPR)

The ENPR-concept revolves around the precautionary principle. It is based on the possibility of negative effects on human health and the environment that could be the consequence of widespread use and thus exposure to nanomaterials of various origins.

[9] UBA (2012).

In order to reduce administrative efforts and costs for notifiers and public authorities and to avoid regulatory overlaps resulting from possibly several national nanoproduct registers, it is recommended to establish a single register on European level; ideally replacing national nanoproduct registers.

Subject to notification are "nanoproducts". The term is used as a general term comprising the following substances, mixtures and articles: substances which are nanomaterials within the meaning of the COM recommendation. Mixtures which comprise or contain nanomaterials above a concentration threshold of 0.001% weight by weight (w/w) referred to the whole mixture. Articles containing nanomaterials, intended to be released under normal or reasonably foreseeable conditions of use. Articles containing nanomaterials above a concentration threshold of 0.1% weight by weight (w/w)[10] referred to the whole article, unless the producer or importer can exclude release from the article to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In case an article is produced or imported that consists of several sub-assemblies, the 0.1%-threshold applies to every incorporated sub-assembly and not to the whole article.

Manufacturers and importers of substances, initial distributors of mixtures and producers and importers of articles have to notify their nanoproducts. Repackaging, relabelling and marketing for an application other than that notified by the initial notifier triggers an independent notification obligation.

Notifiers have to submit the following information: name and address of the notifier, product and trade name (excluding variations of a product), application, functionality of the nanomaterial(s) employed, characterisation of nanomaterial(s), concentration of the nanomaterial in the respective product and manufactured or imported tonnage bands of the nanomaterial(s). The collected data is divided into a publicly accessible and a confidential part. To avoid duplicate reporting obligations for notifiers the ENPR should be designed as a horizontal register that is empowered to collect data on nanoproducts from other substance regulations (e.g. REACH- and CLP-Regulation) and product regulations (e.g. Cosmetics Regulation). Should one or more data points required for the ENPR not be included in the sector regulation, the ENPR-concept postulates to adapt the sector information requirements by means of an umbrella regulation. Thus a notifier has to notify the information only once.

Following the notification the competent authority awards a single ENPR notification number to every notification made and communicates it to the notifier. When the notifier puts a substance, mixture or article on the market that has to be notified, he hands down the ENPR notification number(s) in the production chain to users. Any actor in the production chain who puts an article on the market which is subject to notification according to the conditions listed in Chapter 2.2 has to notify it. This is inter alia the case, if an actor in the production chain modifies a nanomaterial itself or a nanomaterial contained in a mixture or an article in a way that leads to changes in properties of the nanomaterial. Similarly the change of the concentration of nanomaterial used would trigger the obligation to notify.

[10] Referring to the substance in question.

Identification of sectors concerned

Based on the criteria "high production volumes" or "wide dispersive uses" or "sufficient information on uses available from publicly accessible sources" the following nanomaterials were selected for the impact assessment: Carbon Black, Synthetic Amorphous Silica, Aluminium Oxide, Barium Titanate, Titanium Dioxide, Cerium Oxide, Zinc Oxide, Carbon Nanotubes, Nanosilver and Fullerenes. For each of the selected materials, their uses in certain applications and product groups were determined and subsequently they were grouped in the following eleven sectors or categories: Substances, Cosmetics, Health Care, Food & Feed, Coatings & Inks, Cleaning & Disinfection, Rubber Products, Building & Construction, Textiles, Paper Products and Complex Objects & Other Products.

Natural and incidental nanomaterials as well as polymers are excluded from the scope of this study. Nature is extremely prolific when it comes to nanomaterials. Adhering to the definition within Art. 3 (39) REACH of natural substances (including nanomaterials) and recognizing that natural nanomaterials are not well characterised they were omitted from the scope of this study. They cease to be natural when any change is effected that goes beyond the REACH definition of natural substances. Any other treatment than specified in Art. 3 (39) will result in the loss of the 'natural' state. By choosing this limitation a wide range of everyday products such as gardening soil, lime, coal etc. are excluded from the scope of the study. Similarly a definition of incidental nanomaterials became necessary in the course of this study to further focus the ENPR. Without this definition virtually every product would be included in the ENPR making data acquisition, evaluation, and application of the final dataset to specific questions unmanageable. Additionally, polymers are excluded from the scope of the study. Depending on the polymer the molecules can achieve lengths of 1 nm or more. That does not necessarily make them particular. The associated uncertainties led to the exclusion from the scope. In all three cases the specifics of defining the materials in question are subject to debate and need to be revisited in case of an ENPR being implemented.

Expected number of companies and nanoproducts per sector

For each of the abovementioned sectors or categories a quantitative estimation of the number of companies in each sector (obtained from Eurostat for the relevant NACE categories), an estimation of the number of those companies having to notify a product, and an estimation of the number of notifications has been made. As a result as many as 5-8% (or 37.500-58.000) of all 766.660 enterprises whose main activity was in the economic sector investigated may be affected by the implementation of an ENPR. However this general picture is distorted by businesses that were assigned to the sector "complex objects and other products" and which make up the large majority of all companies analysed (roughly 75% or 580.430 enterprises). At the same time, however, they account for only about 6-10% (or 3.000-6.000) of all companies affected.

A more detailed analysis reveals that following sectors could be particularly affected due to a high number of notifications within the sector: "coatings & inks" (90-95% of all companies in this sector), "rubber products" (75-90%), "paper products"(60-80%), "cosmetics" (60-80%) and "health care" (50-80%).

The implementation of the ENPR could lead to as many as 4.1 million notifications, the large share of which can be attributed to coatings & inks (roughly 60%), "paper products"

(around 25%), “rubber” and “textile products” as well as “complex objects and other products” (around 3.5% each). Each company affected needs to submit between 16 and 57 notifications. Whereas the administrative burden for companies affected accounts for 5 to 20 notifications on average, businesses within the sectors health care, paper products and complex objects and other products could be obliged to notify as many as 75 products per company, and entities in the sector coatings & inks could be particularly affected, with up to 610 notifications per company.

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

Direct costs for industry

The costs for industry were analysed in two scenarios:

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

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

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

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

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

- Some sectors could be particularly affected, such as Coatings & Inks with 6.26 -10.20 million hours (e.g. approximately 44-50% of the costs for notifiers in case the product notification must be updated when the formulation has changed and that all costs are attributed to the ENPR [scenario 1a]), Paper Products with approximately 3.01-4.48 million hours, and Textiles with approximately 0.91 - 1.93 million hours.

  On an h/company basis of five years, this corresponds to approximately 790-1220 h/firm, 140-150 h/firm, and 130-150 h/ firm for the sectors Coatings & Inks, Paper Products, and Textiles respectively.

- For sectors with a low number of notifications/company, the ratio of implementation costs / recurring costs is high (often an order of magnitude larger compared to sectors with a high number of notifications/company). An example is cosmetics. This means most of the costs are incurred for the task of modifying company procedures and systems, personnel training, and the first administrative entering of the data.
- For sectors with a high number of notifications or companies, the ratio of implementation costs / recurring costs is low since potentially hundreds of products have to be updated (and checked). An example is coatings & inks.
- In total, implementation costs are approximately 4-5 times as large as recurring costs.
- Distribution of costs for substances, mixtures, articles: For scenario 1a and 2a respectively, substances account for less than 1% of all costs, mixtures for 42-53%, and articles for approximately 47-57%. This changes only slightly for sub-scenario b. In general, substance costs are an order of magnitude lower than both costs related to mixtures and articles. This is to be expected since substances are at the beginning of the production chain, and one substance is used in multiple different products (which all have to be notified) in which a multiplier effect occurs as the substance moves along the production chain.

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

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

Direct costs for a public authority

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

For the ENPR the hardware/software costs are estimated to be approximately 500,000 € assuming a stand-alone system without an interface with other EU regulations collecting information on nanomaterials (e.g. REACH, Cosmetics Regulation). The transfer, modification,

and integration of data from the existing and planned registries in the ENPR database would incur additional costs.

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

Effects on innovation & competition

In both innovation and competition the effects of an ENPR are ambivalent if viewed against a situation with no national nanoproduct reporting scheme. Every administrative action requested through legislation will bind funds and workforce. There are examples from other European legislations such as REACH that point towards positive effects within the sectors innovation and competition but they are hotly debated by the stakeholders involved. The baseline for this project however is a EU with national nanoproduct registers. Existing and emerging national reporting schemes impose individual information demands on companies which will necessarily be much more costly to fulfill than a single ENPR on EU level. Measured against the compliance with several national NPRs and the market distortion that goes along with such different schemes, the ENPR is advantageous.

Assessment of the benefits

Public authorities and governments, consumers and companies can benefit from an ENPR in several aspects.

Public authorities and governments can benefit from an ENPR in at least three ways:

- Gaining knowledge on the main areas of application and on approximate volumes of nanomaterials on the market;
- Improving the enforcement of environmental, consumer and workers´ health legislation and
- Support for possible risk management measures.

First of all an ENPR will enable the public institutions to gain a comprehensive overview on the use of nanomaterials in various sectors in the EU resulting from information to the following questions:

- Which products contain nanomaterials that are intentionally or unintentionally released?
- What kind of nanomaterial(s) is released?

- What is the amount of a nanomaterial that is intentionally or unintentionally released over all sectors?

Focusing on nanoproducts with intentional or unintentional release this information forms the basis for further exposure assessments for humans and the environment, including cumulative and combinatory exposure. Thus the life-cycle of a given nanomaterial can be traced with the information on which products it was used in. This allows narrowing down possible surface modifications and thus allows for distribution models in the environment. Simultaneously the amount of nanomaterial released can be fed into the model to estimate potential risk. Based on information in the ENPR governments and public agencies can develop new or adjust existing research programs for eco- and human-toxicology tailored to the nanomaterials on the market and their possible exposure pathways. Moreover information from the ENPR can support the estimation of the relevance of nanotechnology and of individual nanomaterials for the purpose of setting priorities in enforcement and law-making / regulation.

Secondly, information on the notifier's address, the nanomaterial(s) (characterisation and functionality) and its application will support competent authorities in charge of the permitting and of the enforcement of environmental, consumer and workers' health legislation. For example competent authorities can use the information to check environmental permits (e.g. existing IPPC-/IED-authorisations) regarding provisions on the emission of nanomaterial(s) into air and water or regarding their presence in waste disposed of. With respect to market control the information on the trade name of nanoproducts in combination with the functionality and application of a nanomaterial will support competent authorities conducting market control on products containing nanomaterials. Solely on the basis of analytical measurements it is rather difficult for competent authorities to check whether a product contains a nanomaterial not assessed for that kind of use according to REACH or to sectoral legislation or whether a claimed "nano-effect" of a product is indeed linked to nanomaterials used for the product. The information on characterisation and functionality will help to conduct a more targeted detection.

Thirdly, should a concrete danger be identified resulting from a nanoproduct the identity of the producer and the name of the concrete product as well as the characterisation of the nanomaterial would facilitate the identification of emission sites within the product life-cycle as well as within the environment.

As a benefit for **companies** the ENPR will improve especially the knowledge of companies further down the production chain on nanomaterials they are using as well as increase information throughout the production chain and traceability for all stakeholders. Traceability of nanomaterials throughout the production chain is an important part for risk management for both producers and authorities. That way, all players are enabled to remove products containing nanomaterials from the market if they should prove to be unsafe after all based on latest scientific findings. It must be noted that the survey conducted in the course of this study revealed that companies in the production chain were scarcely aware whether they use nanomaterials or not. In this respect the ENPR-concept will support producers to duly perform their producer responsibility.

Moreover an important condition for trust in a new technology is transparency, including active information about products and research projects regarding these products and nanomaterials. The publicly available information in an ENPR is capable to satisfy this

postulation. An ENPR offering trade name of nanoproducts and applications of nanomaterial will give consumers an overview on the concrete nanoproducts as well as an insight into typical applications of nanomaterials and thus function as an orientation in the market.

The main benefit of an ENPR for **consumers** is to enable them to realize their freedom of choice. If consumers can inform themselves in an ENPR whether an articles contains nanomaterials or not this will contribute considerably to realize their freedom of choice.

In principle a notification number for a nanoproduct facilitates the transfer from the information in the ENPR to the consumer. However, according to the ENPR-concept it is open whether the notification number should refer to the product (product-specific) or to the substance in the nanoform (substance-specific). The following four options to inform the consumer are discussed in chapter 4.6 of this study:

1. The ENPR functions only as a passive source of information for consumer, i.e. there is no notification number displayed on the nanoproduct and the consumer has to research in the database with the help of a product name.
2. A notification number is awarded to each nanomaterial that must be notified. On the product all nanomaterials are visible via their notification number (substance-specific).
3. A notification number is awarded to each product. Consumers can receive information on the nanomaterials contained in that product from the ENPR (product-specific).
4. The fourth option is similar to the third option but beside the product-specific notification number the nanomaterials contained in that product are listed on the product or its packaging.

The four options are discussed and the study concludes that the third option is the most preferable. Like the second option the third option enables the consumers, manufacturers and public authorities to identify a nanoproduct and to obtain further information from the ENPR. Notifiers have to label their product only with one notification number instead of several for each nanomaterial and thus may save costs and have fewer problems with space for the labelling. Furthermore, a product-specific notification makes the communication on nanoproducts in the production chain easier compared to a detailed labelling of all nanomaterials. For example a substance-specific notification number must be changed if a nanomaterial is replaced in the formulation by another nanomaterial. Whereas in such a case a product-specific notification number does not need to be changed, rather the content in the ENPR is changed. Several representatives of industry warn that nano-specific notification numbers on the product can be misunderstood as a hazard warning by consumers. However, a notification number can be also interpreted by consumers as verified by authorities.

Zusammenfassung

Hintergrund und Studienziele

Bereits in der Anfangszeit der öffentlichen Debatte über die möglichen Chancen von Nanomaterialien für die Gesellschaft und den Risiken für die Umwelt und die menschliche Gesundheit wurde ein Nanoproduktregister als Instrument diskutiert mit dem Transparenz über die Verwendung von Nanomaterialien erzielt werden kann. Bis zum Jahr 2013 wurden innerhalb und außerhalb Europas eine Vielzahl von Ansätzen zur Berichterstattung über Nanomaterialien entweder als freiwillige oder verpflichtende Maßnahmen vorgeschlagen oder umgesetzt. Verschiedene EU Staaten u.a. Deutschland unterstützen die Einführung einer europäischen Datenbank oder eines europäischen Registers zur Erhebung der notwendigen Informationen über Produkte, die Nanomaterialien enthalten, um die zur Zeit bestehenden Unsicherheiten beim Gesundheits- und Umweltschutz und die regulatorischen Unzulänglichkeiten zu adressieren. Frankreich hat als erstes Land ein Register eingeführt, dass die Hersteller verpflichtet die Verwendung von Nanomaterialien zu melden. Dänemark und Belgien haben Gesetzesvorschläge zur Einführung einer Notifizierungspflicht für Nanoprodukte veröffentlicht. Im Juni 2012 hat das Umweltbundesamt (UBA) ein „Konzept für ein europäisches Register für nanomaterialhaltige Produkte“[11] (im folgenden UBA-Konzept genannt) veröffentlicht. Nach dem Konzept müssen Hersteller und Importeure von Stoffen, Gemischen, die Nanomaterialien sind oder diese enthalten sowie Erzeugnisse, welche absichtlich oder unabsichtlich Nanomaterialien freisetzen, einen begrenzten Datensatz in ein europäisches Nanoproduktregister (abgekürzt ENPR) melden. Vor diesem Hintergrund war es Ziel dieser Studie, die Folgen des UBA-Konzepts zu ermitteln. Dazu wurden die Sektoren und Unternehmen identifiziert, die von einem ENPR betroffen wären, sowie die Anzahl der Notifizierer und Notifizierungen, Stoffe, Gemische und Erzeugnisse abgeschätzt. Hervorzuheben ist, dass das UBA-Konzept gezielt so angelegt ist, einen breiten Bereich von Nanoprodukten zu erfassen, um die maximalen Kosten eines ENPR zu bewerten. Auf Basis dieser Folgenabschätzung kann der Anwendungsbereich des ENPR im Rahmen einer möglichen Implementierung angepasst werden. So können z.B. Aspekte wie die Fokussierung auf bestimmte Nanomaterialien entsprechend dem Vorsorgeprinzip oder die Beachtung der Verhältnismäßigkeit beim Kosten-Nutzen-Verhältnis des ENPR berücksichtigt werden.

Auf Basis der ermittelten Anzahl von Notifizierungen wurden die administrativen Kosten der betroffenen Unternehmen und der implementierenden Behörde quantifiziert. Anschließend wurden die Auswirkungen des ENPR auf die Innovation und den Wettbewerb sowie die Vorteile für öffentliche Behörden, Regierungen, Konsumenten und Notifizierungspflichtige qualitativ ermittelt. Die Studie schließt mit einer Zusammenfassung der untersuchten Folgen eines ENPR.

[11] UBA (2012).

Konzept für ein europäisches Register für nanomaterialhaltige Produkte (UBA-Konzept)

Das UBA-Konzept basiert auf dem Vorsorgeprinzip und adressiert die möglichen negativen Effekte für die menschliche Gesundheit und die Umwelt als Folge einer weitverbreiteten Verwendung und damit möglichen Exposition mit Nanomaterialien aus unterschiedlichen Quellen.

Ziel ist es, ein Nanoproduktregister auf der EU-Ebene zu implementieren und dadurch nationale Register in den Mitgliedstaaten zu vermeiden. Damit sollen die administrativen Kosten für die Notifizierungspflichtigen und für die zuständige Behörde reduziert werden, die sich insbesondere durch überschneidende Meldungen in den Mitgliedstaaten ergeben.

Regelungsgegenstand sind “Nanoprodukte”. Unter diesen Oberbegriff fallen die folgenden Stoffe, Gemische und Erzeugnisse: Stoffe, die im Sinne der Definitionsempfehlung der EU Kommission als Nanomaterialien einzuordnen sind. Gemische, die aus Nanomaterialien bestehen oder diese beinhalten mit mindestens 0,001 Masseprozent (w/w) bezogen auf das ganze Gemisch. Erzeugnisse, die Nanomaterialien enthalten, deren Freisetzung unter normalen oder vorhersehbaren Verwendungsbedingungen beabsichtigt ist. Erzeugnisse, die Nanomaterialien von mehr als 0,1 Masseprozent (w/w) bezogen auf das Erzeugnis enthalten, solange der Hersteller oder Importeur bei normalen oder vernünftigerweise vorhersehbaren Verwendungsbedingungen einschließlich der Entsorgung eine Exposition von Mensch oder Umwelt nicht ausschließen kann. Wird ein Erzeugnis produziert oder importiert, das aus Teilerzeugnissen besteht, bezieht sich der 0,1%-Grenzwert auf jedes Teilerzeugnis.

Hersteller und Importeure von Stoffen, Gemischen und Erzeugnissen, welche diese erstmalig in Verkehr bringen, müssen dies notifizieren. Eine Notifizierungspflicht besteht auch dann, wenn die Umverpackung, Umetikettierung und Vermarktung für eine andere als die ursprünglich notifizierte Anwendung vorgenommen wird.

Die Notifizierungspflichtigen müssen die folgenden Daten melden: Namen und Adresse des Notifizierungspflichtigen, Produkt- und Handelsname (ohne eine Spezifizierung möglicher Modellvarianten), Anwendung und Funktionalität der verwendeten Nanomaterialien, Charakterisierung des Nanomaterials, Konzentration des Nanomaterials in dem jeweiligen Erzeugnis sowie die importierten Tonnagebänder des Nanomaterials.

Die gemeldeten Daten werden in einem öffentlich zugänglichen Teil und einem vertraulichen – nicht öffentlich zugänglichen – Teil unterschieden. Um doppelte Meldepflichten für die Notifizierungspflichtigen zu vermeiden, sollte das ENPR als horizontales Register ausgestaltet sein mit der Ermächtigung die gemeldeten Daten zu Nanoprodukten aus anderen Stoffregelungen (z.B. REACH- und CLP-Verordnung) und Produktregelungen (z.B. Kosmetikverordnung) in das ENPR zu überführen. Sollten bestimmte Daten für das ENPR nicht im Rahmen der Stoff- und Produktregelungen gemeldet werden, so sieht das UBA-Konzept vor, dass die Stoff- und Produktregelungen um die entsprechende Pflicht zur Meldung von Daten im Wege einer Mantelverordnung ergänzt werden.

Die zuständige Behörde für ein ENPR teilt dem Notifizierungspflichtigen für jede Notifizierung eine Notifizierungsnummer mit. Beim Inverkehrbringen eines notifizierten Stoffes, eines Gemisches oder eines Erzeugnisse teilt der Notifizierungspflichtige diese Nummer seinem Abnehmer in der Herstellungskette mit. Jeder Akteur in der Herstellungskette, der ein Nanoprodukt auf den Markt bringt, das die Voraussetzungen in Kapitel 2.2 erfüllt, muss dieses

Produkt notifizieren. Dies ist unter anderem der Fall, wenn er das Nanomaterial selbst oder das Nanomaterial in einem Gemisch oder Erzeugnis so modifiziert, dass sich die Eigenschaften des Nanomaterials verändern. Die Veränderung der Konzentration des Nanomaterials in einem Gemisch oder Erzeugnis löst ebenso eine Notifizierungspflicht aus.

Ermittlung der betroffenen Sektoren

Anhand eines der folgenden Kriterien “hohes Produktionsvolumen”, „weitverbreitete Verwendung“ oder „ausreichende, öffentlich zugängliche Informationen zur Verwendung von Nanomaterialien“ wurden die folgenden Nanomaterialien für eine Folgenabschätzung ausgewählt: Carbon Black, Siliziumdioxid, Aluminiumoxid, Bariumtitanat, Titandioxid, Ceriumoxid, Zinkoxid, Kohlenstoffnanoröhrchen, Nanosilber und Fullerene. Für jedes der ausgewählten Materialien wurde die Verwendung in bestimmten Anwendungen und Produktgruppen ermittelt und dann in die folgenden elf Sektoren oder Kategorien eingruppiert: Stoffe, Kosmetika, Gesundheitspflege, Lebens- & Futtermittel, Lacke & Farben, Reinigung & Desinfektion, Gummierzeugnisse, Bausektor, Textilien, Papierprodukte sowie komplexe Erzeugnisse & andere Produkte.

Natürliche und zufällig entstehende Nanomaterialien sowie Polymere sind vom Untersuchungsbereich dieser Studie ausgenommen worden. Bei natürlichen Nanomaterialien ist das in der extremen Vielfalt der in der Natur vorkommenden Nanomaterialien begründet. Sie treten hier in jedem natürlichen Kompartiment (Boden, Gewässer, Luft) auf und es liegen kaum Daten über sie vor. Die Definition von natürlichen Stoffen (einschließlich Nanomaterialien) in Art. 3 (39) REACH wurde hier zugrunde gelegt. Jede Veränderung der Stoffe mittels anderer Methoden als der in Art. 3 (39) REACH bezeichneten, führt zum Verlust des Status als „natürliche Stoffe“ und löst eine Registrierungspflicht aus. Durch diese Einschränkung wären Produkte wie Gartenerde, Kalkpulver (Dünger), Kohle, u.a. von der Registrierungspflicht ausgenommen. Aus ähnlichen Gründen waren für diese Studie eine Definition und der Ausschluss von der Notifizierungspflicht für zufällig als Nebenprodukte entstehende Nanomaterialien wichtig. Dies dient dazu die Notifizierungspflicht auf die zur Erfüllung des Auftrages im Sinne des Vorsorgeprinzips nötigen Daten zu fokussieren. Ohne diese Einschränkung wäre nahezu jedes Produkt auf dem Markt für das ENPR zu notifizieren, was zu einer enormen Datenmenge geführt hätte, deren Ermittlung und Auswertung den Rahmen dieser Studie gesprengt hätte. Zudem wurden Polymere vom Untersuchungsrahmen dieser Studie ausgenommen. Je nach Art des Polymers können die Moleküle in zumindest einer Dimension größer als 1 nm sein. Das macht sie nicht notwendigerweise partikulär. Aufgrund der damit verbundenen Unsicherheiten wurden Polymere in dieser Studie nicht berücksichtigt.

In allen drei Fällen: natürliche Nanomaterialien, zufällig entstehende Nanomaterialien und Polymere, sind die jeweiligen Definitionen umstritten und ihre Definition und Exklusion von einem ENPR sollte für den Fall eines Gesetzgebungsverfahrens erneut geprüft werden.

Erwartete Anzahl an Unternehmen und Nanoprodukten pro Sektor

Für jeden der ausgewählten Sektoren oder Produktkategorien wurde die Anzahl aller darin aufgeführten Unternehmen ermittelt (auf Basis von Eurostat und NACE) sowie die Anzahl der notifizierungspflichtigen Unternehmen und der zu erwartenden Notifizierungen geschätzt. Im Ergebnis sind 5-8% (37.500-58.000) der gesamten 766.660 Unternehmen, deren Hauptaktivität in den untersuchten Sektoren liegt, von einem ENPR betroffen. Jedoch wird dieses Ergebnis

verfälscht durch die Unternehmen aus dem Bereich „komplexe Erzeugnisse und andere Produkte“. Diese Unternehmen machen die Großzahl der analysierten Unternehmen aus (rund 75% oder 580.403 Unternehmen), stehen aber gleichzeitig nur für 6-10% (oder 3.000 bis 6.000) der Unternehmen, die bei einem ENPR notifizierungspflichtig wären.

Die Analyse zeigt, dass die folgenden Sektoren aufgrund einer hohen Zahl von Notifizierungen besonders betroffen sind: „Lacke & Farben (90-95% von der Gesamtzahl der Firmen in allen Sektoren), “Gummierzeugnisse” (75-90%), “Papiererzeugnisse”(60-80%), “Kosmetika“ (60-80%) und “Gesundheitspflege” (50-80%).

Bei einer Einführung des ENPR könnten bis 4,1 Millionen Notifizierungen notwendig sein, wovon eine Großzahl auf die Sektoren „Lacke & Farben (rund 60%), “Papiererzeugnisse”(25%), „Gummierzeugnisse“ und „Textilien“ sowie „komplexe Erzeugnisse und andere Produkte“ (jeweils 3.5%). Jedes notifizierungspflichtige Unternehmen müsste zwischen 16 und 57 Notifizierungen vornehmen. Während sich die durchschnittliche administrative Belastung für Unternehmen auf 5 bis 20 Notifizierungen belaufen könnte, sind bei Unternehmen in den Sektoren Gesundheitspflege, Papiererzeugnisse und komplexe Erzeugnisse und andere Produkte mit bis zu 75 Notifizierungen pro Unternehmen rechnen; Firmen im Sektor Lacke & Farben könnten mit 610 Notifizierungen pro Unternehmen besonders betroffen sein.

Besonders auffällig ist, dass neben Pigmenten und Farben, ein großer Anteil der Notifizierungen auf die Verwendung von nanoskaligen Füllstoffen zurückzuführen sein könnte. Füllstoffe werden üblicherweise verwendet, um den Verbrauch von teuren Klebmitteln zu reduzieren und die physikalischen Eigenschaften des Produkts zu verbessern. Zu den Füllstoffen gehören unter anderem Kalziumkarbonat (Papier und Kunststoffe), Siliziumdioxid (Farben, Lacke, Klebstoffe und Abdichtungsmittel, Kunststoffe und Gummi) oder Carbon Black (Gummi und zu einem geringeren Anteil in Kunststoffen und Farben). Auch wenn manche Füllstoffe als “zufällig entstehende Nanomaterialien“ betrachtet werden können, wird nichts desto trotz erwartet, dass ein Großteil dieser Produkte für das ENPR zu notifizieren ist (vorausgesetzt die Konzentrationsschwellenwerte werden überschritten).

Direkte Kosten für die Unternehmen

Die Kosten für die Unternehmen werden anhand von zwei Szenarien untersucht:

- Szenario 1 beschreibt die Folgen eines ENPR, wenn keine Informationen aus anderen Regelungsbereichen genutzt werden können. Im Ergebnis also die Einführung eines ENPR teilweise zu doppelten Meldepflichten führen würde.
- Szenario 2 beschreibt die Folgen eines ENPR, wenn Informationen teilweise aus anderen Regelungsbereichen verwendet werden können (REACH, Kosmetikverordnung, Novel Food Verordnung, Lebensmittelkontaktmaterialienverordnung und der Biozidprodukteverordnung). Im Ergebnis also doppelte Meldepflichten zum Teil vermieden werden können.

Für beide Szenarien wurden noch zwei Unterszenarien untersucht, welche die wiederkehrenden Kosten betreffen:

- Unterszenario a: Die Notifizierung muss nur dann aktualisiert werden, wenn sich eine meldepflichtige Information ändert (nur die geänderte Information muss gemeldet werden);

- Unterszenario b: Die Notifizierung muss jährlich aktualisiert werden.

Für jedes untersuchte (Unter-)Szenario wurden die direkten Kosten für die Unternehmen pro Sektor abgeschätzt unterteilt in Implementierungskosten und wiederkehrende Kosten.

- Vergleicht man die Kosten der beiden Szenarien bei einer 5-jährigen Betrachtungszeit zeigen sich folgende Ergebnisse: Einige Sektoren könnten besonders betroffen sein, wie Lacke & Farben mit 6,26 bis 10,20 Millionen Stunden (so sind z.B. ca. 44-50% der Kosten für Notifizierungspflichtige diesem Sektor zuzurechnen, wenn wie im Szenario 1a die Informationen bei jeder Änderung der Formulierung aktualisiert werden müssen), Papiererzeugnisse mit ca. 3.01 bis 4.48 Millionen Stunden und und Textilien mit ca. 0,91 bis 1,93 Millionen Stunden.

  Bei 5-jähriger Betrachtungszeit ergibt dies in Stunden pro Firma ausgedrückt, 790 bis 1220 h/Firma im Sektor Lacke & Farben, 140 bis 150 h/Firma im Sektor Papiererzeugnisse und 130 bis 150 h/Firma im Sektor Textilien.

- Für Sektoren mit einer geringen Anzahl von Notifizierungen oder Unternehmen ist das Verhältnis der Implementierungskosten zu den wiederkehrenden Kosten hoch (häufig eine Größenordnung höher verglichen mit Sektoren, die eine große Anzahl von Notifizierungen/Unternehmen aufweisen). Ein Beispiel dafür sind Kosmetika. Daraus kann geschlossen werden, dass der Großteil der Kosten für die Anpassung der Unternehmensabläufe, Schulung der Mitarbeiter und die administrativen Anfangskosten bei der Eingabe der meldepflichtigen Daten.
- Für Sektoren mit einer hohen Anzahl von Notifizierungen oder Unternehmen ist das Verhältnis der Kosten zu den wiederkehrenden Kosten niedrig, weil potenziell hunderte Produkte aktualisiert (geprüft) werden müssen. Ein Beispiel dafür sind Lacke & Farben.
- Insgesamt sind die Implementierungskosten 4 bis 5 Mal größer als die wiederkehrenden Kosten.
- Zur Verteilung der Kosten auf Stoffe, Gemische und Erzeugnisse: In Szenario 1a und 2a entfallen weniger als 1% aller Kosten des Registers auf Stoffe, 42–53% entfallen auf Gemische und 47–57% auf Erzeugnisse. Dieses Bild ändert sich nur wenig gegenüber dem Unterszenario b. Im Allgemeinen sind die Kosten für Stoffe eine Größenordnung niedriger im Vergleich zu den Kosten für Gemische und Erzeugnisse. Dies war auch zu erwarten, da Stoffe am Anfang der Herstellungskette liegen und ein Vervielfachungseffekt eintritt, wenn die Stoffe in einer Vielzahl von Produkten entlang der Herstellungskette eingesetzt werden.

Ein Vergleich der Kosten für die Szenarien 1 und 2 (unabhängig von den Unterszenarien a und b) zeigt:

- Gemessen an den Gesamtkosten aller meldepflichtigen Unternehmen führt die Vermeidung von doppelten Notifizierungen (Szenario 2) insgesamt nicht zu einer signifikanten Reduzierung der administrativen Kosten (die Gesamtkosten könnten um 5,5% reduziert werden). Dies lässt sich damit erklären, dass die entlasteten Sektoren (Stoffe, Kosmetika, Lebens- und Futtermittel und Reinigung & Desinfektion) nur einen geringen Beitrag zu den Gesamtkosten (ungefähr 7%) in Szenario 1 beitragen.

- Betrachtet man nur die Sektoren, die mit dem ENPR vergleichbare Informationen erheben, sind bedeutsame Einsparungen zu erwarten:
  a) Stoffe (REACH) ~90-95% Ersparnisse,
  b) Kosmetika (Kosmetikverordnung) ~ 80% Ersparnisse,
  c) Lebensmittel (Novel Food Verordnung) ~ 95% Ersparnisse,
  d) Reinigung & Desinfizierung (BPR) ~ 40% Ersparnisse.
- Alle anderen Sektoren sind nicht von den Parametern in Szenario 2 betroffen, da bei ihnen nicht auf notifizierungspflichtige Informationen aufgrund von bestehenden Rechtsvorschriften zurückgegriffen werden kann.

Direkte Kosten für die zuständige Behörde

Die Abschätzung der Kosten für die zuständige Behörde wurde aufgrund von Erfahrungen von Behörden erstellt, die ähnliche Register verwalten. Es wurden Hard- und Software Kosten sowie administrative Kosten ermittelt.

Für das ENPR liegen die ermittelten Hard- und Softwarekosten bei ca. 500.000 €, wenn ein autarkes System ohne Schnittstelle mit anderen Datenbanken aus EU Regularien (z.B. REACH, Kosmetik-Verodnung) angenommen wird. Der Transfer, die Modifikation und die Integration von Daten aus Datenbanken anderer Regularien in die ENPR Datenbank würde zusätzliche Kosten verursachen.

Die geschätzten administrativen Kosten beinhalten Faktoren wie die Erstellung und den Unterhalt von Anleitungen und Hilfen basierend auf relevanten Regularien, die Erstellung von FAQ's (frequently asked questions; häufig gestellte Fragen) und die Zusammenarbeit mit Interessenvertretern zur Verbesserung des Meldeprozesses. Basierend auf der Anzahl von 28 Mitgliedstaaten wird die notwendige Anzahl von Sachbearbeitern auf 8 im ersten Jahr des Registers geschätzt. Das beinhaltet die Publikation von Berichten für Entscheidungsträger und die Öffentlichkeit. Die Sachbearbeiter würden im ersten Jahr auf die Zuarbeit von weiteren 5-8 unterstützenden Kräften angewiesen sein. Weitere Kosten könnten durch die wissenschaftliche Beurteilung der verwendeten Methoden zur Klassifikation von Nanopartikeln entstehen. Die Gesamtkosten für die Administration in der Implementationsphase hängen stark von der effektiven Definition und Vermittlung von Notifizierungspflichten ab.

Auswirkungen auf Innovation & Wettbewerb

In den Bereichen Innovation und Wettbewerb sind die Effekte eines ENPR zwiespältig, wenn sie mit einer Situation verglichen werden in der keine nationalen oder europäischen Nanoproduktregister existieren. Jede durch Regulation verlangte administrative Tätigkeit bindet Arbeitskräfte und Geld. Es gibt Beispiele von anderen europäischen Regulationen wie z.B. REACH für die positive Effekte in beiden Bereichen aufgezeigt werden können. Diese Ergebnisse sind jedoch umstritten. Die Ausgangssituation für dieses Projekt ist jedoch nicht eine Europäische Union in der keine nationalen Nanoproduktregister existieren. Existierende und in der Schaffung befindliche nationale Register, die individuell unterschiedliche Informationsanforderungen und Geltungsbereiche auferlegen, sind notwendigerweise teurer für betroffene Industriezweige als ein einheitliches Melderegister. Die dadurch entstehende Wettbewerbsverzerrung wäre durch ein ENPR vermeidbar.

Beschreibung der Vorteile

Zuständige Behörden und Regierungen, Konsumenten und Unternehmen können von einem ENPR in vielfältiger Weise profitieren.

Die zuständigen Behörden und Regierungen können von einem ENPR in mindestens drei Arten profitieren:

- Gewinnung von Erkenntnissen über die Exposition von Menschen und der Umwelt durch Nanomaterialien;
- Verbesserung des Vollzugs im Umwelt-, Verbraucher- und Arbeitsschutzrecht;
- Unterstützung bei der Auswahl möglicher Risikomanagementmaßnahmen.

Zuvorderst wird ein ENPR den zuständigen Behörden einen umfassenden Überblick über die Verwendung von Nanomaterialien in verschiedenen Sektoren ermöglichen durch die Beantwortung der folgenden Fragen:

- Welche Produkte enthalten Nanomaterialien, die beabsichtigt oder unbeabsichtigt freigesetzt werden können?
- Welche Arten von Nanomaterialien werden freigesetzt?
- Welche Gesamtmengen an Nanomaterialien werden beabsichtigt oder unbeabsichtigt über alle Sektoren hinweg freigesetzt?

Der Fokus auf Nanomaterialien mit beabsichtigter oder unbeabsichtigter Freisetzung bildet die Grundlage für die weitere Expositionsbewertung von Menschen und der Umwelt, einschließlich einer kumulierten Exposition. Mit den Informationen aus dem ENPR zu den Produkten, in denen Nanomaterialien verwendet werden, kann der Lebensweg eines Nanomaterials verfolgt werden. Dies erlaubt eine Eingrenzung der Oberflächenmodifizierungen und die Erstellung von Verteilungsmodellen für Nanomaterialien in der Umwelt. Weiterhin können die zuständigen Behörden und Regierungen mit den Informationen aus dem ENPR Forschungsprogramme zur Human- und Ökotoxizität für die auf dem Markt befindlichen Nanomaterialien unter Beachtung der Expositionspfade entwickeln bzw. bestehende Programme anpassen. Zudem kann die Information aus dem ENPR dazu verwendet werden, die Relevanz der Nanotechnologien und einzelner Nanomaterialien besser abzuschätzen und Prioritäten beim Vollzug und der Rechtssetzung zu setzen.

Ein weiterer Nutzenaspekt ist die Unterstützung der Genehmigungs- und Überwachungsbehörden im Bereich der Umwelt-, Arbeitsschutz- und Verbraucherschutzvorschriften durch Informationen zur Anschrift des Notifizierungspflichtigen, der Charakterisierung und Funktionalität sowie Anwendung des Nanomaterials. So können die zuständigen Behörden diese Informationen nutzen, um Vorhabengenehmigungen (z.B. die IVU- bzw. IED-Genehmigung) hinsichtlich der Emissionen von Nanomaterialien in der Abluft, dem Abwasser oder dem Abfall zu überprüfen. Mit Blick auf die Marktüberwachung kann der Handelsname eines Produkts in Verbindung mit der Funktionalität und Verwendung eines Nanomaterials bei der Einhaltung von Vermarktungsvorschriften helfen. Denn alleine anhand von analytischen Messungen ist es für die zuständigen Behörden sehr schwierig zu überprüfen, ob ein Produkt Nanomaterialien enthält, die nach REACH oder sektoralen Vorschriften nicht dafür zugelassen sind bzw. ob ein behaupteter Nano-Effekt tatsächlich auf der Verwendung von Nanomaterialien gründen kann.

Als dritter Vorteil ist die Ergreifung von Risikomanagementmaßnahmen zu nennen. Sollte von einem Nanoprodukt eine konkrete Gefahr ausgehen, könnten mit Hilfe der Angaben zu dem Hersteller und den Verwendern sowie der Charakterisierung des Nanomaterials mögliche Emissionspunkte im Lebensweg und in der Umwelt identifiziert werden und mit Risikomanagementmaßnahmen darauf reagiert werden.

Als Vorteil für **Unternehmen** ist eine verbesserte Kenntnis aller Unternehmen in der Herstellungskette, aber insbesondere derer am Ende der Herstellungskette, über die Verwendung von Nanomaterialien zu erwarten. Ferner wird die Rückverfolgbarkeit von Nanomaterialien in der Herstellungskette verbessert. Die Rückverfolgbarkeit spielt für Unternehmen und Behörden eine wichtige Rolle bei der Ergreifung von Risikomanagementmaßnahmen. Auf diese Weise werden alle Akteure in die Lage versetzt ein bestimmtes Nanoprodukt vom Markt zu nehmen, wenn sie sich nach neueren wissenschaftlichen Erkenntnissen als nicht sicher erweisen sollten. Betont werden muss, dass sich bei den Befragungen im Rahmen der Studie herausstellte, dass die Unternehmen in den Herstellungsketten wenig Kenntnis davon hatten, ob sie Nanomaterialien verwenden. Es ist davon auszugehen, dass das ENPR nach dem UBA-Konzept die Akteure in der Herstellungskette bei der Wahrnehmung ihrer Herstellerverantwortung unterstützt.

Darüber hinaus ist Transparenz - einschließlich der aktiven Information über die Verwendung von Nanomaterialien in Produkten - eine wichtige Bedingung für das Vertrauen in eine neue Technologie. Die öffentlich verfügbaren Informationen aus einem ENPR können diese Transparenz befördern. So können die Informationen über die Handelsnamen von Nanoprodukten und die Verwendung von Nanomaterialien den Konsumenten einen Überblick über konkret verfügbare Nanoprodukte liefern sowie einen Einblick in typische Verwendungen von Nanomaterialien bieten; dies zusammen kann den Konsumenten als Orientierung im Markt dienen.

Der zentrale Vorteil eines ENPR für die **Konsumenten** ist, dass ihnen damit die Möglichkeit eröffnet wird zwischen Produkten mit und ohne Nanomaterialien zu wählen (Wahlfreiheit).

Mit Hilfe einer Notifizierungsnummer für das Nanoprodukt soll es den Konsumenten ermöglicht werden, die zur Ausübung der Wahlfreiheit notwendigen Informationen aus dem ENPR zu nutzen. Nach dem UBA-Konzept ist bislang noch offen, ob dies durch eine produktspezifische oder stoffspezifische Notifizierungsnummer umgesetzt werden soll. Die folgenden vier Optionen aus dem UBA-Konzept werden in Kapitel 4.6 der Studie diskutiert:

1. Das ENPR fungiert nur als passive Informationsquelle für Konsumenten, d.h. das Nanoprodukt wird nicht mit einer ENPR-Notifizierungsnummer gekennzeichnet. Der Konsument muss für Informationen über ein Produkt anhand des Produktnamens im ENPR recherchieren.
2. Eine Notifizierungsnummer wird für jedes notifizierungspflichtige Nanomaterial erteilt. Die in einem Nanoprodukt enthaltenen Nanomaterialien sind auf dem Produkt mit der/den Notifizierungsnummer(n) zu kennzeichnen (stoffspezifische Kennzeichnung).
3. Eine Notifizierungsnummer wird nur pro Nanoprodukt erteilt. Der Konsument kann sich über die im Produkt enthaltenen Nanomaterialien im ENPR informieren (produktspezifische Kennzeichnung).

4. Die vierte Option entspricht der dritten Option, aber neben der produktspezifischen Notifizierungsnummer werden zudem die im Produkt enthaltenen Nanomaterialien auf dem Produkt oder der Verpackung angegeben.

Die Diskussion der vier Optionen führt zur Empfehlung der dritten Option. Wie die zweite Option ermöglicht es die dritte Option den Konsumenten, Herstellern und zuständigen Behörden ein Nanoprodukt im Markt zu identifizieren und weitere Informationen zu dem Produkt aus dem ENPR zu entnehmen. Notifizierungspflichtige müssen ihr Produkt nur mit einer produkt-spezifischen Notifizierungsnummer kennzeichnen ohne zusätzlich für jedes Nanomaterial eine eigene Notifizierungsnummer anzugeben. Dadurch können Kosten und Fläche auf dem Etikett gespart werden. Wird ein Nanomaterial durch ein anderes Nanomaterial in einem notifizierungspflichtigen Produkt ersetzt, muss in diesem Fall die produktspezifische Kennzeichnung des Nanoprodukts nicht geändert werden; im Gegensatz zu einer stoffspezifischen Kennzeichnung. Im Zusammenhang mit einer Kennzeichnung befürchten einige Industrievertreter, dass diese von den Kunden als Gefahrenhinweis interpretiert wird. Gleichwohl können Notifzierungsnummern auch als Nachweis einer behördlichen Kontrolle interpretiert werden.

Introduction

1.1 Background

Since the early days of the public debate on the possible benefits of nanomaterials for society and their possible risks for the environment and human health a register for products containing nanomaterials has been discussed as an instrument to facilitate transparency on the use of nanomaterials.

In Germany for example in 2006 consumers participating in the BfR (Federal Institute for Risk Assessment) Consumer Conference on Nanotechnology called for more transparency in the nanotechnology field. Specific reference was made to a labelling requirement for certain product groups.[12] One of the recommendations of the German Federal Government's NanoKommission in the first phase from 2006-2008 was "the creation of an independent form of market overview for consumers in terms of available nanoproducts, so that information relevant to consumers and new scientific knowledge are collated and presented in an understandable way. Information on contents, function, impact and safety should be grouped together."[13] However, in the report on the second phase of the NanoDialog 2009-2011 no "common position on a conception for a legally binding product register, its function or its potential purpose" was agreed between the participants.[14] The Conference of the Environmental Ministers of the Länder (UMK) decided in May 2011 to ask the German Government to promote a nanospecific product register for public authorities on the European level in order to receive information on the properties of nanoproducts available on the European Market.[15]

Moreover, the implementation of a binding product register was postulated in scientific studies.[16]

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[12] Cf. p.3 of the consumer position on nanotechnology formulated on 20 November 2006 within the context of the BfR consumer conference on nanotechnology in foods, cosmetics and textiles. Download at: http://www.bfr.bund.de/cm/220/verbrauchervotum_zur_nanotechnologie.pdf. (as from 4.6.2013).

[13] Cf. "Report and recommendations of the German Federal Government's NanoKommission - Responsible Use of Nanotechnologies, 2008 p.63. Download at: http://ec.europa.eu/health/ph_risk/documents/nanokommission.pdf (as from 4.6.2013).

[14] Cf. Responsible Use of Nanotechnologies – Report and recommendations of the German NanoKommission 2011, p.55. Download at: http://www.bmu.de/fileadmin/bmu-import/files/english/pdf/application/pdf/nano_schlussbericht_2011_bf_en.pdf (as from 4.6.2013).

[15] Cf. UMK (2011).

[16] Cf. Breggin et al. (2009) with reference to a reporting requirement the authors deliberate as follows on p. XIII: "Given the persistence of these knowledge gaps, governments on both sides of the Atlantic should strengthen existing mandatory reporting requirements and, where necessary, create new ones, with a view to gaining a comprehensive overview of the commercial use of nanomaterials. Given the high degree of economic interdependence between the US and EU, any effort to enhance market transparency through improved reporting schemes would benefit from a coordinated effort by both sides." RCEP (2008), p. 69, RN 4.71 follows a similar line:

Up to the year 2013 a number of approaches to report nanomaterials in Europe and other countries, either voluntary or mandatory, have been proposed and implemented.[17] The UK was one of a few states who have implemented a voluntary reporting scheme for nanomaterials. It was implemented in 2006 and reviewed in 2009. In the two years since its implementation 13 data submissions have been registered, two of which came from the academic sector. Experience from the UK reporting scheme suggests that a voluntary scheme – even initiated by government – will not deliver a representative overview of the manufactured nanomaterials available on the EU market. Several EU Member States support the introduction of databases or registries for gathering necessary information on (products with) nanomaterials to address current uncertainties surrounding health and environmental safety and regulatory shortcomings.[18] France has become the first country to require manufacturers to identify uses of substances in nanoform in the frame of a mandatory reporting scheme.[19] The Belgian Federal Public Service Health, Food Chain Safety and Environment and the Danish Environmental Protection Agency plan to set up comparable schemes to be operational in the upcoming years.

Looking at the legal framework in the EU some legal provisions require an authorisation for placing a substance on the market (e.g. in the case of packaging materials) and do not require specific marketing authorisation for the final product containing such a substance. In such cases neither authorities nor consumers necessarily know in which final product nanomaterials are indeed being used. Nevertheless, a range of very diverse resources (manufacturers' information and advertising, market analyses, publicly accessible databases such as the PEN database[20]) show that there are numerous products on the markets that contain nanomaterials. And yet it is not possible to rely on the information contained in those sources being up to date and of good quality for a given product. This is due to the lack of an obligation to report the

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"Of the additional measures that we considered, we were most attracted by the development of some kind of early warning system, one that might be managed by the competent authorities for REACH-VO or by a body or bodies authorised by them to do so. Indeed, as we confront the control dilemma, it seems to us that an early warning system incorporating reporting requirements is a vital component of governance." One of the key recommendations of the SRU (2011), p.4 is: "Products that release nanomaterials or make use of them to achieve specific properties (such as antibacterial properties) should also require mandatory labelling. For other nanoproducts, a notification requirement should be introduced that feeds into a semi-public product register."

[17] Further information can be obtained from the Nanotechnology Industries Association (NIA), see: http://www.nanotechia.org/services/databases-reporting-schemes (as from 4.6.2013).

[18] See Fn. 6.

[19] Cf. The Homepage of the French Environmental Ministry: http://www.developpement-durable.gouv.fr/spip.php?page=article&id_article=30578 (as from 4.6.2013). For more details on the legislation "Décret n° 2012-232 du 17 février 2012 relatif à la déclaration annuelle des substances à l'état nanoparticulaire pris en application de l'article L. 523-4 du code de l'environnement" see: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025377246&categorieLien=id (as from 4.6.2013).

[20] See the database of "The Project on Emerging Nanotechnologies (PEN)" at http://www.nanotechproject.org/inventories/consumer/ (as from 4.6.2013).

utilisation of nanomaterials. Considering the existing and assumed opportunities arising from nanoproducts and the as yet insufficient knowledge of the human toxicology and eco-toxicology of nanomaterials, the introduction of a binding product register provides clarity on which products contain nanomaterials.

An early feasibility study on a nanoproduct register concludes that a register for nanoproducts (nanomaterial, mixtures and articles) produced or placed on the market is workable in practice and should be introduced primarily on the level of the European Union as it will interfere less with the free movement of goods.[21] A register for these products will contribute to a better transparency of nanoproducts on the markets for authorities and other users. From a precautionary perspective, this transparency enables authorities to take risk management measures on nanoproducts as early as possible.[22]

In June 2012 the German Federal Environment Agency (UBA) published a "Concept for a European Register of Products Containing Nanomaterials"[23]. Against the background of the deficits of the existing regulatory framework regarding the evaluation of possible risks for human health and the environment the register should create transparency on the overall use of nanomaterials in consumer products and in open environment. Manufacturers and importers of substances, mixtures which comprise or contain nanomaterials as well as articles that intentionally or unintentionally release nanomaterials should notify a limited set of data to a single European register (for more details see section 2.1).

Article 191 (3), point 3 TFEU states that before measures are taken, the benefits and costs of action and lack of action must be examined, including, where appropriate and feasible, an economic cost-benefit analysis. As a consequence this study has the aim to assess the impacts of a register based on the ENPR-Concept.

1.2 Study objectives

Objective of the study is to analyse the "Concept for a European Register of Products Containing Nanomaterials" published by the German Federal Environment Agency in June 2012 (for details on the concept see Chapter 2 of the study) regarding:

- identify the sectors and companies concerned by an ENPR;
- estimate the number of notifiers, categories of substances, concerned mixtures and articles, and of the number of notifications;
- estimate the cost for notifiers and public authorities;
- describe in a qualitative manner the benefits of an ENPR for public authorities, consumers and notifiers, and
- a comparison of the benefits and costs of an ENPR.

[21] Öko-Institut e.V. (2010).

[22] Öko-Institut e.V. (2010).

[23] UBA (2012).

The central task of this evaluation is the research on how many companies are affected with how many nanoproducts to notify. How is this burden distributed among industry sectors? A limited scope of impact assessment is required to estimate these factors. Possible options matching the problem definition focus on the establishment of an ENPR in comparison to the baseline and sub-scenarios concerning notification duties of the notifiers. Connected to these considerations, the impacts on innovation, competition and the possible benefits such as transparency, traceability as well as an overview on nanoproducts in relevant sectors for oversight and research are to be assessed.

It must be pointed out that the ENPR-concept is deliberately planned to encompass a wide scope of products containing nanomaterials. The reason for this is to gain an estimation of the maximum costs of an ENPR in the preliminary stage to the design of a possible regulation. On this basis the future scope of an ENPR then can be tailored according to the proportionality principle taking into account the cost-benefit ratio of an ENPR.

1.3 Methodology

To meet the study's objectives, the following methodological approach was developed and used:

1. Identification of sectors concerned
    a) Identification of a set of nanomaterials for further analysis (desktop research)
    b) Identification of nanoproducts subject to notification (desktop research)
    c) Development of classification framework to group nanoproducts
2. Estimation of number of notifications
    a) Desktop Research
    - Re-Analysis of sectors
    - Preliminary estimation of number notifications per sector
    - Determination of number of companies per sector (based on NACE[24])
    b) Expert Interviews
    - Verification of uses of nanomaterials in different application areas
    - Verification whether notification obligation arises for nanoproducts selected
    - Complementing existing information
    - Estimation of number of notifications per sector
    - Estimation of number of companies concerned per sector
    - obtaining reliable estimates as to the time required to retrieve and submit information
3. Estimation of costs
    a) Analysis of existing legal frameworks
    b) Estimation of direct costs for industry
    c) Estimation of direct costs for authorities
4. Qualitative assessment of effects on innovation and competition
    a) Distortion of the internal European Market
    b) Burden on micro, small, and medium enterprises
5. Assessment of benefits
    a) Data evaluation and aggregation for human health and environmental purposes
    b) Consumer information and transparency

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

c) Producer awareness of NM or NM containing products in their segment of the production chain – worker protection

d) Targeted research

e) Government oversight - traceability

Further details on the methodological approach can be found in relevant chapters of this study.

2 Concept of a European Register of Products Containing Nanomaterials (ENPR)

As the ENPR-concept serves as the basis for this study in this chapter the general concept and aim of the ENPR, the setting and terminology used and the objects of notification will be explained. In the following chapters, the general concept and main pillars of the ENPR are presented:

2.1 General concept of the ENPR

The concept for an ENPR revolves around the Precautionary Principle[25]. It is based on the possibility of negative effects on human health and the environment that could be the consequence of widespread use and thus exposure to nanomaterials of various origins.[26]

In order to reduce administrative efforts and costs for notifiers and public authorities and to avoid regulatory overlaps resulting from possibly several national nanoproduct registers, it is recommended to establish a single register on European level. Ideally, the ENPR will then replace national nanoproduct registers. The register shall be managed by one central European institution and the communication between the ENPR and notifiers as well as with Member States´ competent authorities shall be conducted electronically.

Another important pillar of the concept is to avoid duplicate reporting obligations for notifiers. Therefore the concept includes the postulate that the ENPR is a horizontal register that is empowered to collect data on nanoproducts from other substance regulations (e.g. REACH- and CLP-Regulation) and product regulations (e.g. Cosmetics Regulation and regulations in the food and feed sector). Should one or more data points required for the ENPR not be included in the sector regulation, the ENPR-concept postulates to adapt the sector information requirements by means of an umbrella regulation.

To estimate the exposure of the human population and the environment several data are essential which are listed in Chapter 2.4 of this study. It is sufficient to say that a valid exposure assessment needs to be based not only on the pure number of substances in the nanoform on the market but also on their life-cycle. The life-cycle reveals where possible exposures can occur during the production, use, and end-of-life phase. The same nanomaterial can be integrated in a wide range of products that are used and discarded in very different ways. The key term for this motivator is “traceability” of nanomaterials in nanoproducts. This traceability is essential for competent authorities to prioritize environmental enforcement activities and to monitor possible exposure pathways of nanomaterials. ENPR providing sector-wide information on a nanomaterial and its presence in a product from which it is released deliberately or unintentionally forms the basis to estimate exposure for humans and the environment, including cumulative and combinatory exposure.

According to the concept it is recommended to divide the collected data into a publicly accessible and a confidential part (see Chapter 2.5). The public part will contain information for

[25] COM (2000).

[26] UBA (2012) p. 2.

consumers empowering them with the freedom of an informed choice between the products they wish to consume and thereby increasing the market transparency. A part of this measure is the inclusion of a notification number with the product.

2.2 Subject to notification

For the purpose of this study "nanoproduct" is used as a general term comprising substances and mixtures which are nanomaterials or contain nanomaterials and certain articles containing nanomaterials. According to the concept for an ENPR the objects to be notified are defined with respect to REACH as following:

1. Substances[27] which are nanomaterials within the meaning of the COM recommendation.

   Article 3 (1) of REACH defines a substance as "a chemical element or its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition". According to the recommendation of the European Commission published in October 2011:[28]

   "*2. Nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. [...]*

   3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."

2. Mixtures which comprise or contain nanomaterials above a concentration threshold of 0.001% weight by weight (w/w)[29] referred to the whole mixture. If the cut-off value according to Article 11 CLP-Regulation[30] leads to a lower threshold, then this threshold has to be applied. In the case of "mixtures", the definition in Article 3 (2) of REACH is applied, according to which a mixture means "a mixture or solution composed of two or more substances".

3. Articles containing nanomaterials, intended to be released under normal or reasonably foreseeable conditions of use (analogous to Article 7 (1) of the REACH Regulation).

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[27] It is generally assumed that nanomaterials fall within the definition of substances in REACH and CLP Regulation.

[28] Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU), OJ L 275, 20.10.2011, p.28.

[29] Referring to the substance in question.

[30] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p.1, last amended Commission Regulation (EU) No 286/2011 of 10 March 2011, OJ L 83, 30.3.2011, p.1.

4. Articles containing nanomaterials above a concentration threshold of 0.1% weight by weight (w/w)[31] referred to the whole article, unless the producer or importer can exclude exposure from the article to humans or the environment during normal or reasonably foreseeable conditions of use including disposal (analogous to Article 7 (2) and (3) REACH).

In accordance with Article 3 (3) of REACH "article" means "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition." In case an article is produced or imported that consists of several sub-assemblies, the 0.1%-threshold applies to every incorporated sub-assembly and not to the whole article.[32]

2.3 Addressees of the duty to notify

The focus of our examination in this regard is to determine which natural or legal persons will be required to report nanomaterials and products containing nanomaterials to a European institution responsible for the ENPR. As the aim of reporting is to cover as comprehensively as possible all nanoproducts in terms of the register that are produced or placed on the market in the EU, the mandatory notification requirement must apply to manufacturers and importers of substances, initial distributors of mixtures and producers and importers of articles. "Placing on the market" in this context shall mean the first supplying or making available of a nanoproduct by a manufacturer, importer or distributor, whether in return for payment or free of charge, to a third party in the EU; import shall also be deemed to be placing on the EU-market.[33] Repackaging, relabelling and marketing for an application other than that notified by the initial notifier triggers an independent notification obligation.

2.4 Information to be notified

Regarding the evaluation of administrative burden for a notifier and competent authorities caused by the notification procedure, the analysis has to define the range of information. According to the concept of an ENPR, notifiers shall submit the following information to the competent authority:

- Name and address of the notifier,
- Product and trade name (excluding variations of a product),
- Application,
- Functionality of the nanomaterial(s) employed,

[31] Referring to the substance in question.

[32] Following the 'once an article, always an article' interpretation that is shared by the Member States Denmark, Austria, Belgium, Germany, France, Norway, and Sweden. Likewise, it is in principle possible to refer with the threshold to a homogenous material for the purpose of the ENPR. However, the latter position will not part of this study.

[33] Cf. the definitions of the terms "placing on the market" in Article 3 (12) REACH and "import" in Article 3 (10) REACH.

- Characterisation of nanomaterial(s),
- Nanomaterial concentration in the respective product, and
- Manufactured or imported tonnage bands of the nanomaterial(s).

Concerning the characterisation of nanomaterial, the following data must be submitted in order to comply with the definition for nanomaterials: information on particle size and distribution, shape (length, width, form, etc.), crystallinity , chemical composition, - where applicable - specific surface area, and in case of surface modifications its chemical composition.

2.5 Publicly accessible data

The following information in the product register is planned to be publicly available:

- Product and trade name,
- Application,
- Functionality of the nanomaterial(s) employed, and
- Parts of the characterisation of nanomaterial(s).

Information which as a trade secret will not be made publicly available:

- Name and address of the notifier,
- Volume of nanomaterial(s) manufactured or imported and
- Nanomaterial concentration in the respective product.

2.6 Notification procedure

This chapter gives a short overview of the notification procedure in order to outline those activities that are relevant to estimate the administrative costs of an ENPR for both the competent authority and notifiers.

As soon as the addressee of the ENPR (i.e. manufacturers and importers of substances, initial distributors and importers of mixtures and producers and importers of articles) is obliged to notify a nanoproduct (for more details see Chapter 2.3), it is foreseen that he has to submit the data required (see Chapter 2.4) to a competent European authority[34]. The notification must be sent through electronic means in a format defined by the competent authority.

In case the notifier has already submitted data on his nanoproduct to a competent authority due to informational obligations in other regulations (e.g. on a nanomaterial according to REACH registration or on a biocidal product according to the Biocidal Products Regulation[35]), he shall not be obliged to notify to the ENPR. In this case, the information requirements shall be solely based on the other (product) regulation as a lex specialis in order to avoid duplicate

[34] UBA (2012), p. 2.

[35] 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 biocidal products, OJ L 167, 27.06.2012, p.1; (thereinafter called: BPR).

obligations.[36] To this end the data requested due to (product) legislation being lex specialis must be harmonized with the ENPR data requirements (for a comparison on the information obligation between an ENPR and other regulations, see Chapter 4.2.1 ff.).

Following the notification the competent authority awards a single ENPR notification number to every notification made and communicates it to the notifier. When the notifier puts a substance, mixture or article on the market that has to be notified, he hands down the ENPR notification number(s) in the production chain to users corresponding to the substance, mixture or article. In the ENPR-concept it is open how the notification number shall be communicated down the production chain. In principle, two ways are possible either by putting the notification number on the product label[37] or by including the number in relevant documents, like trading and accountancy documents as well as invoices.

Any actor in the production chain who puts an article on the market which is subject to notification according to the conditions listed in Chapter 2.2 has to notify it. This is inter alia the case, if an actor in the production chain modifies a nanomaterial itself or a nanomaterial contained in a mixture or an article in a way that leads to changes in properties of the nanomaterial. Similarly notification obligation is a consequence of changing nanomaterial concentration in a product. The same is true for repackaging, relabeling and marketing of a nanoproduct for an application other than that notified by the initial notifier.

In principle there are two possibilities to update the information in the ENPR. Either information submitted to the competent authorities is updated by the notifier as soon as there are changes to this data (cf. the duty in REACH) or the information is updated on a yearly basis, e.g. at the beginning of each calendar year (both sub-scenarios are analysed in Chapter 4.3).

[36] UBA (2012), p. 11 ff.

[37] UBA (2012).

3 Identification of sectors concerned

The aim of this chapter is to identify industry sectors that will be affected by the implementation of an ENPR and to set the basis for the assessment of social and economic impacts of an ENPR.

To this end, the following steps have been taken to address the issue:

- Identification of nanomaterials that fall outside the scope of the ENPR,
- Identification of a set of nanomaterials for further analysis,
- Identification of nanoproducts subject to notification, and
- Development of classification framework to group nanoproducts.

3.1 Nanomaterials and the scope of the ENPR

3.1.1 Release of nanomaterials under reasonably foreseeable conditions

The phrasing "reasonably foreseeable conditions" encompasses the life-cycle of a given article during the "use" and the "end-of-life" phase. Interpreting the concept of the ENPR provided by the Federal Environment Agency the following aspects become relevant for the further proceedings of this assessment:

The production phase is governed by a different set of rules that ensure proper worker and environmental protection. Some articles such as e.g. cosmetics[38] or surface coatings[39] expose users and the environment to nanomaterials during their use and their end of life phases. Here the need to notify to the proposed ENPR is obvious. Other articles are not as obvious.

Release at different points within the use phase:

Car tires for example can contain several nanoscale substances embedded in their matrix such as carbon black, zinc oxide or titanium dioxide, and potentially carbon nanotubes (CNTs) in the future. No nanomaterial release has been reported so far for the end-of-life disposal either via landfill or incineration. During the use-phase of tires there is however some indication of ultrafine particle release which would make it necessary for them to be notified.[40] It is unclear how much of the ultrafine fraction reported in this publication is due to tire abrasion but it is an example of potential nanomaterial release from a composite material. Other products such as some coatings and finishes include nanomaterials and might be relevant for notification until they are applied to a surface and dried there. The finish of a car for example contains nanomaterials in the form of pigments and occasionally others to convey desirable properties like for example scratch resistance. There is data available on abrasion and wear of such coatings showing no release of nanoparticles or agglomerates. According to the findings of

[38] Nazarenko et al. (2011); Nazarenko et al. (2012a, 2012b).

[39] Broekhuizen (2011); Broekhuizen & Broekhuizen (2009).

[40] Lin et al. (2005).

Golanski et al. the nanoparticles of the tested coatings remain embedded in the paint matrix during abrasion induced release into air and water.[41] Such proof could make it unnecessary to notify a product because it is coated with a finish that is similar from a structural and composition point of view (QSAR, read across, non-testing methods). Similar considerations might be relevant for other composite materials. In the case of CNT containing polymer pellets this has also been shown.[42]

End of life:

The end of the life phase is the least researched area in the life cycle of nanoproducts. In a review article from Hischier & Walser (2012) it is shown that looking at the literature from the past decade only six of the 17 publications concerning themselves with LCA deliver a full cradle to grave analysis. The others either ignore the use phase or the end of life. The reason for this is partially to be found in the available measurement methods. It is extremely difficult to conduct measurements in the environment due to lack of sensitivity of most measurement equipment, difficulties to distinguish between natural and engineered nanomaterials, and transformation processes of nanomaterial in the environment. At the same time the use and end-of-life phases are the ones containing the highest probability for release. Keller et al. (2013) have modelled the global emission of engineered nanomaterial for 2010 using production data, literature data, and accepted models for different nanomaterials and sectors they are used in. They estimate a release of nanomaterials at the end of the respective product lifecycles of ca. 318.000 tons as a worst case scenario. At least two thirds of this worst case scenario global emission of nanomaterials is accounted for by landfills. The authors do not estimate whether or not nanomaterials are freed from landfills as the technological standards vary too much globally. The global ENM emission by environmental compartment is estimated as follows:

- Landfill: 63-91 %,
- Soil: 8-28 %,
- Water: 0.4-7 %, and
- Air: <1.5 %.

As can be seen by the variation between low and high estimates the numbers are influenced by a large number of factors as well as significant lack of knowledge on nanomaterial´s end-of-life aspects. Similar results were also obtained by Mueller et al. (2013). The bottom ash produced in municipal solid waste incinerators can also be used for construction materials including road construction.[43] In these applications the fate of the included nanomaterials is unclear. Research suggests leaching of heavy metals from i.e. roads but further research is necessary.[44]

[41] Golanski et al. (2011).

[42] Wohlleben et al. (2011, 2013).

[43] Lee et al., (2011); Vegas et al., (2008).

[44] Todorovic, (2006).

It is also evident that the emission of nanomaterials from landfills is a significant possibility to influence the exposure considerations of many nanoproducts. Either by controlling the disposal of nanomaterials or by the ability of the landfill sites to retain the nanomaterial on site applying technical modifications exposure can be significantly reduced and thus the amount of necessary notifications of nanomaterial could be curtailed sharply.

Case study cerium oxide:

As elucidated above the tracking of nanomaterials at the end of their lifecycle is difficult and not yet heavily researched. Scientists are directing their efforts at this life cycle phase increasingly.[45] Many of these studies model the end of life phase of various nanomaterials. An example of a nanomaterial whose disposal in a specific waste pathway has been researched is cerium oxide in waste incineration plants.

Cerium oxide is chosen as an example as it is relevant and easy to detect. It is relevant because cerium oxide is added to many products that are combusted as a matter of course or after their use phase. To cite a prominent example: Cerium oxide is an additive to car fuels.[46] These are combusted during their use phase and there is little data as to the fate of cerium oxide particles after the combustion yet. Though the emitted concentration is below the NOEL (no observed effect level) nothing is known about the dispersion and accumulation characteristics in for example cities.[47] It is, however, a prominent source of exposure that lends itself as an example. Cerium oxide has been combusted in experimental studies in waste incineration plants giving an indication of its fate in such a process.[48] As stated above it was used in the study because it is easy to detect, as the background levels of cerium oxide in nature are very low, thereby increasing the ease of measurement. These experiments have shown that the nanoparticles are not freed via the exhaust systems of an incineration plant, but they can be found in agglomerated form on the remains of the incineration process and in the particle filters. Both have to be discarded at a later point. The slag that remains of the process is increasingly harvested for metals in processes grouped under the term landfill mining. Not only does the (in this case) nanomaterial containing slag get deposited on a landfill from where the release of nanomaterial to the environment and the exposure of workers is possible but there are dedicated processes to recover other valuable materials in the course of which workers are likely to be exposed to nanomaterials.

Cerium oxide is a very stable metal oxide with melting temperatures around 2400 °C. Not all nanoparticles are as stable at higher temperatures and would survive the processes in an incinerator, but not all waste is incinerated either. As an example it demonstrates well why end

[45] Friege (2012); Gerlofs-Nijland et al. (2008); Golanski et al. (2011); Kiser et al. (2009); Lowry et al. (2012); Mueller et al. (2013); Nowack et al., (2012).

[46] Farfaletti et al. (2005).

[47] Park et al. (2008).

[48] Walser et al. (2012); Wiesner & Plata (2012).

of life exposure is a valid concern that needs to be addressed through research and should be taken into account by producers.

This case study also demonstrates the need for application and thus life cycle specific considerations to accurately assess the release of and the exposure to nanomaterials.

As regards the scope of the ENPR, it is the duty of the notifiers to demonstrate that there is no release of nanomaterial from their article under reasonably foreseeable conditions in case they want to avoid notifying to the ENPR. Certainly, the notifiers can use generic arguments based on results from studies for similar cases. Nevertheless, they will have to argue for their individual article.

3.1.2 Natural and incidental nanomaterials and polymers

Natural nanomaterials or polymeric nanomaterials such as micelles or dendrimers are excluded from the scope of this study. The exclusion from the scope of the study is argued with the fact that REACH defines "substances which occur in nature" in Article 3 (39) as "a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means." Adhering to this definition any other treatment of natural nanomaterials than specified in Art. 3 (39) REACH will result in the loss of the 'natural' state. Nature produces myriads of nanomaterials. Every natural compartment contains a multitude of nanomaterials in constant flux of genesis, transformation, and disappearance. Especially the soil is particularly rich in organic and inorganic nanomaterials. Consequently products like gardening soil, basic types of cement, sands (decorative or functional), lime, coal etc., but also flour would have to be analysed and potentially registered. The data to assess the consequences of registering naturally occurring nanomaterials is not available and therefore excluded from the study.

If a nanomaterial of natural origin is however modified via e.g. surface chemistry, intentionally or unintentionally, they are effectively engineered nanomaterials. When an ENPR is established however, the task of defining precisely how to deal with natural nanomaterials will have to be revisited.

Furthermore incidental nanomaterials are excluded from the scope of this study since the definition of "incidental" in the scope would include virtually every product on the market because of the widespread use, for example for ground calcium carbonate, the authors have assumed for the purpose of this analysis that powders with a Dv50 > 5 μm are considered incidental and omitted from consideration. Examples of such substances are fine powders such as ground cement (without an additive in the nanoform), ground calcium carbonate (typical Dv50 ~ 5 μm), etc. Without this amendment the ENPR would become impossible to manage and enforce. Part of above reasoning also holds true for polymers. The vast majority of polymers is of natural origin including most lipids, proteins, sugars, etc. They are nanomaterials under the definition of having one or more dimension between 1-100 nm. Engineered polymers arguably fall under the same distinction from natural polymers as engineered vs. natural nanomaterials do. Because they are tailored to every conceivable need and come with their own batch to batch variations (i.e. length distribution) they are excluded for practical reasons similarly to their exclusion from REACH (see recital 41 in REACH). In the recommendation for a definition of nanomaterials of the European Commission they are

excluded by defining them as non-particular and thus not subject to the definition of nanomaterial.[49] It would be extremely cost intensive to define all polymer variations occurring in a batch and then declaring them separately. However, as the monomers have to be registered under REACH information on them would be available for the ENPR.[50] It is, however, true that polymers can be produced as nanoparticles. This is also an area where the particular handling of such cases and the boundaries involved will have to be addressed upon implementation of an ERPN. The existing definitions are insufficient to conclusively include or exclude polymers with a chain length giving them one dimension larger than 1 nm. They were therefore excluded from the scope of this study.

3.2 Identification of a set of nanomaterials for further analysis

Nanomaterials comprise a heterogeneous group of different substances. A recent study by Risk and Policy Analysts reported that there may be between 500 and 2000 different nanomaterials on the market.[51] A comprehensive analysis of the entire nano-market in order to estimate the number of products containing nanomaterials is therefore not feasible. Consequently, the initial assessment of impacts resulting from the implementation of an ENPR was confined to a representative set of products and product groups.

In principle, there are two options for the identification of these sets, either from the perspective of nanomaterials themselves ("bottom-up"), or from the perspective of product or industry areas ("top-down"). As the number of products containing nanomaterials appears much higher than the number of nanomaterials, the former approach has been chosen initially.

The selection of nanomaterials was based on one of the following criteria:

- High production volumes,
- Wide dispersive uses and
- Sufficient information on uses available from publicly accessible sources.

As a starting point, information on effective quantities of nanomaterials in circulation was collected. This analysis was confined to recent publications (2009-2012) to take into account the very fast development of the markets for nanotechnology. Moreover, studies focusing on different economies were considered as it appears that the relative production volumes in Europe are comparable to other industrialized regions.[52] Although published data should be

[49] European Commission. (EUCOM, 2011). Questions and answers on the Commission Recommendation on the definition of nanomaterial. MEMO/11/704

[50] CIRS (2011).

[51] Risk & Policy Analysts Limited (2012).

[52] EUCOM (2012a).

seen only as rough estimates, they nevertheless provide a valuable picture with regards to their relative market shares.[53]

Table 1: Annual production volumes of selected nanomaterials.[54]

Annual Production Volumes and Uses	Global production volume in t/a	U.S. global production volumes in t/a	Uses in Japan in t/a
Carbon Black	9,600,000	n.a.	1,000,000
Synthetic Amorphous Silica	1,500,000	n.a.	13,500
Aluminium Oxide	200,000	n.a.	n.a.
Barium Titanate	15,000	n.a.	n.a.
Titanium Dioxide	10,000	7,800 – 38,000	1,250
Cerium Oxide	10,000	35 – 700	n.a.
Zinc Oxide	8,000	n.a.	480
Carbon Nanotubes	Several hundred – few thousands	55 – 1,101	60 1)
Nanosilver	20	2.8 – 20	50 2)
Fullerenes	n.a.	2 – 80	2

1) MWCNTs: 60 tons; SWCNTs: 0.1 tons.2) Silver and inorganic particles. "N.a." means "not available".

Carbon black and synthetic amorphous silica (SAS) represent by far the largest volume of nanomaterials currently on the market (almost 85% and 12% of total nanomaterial on the market, respectively). Besides, nanomaterials such as aluminium oxide (Al2O3), cerium oxide (Ce2O), titanium dioxide (TiO2) and zinc oxide (ZnO) were found to be quantitatively among the most relevant. In general, estimates on the production volumes vary significantly and may reflect the rapidly changing landscape as well as proprietary issues.

In addition, nanomaterials that were suspected to have a wide dispersive use were considered for further analysis, such as fullerenes, carbon nanotubes (CNTs), nanosilver and pigments.

On the other hand, also barium titanate as an important nanomaterial for the electronics industry was found to be produced at comparatively high quantities (15.000t/a). However, this nanomaterial was exempted from the first preliminary analysis as it was assumed to be applied at concentrations well below the threshold set in the register.

3.3 Identification of nanoproducts subject to notification

For each of the selected materials, their uses in certain applications and product groups were determined by desktop research.

The following sources of information were examined:

- European Commission: "Types and Uses of Nanomaterials"[54], and

[53] Hendren et al. (2011); The National Institute of Health Sciences (NIHS) Japan (2009).

[54] EUCOM (2012b).

- DaNa – a knowledge platform supported by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)[55]

The provisions of the ENPR provide for certain notification exemptions, for instance in cases where relevant concentration thresholds are not met or in case of articles when exposure to humans or the environment is excluded (see Chapter 2.2).

Therefore, all products containing nanomaterials were critically reviewed with regards to the following issues:

- Are product groups classified as articles or mixtures?
- Can certain product groups be excluded from further analysis *a priori* as relevant concentration thresholds are not exceeded or because exposure can be excluded (considering the entire life cycle)?

An overview of the results of these activities as well as the final selection of product groups for further assessment are provided in Annex 7.1. It is important to note that the compilation of different uses for selected nanomaterials is far from being comprehensive, but rather it merely constituted the basis for consulting experts in the field to be able to further substantiate and complement the results obtained thus far (see Chapter 4).

3.4 Development of classification framework to group nanoproducts

In order to present a relatively large set of information in a comprehensible way, previously selected "nanoproducts" (Chapter 3.2) were assigned to several categories. This approach also aimed at:

- facilitating the identification of sectors that are significantly affected by the implementation of an ENPR, and
- facilitating the identification of suitable experts (e.g. industry associations) in the field.

Product categorization frameworks have been developed within the frame of various legislations. However, these frameworks appeared less appropriate as most of these were considered too complex. For instance, European production statistics is based on classification of goods according to the so-called "Prodcom classification of products", which includes approximately 3900 product categories[56].

The development of categories has therefore been based on the recent work of the Danish Environmental Protection Agency with regards to the establishment of a nanoproduct database[57] and adapted to take into account both the specific provisions of the ENPR proposed by the German Federal Environment Agency and the results obtained thus far.

[55] DaNa (2013).

56 "Eurostat International Trade and Prodcom Database." www.destatis.de. (as from 3.4.2013).

[57] Fischer et al. (2012).

3.5 Results

For the purpose of this study, all nanoproducts identified were grouped into the following sectors or categories:

1. Substances,
2. Cosmetics,
3. Health Care,
4. Food & Feed,
5. Coatings & Inks,
6. Cleaning & Disinfection,
7. Rubber Products,
8. Building & Construction,
9. Textiles,
10. Paper Products, and
11. Complex Objects & Other Products.

4 Evaluation of Impacts of an ENPR

This chapter aims at assessing potential impacts that result from the implementation of an ENPR. The impact assessment provides:

- a quanti
- tative estimate of the number of notifications to be expected for various product categories (Chapter 4.1),
- an assessment on the availability of data for the ENPR from sector regulation (Chapter 4.2),
- an overview of the financial burden for industry (Chapter 4.3),
- an overview of the financial burden for authorities (Chapter 4.4),
- a qualitative description of effects on innovation & competition (Chapter 4.5), and
- a qualitative description of the resulting benefits (Chapter 4.6).

The figures and estimations presented here refer to the European market, unless otherwise indicated.

4.1 Expected number of companies and nanoproducts per sector

The goal of this section is to provide an estimate of both the number of companies affected by the register and the number of total notifications per identified sector.

In view of the lack of extensive publicly available data on nanoproducts and companies handling or producing them (e.g. studies, production statistics), obtaining any sufficiently reliable estimates constitutes a major challenge.

In order to draw the most accurate picture possible, the following steps have been taken to address the issue:

1. Desktop Research

    a) Re-Analysis of sectors

    In order to obtain a more detailed picture of different categories previously identified, each sector was re-analyzed (using sector-specific studies). Specifically, this approach has been employed to complement the results obtained thus far and to get a sector-specific overview about the kinds of nanoproducts that are likely to be subject to notification. An overview of all sectors concerned is provided in Chapters 4.1.1 to 4.1.11.

    b) Preliminary estimation of number notifications per sector

    Initially, the preliminary total number of notifications per sector was estimated based on the authors' in-house experience (from preliminary expert interviews) as well as publicly available studies and reports. As part of the desktop research, companies likely to have to notify nanoproducts were investigated (e.g. their product portfolio was analysed) and the number of products to be notified per company was estimated. It is important to note, however, that these figures were merely used as a

starting point for the second step in which the knowledge of various experts in the relevant fields was used in an attempt to develop more reliable estimates.

c) Determination of number of companies per sector

The total numbers of companies per sector were obtained using the European Classification of Economic Activities (NACE), a framework for the collection, production and dissemination of statistics on economic activities in Europe. NACE consists of a hierarchical structure, defined by sections, divisions, groups and classes. For the purpose of this study, only economic activities (NACE codes) in Section C (Manufacturing) were further considered and assigned to sectors previously identified since only companies in this NACE section are required to notify nanoproducts according to notification procedure assumed for this study (see Chapter 2.6 for details on the notification procedure).

Using this approach, the total number of businesses per sector was obtained. It must be stressed that only a portion of these companies may be affected by the implementation of an ENPR. During the desktop research, it was also noted approximately how many of the investigated companies were likely to be required to notify products based on their published product portfolio (and therefore providing a rough estimate of the fraction of companies required to notify at least one product). Again, these figures were used subsequently to develop more realistic and objective assessments by experts.

2. Expert Interviews

For each groups and sectors likely to be concerned by the implementation of an ENPR, qualified experts (including manufacturers of substances, associations, NGOs, experts from academia) were identified on the basis of a desktop research and interviewed by telephone (Dec 2012 – March 2013)) in the second step.

These activities were partially complemented by industry association and individual company surveys to compile information and aimed at:

- verifying the uses of nanomaterials,
- verifying whether notification obligations arise for certain products,
- complementing existing information,
- developing realistic estimates regarding the number of notifications to be expected per sector,
- developing realistic estimates regarding the fraction of total companies that may be affected per sector, and
- obtaining reliable estimates as to the time required to retrieve and submit information (needed to estimate costs for industry, see Chapter 4.3)

In total, 46 associations, 45 companies, and a total number of 16 representatives from NGOs, authorities and members of academia were contacted and interviewed.

4.1.1 Substances in nanoform

In general, expert interviews indicated that many materials are imported into the EU and sold as separate substances according to their characteristics and qualities. This is reflected in a rather large numbers of notifications to be expected (compared to the total number of nanomaterials on the market). A good overview of available products on the global market is provided by nanowerk[58].

Typical products to be notified

Typical products that may be subject to notification include (amongst many others):

- Pigments of different types (e.g. inorganic and organic pigments), used in various applications (e.g. plastics, paints, textiles, ceramics, building and construction),
- CNT (e.g. to confer antistatic properties),
- Rare earth metals (e.g. for catalysis),
- Boehmite (e.g. for abrasion resistance in coatings),
- Nanosilver (e.g. for antimicrobial properties),
- SAS (e.g. as a filling material), and
- Precipitated calcium carbonate (PCC) (e.g. as a filling material).

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) were considered:

- C20.12 - Manufacture of dyes and pigments,
- C20.13 - Manufacture of other inorganic basic chemicals,
- C20.14 - Manufacture of other organic basic chemicals, and
- C20.4 - Manufacture of basic precious and other non-ferrous metals.

4.1.2 Cosmetics

In principle, the use of nanomaterials in cosmetic products can be broadly classified in two important categories, namely the use as UV protecting agent and the use as encapsulation or carrier system. The latter includes dendrimers (not yet commercialized), nanocrystals, liposomes nanoemulsions, micelles and lipid-nanoparticles that are used to transport agents (e.g. vitamins) into deeper skin layers. These nanomaterials are found in numerous products, amongst others in some skin and hair care products.[59] However, products containing these

[58] http://www.nanowerk.com/index.php (as from 3. 4. 2013).

[59] Greßler et al. (2010)

materials are not within the scope of the study (see Chapter 3.1.2) and it should be discussed whether they should be notified when setting up an ENPR.

Both titanium dioxide and zinc oxide block the harmful effects of UV-light, while appearing transparent when used at nanoscale. As the relevant concentration thresholds are exceeded[60], a very large share of these products may need to be notified under the proposed obligations.

In addition to these applications, numerous other nanomaterials can be found in cosmetic products. These include, amongst others:

- Carbon black (e.g. eyeliner, mascara),
- SAS (e.g. face powders),
- Aluminium oxide (e.g. toothpaste),
- Nanosilver (e.g. toothpaste, creams, soaps),
- Fullerenes (e.g. anti-ageing creams)[61]

In general, as data availability is scarce and industry appears reluctant to share information on the use of nanomaterials, the share of products containing nanomaterials above the thresholds defined within the ENPR is extremely difficult to estimate. As the Cosmetics Regulation (EC) No 1223/2009[62] (see Chapter 4.2.1.2) will require cosmetics manufacturers to list any nanoparticles contained in products marketed within the European Union, more data will become available. Expert consultation indicated that as many as half a million cosmetic products may be on the market in Europe.

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) toothpastes (aluminium oxide, nanosilver, pigments) anti-ageing creams (fullerenes, SAS), mascara, eyeliners (pigments/carbon black), face powders (SAS, pigments), sunscreen products (titanium dioxide and zinc oxide).

Use of statistical data

For the purpose of this study, statistical data of the following economic activity (as defined by NACE) was considered:

- C20.4.2 - Manufacture of perfumes and toilet preparations

[60] Patents GB2206339(A) (1989-01-05) and US2011171148(A1) (2011-07-14).

[61] Experts in the field stressed that cosmetic products containing fullerenes are currently not manufactured in Europe. Notwithstanding this, these kinds of products may be available on the world-wide market.

[62] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products , OJ L 342, 22.12.2009, p.59 (thereinafter called: Reg. 1223/2009).

4.1.3 Health Care

Nanotechnology applications in medicine typically fall into one of the following categories:

- Targeted drug delivery systems,
- Diagnosis and implants, and
- Therapeutic approaches involving nanomaterials.

In general, it must be noted that the term "nanomedicine" is often not clearly defined and may comprise applications that would not be considered using nanomaterials on the basis of the definition proposed by the European Commission (e.g. the use of "nanoscale" DNA fragments on chips as a diagnostic tool). This implies that any estimates on the use of nanomaterials within this sector needs to be critically reviewed as to whether notification obligations occur.

Drug delivery systems are used to accumulate substances in specific tissues. They can either be based on the use of liposomes (embedding active substances) or associated with delivery systems at nanoscale (e.g. macromolecules such as proteins or polymers). Current applications on the market still appear limited; however there are some cytostatic pharmaceuticals available[63]. Nonetheless, due to the specific provisions of the ENPR, these kinds of applications currently do not fall under the scope of the study (macromolecular carrier systems are not considered "particulate" nanomaterials, see Chapter 3.1). As the market of nano-based pharmaceuticals has been reported to grow significantly in coming years, it yet remains to be seen whether at least some applications may become relevant with regards to notification obligations.

Materials in the nanoform are also used in medicinal products for diagnostics and implants. For instance, colloidal albumin is used as a carrier of medical radioisotope atoms[64] that is commonly applied in radiodiagnostic examinations. Implants can be either coated using nanomaterials (e.g. calcium phosphate crystals for dental implants[65]) or by using nanomaterials as implant materials. Many of these applications have not been commercialized yet as to the comparatively high costs. A good overview of potential applications has been provided by ObservatoryNano.[66] Irrespective of this situation, only a minor share of products (if any) is to be expected to fall under the scope of the ENPR as most of them are either nanocomposites, comprise the use of natural nanomaterials or their concentration is expected to be well below the thresholds set by the ENPR (see Chapter 2.2).

[63] Further information is provided by the European Medicines Agency (EMA): http://www.emea.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000345.jsp&mid=WC0b01ac05800baed9 (as from 14.5.2013).

[64] http://www.iba-molecular.com/products/nanocis (as from 14.3.2013).

[65] http://www.biomet.com (as from 14.3.2013).

[66] ObservatoryNano (2009a).

Therapeutic approaches involving nanomaterials are at an early stage of market development and only very few products have been found to be commercialized so far (e.g. Vivagel®[67]). These products have therefore not been considered in the course of this study as they appear to be based primarily on the use of nanosized macromolecular carrier systems (see Chapter 3.1).

In addition, several publications have reported the use of nanosilver in wound dressings.[68] Expert consultation suggests that in some cases, coatings do not necessarily contain nanosized silver and no information could be obtained as to the amount of nanosilver typically used in these kinds of applications. Both the number of affected companies and the number of products therefore appear to be comparatively low.

With regards to pharmaceuticals, highly dispersed SAS is commonly used as pharmaceutical excipient which functions as a glidant or free-flow additive to provide improved tablet production efficiencies and tablet uniformity and strength.[69] As percent ratios typically vary between 0.1 % and 10 %, most tablets and capsules may be affected with regards to notification obligations.

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) pain killers in tablet form, contraceptive agents and suppositories (all containing SAS), and wound bandages containing nanosilver.

Use of statistical data

For the purpose of this study, statistical data of the following economic activity (as defined by NACE) was considered:

- C21.2 - Manufacture of pharmaceutical preparations.

4.1.4 Food and Feed

Recent developments in nanosciences and nanotechnologies offer new opportunities for innovation to food and related sectors worldwide. In principle, the use of nanotechnology within this sector can be divided into:

- Food Packaging,
- Food Production,
  a) sensors and diagnostic devices (e.g. bioarrays),
  b) disease and pest control (e.g. nano formulated agrochemicals),
  c) water and nutrient control (e.g. water filters treated coated with nanomaterials),

[67] http://www.starpharma.com/vivagel (as from 14.3.2013).

[68] ObservatoryNano (2009a).

[69] ObservatoryNano (2009a).

d) Genetic engineering of plants/lifestock (use of nanoparticles for transfections), and

e) Synthesis of nanocomposites from plant materials (e.g. cellulose nanofibres);

- Food Processing,

a) Quality control (e.g. “nano”sensors and microarrays for detection of chemical contaminants),

b) Processing technology (e.g. “nano”coatings to prevent biofilm formation, nanofiltration systems), and

c) Functional Foods (e.g. encapsulation of nutrients to increase bioavailability, enhance taste, texture and consistency of foodstuffs or mask an undesirable taste or odour).

The main focus so far appears to be on food packaging with some products already being commercially available. For the present study, these kinds of products were not further considered, based on the assumption that relevant concentration thresholds are not exceeded.

The use of nanotechnology in the remaining areas is still in its infancy with only few products on the market yet and thus, the number of notifications appears to be negligible.

However, the conventional forms of SAS and titanium dioxide are permitted food additives (E551 and E171, respectively), and there is a concern that the conventional forms may also contain a nano-sized fraction due to size range variation which may lead to a large number of notifications within this sector.

Typical products to be notified

Due to the use of food additives such as E 551 or E 171 (see above) typical products that may be subject to notification may include table salt, soup powder, seasonings, sliced cheese, ketchup, chewing gum or tablets.

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) was considered:

- C10.8 - Manufacture of other food products and
- C11.0.7 - Manufacture of soft drinks; production of mineral waters and other bottled waters.

4.1.5 Coatings and inks

Coatings are used in a wide variety of industry sectors, from construction over medical devices to electronics. However, due to the thresholds defined within the register (see Chapter 2.2), coated articles are generally not expected to fall under notification obligations. These may comprise, amongst many others, food contact materials, filter systems for vacuum cleaners, computer keyboards, nanosilver-coated refrigerators or antibacterial wallpapers.

The same cannot be said, however, for coatings agent *per se*, such as paints, varnishes, printing inks or powders and dispersions that have been developed for various coating applications, for example:

- Addition of nanosilver or titanium dioxide confers antimicrobial properties. Antimicrobial paints are already used in hospitals as well as in schools, offices, and in public transportation.
- Addition of UV-protecting agents such as titanium dioxide or zinc oxide provides protection from the deterioration caused by UV radiation.
- SAS based nano-coatings and titanium dioxide may be used to alter the surface wetting properties of surfaces. SAS can be used to provide super hydrophobic surfaces, i.e. drops of water roll off free of residue, taking any impurities with them ("self-cleaning surfaces"). Titanium dioxide displays hydrophilic properties that induce the complete spreading of a water droplet to near-zero contact angle and can therefore prevent fogging. At the same time, the photo catalytic properties of titanium dioxide can be used for the degradation of organic pollutants. As nanoscale titanium dioxide is also transparent, it can be used in glass coatings ("self-cleaning windows"). In short: These nano-based coatings are also "self-cleaning", first dissolving dirt in the water film, decomposing the organic matter that can eventually be carried away. Aluminium Oxide is often used to provide surface coatings with scratch resistance.
- Addition of pigments such as nanoscale ferric oxide particles used in pigment applications or the use of pigments to improve dispersibility and coating properties.

As to the notification obligations of the register, it is difficult to obtain reliable data on the share of products that contain these nanomaterials. Expert consultation suggests that due to the use of these nanomaterials, between 1-3% of all products may be affected. It has been estimated that there are around 600.000 different formulations for paints and printing inks available on the German market[70] which in turn constitutes around 25% of the European market[71].

Moreover, experts also indicated that in addition, virtually every product within this industry sector is to be considered a product containing nanomaterials that needs to be notified. This is due to the use of fillers and pigments (in relevant concentrations) which may need to be classified as nanomaterials according to the definition proposed by the European Commission.[72]

Typical products to be notified

Typical products that may be subject to notification include printing inks (e.g. textile inks, graphical inks for papers & boards, graphical inks for plastics, industrial inks), various paints, and varnishes. Each categories has many more masterbatches / or concentrated pigment-based pastes that would also be subject to notification.

[70] Verband der deutschen Lack- und Druckfarbenindustrie e.V. (2012).

[71] Personal communication.

[72] Ecological and Toxicological Association of the Dyes and Organic Pigments Manufacturers (ETAD) (2009).

For instance, according to experts' estimates there may be around 200-300 organic pigments that are placed on the European market in the form of around 2000 different mixtures, which are, in turn, used in manufacturing masterbatches for various applications.

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) were considered:

- C20.3 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics.

4.1.6 Cleaning and Disinfection products

The identification of uses of nanomaterials in cleaning and disinfection products is often based on "nano-claims" by manufacturers, without providing further details. In general, nanomaterials may be used to:

- produce films that can be applied to surfaces (e.g. windows, car windscreens, kitchen working plates), thereby facilitating easier cleaning (SAS-based, titanium dioxide), and
- provide products with antibacterial properties (mostly nanosilver)[73].

Articles that are coated with these products were not considered for further analysis as the concentration of nanomaterials is well below the thresholds set by the ENPR (e.g. certain washing machines, water filters) (see Chapter 2.2).

According to industry experts consulted in the course of this study, some of the products with nano-claims may instead contain waxes and fluorocarbon polymers instead of nanomaterials. All experts emphasized that the use of nanomaterials within this industry sector is confined to a comparatively low number of products. This trend is also backed by a survey among members of the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.)[74]. However, there were also occasional comments that some products may also contain filling materials (e.g. SAS-based).

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) shoe deodorants, cleaning agents, polishing agents.

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) were considered:

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[73] Various products can be found in public inventories such as the Woodrow Wilson database (http://www.nanotechproject.org/) or the online database of the German environmental NGO '**BUND**' (http://www.bund.net/nanodatenbank/).It must be noted that the information provided in these databases is solely based on claims and advertisements of manufacturers.

[74] Personal communication. A.I.S.E. represents more than 900 companies in the field.

- C20.2 - Manufacture of pesticides and other agrochemical products, and
- C20.4.1 - Manufacture of soap and detergents, cleaning and polishing mixtures.

4.1.7 Rubber products

Both carbon black and amorphous synthetic silica are used as reinforcing fillers in the rubber industry. In fact, it has been reported that over 80% of the total production of carbon black is used in rubber products.[75] The fillers provide a large degree of strengthening of the rubber network, resulting in a substantial increase in stiffness, tensile strength, and resistance to abrasion.[76] In addition, zinc oxide may be added to prevent UV and bacterial degradation.

Rubber products comprise a range of different products, for instance tyres, hoses, tubes, vibration mounts, wiper blades, rubber based adhesives and sealants, conveyor belts, footwear and belts. As a result of the vulcanization process, nanomaterials are embedded in a three-dimensional network that is chemically indescribable. However, there have been ongoing discussions as to whether environmental exposure can occur as a result of the wear of tyres.[77]

Consequently, given that unequivocal data on end-of-life aspects is not readily available for all products, it was assumed that all rubber products containing nanomaterials at relevant concentrations are subject to notification obligations.

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) summer tyres, winter tyres, bicycle tyres, tractor tyres, belts, gaskets, rubber hoses, rubber conveyer belts, rubber sheets, rubber fittings and seals, footwear, wiper blades etc.

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) were considered:

- C22.1.1 - Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres, and
- C22.1.9 - Manufacture of other rubber products.

4.1.8 Building and Construction

Many potential applications for nanotechnology in building and construction have been described. However, the number of products on the market remains rather low due to the comparatively high costs of these materials.[78] Similar observations were made in the course of

[75] EUCOM (2012a).

[76] European Tyre & Rubber Manufacturers' Association (ETRMA) (2012)

[77] It must be noted that nanoparticles released under this conditions are still associated with the rubber matrix.

[78] Broekhuizen & Broekhuizen (2009).

the present study. In view of the current discussions on energy efficiency, nano-based solutions are expected to play a more important role in the near future. The use of nanomaterials currently focuses on[79]:

- Coatings (e.g. titanium dioxide, zinc oxide, silver, SAS, aluminium oxide, cerium oxide),
- Insulation materials (SAS),
- Fire protection (SAS), and
- Cement-based products (titanium dioxide, SAS).

By far the most important application of nanomaterials within the building and construction sector appears to be the use of nano-based coatings and paintings. These products can be used in a wide variety of applications, from plastics to steel. At present, the focus appears to be set on anti-bacterial coatings and products that confer photo-catalytic and self-cleaning properties, using titanium dioxide and zinc oxide. According to several industry experts who spoke off the record, the use of nanosilver as an antimicrobial agent seems to decline due to recent public debates on the safe use of this nanomaterial. In addition, UV-protective coatings are available, some of which are based on nanotechnology (titanium dioxide, zinc oxide, cerium oxide). Due to the thresholds defined within the register, coated articles are not expected to fall under notification obligations[80].

Insulation materials generally do not contain nanoparticles but some specialized products are made of SAS-based nano-foam, composed of up to 99.98 % air by volume[81]. Some of these materials are designed for fire protection. They consist of cross-linked SAS particle networks with a nanopore structure that is finer than the pore structure of the aggregated particles in precipitated SAS. However, taking into account the scope of the ENPR, these products do not fall under the notification obligations (nanostructured materials with an internal or surface structure in the range between 1-100 nm are excluded from the scope of the ENPR, see Chapter 2.2.

Recent research has demonstrated that properties of cement based products (e.g. mortar, concrete) can be modified by nanomaterials. For instance, the addition of nanoscale SAS particles enhances the density and strength of concrete.[82] In addition, the photo-catalytic and antimicrobial properties of titanium dioxide can be used to manufacture products like paving stones of roof tiles that catalyse the degradation of organic pollutants or nitrogen oxides from vehicular traffic.[83] Consultation of experts confirmed that the total market share of these

[79] Greßler & Gazsó (2012).

[80] Coatings are covered separately (see Chapter 4.1.9).

[81] Cf. http://www.aerogel.org (as from 14.3.2013).

[82] Greßler & Gazsó (2012).

[83] Chen & Mao (2007).

products appears small, confirming the results of a previous study.[84] Moreover, the final concentration of nanoparticles in articles is very likely to be below the threshold that necessitates a notification. Consequently, notification obligations may only become relevant for some cement based mixtures (e.g. adhesive mortars, concrete products), that are used in special applications.

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) photocatalytic cement and self-cleaning roofing tiles (SAS, titanium dioxide), special adhesives (SAS).

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) were considered:

- C20.5.2 - Manufacture of glues,
- C23.2 - Manufacture of refractory products,
- C23.3 - Manufacture of clay building materials,
- C23.5 - Manufacture of cement, lime and plaster, and
- C23.6 - Manufacture of articles of concrete, cement and plaster.

4.1.9 Textiles

The textile industry has been one of the pioneers in commercialising products incorporating nanotechnology. This growing interest of the textile industry in nanotechnology has led to the development of several new applications/products for textiles. However, only few of these applications have already reached the market.[85] Expert consultations confirmed these findings and revealed that market penetration is still considered low and one of the reasons may be related to the comparatively high costs. It is estimated that less than 1% of all textiles incorporate nanomaterials.

In principle, nanomaterials can be applied either at the stage of fibre production or in the course of finishing processes (e.g. coating).

Commercially available textiles with nanotechnology include

- Self-cleaning textiles (SAS-based water-repellent textiles, e.g. outdoor textiles),
- Anti-microbial/Anti-odour textiles (Nanosilver based products such as socks or underwear), and
- UV-Protection textiles (zinc oxide, titanium dioxide).

[84] Greßler & Gazsó (2012).

[85] ObservatoryNano (2009b).

Based on expert's opinion, the majority of these textiles are coated with nanomaterials. However, with respect to the notification obligations set out in the register, none of these products is expected to contain nanomaterials above the concentration thresholds. Following this, the large share of notification obligations within this sector currently seem to be confined to textile finishing agents, and some textile products where matting agents (e.g. titanium dioxide) are used above the relevant concentration thresholds.

However, several experts expressed their concerns that fillers (e.g. SAS) used in certain industrial textiles may need to be considered as nanomaterials under the current definition published by the European Commission and manufacturers and importers would have to notify them. Due to these uncertainties, obtaining reliable estimates with regards to the number of companies and products affected is challenging.

Interestingly, several companies mentioned consumer resistance to nanosilver due to public debate on the safe use of this nanomaterial. According to opinions of representatives from industry industry appears to be moving away from the use of nanosilver as anti-microbial agent in clothing. This observation is supported by a Danish study where a systematic approach revealed that there are only very few textiles containing nanosilver on the market.[86] Moreover, according to the new Biocidal Products Regulation No. 528/2012 textiles treated with nanosilver are considered "treated articles" and in order to place them on the market have to fulfil several data requirements (see also section 4.2.1.3).

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) carpets, tents, upholstery products (filling materials), textile finishing agents (pigments, fillers, nanosilver, titanium dioxide) and CNT-supported yarns.

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) were considered:

- C13 - Manufacture of textiles,
- C14 - Manufacture of wearing apparel, and
- C15.1 - Tanning and dressing of leather; manufacture of luggage, handbags, saddlery and harness; dressing and dyeing of fur.

4.1.10 Paper Products

Paper products are made of cellulose pulp derived from wood, rags or grasses, processed into flexible sheets and used for writing, printing, drawing, wrapping, and covering walls.

The use of nanomaterials can be roughly categorised as:

- Use of nanomaterials during manufacture of paper and paperboard and

[86] Danish Ministry of Environment, (2012).

- Use of nanomaterials during manufacture of articles of paper and paperboard.

In principle, virtually all original articles within this sector contain nanomaterials, most of them due to the use of pigments to manufacture printed articles, some of them as they are coated with nanosized materials to improve gloss, hydrophobicity, opacity or ink absorption (calcium carbonate or SAS-based nanomaterials, aluminium oxide). It must be stressed that these kinds of applications of nanomaterials would not lead to any notification obligations as the concentration thresholds set out in the register are unlikely to be exceeded.

However, a large share of products contains filling materials to reduce costs and to improve the characteristics of the paper products (e.g. durability, brighter papers, and better printing surfaces). One of the most important fillers used in this sector is precipitated calcium carbonate (PCC), whose particle sizes range from 60 nm to 150 nm.[87] Consequently, a significant number of notifications is to be expected within this sector.

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) envelopes, paperboard, playing cards, ink-jet paper (filling materials such as PCC).

Use of statistical data

For the purpose of this study, statistical data of the following economic activity (as defined by NACE) was considered:

- C17 - Manufacture of paper and paper products.

4.1.11 Complex objects and other products

Assembled or complex objects refer to objects that consist of single articles and also possibly mixtures. A car is an obvious example of a complex object with many articles. A refrigerator is an example of a complex object with articles and a mixture (the coolant).

By far the most important application of nanomaterials within this sector appears to be the use of nano-based coatings and pigments. As outlined before, due to the thresholds defined within the register (see Chapter 2.2), coated articles are generally not expected to fall under notification obligations.

However, notwithstanding these considerations, a large number of notifications can be expected, the large share of which is likely to be due to the use of filling materials (e.g. SAS based nanomaterials, carbon black or PCC in textiles, rubber, plastics, sealants and adhesives, which in turn are often part of complex objects). Some of these individual components comprising complex objects exist as original products in the production chain as precursors to the final assembled article. They must be notified as they exceed the 0.1 wt.-% criteria for unintentional release (see Chapter 2.2). If they contain nanomaterials, intended to be released under normal or reasonably foreseeable conditions of use, they have to be notified irrespective

[87] ObservatoryNano (2011).

of the 0.1 wt.-% criteria. In addition, numerous other products likely to fall under the notification procedure of the ENPR were identified in the course of this study. As it was not possible to assign these products to any of the other categories and to account for the administrative burden associated with the notification of these kinds of products they are listed in this category.

Typical products to be notified

Typical products that may be subject to notification include (amongst many others) sports equipment (e.g. bicycles, tennis rackets, golf clubs), several components of complex articles with nanomaterial fillers such as specialized plastic components, finished upholstery products for complex objects, lubricants, polishing agents used in semiconductor/microchip fabrication (CMP[88] slurries containing cerium oxide), diesel fuel additives (cerium oxide) and certain catalysts (aluminium oxide, cerium oxide, nanosilver).[89]

Use of statistical data

For the purpose of this study, statistical data of the following economic activities (as defined by NACE) were considered:

- C20.59 - Manufacture of other chemical products n.e.c.,
- C25 - Manufacture of fabricated metal products, except machinery and equipment,
- C26 - Manufacture of computer, electronic and optical equipment,
- C27 - Manufacture of electrical equipment,
- C28 - Manufacture of machinery and equipment n.e.c.,
- C29 - Manufacture of motor vehicles, trailers and semi-trailers,
- C30 - Manufacture of other transport equipment,
- C31 - Manufacture of furniture, and
- C32.3 - Manufacture of sports goods.

4.1.12 Results

The following tables (table 2 and table 3) provide an overview of the number of companies in each sector (obtained from Eurostat for the relevant NACE categories), an estimated range of the fraction of companies in each sector likely to notify a product, and an estimated range of the number of companies per sector likely to notify a product, and an estimation of the number of notifications.

The formula for estimating the number of affected companies per sector is:

[88] Chemical Mechanical Polishing/Planarization.

[89] EUCOM (2012a).

Number of companies affected
= Total number of companies ∗ fraction of companies affected

The method for estimating the number of products to be notified per sector as well as the main sources of information is outlined in Annex 7.3. It should be noted that industry experts or individuals provided different estimations on the fraction of companies affected or the number of products to be notified; therefore, the authors grouped the lower ranges together for an average "minimum" value and the upper ranges together for an average "maximum" value as seen in the following tables. These "minimum" and "maximum" do not reflect absolute values but more likely lower and upper range for the parameter in question.

Table 2: Overview of the estimated number of companies in total for each sector, and the number affected (having to notify a product).

Sectors	Companies				
	total	Percent affected		Absolute number affected	
		min	max	min	Max
Total	766.660	5%	8%	37.500	58.000
1. Substances	3.180	20%	40%	700	1.300
2. Cosmetics	4.400	60%	80%	2.600	3.500
3. Health Care	3.800	50%	80%	1.900	3.000
4. Food & Feed	9.170	5%	10%	500	900
5. Coatings & Inks	4.400	90%	95%	4.000	4.200
6. Cleaning & Disinfection	4.350	30%	60%	1.300	2.600
7. Rubber Products	8.500	75%	90%	6.300	7.800
8. Building & Construction	2.600	20%	40%	500	1.100
9. Textiles	127.330	5%	10%	6.000	13.000
10. Paper Products	18.500	60%	80%	11.000	15.000
11. Complex Objects & Other Products	580.430	0,5%	1%	3.000	6.000

Table 3: Overview of the estimated number of notifications in total for each sector, and the number per company affected (having to notify a product).

Sectors	Notifications									
	Total		Total per company affected		Substances		Mixtures		Articles	
	Min	max	min	max	min	max	min	max	min	max
Total	2.400.000	4.100.000	16	57	7.000	10.500	1.574.800	2.641.500	838.200	1.480.500
1. Substances	7.000	11.000	5	16	7.000	11.000	--	--	--	--
2. Cosmetics	23.000	35.000	7	13	--	--	23.000	35.000	--	--
3. Health Care	70.000	145.000	23	75	--	--	70.000	145.000	100	200
4. Food & Feed	2.000	15.000	2	32	--	--	2.000	15.000	--	--
5. Coatings & Inks	1.500.000	2.400.000	350	610	--	--	1.500.000	2.400.000	--	--
6. Cleaning & Disinfection	11.000	26.000	4	20	--	--	11.000	26.000	--	--
7. Rubber Products	85.000	170.000	11	27	--	--	--	--	85.000	170.000
8. Building & Construction	2.800	5.300	3	12	--	--	1.300	3.300	1.500	2.000
9. Textiles	20.000	185.000	2	31	--	--	--	--	20.000	185.000
10. Paper Products	650.000	950.000	43	86	--	--	--	--	650.000	950.000
11. Complex Objects & Other Products	100.000	150.000	16	59	--	--	--	--	100.000	150.000

As many as 5-8% (or 37.500-58.000) of all 766.660 enterprises whose main activity was in the economic sector investigated (covering manufacturing or NACE section C) may be affected by the implementation of an ENPR.

The general picture is distorted, however, by businesses that were assigned to the sector "complex objects and other products" and which make up the large majority of all companies analysed (roughly 75% or 580.430). At the same time, however, they account for only about 6-10% (or 3.000-6.000) of all companies affected.

A more detailed analysis reveals that

- some sectors could be particularly affected, such as coatings & inks (90-95% of all companies in this sector), rubber products (75-90%), paper products(60-80%), cosmetics (60-80%) and health care (50-80%).
- the implementation of the ENPR could lead to as many as 4.1 million notifications, the large share of which can be attributed to coatings & inks (roughly 60%), paper products (around 25%), rubber and textile products as well as "complex objects and other products" (around 3.5% each).
- the weighted average administrative burden for all companies is between 16 and 57 notifications where the median value lies between 7 and 32. Businesses within the sectors health care, paper products and complex objects and other products could be obliged to notify as many as approximately 86 products per company. Entities in the sector coatings & inks could be strongly affected, with up to 610 notifications per company.

Most strikingly, it appears that besides pigments and paints, the large share of notifications may be attributed to filling materials.

As indicated above, fillers are commonly used materials to reduce the consumption of expensive binder material and to improve the physical properties of the resulting material. Filling materials include, amongst others, calcium carbonate (paper and plastics), SAS (paints, coatings, adhesives and sealants, plastics and rubber) or Carbon Black (rubber and to a minor extent in plastics and paints).[90]

Although some fillers may need to be considered "incidentally formed nanomaterials" (see Chapter 3.1.2), a large share of products containing these kinds of materials could nonetheless fall under the notification scheme of the register (given that relevant concentration thresholds are exceeded).

4.2 Assessment of direct and indirect costs of an ENPR

The aim of this chapter is to estimate the direct and indirect costs for industry. To this end, results from chapter 4.1 (number of companies affected and number of nanoproducts) are used in chapters 4.2.3 and 4.2.4 to calculate the direct costs to industry and public authorities.

[90] ObservatoryNano (2011).

4.2.1 Data available for ENPR from other regulations

The concept of the ENPR aims to reduce the administrative burden for notifiers by avoiding the duplication of data registration (see Chapter 2.1). Therefore, this chapter has the aim to identify and compare the data which must be notified under an ENPR with the data already notified under existing substance-related as well as product-related regulations. First of all, the data required by an ENPR is listed and then compared with the existing regulations. According to the concept of an ENPR the notifier shall deliver information on:

- Name and address of the notifier,
- Product and trade name,
- Application,
- Functionality of the nanomaterial(s) employed,
- Characterisation of nanomaterial(s),
- Volume of nanomaterial manufactured or imported,
- Nanomaterial concentration in the respective product, and
- ENPR notification number (product-/substance-specific).

REACH / CLP

In the following analysis provisions of REACH will be examined against the background of whether and which data REACH can deliver for an ENPR.

So far, REACH and CLP do not contain a definition of the term “nanomaterial” in the legal body text. However, the Commission has recommended a definition which itself is not legally binding but already started to be made legally binding in product regulations like in Art. 3 (1) (z) Biocidal Products Regulation (BPR) (see Chapter 4.2.1.3). Therefore the Commission’s recommendation (see Chapter 2.1) will be used for this study as a basis for the comparison of the scope of the regulation with other regulations.

Comparing the information to be submitted to ECHA under REACH and the information that would be required under an ENPR the following can be stated:

According to the ENPR-concept notifiers shall submit name and address of the notifier, product and trade name (excluding variations of a product), application, functionality of the nanomaterial(s) employed, characterisation of nanomaterial(s), nanomaterial concentration in the respective product, and manufactured or imported tonnage bands of the nanomaterial(s). Concerning the characterisation of nanomaterial for an ENPR, the following data must be submitted in order to comply with the definition for nanomaterials: information on particle size and distribution, shape (length, width, form, etc.), crystallinity, chemical composition, - where applicable - specific surface area, and in case of surface modifications its chemical composition.

As it is stated in Annex VI REACH the notifier has to submit the following information in order to identify a substance:

- Name or other identifier of each substance (Name(s) in the IUPAC nomenclature or other international chemical name(s), other names (usual name, trade name,

abbreviation), EINECS or ELINCs number (if available and appropriate), CAS name and CAS number (if available) and other identity code (if available),

- Information related to molecular and structural formula of each substance, and
- Composition of each substance and all information necessary for a sufficient identification of substance.

There is an on-going discussion if and how far provisions in the main body text as well as the annexes of REACH have to be adapted in order to regulate nanomaterials.[91] However, according to the ECHA Guidance Document on registration "the registration dossier should include the information of the substance in both the bulk form and the nanoform."[92] According to that formulation the characterisation of a nanomaterial has to be included in the registration dossier and thus is available for the purpose of an ENPR. However, future amendments of data requirements for nanomaterials in REACH will affect the costs that registrants in REACH and notifiers to an ERPN will have.

The ENPR-concept so far does describe who should be subject to notify a substance, mixture or article to the ENPR, but it does not describe if and how the information on a nanoproduct is communicated down the production chain in order to enable those actors to notify their nanoproduct(s). Either each actor in the production chain has to check whether he uses nanomaterials (most likely by asking his supplier) or an ENPR-notification number is passed down the production chain. For substances and mixtures this ENPR-notification number could be identical with the REACH registration number of the respective nanomaterial. However, the rules in REACH regarding the communication of the registration number down the supply chain show that there are difficulties for down-stream users to obtain the (full) registration number. For example, a supplier who is a distributor or a downstream user may omit the segment of the registration number which refers to the individual registrant of a joint submission (the last four digits of the original full registration number), see section 1.1 Annex II REACH.

Further problems in communicating an ENPR notification down the production chain occur if a down-stream user buys the same nanomaterial from different suppliers, as he will receive different notification numbers. In this case the down-stream user will have to relate the information to be notified to ENPR (e.g. the characteristics of the nanomaterial or the concentration) to the different notification numbers which he has received himself.

One important hurdle for data submission in REACH and subsequently for data which is available for an ENPR is the registration-threshold of 1 t/a and per manufacturer/importer for a substance in REACH. If a nanomaterial together with a chemically identical bulk material is manufactured or imported in quantities of 1 t/a or more, information on the nanomaterial should be available, too, even if the quantity of the registered nanomaterial is less than 1 t/a. This is due to the fact that all identified uses of a substance have to be registered (see Art. 10 (a)

[91] EUCOM (2012b).

[92] ECHA (2012), p. 26.

(iii) REACH), which includes uses below 1 t/a. However, if a nanomaterial is not chemically identical with a bulk material (e.g. carbon nanotubes with carbon), the nanomaterial itself must be manufactured or imported in quantities of 1 t/a or more in order to be registered. Even so, if the latter is not the case manufacturers and importers of nanomaterial will have to collect specific information to notify them to the ENPR. Most likely, this fact will cause further costs on the side of SME producing, modifying, or using nanomaterials. However, it must be noted that the EU Commission estimates that 99.9% of all nanomaterials on the market in terms of production volumes and sales are produced in quantities above 1 t/a[93]. However, other stakeholders expect lower figures. Although the total availability of a nanomaterial on the market does not give an exact picture of the data available according to REACH as the registration duties depend on the amount of a substance per manufacturer / importer, it can be assumed that for a large extent of nanomaterials data will be available as they will be above the registration threshold. However, for those nanomaterials which are phase-in substances the registration data will not be available before the registration deadline of 2018.

Finally, REACH will not deliver data on those substances which are excluded from the registration according Art. 2 (5) (a) and (b) REACH. The exemption covers substances used in:

- medicinal products for human or veterinary use (either Regulation (EC) No 726/2004 on Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; or Directive 2001/82/EC on the Community code relating to veterinary medicinal products; or Directive 2001/83/EC on the Community code for medicinal products for human use).
- food or feeding stuffs (including food additive in foodstuffs within the scope of Council Directive 89/107/ECC; as a flavouring in foodstuffs within the scope of Council Directive 88/388/ECC and Commission Decision 1999/217/EC; as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 and in animal nutrition within the scope of Council Directive 82/471/EEC).

Irrespective of the tonnage threshold in REACH, under the CLP Regulation any manufacturer, importer or downstream user of a substance or mixture must classify it according to its hazardous properties, if necessary label it, and supply specific information on it according to Art. 4 (1) CLP Regulation. Moreover, according to Art. 40 (1) CLP Regulation the manufacturer or importer of a substance classified as hazardous shall notify to the Agency:

- the identity of the registrants(s) responsible for placing the substance or substances on the market,
- the identity of the substance or mixture, and
- the classification of the substance.

To sum it up:

[93] EUCOM (2012c).

In general, REACH will deliver data on nanomaterials as phase-in substances put on the market from 2018 at the latest which is congruent with the following data requirements of an ENPR:

- name and address of the notifier of a substance and mixture,
- product and trade name of the nanomaterial as a substance or in a mixture; but not for articles,
- functionality of the nanomaterial(s) employed, and
- characterisation of nanomaterial(s) to the extent at present.

If a nanomaterial that is not chemically identical with a bulk material is manufactured or imported in quantities of less than 1 t/a, the above mentioned data is not available from REACH unless the registrant manufactured or imported at least 1 t/a of a chemical substance in total, including both the bulk material and the chemically identical nanomaterial. Furthermore REACH will not deliver data for medicinal products for human or veterinary use and for food or feeding as they must not be registered within REACH. No data is available from REACH regarding biocidal substances and plant protection substances, which are taken as registered according to REACH.

In any case REACH will not deliver data on:

- the application of a nanomaterial as the usage categories in REACH are very broad,
- the nanomaterial concentration in the respective product, and
- manufactured or imported tonnage bands of the nanomaterial(s) when registered together with the chemically identical bulk material.

Cosmetics Regulation

The Cosmetics Regulation requires from manufacturers, importers and distributors to notify to the Commission cosmetic products containing nanomaterials by electronic means six months prior to being placed on the market (Art. 13 (1) Reg. 1223/2009). The information notified to the Commission must contain at least the following information for every cosmetic product (Art. 13 (1) and 16 (3) Reg. 1223/2009):

- the name and address of the responsible person where the product information file is made readily accessible;
- the category of cosmetic product and its name or names, enabling its specific identification;
- the presence of substances in the form of nanomaterials and their identification including its chemical name (IUPAC) and other descriptors as specified in Point 2 of the Preamble to Annexes II to VI of the Cosmetics Regulation;
- the specification of the nanomaterial including size of particles, physical and chemical properties;
- an estimate of the quantity of nanomaterials 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.

When this study was conducted the above mentioned data set was not available as the Cosmetics regulation entered into force on 11 July 2013 (cf. Ar. 40 (2)). Moreover the catalogue of all nanomaterials contained in cosmetic products, including those used as colorants, UV filters and preservatives based on the above mentioned information will be published by the EU Commission earliest 11 January 2014 (Art. 16 (10) (a) Reg. 1223/2009). The catalogue must be updated regularly by the Commission and made publicly available. The catalogue must also indicate the category of cosmetic product and the reasonably foreseeable exposure conditions.

In addition to the catalogue, the Commission must also produce a status report, which will be presented annually to the European Parliament and the Council. The annual status report will give information on developments in the use of nanomaterials in cosmetic products within the Community, including those used as colorants, UV filters and preservatives. The report update shall summarise, in particular, 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 cooperation programmes. The first report shall be presented by 11 July 2014.

Last, the Cosmetics Regulation also provides that cosmetic products may be placed on the market only where the container and packaging bear specified information for consumers (Art. 19 (1) (g) Reg. 1223/2009). Among other things, all ingredients present in the form of nanomaterials must be clearly indicated in the list of ingredients. The names of these ingredients must be followed by the word "[nano]". This obligation does not apply until 42 months after the Cosmetics Regulation enters into force – in other words until mid-2013.

Against the background of the comprehensive obligations to deliver data on nanomaterials to the competent authority within the Cosmetic Regulation, the complete set of data necessary for an ENPR is available from the Cosmetic regulation, i.e.:

- Name and address of the notifier,
- Product and trade name,
- Application,
- Functionality of the nanomaterial(s) employed,
- Characterisation of nanomaterial(s),
- Volume of nanomaterial manufactured or imported,
- Nanomaterial concentration in the respective product, and
- Manufactured or imported tonnage bands of the nanomaterial(s).

According to Art. 16 (2) Reg. 1223/2009 information listed supra shall not be notified to the Commission if a nanomaterial is used as a colorant, UV-filter or preservative regulated under Art. 14, unless expressly specified. In the Cosmetics Regulation colorants, UV-filters or preservatives are stated in the Annexes IV, V and VI as a positive list of substances permitted in cosmetic products (cf. Art. 14 (1) (c) and (d) Reg. 1223/2009). Other than those listed substances are not allowed as UV-filter or preservative in a cosmetic product. With respect to existing

substances already listed in the Annexes III to VI the Cosmetics Regulation explicitly states that they do not cover nanomaterials, except where specifically mentioned.[94] Consequently, manufacturers who want to use a nanomaterial as a colorant, UV-filter or preservative will have to submit the information according to Art. 16 if it should be included in an Annex.

Nevertheless, the availability of information from the Reg. 1223/2009 is restricted by the present definition of the term "nanomaterial" for the purpose of the Regulation at the moment. Art. 2 (1) (k) Reg. 1223/2009 defines nanomaterial as "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm"[95]. As a consequence, soluble and natural nanomaterials are not covered by the informational obligations of the Regulation and must not be notified in the Cosmetics Regulation, but in the ENPR.

Biocidal Products Regulation

The scope of the European Biocidal Products Regulation (EU) No. 528/2012[96] (BPR), which will come into force in September 2013 and will replace the previous Biocides Directive 98/8/EC[97] (BPD), covers "active substances"[98] and "biocidal products"[99] as well as articles and materials treated with biocidal products[100] (including furniture and textiles). Excluded from the scope are

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[94] Cf. No 3 of the preamble to Annex II to VI Reg 1223/2009.

[95] Cf. The EU Commission aims to update the definition in the Cosmetics Regulation 1223/2009 with the definition in the EU Recommendation as soon as possible, see: BEUC, Nano-materials in cosmetic products: definition needs to effectively protect consumers, http://www.beuc.org/custom/2012-00537-01-E.pdf (from 26.3.2013). An adjustment of the definition in view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies to technical and scientific progress and to definitions subsequently agreed at international level is intended by the Regulation, cf. Art. 2 (3).

[96] See FN 14.

[97] Directive 98/8/EC of the European Parliament and of the Council of 16.02.98 concerning the placing of biocidal products on the market. OJ L 123, 24.04.98, p.1.

[98] "Active substance" is defined "as a substance or a micro-organism that has an action on or against harmful organisms" (cf. Art. 3 (1) (c) BPR).

[99] "Biocidal product" is defined as "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, [and] any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action" (cf. Art. 3 (1) (a) BPR).

[100] "Treated article" is defined as "any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products" (cf. Art. 3 (1) (l) BPR), But a treated article that has a primary biocidal function shall be considered a biocidal product (cf. Art. 3 (1) (a) BPR).

other products that are sufficiently covered by existing legislation (including food and feed, food and feed additives and processing aids), cf. Art. 2 (2) BPR.

According to Art. 3 (1) (z) BPR a nanomaterial is defined as "a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm-100nm. Fullerenes, graphene flakes, and single wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered nanomaterials". The nanomaterial definition of the BPR thus is widely congruent with the Commission´s recommended definition besides the fact that incidental nanomaterials are excluded from the scope of the BPR. It must be noted that Art. 3 (3) BPR entitles the Commission at the request of a Member State to decide by means of implementing acts whether a substance is a nanomaterial and whether a specific product or group of products is a biocidal product or a treated article or neither.

The ECHA will establish and maintain an information system called "Register for Biocidal Products" (Art. 71 BPR). The Register will cover information on the terms and conditions of the authorization, the summary of the biocidal product characteristics referred to in Art. 22 (2) BPR and the assessment report of the biocidal product. Consequently, information in the Register for Biocidal Products which could be used for an ENPR covers (cf. Art. 22 (2) BPR):

- trade name of the biocidal product,
- name and address of the authorisation holder,
- qualitative and quantitative composition in terms of the active substances and non-active substances,
- manufacturers of the active substances (names and addresses including location of manufacturing sites),
- type of formulation of the biocidal product, and
- product-type and, where relevant, an exact description of the authorised use.

However, it must be pointed out that the availability of data on "active substances" which are nanomaterials, "treated articles" and "biocidal products" containing nanomaterials has the following restrictions:

- Following Art. 4 (4) BPR the approval of an active substances shall not cover nanomaterial except where explicitly mentioned. However, it remains unclear which are the consequences of Art. 4 (4) for those nano-forms of existing active substances that are legally on the market today, as the existing review process of active substances on the market does not refer to particle size.
- If a treated article contains an active substance in a nano-form, the person responsible for placing on the market of such a treated article has to label them with the name of all nanomaterials contained in the biocidal product, followed by "[nano]" (cf. Art. 58 (3) (d) BPR). The labelling duty enters into force on 1 September 2013 (Art. 97 BPR). However, the information on the active nano-substances used in the treated article will be hampered in its effectiveness due to transitional measures under Art. 94 (1) BPR. Treated articles (including those containing nanomaterials) which are on the market on 1 September 2013 can continue to be placed on the market if the application for the

approval of the active substance is submitted at the latest by 1 September 2016. If treated articles have a primary biocidal function (e.g. food contact material) and are not covered by the BPD but by the BPR, the deadline for authorization is 1 September 2017 if they were available on the market on 1 September 2013 (cf. Art. 93 (1) BPR).

- If a biocidal product contains nanomaterials, each reference to nanomaterials must be labeled following "[nano]" (Art. 69 (2) (b) BPR).

Finally, Member States shall report every five years on the implementation of the BPR, including information on the use of nanomaterials in biocidal products and the potential risks (Art. 65 (3) (d) BPR).

Against the background of the data requirements under the BPR the following data available in the Register for Biocidal Products could be used for the ENPR:

- Name and address of the authorisation holder, names and addresses of manufacturers of the active substances (= name and address of ENPR notifier),
- Trade name of the biocidal product (= product and trade name),
- Product-type and, where relevant, an exact description of the authorised use (= application), but not the concrete product, and
- Type of formulation of the biocidal product and qualitative and quantitative composition in terms of the active substances and non-active substances (= nanomaterial concentration in the respective product; characterisation of nanomaterial(s)).

Nevertheless, the following data on active substances and biocidal products is not available for the purpose of the ENPR and will have to be submitted additionally:

- Volume of nanomaterial manufactured or imported,
- Functionality of the nanomaterial(s) employed.

With regard to treated articles the following restrictions on the data availability are at hand:

- If the treated article contains nanomaterials and will be on the market on 1 September 2013, data will be available 1 September 2016 at the latest; for treated articles that have a primary biocidal function (e.g. food contact material) even latest 1 September 2017.[101]

Food information to the consumer

The Regulation (EU) No. 1169/2011 on food information to consumers[102] addresses engineered nanomaterial and defines them in Art. 2 (t) as „ ... any intentionally produced material that has

[101] The deadlines might be further postponed as the Commission has identified problems with the transitional rules of the Biocidal Products Regulation, i.e. "an un-intended market freeze of up to eleven years for articles treated with biocidal substances which are legal on the EU market, but which have not yet been evaluated at EU level." Therefore a new Proposal has been made for the Regulation of the European Parliament and of the Council amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products with regard to certain conditions for access to the market, COM (2013) 288 final.

one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale." Compared to the EU Recommendation it must be noted that due to the definition "natural" and "incidental" nanomaterial are not covered by the scope of Regulation (EU) No. 1169/2011.

The data on nanomaterials required in the Regulation (EU) No. 1169/2011 does not correspond in many ways with the data requirement of an ENPR[103]: Although the name of the producer and the name of the food shall be its legal name (cf. Art. 17 (1) Regulation (EU) No. 1169/2011), the concrete food-product containing nanomaterials must not be notified to the authorities giving the producer's name as well as the name or trade name of the food-product. According to Art. 18 (3) all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients on the product. The names of such ingredients shall be followed by the word "nano" in brackets. Therefore the producer must be aware of the nanomaterial(s) he uses in his food-product and it can be expected that he has further information on the used nanomaterial(s). However, the Regulation (EU) No. 1169/2011 does not require the producer to provide information to the competent authority on the application, the functionality of the nanomaterial(s) employed, characterisation of nanomaterial(s), the volume of nanomaterial manufactured or imported and the nanomaterial concentration in the respective product.

Food additives

With a view to ensuring a high level of health and consumer protection, certain substances such as food additives, food enzymes and food flavourings must, prior to being placed on the market in or on foods, undergo a common assessment and authorisation procedure in accordance with Regulation (EC) No 1331/2008[104]. Food additives, food enzymes and food flavourings must not be placed on the market or used in foodstuffs for human consumption, in accordance with the conditions laid down in each sectoral food law unless they are included on a Community list of authorised substances. Common criteria and requirements for assessment and authorisation of the aforementioned substances are set out in the sectoral food laws

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[102] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ EU L 304, 21.11.2011, p. 18.

[103] For an overview of the regulation of nanomaterial in the food sector see: http://nanoinformation.at/rechtliches/oesterreich-und-eu/chemikalien.html (from 15.3.2013).

[104] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L 354, 31.12.2008, p.1.

(Regulation (EC) No 1333/2008 on food additives[105], Regulation (EC) No 1332/2008 on food enzymes[106] and Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties[107]).

Clear and unambiguous designation of food enzymes and flavourings in nanoform and labelling of foods containing them is not envisaged under the sectoral laws. However, the provisions of the Novel Food Regulation apply where enzymes and flavourings fall within its scope.

In contrast to the aforementioned sectoral laws, explicit provision is made on the use of nanomaterials in additives already permitted, in other words included in the Community list. In accordance with Article 12 of Regulation (EC) No 1333/2008, when a food additive already approved under the Regulation is made using production methods or starting materials that are significantly different from those included in the risk assessment performed by the authority, or from those to which the established specifications refer, it must be submitted to the relevant authority for evaluation. “Significantly different” may refer to a change in production method or a change in particle size, for example through the use of nanotechnologies. Such a food additive then requires a new entry in the Community list or a change in the specification before it can be placed on the market.

The information requirements for the placing on the market of food additives, food enzymes and food flavourings do not correspond exactly to the requirements of the nanoproduct register. Although an additive already included in the positive list of permitted additives requires a new entry if it is a nanomaterial, the positive list principle means that national authorities can only tell that an additive is permitted for use as a nanomaterial. They cannot tell, meanwhile, whether and in which specific foods a nanoscale additive is used as no nano-specific indication is given. If the additive is a novel food, then even under the Novel Food Regulation currently in force, it must be labelled to indicate the procedure by which that characteristic or property was obtained (for example modification using nanotechnology). Specific labeling of the additive as a nanoscale substance is not envisaged, however. As the Regulation on food additives does not provide a definition of nanomaterials, there is no provision that makes it clear for the applicant or the authority when an additive should be considered a nanomaterial. Moreover, under the current provisions there is no requirement to indicate the amount of a nanomaterial in products to be placed on the market.

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[105] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, p.16.

[106] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes, and amending Council Directive 83/417/EEC, Regulation (EC) No 1493/1999 of the Council, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97, OJ L 354, 31.12.2008, p.7.

[107] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods, and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC), OJ L 354, 31.12.2008, p.34.

Food contact material

In accordance with Article 3 (1) of Regulation (EC) No 1935/2004[108], materials and articles intended to come into contact with foodstuffs – including active and intelligent materials and articles – must be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health. Art. 4 of Regulation (EC) No 1935/2004 also sets out provisions concerning active and intelligent food contact materials and articles. Active materials are materials containing active constituents intended to come into contact with food in order to actively maintain or improve the condition of the food. Intelligent materials are intended to monitor the condition of foodstuffs. In accordance with Art. 5 of Regulation (EC) No 1935/2004, specific provisions may be made for particular groups of materials and articles listed in Annex I of the Regulation, such as glass, plastic or SAS.[109] Following Art. 5 (1) (m) Regulation (EC) No 1935/2004, the Commission can establish and maintain a publicly available Community Register of authorised materials or articles or, under Art. 5 (1) (e), establish specific limits on the migration of certain chemicals or other constituents into or on to food from packaging, cooking devices or utensils. Requirements for active and intelligent materials are expanded and set out in detail in Regulation (EC) No 450/2009[110]. As regards migration limits for the use of nanoparticles, the Regulation provides that risk should be assessed on a case-by-case basis until more information is known about such new technology.

Prior to being approved, substances listed in Annex I of Regulation (EC) No 1935/2004 must undergo a safety assessment by the European Food Safety Authority (EFSA). The EFSA has produced Guidelines on assessing substances. According to the EU Commission, these Guidelines need to be adapted to enable identification of nano-scale materials, too. Furthermore, risk assessment needs to be adapted to the specific risks that arise from the use of nano-scale substances. According to Art. 7 of Regulation (EC) No 450/2009, the Community list entry for such packaging materials must include the:

- identity of the substance(s),
- function of the substance(s),
- reference number, and
- where necessary the conditions of use of the substance(s) or component.

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[108] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p.4; last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 L 188, 18.7.2009, p.14.

[109] A list of legislation on specific materials can be found at: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm (accessed 28.3.2013).

[110] Commission Regulation (EC) No 450/2009 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, OJ L 135, 30.5.2009, p.3.

One example of a case-by-case assessment of nanomaterials for use in particular food packaging materials can be found in a Scientific Opinion published by EFSA[111]. This document authorises the use of titanium nitride nanoparticles in quantities of up to 20 mg/kg in PET (polyethylene terephthalate) bottles. When considering materials for inclusion in the positive list (list of authorised materials), the EFSA's assessment thus appears to be use- and process-based. Even where nanomaterials are included in the positive list, manufacturers of food contact materials have no obligation under Regulation (EC) No 1935/2004 to inform their customers about the nature and amount of potential migrations.

As regards labelling, Art. 15 of Regulation (EC) No 1935/2004 stipulates that materials and articles intended to be placed on the market must be accompanied by the name or trade name and, in either case, the address or registered office of the manufacturer, processor or seller established within the Community and responsible for placing on the market. In the case of active materials and articles, information must be provided on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component. However, there is no provision for a specific labelling to indicate the use of nanomaterials.

The EU Commission assumes that existing provisions on packaging materials provide an adequate basis for the protection of human health as regards the use of nanomaterials. Businesses using authorised packaging materials have an obligation to inform the Commission immediately of any new scientific or technical information that might affect the safety of the authorised substance(s). The responsible authorities can then review the safety assessment and, where there is a danger to human health, suspend or modify authorisation of the material.[112]

When including materials and articles in the positive list, the EFSA recognises whether they are nanomaterials if the applicant provides this information. However, this does not mean that the national authorities can tell whether a specific packaging material contains nanomaterials. The existing provisions on labelling, including those relating to active and intelligent packaging materials, do not provide specifically for nano-specific labelling of a product (packaging material or food contact article). As Regulation (EC) No 1935/2004 contains no definition of nanomaterials, there is no provision that makes it clear for the applicant or the authority when a nanomaterial is present. Moreover, neither the EFSA nor the national authority has information on the quantity of nanomaterials in products that are to be placed on the market.

Novel Food Regulation

Nanomaterials regarded as novel foods or novel food ingredients fall within the scope of the Novel Food Regulation[113] and thus will have to undergo an authorisation procedure in order to

[111] EFSA (2013)

[112] Möller & Hermann (2009).

[113] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ No L 43, 14.2.1997, p.1, last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure

access the market. In the authorisation procedure, the applicant must submit a safety assessment for the novel food or food ingredient. The relevant Member State then produces an initial assessment report which will generally contain recommendations on the following points (cf. Art. 7 (2) of the Novel Food Regulation):

- the conditions of use of the food or food ingredient;
- the designation of the food or food ingredient;
- the specification of the food or food ingredient and
- specific labelling requirements.

If the novel food or food ingredient is approved, the manufacturer must ensure that, on the packaging, the final consumer is informed of "any characteristic or food property which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient" (such as composition, nutritional value or nutritional effects, intended use of the food), and of "the procedure by which that characteristic or property was obtained." (Art. 8 (1) Novel Food Regulation). However, the Novel Food Regulation does not require the producer to provide information to the competent authority on the trade name of the product, the application of the nanomaterial, the functionality of the nanomaterial(s) employed, characterisation of nanomaterial(s), the volume of nanomaterial manufactured or imported and the nanomaterial concentration in a concrete product.

Medicinal products for human or veterinary use

So far, the provisions for medicinal products for human use in Directive 2001/83/EC[114] do not contain nano-specific regulations. However, in 2012 a proposal for a regulation of the European Parliament and of the Council on medical devices[115] was published which plans to introduce several nano-specific rules in the Directive, inter alia a definition for nanomaterial corresponding with the recommended definition of the Commission and labelling requirements if an device incorporates or consists of nanomaterial unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.

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referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny - Adaptation to the regulatory procedure with scrutiny - Part Four, OJ L 188, 18.7.2009, p.14.

[114] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p.67, last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012, OJ L 299, 27.10.2012, p.1.

[115] Proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, 26.9.2012, COM(2012) 542 final, 2012/0266 (COD).

4.2.2 Results on available information for an ENPR

The analysis of data requirements in existing legislation shows that in principle a clear line can be drawn between information available for competent authorities on the nanomaterial itself and on the information on nanomaterial(s) in a concrete product. On the one hand CLP, REACH and product-specific regulations excluded from the scope of REACH, like food and food additives or food contact materials, require information on the nanomaterial, e.g. on the name of the notifier, the name of the nanomaterial, the functionality and the characterisation of the nanomaterial. On the other hand authorities have no information on the product and trade name of specific products containing nanomaterial(s), the application, the manufactured or imported volume of nanomaterial(s) in products and the concentration of nanomaterial(s) in products. There are two exceptions from this picture which are the Cosmetic Regulation and the Biocidal Products Regulation (BPR) which in general require information on the nanomaterial and on products containing nanomaterials equivalent to the data requirements of the ENPR.

For nanoproducts (substances, mixtures and articles) that do not fall within the scope of the analysed regulations in chapter 4.2.1 a notification duty will result from ENPR provisions. In these cases the gathering of information relevant for an ENPR and the costs associated with that will have to be borne by the notifiers.

The following Table 4 summarizes the results of the comparison on data available for an ENPR from other regulations:

Table 4: Comparison on data required for the ENPR and those data notified under existing regulations.

Data of ENPR	REACH	CLP	Novel food	Food information to consumer	Food contact Material	Cosmetics Reg.	BPR
Definition of NM	+	+	-	+/- (not incidental and natural NM)	-	+/- (not soluble and natural NM (update planned))	+/- (not incidental NM)
Name and address of notifier	+	+ (if hazardous)	+/- (not for specific product)	-	+/- (not for specific product)	+	+/- (not for treated article)
Product and trade name	+ (substances/ mixtures) - (articles)	+ (if hazardous)	+/- (not for specific product	-	+/- (not for specific product)	+	+/- (only product type)
Application	- (only product categories)	_	+/- (only approved materials)	-	+/- (not for specific product)	+	+
Functiona-lity	+	-	+/- (only approved materials)	-	+	+	+
Characterisation	+	- (only if hazardous)	+/-Only approved materials	-	+/- (not for specific product)	+	+
Manufactured or imported volume of NM in products	- (no total volume)	- (no total volume)	_	-	-	+	-
Concentration of NM in product	-	-	-	-	-	+	+/- (not for treated article)
"+" = data identical with ENPR is transmitted to public authorities ; "-" = no data equivalent with ENPR is transmitted to public authorities							

4.3 Direct costs of an ENPR for industry

4.3.1 Setting of boundary conditions for the analysis

As stated before, it is assumed that all information required for notifying substances, which are registered above 1 t/a and which fall within the scope of REACH, will be available at the latest by 2018 due to REACH obligations.

For the following analysis, it is assumed that all substance information (e.g. particle size distribution) is available to the initiators of the production chain [116] and therefore only the administrative costs of collating the available data and entering it in the format specified by the public authority is considered.

The function of the notification process is described in Chapter 2.6. Only actors in the production chain that change the composition of a nanoproduct are obliged to submit a notification: the costs attributed to collating, submitting the data, as well as incorporating the registration number into the product documents is included in the estimations. If a company does not change the composition of a nanoproduct (e.g. distributor of products), the company is not required to register the product: the cost for these actors to communicate the notification number to the subsequent actor in the production chain was not included in the estimations of the direct costs to industry and is considered to have only relatively small amount compared to the total costs.

The estimation of the direct costs incurred by industry was calculated based on the results from Chapter 4.1 which estimated the number of notifiers and number of notifications per notifier according to a grouping of economic activities (NACE). The NACE categories also include importers of products and therefore all actors having to notify products according to Chapter 2.6 are also included in the cost estimation. Initial, intermediate, and final products are all accounted for in the NACE categorisation; however no attempt was made to distinguish the "state of the product" since this is irrelevant to the notifier and has no bearing on the estimated costs. The costs incurred by industry was calculated on a company-based approach as opposed to a substance production chain approach which would attempt to track the supply chains of individual substances along the product chain. The difficulty with this second approach, is that it is an indirect estimation that could lead to double counting (e.g. a company could be involved in the production of several nanomaterials which must be notified; however the supply chain approach would could count this same company more than once and would lead to an overestimation of the costs). In the end, the direct costs are incurred by individual companies; the cost consisting of a base cost and a variable part which is a function of the number of products to be notified. Therefore, the company-based approach was considered to provide the most accurate results since it provides a direct estimate of the number of companies to notify products and the number products a company must register.

[116] Sequence of productive (i.e. value- added) activities leading to end use.

The basis for the costs, the formulas for estimating the costs, and the inputs for these formulas are described in the following section.

4.3.2 Composition of costs

In order to comprehensively estimate the administrative burden to industry, the costs imposed on industry was estimated on a sector-by-sector basis and separated into two types of costs:

- one-off implementation costs: are costs incurred only in the implementation phase of the register including all costs related to the first notification of the product (including the first notification) and
- recurring costs: are costs that occur after the implementation phase of the register and are costs occurring after the first notification of the product. To investigate the effects of different possibilities of monitoring notified products, recurring costs have been separated into two scenarios – notified annually (subsequently referred to as sub-scenario a) or only when a change to the product occurs (subsequently referred to as sub-scenario b).

All administrative costs are expressed in hours.

The inputs for the compositions of costs as described below were obtained based on interviews with several national industry associations as well as companies notifying products for the French NPR. The interviewed companies provided a wide range of values; the authors removed the high and low responses and averaged the remaining values. The authors also adjusted the average values assuming that the European competent authority for an ENPR will provide detailed guidance and also cooperate with the industry associations in advance of implementing the ENPR in order to minimise any confusion, industry costs associated with implementing and operating the ENPR.

As a quality control check with respect to the electronic submission of the data, the authors examined a realistic example template of a possible nanoproduct register and tested the time required to arrive at the estimated values in this study.

4.3.3 Implementation costs

The values for implementation costs were obtained from survey responses, phone interviews, and from contact with international companies required to notify products in the national French register. The responses were also cross-referenced with Danish Ministry of Environment NPR Study [117], however it should be noted that the company sample size of the Danish study was relatively small. Within each sector, the variation in estimated implementation costs was significant since, depending on the sector, companies were uncertain if they had nanoparticles in their products and how they could determine the presence of nanomaterials since the further down the production chain a downstream user is, the less transparent is the information; additionally, companies are concerned about the function of the product, not the composition. Furthermore, it is difficult for interviewees to imagine what a register would look

[117] Fischer et al. (2012).

like and how much time is required to implement and administer the register. Therefore, the consultants selected realistic values for the implementation costs.

Implementation costs are costs associated with first setting up the system to deal with the regulation and are usually incurred in the first year. Implementation costs may also be incurred when a new product is developed and put on the market. These costs can be broken down into the two following components:

1. Base implementation costs:
    a) training of personnel to understand ENPR requirements,
    b) determining whether products must be notified (e.g. screening products offered by the company),
    c) responding to customer inquiries,
    d) adapting existing product database to ENPR requirements,
2. Administrative implementation costs: collation of information and submitting data for the first notification.

The base implementation costs are calculated as follows:

$$= (No.companies\ not\ having\ to\ notify) * Costs\_per\_company_{implementation.not\ notify,i} + (No.companies\ having\ to\ notify\ a\ product) * Costs\_per\_company_{implementation.notify,i}$$

The administrative implementation costs are calculated as follows:

$$= (No.of\ products\ to\ be\ notified) * Costs\_per\_product_{implementation.admin,i}$$

Where

i = either substance manufacturer or intermediate/final product manufacturer

Expert consultation suggested that there are base implementation costs for every company dealing with nanomaterials. Base implementation costs are calculated on a per company basis and are dependent on whether or not notification obligations occur.

- Entity not required to notify 5h/company
- Entity required to notify 40h/company

Even companies not having to notify products will be slightly affected (an average of 5 hours has been estimated for familiarizing with requirements and determining whether products must be notified). On the other hand, substance manufacturers having to notify products would require an average of 40 hours to implement the ENPR due to an increased administrative burden. The above-stated costs are values based on responses from several industry associations and many companies having experience with the national French register.

For entities that are obliged to submit notifications, there will be further administrative implementation costs (e.g. collect and submit the required data to the public authorities, answering customer inquiries, adapting databases). These costs are calculated on a per products basis as they are dependent on the number of notifications to be submitted. In addition, the position in the production chain needs to be taken into account.

- substance manufacturers 3.8h/product;

- intermediate and final product manufacturers 1.25h/product.

The difference lies in the fact that substance manufacturers must submit particle characterisation data and are at the same time expected to deal with more customer inquiries (which is time consuming) whereas other down-stream notifiers receive the notification number and can submit this in exchange for re-entering the particle characterisation data.

4.3.4 Recurring administrative costs

The recurring administrative costs are calculated on a per product basis and constitute the following costs:

- personnel costs involved in collecting the required data and
- personnel costs involved in submitting the register data.

The estimates of the recurring administrative costs are calculated as follows:

$$= (No.\,of\ products\ to\ be\ notified) * (Costs\ per\ product_{recurring.admin,i}) * f_x$$

where

i = either substance manufacturer or intermediate/final product manufacturer

f = frequency factor (how many times per year must a notification be updated)

x = either when product changes or annually.

The annually recurring costs were obtained from written survey responses and phone interviews with different actors in the value chain. Analogous to the implementation costs, there are significant variations in the obtained values within and between sectors and in different parts of the value chain due to the uncertainty of the presence of nanoparticles in many products, as well as the assumed difficulty in obtaining the data required for the register. However, as stated above, if the notification process proposed in Chapter 2 is implemented, all information will be on hand and the costs per product should be reasonable:

- substance manufacturers 0.5h/product,
- intermediate and final product manufacturers 0.7h/product

4.3.5 Overview on implementation and recurring costs

The following table 5 summarises the inputs for the previously mentioned costing formulas. The administrative implementation and recurring costs are outlined and characterised per production chain actor.

Table 5: Notification requirements for the cost analysis corresponding to the notification obligations as described in chapter 2.

Professional User Type in Value Chain	Manufacturer or Importer of Substance	Intermediate or Final Product Manufacturer	Required for recurring costs
Name and address of notifier	✓	✓	N
Product and trade name	✓	✓	N
Notification number from previous professional user	N.R.	✓	N
Application	✓	✓	N
Functionality[a]	✓	✓	N
Volume of manufactured or imported product	✓	✓	Y
Concentration of nanomaterial in product[b]	N.R.	✓	Y
Nanomaterial characterisation[c]	✓	N.R.	N
Implementation administrative costs [h/product]	3,8	1,25	
Recurring administrative costs [h/product]	0,5	0,7	

a Refers to the functionality of the nanomaterial in the produced product (e.g. UV protection, abrasion resistance);

b Refers to the concentration of substance or mixture present in the new finished intermediate or original product;

c Only required by the manufacturer or importer of a NM. If an intermediate or final product manufacturer utilizes a non-notified substance to produce another product, they must notify both the substance and the product.

N.R. means "not relevant".

4.3.6 Frequency factors

Costs were compared on a 5 year basis (first year = implementation costs, then 4 years recurring costs) to assess how costs evolve over time.

To this end, an estimate of the accumulated costs is provided, under the assumption that the total number of notifications does not change. This analysis takes into account that the product turnover is sector-dependent. Rough estimates of the turnover-rates (or "frequency factors") have been obtained from interviews with individual companies, industry experts, and own market research by analysing product lines on websites. Some sectors that have a high turnover in products like textiles (industrial textiles as well as apparel) have a higher frequency factor (e.g. 0.5), whereas other sectors with a low turnover such as substances have a low frequency factor (e.g. 0.1). Annual notifications have a frequent factor f=1.

4.3.7 Scenarios

As outlined before, the concept of an ENPR aims to reduce administration burden for notifiers by avoiding the duplication of data registration. Analysis of various legal provisions (see

section 4.2.1) revealed that manufacturers and importers of products containing nanomaterials are already obliged to submit (ENPR-)relevant data in the frame of REACH, the Cosmetics Regulation, the Biocidal Products Regulation (BPR), the Novel Food Regulation and the Food Contact Material Provisions.

Following these results, two scenarios were analysed:

1. All associated costs of the register are attributed to the ENPR, and
2. Costs already attributed to other regulations are not counted for the ENPR.

Furthermore, in the absence of further specifications as to the reporting procedure, for every scenario, a sub-scenario affecting the recurring costs was investigated; the sub-scenarios are:

- *Sub-scenario a*: the product notification must be updated only when the formulation has changed (only information that has changed must be updated), or
- *Sub-scenario b*: the product notification to be updated yearly.

4.3.8 Results

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

The evaluation of the relative weight of costs is difficult to determine. For instance, comparing the costs to annual turnovers in each sector would not be appropriate as the large share of the turnover can be attributed to large firms, whereas the large share of notifications is attributed to SMEs. However, to put the costs into perspective, the average costs per firm is provided for each sector, distinguishing between companies having to notify and the ones that would only bear the "base implementation costs" (see above).

The following tables 6 to 9 provide an overview of costs for each scenario (and sub-scenarios).

Scenario 1: All costs are allocated to the ENPR

Scenario 1 specifies the impacts resulting from the implementation of an ENPR, if no information gained in other legislative frameworks is used. As a consequence, implementation of the ENPR would involve duplication of efforts in case an ENPR-relevant information has to be registered in a specific sector already.

Table 6: Overview of the costs for scenario 1a (products are updated whenever there is a change in their formulation) and 1b (products are updated yearly) per sector. Frequency factor: representing the fraction of products per sector that require updating per year (i.e. when the formulation changes).

Sectors	Average Costs per Firm [h/firm]						Total Costs [h]									
	Companies not notifying		Implementation Year		Recurring Costs		Implementation Year		Recurring		Total costs after 5 years for Scenario 1a			Total costs after 5 years for Scenario 1b		
	min	max	min	max	min	max	min	max	min	max	freq. Factor	min	max	freq. Factor	min	max
Total	--	--	--	--	--	--	5.480.000	11.730.000	1.680.000	2.900.000	--	7.054.000	14.612.000	--	12.197.000	23.340.000
1. Substances	5	5	40	138	3	8	60.000	110.000	3.500	5.300	0,1	61.400	112.120	1	74.000	131.200
2. Cosmetics	5	5	40	73	5	9	140.000	200.000	16.400	24.600	0,25	156.400	224.600	1	205.600	298.400
3. Health Care	5	3	59	173	16	53	180.000	340.000	50.000	100.000	0,25	230.000	440.000	1	380.000	740.000
4. Food & Feed	5	5	30	62	2	15	60.000	100.000	1.000	10.500	0,25	61.000	110.500	1	64.000	142.000
5. Coatings & Inks	5	5	512	867	246	428	2.140.000	3.440.000	1.030.000	1.690.000	0,25	3.170.000	5.130.000	1	6.260.000	10.200.000
6. Cleaning & Disinfection	5	5	25	158	3	41	70.000	220.000	6.500	53.500	0,25	76.500	273.500	1	96.000	434.000
7. Rubber Products	5	5	47	86	8	19	370.000	550.000	60.000	120.000	0,25	430.000	670.000	1	610.000	1.030.000
8. Building & Construction	5	5	20	109	2	8	30.000	60.000	1.900	3.500	0,1	30.760	61.400	1	37.600	74.000
9. Textiles	5	5	22	136	1	20	850.000	1.430.000	15.000	125.000	0,5	880.000	1.680.000	1	910.000	1.930.000
10. Paper Products	5	5	86	166	29	58	1.290.000	1.880.000	430.000	650.000	0,15	1.548.000	2.270.000	1	3.010.000	4.480.000
11. Complex Objects & Other Products	5	5	47	178	11	42	270.000	3.400.000	70.000	120.000	0,5	410.000	3.640.000	1	550.000	3.880.000

Table 7: Overview of the costs for scenario 1a (products are updated whenever there is a change in their formulation) and 1b (products are updated yearly) according to product type.

Product Type	Total Costs [h]							
	Implementation		Recurring		Total costs after 5 years for Scenario 1a		Total costs after 5 years for Scenario 1b	
	min	max	min	max	min	max	min	max
Substances	60.000	110.000	3.500	5.300	61.400	112.120	74.000	131.200
Mixtures	2.605.000	4.330.000	1.104.850	1.880.350	3.709.280	6.209.300	7.024.400	11.851.400
Articles	2.795.000	7.290.000	575.950	1.016.750	3.283.380	8.290.700	5.098.800	11.357.000

Scenario 2: Costs attributed to other regulations are not counted for the ENPR

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

Table 8: Overview of the costs for scenario 2a (products are updated whenever there is a change in their formulation) and 2b (products are updated yearly) per sector. Frequency factor: representing the fraction of products per sector that require updating per year (i.e. when the formulation changes).

Sectors	Average Costs per Firm [h/firm]						Total Costs [h]									
	Companies not notifying		Implementation Year		Recurring Costs		Implementation Year		Recurring		Total costs after 5 years for Scenario 2a			Total costs after 5 years for Scenario 2b		
	min	max	min	max	min	max	min	max	min	max	freq. Factor	min	max	freq. Factor	min	max
Total	--	--	--	--	--	--	5.190.000	11.190.000	1.680.000	2.870.000	--	6.768.000	14.035.000	--	11.737.000	19.580.000
1. Substances	0	0	3	8	3	8	3.500	10.000	3.500	5.300	0,1	4.900	12.120	1	14.000	31.200
2. Cosmetics	0	0	5	9	5	9	20.000	20.000	16.400	24.600	0,25	36.400	44.600	1	85.600	118.400
3. Health Care	5	5	59	173	16	53	180.000	340.000	50.000	100.000	0,25	230.000	440.000	1	380.000	740.000
4. Food & Feed	0	0	2	11	2	15	0	10.000	1.000	10.500	0,25	1.000	20.500	1	4.000	52.000
5. Coatings & Inks	5	5	512	867	246	428	2.140.000	3.440.000	1.030.000	1.690.000	0,25	3.170.000	5.130.000	1	6.260.000	10.200.000
6. Cleaning & Disinfection	5	5	6	26	3	12	20.000	50.000	6.500	16.000	0,25	26.500	66.000	1	46.000	114.000
7. Rubber Products	5	5	47	86	8	19	370.000	550.000	60.000	120.000	0,25	430.000	670.000	1	610.000	1.030.000
8. Building & Construction	5	5	20	109	2	8	30.000	60.000	1.900	3.500	0,1	30.760	61.400	1	37.600	74.000
9. Textiles	5	5	22	136	1	20	850.000	1.430.000	15.000	125.000	0,5	880.000	1.680.000	1	450.000	1.450.000
10. Paper Products	5	5	86	166	29	58	1.290.000	1.880.000	430.000	650.000	0,15	1.548.000	2.270.000	1	3.010.000	4.480.000
11. Complex Objects & Other Products	5	5	47	178	11	42	270.000	3.400.000	70.000	120.000	0,5	410.000	3.640.000	1	840.000	1.290.000

Table 9: Overview of the costs for scenario 2a (products are updated whenever there is a change in their formulation) and 2b (products are updated yearly) according to product type.

Product Type	Total Costs [h]							
	Implementation		Recurring		Total costs after 5 years for Scenario 2a		Total costs after 5 years for Scenario 2b	
	min	max	min	max	min	max	min	max
Substances	3.500	10.000	3.500	5.300	4.900	12.120	17.500	31.200
Mixtures	2.375.000	3.890.000	1.104.850	1.842.850	3.479.280	5.731.800	6.794.400	11.261.400
Articles	2.795.000	7.290.000	575.950	1.016.750	3.283.380	8.290.700	5.098.800	11.357.000

General Results

Irrespective of any scenario analysed, the comparison of costs on a 5 year basis reveals that:

- Some sectors could be particularly affected, such as Coatings & Inks with 6.26 -10.20 million hours (e.g. approximately 44-50% of the costs for notifiers in case the product notification must be updated when the formulation has changed and that all costs are attributed to the ENPR [scenario 1a]), Paper Products with approximately 3.01-4.48 million hours, and Textiles with approximately 0.91 - 1.93 million hours.

  On an h/company basis of five years, this corresponds to approximately 790-1220 h/firm, 140-150 h/firm, and 130-150 h/ firm for the sectors Coatings & Inks, Paper Products, and Textiles respectively.

- For sectors with a low number of notifications or companies, the ratio between implementation costs and recurring costs is high (often an order of magnitude larger compared to sectors with a high number of notifications or companies). An example is cosmetics. This means most of the costs are incurred for the task of modifying company procedures and systems, personnel training, and the first administrative entering of the data.
- For sectors with a high number of notifications or companies, the ratio between implementation costs and recurring costs is low since potentially hundreds of products have to be updated (and checked). An example is coatings & inks.
- In total, implementation costs are approximately 4-5 times as large as recurring costs.
- Distribution of costs for substances, mixtures, articles: For scenario 1a and 2a respectively, substances account for less than 1% of all costs, mixtures for 42-53%, and articles for approximately 47-57%. This changes only slightly for sub-scenario b. In general, substance costs are an order of magnitude lower than costs related to mixtures and articles. This is to be expected since substances are at the beginning of the production chain, and one substance is used in multiple different products (which all have to be notified) in which a multiplier effect occurs as the substance moves along the production chain.

The general trends described above hold true for scenario 1 and scenario 2. While the implementation and recurring costs for both sub-scenarios are the same, the accumulated costs differ as to the sector-dependant product turnover. In addition, comparison of costs on a 5 year basis reveals that for sectors with a high number of notifications/company, the annual submission of an updated notification dossier (sub-scenario b) would lead to a significant increase in administrative costs compared to sub-scenario a (update whenever there is a change in their formulation). For instance, implementing sub-scenario b would lead to an almost two-fold increase in accumulated costs for sectors such as coatings & inks or paper products in comparison to sub-scenario a.

Comparison of scenarios

Comparison of the costs of the two scenarios (see table 10) for sub-scenario (a) where products are updated when there is a change in the product formulation reveals that:

- When considering all companies together, scenario 2 (avoiding duplicate notification) does not lead to a significantly reduced administrative burden. Total costs may be reduced by 5.5%. This is explained by the fact that sectors which benefit from scenario 2 (Substances, Cosmetics, Food & Feed, and Cleaning & Disinfection) have little share to the overall costs (around 7%) in scenario 1.
- significant savings are expected in the sectors with regulations requiring information on nanoproducts congruent with the ENPRs (scenario 2):
  a) Substance manufacturers (REACH) ~ 90-95% savings,
  b) Cosmetics (Cosmetics Regulation) ~ 80% savings,
  c) Food (Novel Food Regulation) ~ 95% savings,
  d) Cleaning and Disinfection (Biocidal Product Regulation)[118] ~ 40% savings.
- All other sectors are not affected by the parameters under scenario 2 since they are not already notified according to an existing regulatory scheme.

The trend holds true for sub-scenario (b).

Table 10:Comparison of the costs for scenario 1a and scenario 2a. The sectors highlighted are those affected by existing regulations requiring information on nanoproducts congruent with the ENPRs.

Sectors	Scenario 1: All Costs ENPR		Scenario 2: Costs Shared	
	costs after 5 years		costs after 5 years	
	min	max	Min	max
Total	7.054.000	14.612.000	6.769.000	14.035.000
1. Substances	61.400	112.120	4.900	12.120
2. Cosmetics	156.400	224.600	36.400	44.600
3. Health Care	230.000	440.000	230.000	440.000
4. Food & Feed	61.000	110.500	2.100	20.900
5. Coatings & Inks	3.170.000	5.130.000	3.170.000	5.130.000
6. Cleaning & Disinfection	76.500	273.500	26.500	66.000
7. Rubber Products	430.000	670.000	430.000	670.000
8. Building & Construction	30.760	61.400	30.760	61.400
9. Textiles	880.000	1.680.000	880.000	1.680.000
10. Paper Products	1.548.000	2.270.000	1.548.000	2.270.000
11. Complex Objects & Other Products	410.000	3.640.000	410.000	3.640.000

[118] Some products may contain nanomaterials that are not covered by the BPR (e.g. filling materials in certain cleaning pastes). This explains the comparatively small savings that are to be expected for the sector cleaning & disinfection.

4.4 Direct costs of an ENPR for public authorities

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

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

The estimated administrative costs include functions such as providing guidance based on relevant regulations, establishing FAQ to help streamline the process, working with stakeholders to improve the notification procedure (including type of information required in the notification). Since all Member States are involved in an ENPR (28 in total), the number of desk officers is estimated to be at least 8 for the first year of implementation to carry out the administrative requirements associated with the register, including the yearly publication of any reports containing aggregate data for decision makers and the public. A similar number of support staff is also anticipated in the first year of implementation.

Manual checking of the data is not required since a function can determine the validity of the data entered. Costs associated with the scientific assessment include determining if the correct particle analysis method for classifying substances as nanomaterials is employed (e.g. imaging techniques and the transformation to a number-based distribution). The estimated costs for establishment of the database does not include costs related to harmonising the data structure and the transfer of data between different registers (e.g. with the cosmetics database) which could lead to extra costs.

According to interviews with public authorities, the priority of European and national inspections change from year to year. Furthermore, many inspections of companies examine compliance with several different regulations. Therefore, there is no anticipated increase in the workload for inspectors, just a change in priority.

The costs incurred for public authorities in the implementation phase can depend heavily on the effectiveness of implementation which includes providing clear definitions and guidance on the scope of the registry.

4.5 Effects on innovation & competition

Establishing an EPRN aims at enhancing transparency with regard to types, amounts and applications of nanomaterials. Although the concept of the register foresees both a “public” and a “confidential” section, any disclosure of information may impact both competition and innovation.

Potential impacts may be inferred from the establishment of other information duties, e.g. REACH and in particular from the current discussion as to how to adapt the legislative provisions to adequately address nanomaterials[119].

4.5.1 Innovation

Administrative costs result in the unbalanced distribution of resources, thereby hampering innovation activities. This may prove particularly problematic for SMEs as the backbone of Europe's economy and a key driver of innovation. Moreover, in view of recent public debates and even calls for bans, increased transparency could further deteriorate the situation. Consequently, development efforts or even launching of new products containing nanomaterials may decline. These concerns are similar to the concerns voiced with regard to the REACH implementation which have been reviewed in 2012.[120] Similarly to this case these effects are likely to surface in the short term for the proposed ENPR if at all. In contrast to the situation with REACH, however, many SMEs are only partially affected as some or all of the information requirements already have to be fulfilled for other regulations (see Chapter 4.2.1 ff.). This mitigates the administrative burden imposed on the drivers of innovation in Europe somewhat. Costs that are generated by the introduction of an ENPR could however be transferred to the consumer as noted by the Danish Environmental Protection Agency. The actual transferral of costs will be dependent on several factors in the individual market segments among which the price elasticity for a given market plays an important role. At the same time, as this effect encompasses all Member States of the European Union the market distortion the agency warned against would not occur within the EU. In the long term positive effects are likely to gain momentum. Similarly to the situation faced with the implementation of REACH the establishment of an EPRN has the potential to increase R&D and innovation. Individual products containing nanomaterials that are problematic in the given application are candidates for research on substitution of the nanomaterials in question. This research is driven not only by the ambition of companies to produce an optimized product but also by competition with other products on the market and within the ENPR.

On a larger scale the early and comprehensive collection of data on distribution and type of nanomaterials used offers the opportunity to monitor overall release patterns for any given nanomaterial. While low concentrations of a nanomaterial in a product might be non-hazardous the combination of several products from different categories could amount to exposure levels for individuals or the environment that are noteworthy. Such patterns can only be discerned with the aid of a unified database such as the ENPR. Any emerging pattern worthy of concern could be identified early and communicated to individual industry sectors, thus providing impetus for potential innovative, substitutions that were not deemed necessary

[119] The latter has been addressed in the study „Examination and assessment of consequences for industry, consumers, human health and the environment of possible options for changing the REACH requirements for nanomaterials" for the European Commission, Joint Research Centre, which was part of the NANO SUPPORT project. Final report to be published.

[120] Centre for Strategy & Evaluation Services (2012).

previously. The strategic decision making that becomes possible for stakeholders is a significant tool that directs innovation in a qualitative (problem oriented) way. Establishing a register of products containing nanomaterials may even provide authorities with a tool to initiate targeted research funding.

Furthermore publicly accessible information systems may be used by companies that have not yet entered the nanomarket and that are looking for solutions to further improve their products or to identify market gaps.

4.5.2 Competition

Enhanced transparency and disclosed information may induce in competitive disadvantages, especially for innovative firms. This is backed by observations that many companies that were contacted within the frame of this study were reluctant to provide information on the use of nanomaterials.

As the collection of information on a voluntary basis has been shown to be inefficient[121] also because of concerns related to the disclosure of proprietary information a legal scaffold, ensuring the responsible and transparent handling of the provided information is of essence. The information provided has to be differentiated carefully for publicly accessible data and data only accessible to parts of the EU governments. A legal framework offers room to protect critical information while informing the public.

Even in such a setting the increase in competition between enterprises is expected. As elaborated in the previous chapter the increased competition is expected to partially shape efforts to innovate by highlighting potentially existing or emerging hazards connected to individual products.

While competition is likely to be influenced by the data publicly available on the register, the effect of several differing NPRs in the EU introduces a severe distortion into the EU market. Especially SMEs are likely to be negatively impacted by such a selection criterion that does not select for the quality of the product but for the financial power of the individual enterprise to fulfil differing requirements administratively and technically.[122] SMEs will be disproportionally taxed by additional information requirements as they tend not to have a portfolio of products that can buffer added expense in one segment compared to larger companies. The need to notify in several countries within Europe would stretch their means and favour large companies.

Complementary to the potential, competition increasing effects of the ENPR public acceptance of a specific product can be increased by being able to openly highlight the non-hazardous properties of the nanomaterial containing products within the framework of an objective dataset as provided for the ENPR. This will not only increase public acceptance of a given product but also will have effects on the corporate image which are stronger for SMEs than for

[121] Milieu & RPA (2009).

[122] Milieu & RPA (2009).

large enterprises due to the limited product portfolio. Additionally the positioning of competitors can be assessed with greater ease.

4.6 Assessment of the Benefits of an ENPR

A European Register for Products containing nanomaterials can produce benefits mainly for the following groups:

- Public authorities, public agencies and governments,
- Consumers, and
- Companies.

The benefits were identified and described more detailed in the following chapters.[123]

4.6.1 Public authorities & agencies and governments

The benefits for public authorities & agencies and governments dealing with nanomaterials can be best illustrated looking at the information on nanomaterials available for them at present. Without an ENPR authorities have only information on nanomaterials in special sectors and even there the information it is not always complete compared with the information required for an ENPR (see Chapter 4.2.1 ff.). This information deficit is not removed by existing product registers on the national level (e.g. Switzerland[124] and Sweden[125]).[126] These registers do not sufficiently provide an overview on the market with nanomaterials as they focus on dangerous substances/mixtures and not on articles. Finally, the EU's rapid alert system for non-food consumer products (RAPEX) cannot be regarded as moderate means that are equally effective by comparison with a mandatory reporting requirement. RAPEX enables market surveillance authorities to inform each other if measures are put in place with regard to a consumer product that presents a serious risk to consumer health and safety. However, it only intervenes, in the event of a specific threat to human health. Hazards in the workplace and environmental hazards are not covered. Moreover, the RAPEX system does not enable the competent authorities to obtain an overview of nanoproducts available on the market and reporting via RAPEX tells them nothing about whether the product in question contains nanomaterials.

However, in other sectors and with an eye on an overall sector perspective authorities are lacking the following information:

- Which products contain nanomaterials that are intentionally or unintentionally released? – Product and trade name requested for an ENPR will help here;

[123](Möller & Hermann (2009); UBA (2012), p. 6.

[124] Cf. Chemical product register, see https://www.rpc.admin.ch/rpc/public/index.xhtml? (as from 4.6.2013).

[125] Cf. KEMI, Kemikalieninspektionen, see: http://www.kemi.se/Start/Produktregistret/ (as from 4.6.2013).

[126] Ahrens et al. (2001).

- What kind of nanomaterial(s) is released? – functionality, application and characterisation of the used nanomaterial requested for an ENPR will help here;
- What is the amount of a nanomaterial that is intentionally or unintentionally released over all sectors? – produced and imported amount of nanomaterials and concentration of nanomaterials in a nanoproduct requested for an ENPR will help here.

An essential benefit for public authorities/agencies and governments is to gain a comprehensive overview of nanomaterials used in various sectors on the market. This information will enable them to draw various conclusions, e.g. on the amount of nanomaterials used in products or the possible exposure pathways for those nanomaterials. Governments and public agencies can use such information to develop new or adjust existing research programs for eco- and humantoxicology tailored to the nanomaterials on the market and their possible exposure pathways.

A general market overview can support the estimation of the relevance of nanotechnology and, where appropriate, individual nanomaterials for the purpose of deciding on the setting of priorities in enforcement and law-making / regulation.[127] For example competent authorities in the Member States can use the information in the register to get an overview on workplaces where workers can be exposed to nanomaterials. In fact, it may be not very present to reasonable number of producers of mixtures and articles containing nanomaterials whether their products contain nanomaterials.

Exposure to nanomaterials

Exposure to nanomaterials is difficult to quantify as they can be emitted throughout the life-cycle of a nanomaterial containing product. Many factors such as the bond between the nanomaterial and its surrounding matrix, the agglomeration state of nanoparticles in for example a liquid or a gas, the application area of the product, etc. play a role in emission.

The available data on emission, behaviour in environmental media, and exposure to human and environment is still scarce and major research efforts are underway to close the gaps. . Any new information concerning these aspects can be transferred into exposure assessments with greater ease with the data collected within an ENPR.

An ENPR providing information across sectors on a nanomaterial and on nanoproducts from which an intentional or unintentional release is possible forms the basis for further exposure assessments for humans and the environment, including cumulative and combinatory exposure. Thus the life-cycle of a given nanomaterial can be traced with the information on which products it was used in. This allows narrowing down possible surface modifications and thus allows for distribution models in the environment. Simultaneously the amount of nanomaterial released can be fed into the model to estimate potential risk.

Should a concrete risk be identified resulting from a nanoproduct the identity of the producer and the name of the concrete product as well as the characterisation of the nanomaterial

[127] UBA (2012), p. 3.

would facilitate the identification of emission sites within the product life-cycle as well as within the environment.

Although risk assessment and enhanced reaction time might not be the primary applications of the ENPR the benefits available through the collection of the relatively few data points necessary for the ENPR are foreseeably significant in this context.

Improving the enforcement of environmental, consumer and workers´ health legislation

Information on the notifier's address, the nanomaterial(s) (characterisation and functionality) and its application will support competent authorities in charge of the permitting and of the enforcement of environmental, consumer and workers´ health legislation. For example competent authorities can use the information to check environmental permits (e.g. existing IPPC-/IED-authorisations) regarding provisions on the emission of nanomaterial(s) into air and water or regarding their presence in waste disposed of.

With respect to market control the information in an ENPR on the product and trade name of nanoproducts in combination with the functionality and application of a nanomaterial will support activities of competent authorities when conducting market control on products containing nanomaterials. Whereas it is rather difficult for competent authorities only on the basis of analytical measurements to check:

- whether a product contains a nanomaterial not assessed for that kind of use according to REACH or to sectoral legislation or
- whether a claimed "nano-effect" of a product is indeed linked to nanomaterials used for the product.

The information on characterisation and functionality will help to conduct a more targeted detection.

Finally, information in an ENPR improves traceability of nanomaterials which is essential for the national competent authorities to prioritize environmental enforcement activities.

4.6.2 Companies producing nanoproducts

Traceability of nanomaterial(s) in products

Traceability[128] of products in the production chain is a well established instrument either on a voluntary basis in industry (e.g. in the automotive sector the IMDS („International Material Data System")) or as a mandatory requirement, e.g. in food sector within the Regulation (EU) No 178/2002[129] and across sectors due to Directive 2001/95/EC on general product safety[130].

[128] SRU (2011), Rn 524 und Rn. 563 regarding traceability as an instrument in the food and non-food sector.

[129] Regulation (EC) No 178/2002 of the Euopean 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, OJ L 31, 1.2.2002, p. 1.

"Traceability is an axiom in the international framework (FAO/WHO Codex Alimentarius) and in the EU in food law and has applied to certain products for many years already. Traceability puts all players in a position to remove products with certain nanomaterials from the market, should they, after approval, turn out not to be safe after all – based on new scientific findings."[131]

This is achieved by a unique identification of a product, the name and address of the producer which is passed on in the production chain.

However, the instrument as described for the food sector and for purpose of general product safety does not require from the producers to inform about ingredients in a product, respectively there is no duty to inform in the production chain on the presence of nanomaterials. As a consequence actors in the production chain will find it more difficult to inform themselves on the presence of nanomaterials in a product.

As the ENPR introduces the duty to notify nanoproducts and requires the passing of the notification number in the production chain the mentioned deficits will be avoided. Consequently traceability on nanomaterials and products containing nanomaterials will improve companies´ knowledge on the substances they are using and manufacturing, and increase information throughout the production chain and traceability for all stakeholders. It must be pointed out that product responsibility can only be perceived with knowledge of the composition of a product in the production chain. One result of the survey conducted in the course of this study was that companies in the production chain were not aware whether they use nanomaterials or not.

Moreover traceability of nanomaterials throughout the production chain is an important part for risk management for both producers and authorities. That way, all players are enabled to remove products containing nanomaterials from the market if they prove to be unsafe after all based on latest scientific findings. The instrument enables producers to duly perform their producer responsibility.[132]

How the ENPR can interact with existing voluntary information systems can be illustrated with the IMDS in the automotive sector. The IMDS is a detailed system in the sector that collects information for every component part in a material data sheet. The data sheet facilitates the actors in the production chain to inform themselves on the used materials and substances in the material and thus enables traceability. Furthermore the information is used in the latter recycling of vehicles.[133] In order to support producer responsibility information on nanomaterials contained in the component parts could be introduced in the system. The notification duties of an ENPR would make the inclusion of information in the IMDS

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[130] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4.

[131] Möller & Hermann (2009), p. 146.

[132] UBA (2012), p. 6.

[133] BASF SE (2012).

compulsory and thus reliable for other actors in the production chain. On the other hand a modified IMDS would ease the administrative burden for all actors to comply with the notification duties of the ENPR.

Public acceptance of nanomaterials and nanoproducts

Information on nanomaterials and their uses is the basis for public acceptance of nanomaterials and nanoproducts on the long run. An important condition for trust in a new technology is transparency, including active information about products and research projects regarding these products and nanomaterials.[134] One of the central topics of consumers participating in the BfR´s Consumer Conference on Nanotechnology was the postulation to have graduated information offers on nanotechnology ranging from easy to understand general overview on nanomaterials and nanoproducts to scientific based and more complex information.[135]

The information in an ENPR planned to be publicly available (see Chapter 2.5.) is capable to satisfy this postulation. An ENPR offering trade name of nanoproducts and applications of nanomaterial will give consumers an overview on the concrete nanoproducts as well as an insight into typical applications of nanomaterials and thus provide orientation in the market. More detailed information on the characterisation of nanomaterials and their functionality can serve as a basis for consumers to receive a deeper scientific insight into nanotechnology. In this way the ENPR can contribute to build consumer confidence in the applications of nanomaterials. Consumers´ need for information with respect to both actual and individually perceived risks will be taken care of. Information provided to consumers with an ENPR helps consumers in dealing with scientific and technical uncertainties of especially new applications of nanomaterials. Without transparent information in an ENPR addressing also scientific and technical issues, it might happen that the discussion about uncertainties regarding risks will be shifted to other levels, like the emotional/psychological or social/ethical.[136]

Last but not least, no or not sufficient information on nanoproducts from the perspective of consumers leaves them with the impression that the high expectations linked to the nanotechnology might not be fulfilled. The reasons for that are a decrease in the knowledge of consumers about nanoproducts on the market, their functioning and benefits and a loss of trust in regulation due to the invisibility of the producers and products.

4.6.3 Consumers

If consumers can inform themselves whether an articles contains nanomaterials or not with the help of an ENPR this will contribute considerably to realize their freedom of choice. Based on information consumers can obtain from the ENPR (concrete product name, application and function of the nanomaterial) and further extended producer information, which they will

[134] Möller & Hermann (2009), p. 88.

[135] See Fn 1.

[136] Öko-Institut e.V. (2009), p. 103.

either have or can research proactively (e.g. on the benefits and risks of a nanomaterial), enables consumers to make their own benefit-risk assessment on a certain nanoproduct. The ENPR-concept sees four options to inform consumer on the presence of a nanomaterial in a product. In principle a notification number for a nanoproduct facilitates the transfer from the information in the ENPR to the consumer. It must be noted that so far in the ENPR-concept, it is not decided whether the notification number should refer to the product (product-specific) or to the substance in the nanoform (substance-specific). The four options are:

1. The ENPR functions only as a passive source of information for consumer, i.e. there is no notification number displayed on the nanoproduct and the consumer has to research in the database with the help of a product name.
2. A notification number is awarded to each nanomaterial that must be notified. On the product all nanomaterials are visible via their notification number (substance-specific).
3. A notification number is awarded to each product. Consumer can receive information on the nanomaterials contained in that product from the ENPR (product-specific).
4. The fourth option is similar to the third option but beside the product-specific notification number the nanomaterials contained in that product are listed on the product or its packaging.

Discussing the arguments in favour of and against the four options from the perspective of the consumers, public authorities and notifiers reveals the following picture:

Option 1:

This option makes it considerably more difficult for consumers and public authorities to identify a product they want to purchase or have to deal with, as a nanoproduct without any doubt. The use of the ENPR would be limited for those actors as a change in the formulation of the product will not be visible for them if the product name stays the same.

For notifiers this option has the advantage that no costs for labelling the nanoproduct would occur. However, they still will have to face the costs to communicate the notification number in the production chain. Moreover, without a notification number on the product consumers cannot misunderstand it as a hazard warning.

Option 2:

With the notification number for nanomaterials option 2 enables consumers, manufacturers and public authorities to identify a product containing nanomaterials and thus to obtain further information from the EPRN. Regarding complex products which are assembled from a lot of components, the information on nanomaterials in that complex product can become non-transparent quite easily.

For notifiers the labelling of all nanomaterials on the product can be expensive and may in some cases lead to problems due to limited space on the product or packaging. Several representatives of industry warn that nano-specific notification numbers on the product can be misunderstood as a hazard warning by consumers. However, a notification number can also be interpreted by consumers as verified by authorities.

It remains to be open, if a substance-specific notification number on the product is understood as a hazard warning by consumers.

Option 3:

As option 2 this option enables the consumers, manufacturers and public authorities to identify a nanoproduct and to obtain further information from the ENPR. Notifiers have to label their product only with one notification number instead of several for each nanomaterial and thus may save costs and have fewer problems with space for the labelling. Furthermore, a product-specific notification makes the communication on nanoproducts in the production chain easier compared to a detailed labelling of all nanomaterials. For example a substance-specific notification number must be changed if a nanomaterial is replaced in the formulation by another nanomaterial. Whereas in such a case a product-specific notification number does not need to be changed, rather the content in the ENPR is changed.

It remains to be open, if a product-specific notification number on the product is understood as a hazard warning by consumers.

Option 4:

Option 4 as well as option 2 and 3 enables consumers, manufacturers and public authorities to identify a nanoproduct. However, the added value of the additional labelling with the nanomaterials contained in the product is questionable. One possibility would be that informed consumers who want to purchase a nanoproduct with a specific nanomaterial or who do not want to buy it, can decide immediately without looking in the ENPR.

Notifiers will have higher labelling costs and problems with space on the label of the product compared to option 3.

If a product is labelled with a product-specific notification number and additionally nanomaterials are named on the product, the chances that consumers will understand this as a hazard warning is likely to be higher than in the other options.

In comparison of all four options the third option seems to be favourable with respect to a balance of benefits and drawbacks for all actors.

Option 1 is discarded as for the consumer option 1 is not really practicable in terms to support an active purchase decision for or against a product. It is not always sure whether the consumer can identify a nanoproduct in the ENPR based on the product name and it will take him more effort compared to other options. The option of a substance-specific notification number is discarded, because it will become difficult for consumers and the production chain in case of complex products. Finally option 4 is linked to the highest labelling efforts for notifiers and a higher risk that the labelling is misunderstood as a hazard warning by consumers.

4.7 Qualitative assessment of the impacts on innovation and competition and of the benefits

In the following table 11 an overview on the qualitative impacts of a baseline scenario (no implementation of an ENPR) versus the implementation of an ENPR is given. The impacts listed below are independent of the scenarios and sub-scenarios explained in chapter 4.3.7. Neither the question of who is ultimately shouldering the costs for the information gathering and administration, nor the exact frequency of information updating has a qualitative impact compared to the baseline.

Table 11: Qualitative impacts of the baseline scenario vs. the introduction of an ENPR.

	Baseline	ENPR
Administrative burden	- compliance with national NPRs	+/- compliance with ENPR but presumably not with national NPRs
EU market distortion	-	+
Data collection for exposure assessments	-	+
Transparency for consumers	-	+
Worker protection	+/-	+
Consumer freedom of choice	-/+ Only in those sectors with labelling-requirements for nanoproducts	+
Traceability	-	+

"+" denotes a positive impact whereas "–" denotes a negative development.

As can be seen from the table above, the baseline scenario includes compliance with existing and upcoming national NPRs. Additional national NRPs would increase the administrative costs and the distortion of the European internal market. The data collection for exposure assessments would be difficult to harmonise across member state boundaries and the locally gathered data might be incompatible, thereby negatively impacting transparency and freedom of choice for consumers, worker protection, and traceability. On the Member State level worker protection would be possible if the Member State in question has a NPR. Similarly the freedom of choice for the consumer would only be increased locally and also only if the local NPR actually enforced labelling or otherwise consumer-accessible information.

In comparison establishing an ENPR has the advantages of alleviating the aforementioned problems with market distortion, data collection and usage, worker protection, freedom of choice for consumers, and traceability. It would only partially alleviate the administrative costs placed on companies and authorities. Assuming that national NPRs would be replaced by an ENPR, plans for future national NPRs would be abandoned, and only one notification obligation on EU level would remain. As shown in the quantitative assessments it would however still generate considerable costs for industry and administration.

5 Overall Evaluation of the impacts of an ENPR

Chapter 5 resumes the most important impacts of an ENPR regarding the costs and benefits (Chapter 5.1 – 5.4) followed by a sensitivity analysis of the results in chapter 5.5 and a final assessment of the costs against the benefits (Chapter 5.6).

5.1 Companies and nanoproducts per sector affected by an ENPR

In general, as many as 5-8% (or 37.500-58.000) of all 766.660 enterprises whose main activity was in the economic sector investigated (covering manufacturing or NACE section C) may be affected by the implementation of an ENPR.

The general picture is distorted, however, by businesses that were assigned to the sector "complex objects and other products" and which make up the large majority of all companies analysed (roughly 75% or 580.430). At the same time, however, they account for only about 6-10% (or 3.000-6.000) of all companies affected.

A more detailed analysis reveals that:

- Some sectors could be particularly affected, such as coatings & inks (90-95% of all companies in this sector), rubber products (75-90%), paper products (60-80%), cosmetics (60-80%) and health care (50-80%).
- the implementation of the ENPR could lead to as many as 4.1 million notifications, the large share of which can be attributed to coatings & inks (roughly 60%), paper products (around 25%), rubber and textile products as well as "complex objects and other products" (around 3.5% each).
- the weighted average administrative burden for all companies is between 16 and 57 notifications where the median value lies between 7 and 32. Businesses within the sectors health care, paper products and complex objects and other products could be obliged to notify as many as approximately 86 products per company. Entities in the sector coatings & inks could be strongly affected, with up to 610 notifications per company.

Most strikingly, it appears that besides pigments and paints, the large share of notifications may be attributed to filling materials. As indicated above, fillers are commonly used materials to reduce the consumption of expensive binder material and to improve the physical properties of the resulting material. Filling materials include, amongst others, calcium carbonate (paper and plastics), SAS (paints, coatings, adhesives and sealants, plastics and rubber) or Carbon Black (rubber and to a minor extent in plastics and paints).[137] Although some fillers may need to be considered "incidentally formed nanomaterials" (see Chapter 3.1.2), a large share of products containing these kinds of materials could nonetheless fall under the notification scheme of the register (given that relevant concentration thresholds are exceeded).

[137] *ObservatoryNANO Factsheets March (2012*).

5.2 Direct costs for industry

Two scenarios were analysed in chapter 4.3.7:

1. All associated costs of the register are attributed to the ENPR (scenario1), and
2. Costs attributed to other regulations are not counted for the ENPR (scenario 2).

Additionally two sub-scenarios affecting the recurring costs were investigated:

- the product notification must be updated only when the formulation has changed (only information that has changed must be updated) (sub-scenario a), and
- the product notification to be updated yearly (sub-scenario b).

The comparison of scenarios 1 and 2 shows that scenario 2 compared with scenario 1 does not lead to a significantly reduced administrative burden when considering all companies concerned in the present study of the ENPR-concept. (Total costs may be reduced by 5.5%. This is explained by the fact that sectors which benefit from scenario 2 (Substances, Cosmetics, Food & Feed, and Cleaning & Disinfection) have little share to the overall costs (around 7%) in scenario 1.Whereas significant savings are expected for those sectors with regulations requiring information on nanoproducts congruent with the ENPRs (scenario 2):

- Substance manufacturers (REACH) ≈ 90-95% savings,
- Cosmetics (Cosmetics Regulation) ≈80% savings,
- Food (Novel Food Regulation and Food Packaging) ≈ 95% savings,
- Cleaning and Disinfection (Biocidal Product Regulation)[138] ≈ 40% savings.
- All other sectors are not affected the parameters under scenario 2 since they are not already notified according to an existing regulatory scheme.

Moreover, the analysis of scenario 1 and 2 shows that declaring substances accounts for only 1% of all costs, while notifications of mixtures and articles account for 45-54% each.

Irrespective of any scenarios analysed, the comparison of costs on a 5 year basis reveals that:

- Some sectors could be particularly affected, such as Coatings & Inks with 6.26 -10.20 million hours (e.g. approximately 44-50% of the costs for notifiers in case the product notification must be updated when the formulation has changed and that all costs are attributed to the ENPR [scenario 1a]), Paper Products with approximately 3.01-4.48 million hours, and Textiles with approximately 0.91 - 1.93 million hours.

  On an h/company basis of five years, this corresponds to approximately 790-1220 h/firm, 140-150 h/firm, and 130-150 h/ firm for the sectors Coatings & Inks, Paper Products, and Textiles respectively.

[138] Some products may contain nanomaterials that are not covered by the BPR (e.g. filling materials in certain cleaning pastes). This explains the comparatively small savings that are to be expected for the sector cleaning & disinfection.

- For sectors with a low number of notifications/company, the ratio of implementation costs / recurring costs is high (often an order of magnitude larger compared to sectors with a high number of notifications or companies). An example is cosmetics. This means most of the costs are incurred for the task of modifying company procedures and systems, personnel training, and the first administrative entering of the data.
- For sectors with a high number of notifications/company, the ratio of implementation costs / recurring costs is low since potentially hundreds of products have to be updated (and checked). An example is coatings & inks.
- In total, implementation costs are approximately 4-5 times as large as recurring costs.
- Distribution of costs for substances, mixtures, articles: For scenario 1a and 2a respectively, substances account for less than 1% of all costs, mixtures for 42-53%, and articles for approximately 47-57%. This changes only slightly for sub-scenario b. In general, substance costs are an order of magnitude lower than costs related to mixtures and articles. This is to be expected since substances are at the beginning of the production chain, and one substance is used in multiple different products (which all have to be notified) in which a multiplier effect occurs as the substance moves along the production chain.

5.3 Direct costs for competent authority

The estimated direct costs for a central competent authority or agency running the ENPR consist of the following elements:

- approximately 500,000 € for the establishment of the register database (Hardware/software costs);
- Based on the number of Member States involved in an ENPR, the number of desk officers is estimated to be at least 5-8 for the first year of implementation to carry out the administrative requirements associated with the register (Administrative costs).

The estimated administrative costs include functions such as providing guidance based on relevant regulations, establishing FAQ to help streamline the process, working with stakeholders to improve the notification procedure (including type of information). It is assumed that the data is controlled via a function that ensures that all data is present and in the proper form, therefore no manual checking of the data is required.

Further additional costs related to the operation of the ENPR (not included in the costs stated above) cover:

- costs related to harmonizing the data structure and the transfer of data between sectoral registries and the ENPR;
- scientific assessment involved in determining if the correct particle analysis method for classifying substances as nanomaterials is used;
- scientific evaluation of studies submitted by notifiers demonstrating that exposure to people and the environment can be excluded.
- Inspection at companies. However, the priority inspections change from year to year and many inspections of companies examine compliance with several different

regulations. Therefore, there it is assumed that there is no anticipated increase in the workload for inspectors, but a change in priority.

5.4 Benefits of an ENPR

The benefits of an ENPR are an overview on nanomaterials and nanoproducts obtainable on the market, the traceability of the production of nanomaterials and lastly to enable the freedom of choice for consumers.

With the help of an ENPR public authorities/agencies and governments gain a comprehensive overview of nanoproducts available on the market across all sectors affected, enabling them to draw various conclusions, e.g. on the amount of special nanomaterials used in products in various sectors or the possible exposure pathways for those nanomaterials. Subsequently, governments and public agencies can use such information to improve their law enforcement as well as to develop new or adjust existing research programs for eco- and humantoxicology tailored to the nanomaterials on the market and their possible exposure pathways.

The traceability of nanomaterials throughout the production chain is an important part for risk management for both producers and authorities. That way, all players are enabled to remove products containing nanomaterials from the market and a basis for public acceptance of the technology and the products in the long run is secured.

As a third benefit an ENPR can support the freedom of choice for consumers concerning the purchase of products containing nanomaterials as well as the trust in the applications of the materials can be supported depending on the public available information in an ENPR.

5.5 Sensitivity analysis of the results

The sensitivity of the results of the impact assessment is discussed in the following:

- Due to significant lack of information on the release of nanomaterials during their life cycle it is difficult for notifiers to predict whether they have to notify their nanoproduct and it is difficult to predict what will be accepted as scientific evidence that no release occurs. However, it must be noted that for example manufacturers of nanomaterials shall address in the chemical safety assessment all stages of the life-cycle of the substance resulting from the manufacture and identified uses (see for example Annex 1 of REACH). Thus they should possess knowledge on the release of nanomaterials.
- The terms ‘natural nanomaterial’, ‘incidental nanomaterial’, and the potential inclusion of certain polymers or nanoparticles made out of polymers will have to be addressed if an ENPR is implemented. Depending on the individual definitions this might lead to a higher number of notifications than estimated in this study.
- High uncertainty exists for the products in the sector “Complex Objects and other products” which consists of hundreds of components, many being imported, and the composition unknown.
- Regarding information on nanomaterials as phase-in-substance that are produced or imported below 1 t/a it remains unclear to which extent information is available under REACH. A nanomaterial that is chemically identical with a bulkmaterial that is manufactured or imported in quantities of 1 t/a or more, should be registered within REACH, even if the quantity of the nanomaterial itself is less than 1 t/a. This is due to

the fact that all identified uses of a substance have to be registered. In case a nanomaterial is not chemically identical with a bulkmaterial it must be manufactured or imported in quantities of 1 t/a or more in order to be registered within REACH. According to the EU Commission 99.9% of all nanomaterials on the market in terms of production volumes and sales are produced in quantities above 1 t/a.[139] However, other stakeholders expect lower figures.

- Down-stream users might decide not to use nanomaterials for their products in order to avoid costs engaged with the ENPR.
- Consequences of different definitions for nanomaterials for the sectoral legislation and for the ENPR. According to the ENPR-concept the notification of nanoproducts is based on the recommendation of EU-Commission for a definition of nanomaterials 2011/696/EC. The Commission recommendation being overarching builds the basis for the definition of nanomaterials in sectoral legislation, e.g. in the Cosmetics Regulation or the food sector. However, the definitions in the sectoral legislation show deviations from the EU recommendation narrowing or extending the scope of the definition, for example in the food sector a 10%-threshold for the nanomaterial definition is discussed. As a consequence one could assume that more nanoproducts will have to be notified under the ENPR than according to the sectoral legislation. To options are at hand to deal with that inconsistency. One is to use the same definition for nanomaterials throughout all sectoral legislations and the ENPR. The other option is to base the notification duty of the ENPR on the sectoral definition of a nanomaterial and to use the EU recommendation only subsidiary for those sectors in the scope of the ENPR where no sectoral definition exists.
- It remains to be seen, whether national nanoproduct registers of Member States, like the French register or those likely to be implemented in the near future, will be cease to exist in case an ENPR on EU-level is introduced. Therefore it remains unclear, whether the notifiers will face only the administrative burden of one ENPR without additional administrative costs due to national registers.

5.6 Assessing costs and benefits of an ENPR

A weighing up of the costs and benefits of an ENPR is only possible to a limited extent. This is not only due to the uncertainties the researched costs and benefits show (described in Chapter 5.5) but also to the methodological disparities of quantitative estimation of the direct costs for notifiers and public authorities compared with a qualitative estimation of the benefits. Moreover the character of the ENPR as a precautionary instrument makes a comparison of costs and benefits rather difficult. “The costs of preventive actions are usually tangible, clearly allocated and often short term, whereas the costs of failing to act are less tangible, less clearly distributed and usually longer term, posing particular problems of governance. Weighing up the overall pros and cons of action, or inaction, is therefore very difficult, involving ethical as

[139] EU COM (2012b).

well as economic considerations [...]"[140] In the end it will be a political decision to decide if and to which extend an ENPR is considered to be appropriate and proportionate.

Nevertheless, the qualitative assessment of the benefits in chapter 4.6 has demonstrated that an ENPR could bring additional value for public authorities, consumers and companies involved in nanotechnology. National product registers for nanomaterials in the EU have been introduced in France and are planned to be introduced for example in Denmark and Belgium. It is at hand, that the concept of an ENPR will help to avoid a multiplication of administrative costs for both sides, companies producing and importing those products and national competent authorities responsible to run their register.

Finally, from a legal point of view it can be discussed whether a register is the proportionate instrument in the light of the precautionary principle to govern the safe use of nanomaterials and products containing them. However, the introduction of an ENPR is the mildest legal instrument to control the production and use of nanoproducts compared to a restriction, a ban or a moratorium on one or more of these products.

[140] Möller & Hermann (2009).

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7 Annexes

7.1 Final selection of product groups

This Annex gives an overview of selected nanomaterials in various products analysed for the purpose of this study. The provisions of the register provide for notification exemptions. Therefore, all products were examined as to whether they may need to fall under the scope of the register:

"+" means potentially relevant in terms of notification obligations, and

"-" means exempted from notification obligations.

Nanomaterial	Product	Category/Sector	Relevant for ENPR
Aluminium Oxide	Rubber Products	Rubber Products	+
Aluminium Oxide	Coating Agent (e.g. for Cutting and grinding tools, Automobile Exteriors, Safety Glasses and Scratch-Resistant Windows for Barcode, Scanners, Flooring, Light bulbs, Paper)	Coatings & Inks	+
Aluminium Oxide	Paints	Coatings & Inks	+
Aluminium Oxide	Varnishes	Coatings & Inks	+
Aluminium Oxide	Catalysts	Complex Objects & Other Products	+
Aluminium Oxide	Polishing Agent (e.g. for Precious Stones, Metals, and Wafers)	Complex Objects & Other Products	+
Aluminium Oxide	Master Batches	Coatings & Inks	+
Aluminium Oxide	Toothpaste	Cosmetics	+
Aluminium Oxide	Carpets (Filling Material)	Textiles	+
Aluminium Oxide	Paper Products	Paper Products	+
Aluminium Oxide	Plastics	Complex Objects & Other Products	-
Aluminium Oxide	Coated High Quality Inkjet Paper	Paper Products	-
Aluminium Oxide	Coated Cutting Tools	Complex Objects & Other Products	-
Aluminium Oxide	Coated Safety Glasses	Complex Objects & Other Products	-
Aluminium Oxide	Coated Barcode Scanners	Complex Objects & Other Products	-
Aluminium Oxide	Light bulbs	Complex Objects & Other Products	-
Aluminium Oxide	Ceramic Products (e.g. Filtration Membranes)	Complex Objects & Other Products	-

Aluminium Oxide	Transparent Ceramic Bodies for High-Pressure Lamps	Complex Objects & Other Products	-
Aluminium Oxide	Ignition Plugs	Complex Objects & Other Products	-
Carbon Black	Food Contact Material	Food & Feed	-
Carbon Black	Plastics	Complex Objects & Other Products	-
Carbon Black	Tyres	Rubber Products	+
Carbon Black	Hoses	Rubber Products	+
Carbon Black	Tubes	Rubber Products	+
Carbon Black	Vibration mounts	Rubber Products	+
Carbon Black	Wiper Blades	Rubber Products	+
Carbon Black	Décor Paper	Paper Products	-
Carbon Black	Fibres	Textiles	-
Carbon Black	Carbon Brushes	Complex Objects & Other Products	-
Carbon Black	Carbon Electrodes	Complex Objects & Other Products	-
Carbon Black	Adhesives and Sealants (rubber based)	Rubber Products	+
Carbon Black	Conveyor Belts	Rubber Products	+
Carbon Black	Footwear	Rubber Products	+
Carbon Black	Belts	Rubber Products	+
Carbon Black	Inks	Coatings & Inks	+
Carbon Black	Paints	Coatings & Inks	+
Carbon Black	Varnishes	Coatings & Inks	+
Carbon Black	Mascara	Cosmetics	+
Carbon Black	Cemetry Soil	Complex Objects & Other Products	-
Carbon Black	Flower Soil	Complex Objects & Other Products	-
Carbon Black	Batteries	Complex Objects & Other Products	+
Carbon Black	Toner	Coatings & Inks	+
Carbon Black	Master Batches	Coatings & Inks	+
Cerium dioxide	Polishing Agents (e.g. for Glass Surfaces and Silicon Wafers)	Complex Objects & Other Products	+

Cerium dioxide	Fuel Cells	Complex Objects & Other Products	+
Cerium dioxide	Diesel Fuel Additive	Complex Objects & Other Products	+
Cerium dioxide	Catalysts	Complex Objects & Other Products	+
Cerium dioxide	Gas Mantles	Complex Objects & Other Products	+
Cerium dioxide	Coating Agent (e.g. for Optical, Electro-Optical, Microelectronic and Optoelectronic Devices, Steel, Metal Products)	Coatings & Inks	+
Cerium dioxide	Paints	Coatings & Inks	+
Cerium dioxide	Master Batches	Coatings & Inks	+
Cerium dioxide	Coating Agent (e.g. for Optical, Electro-Optical, Microelectronic and Optoelectronic Devices)	Coatings & Inks	+
Cerium dioxide	Coated Steel	Coatings & Inks	-
Cerium dioxide	Coated Eletronic Devices	Coatings & Inks	-
CNT	Plastics (e.g. Disc Drive Components, Automotive Plastic Fuel Lines, Fenders)	Complex Objects & Other Products	+
CNT	Coating Agents	Coatings & Inks	+
CNT	Paints	Coatings & Inks	+
CNT	Electrodes	Complex Objects & Other Products	+
CNT	Batteries	Complex Objects & Other Products	+
CNT	Fuel Cells	Complex Objects & Other Products	+
CNT	Displays	Complex Objects & Other Products	+
CNT	Transparent Conductors	Complex Objects & Other Products	+
CNT	Tennis raquets	Complex Objects & Other Products	+
CNT	Badminton raquets	Complex Objects & Other Products	+
CNT	Baseball bats	Complex Objects & Other Products	+
CNT	Icehockey sticks	Complex Objects & Other Products	+
CNT	Surfborards	Complex Objects & Other Products	+

CNT	Ski	Complex Objects & Other Products	+
CNT	Ski Poles	Complex Objects & Other Products	+
CNT	Bicycle frames	Complex Objects & Other Products	+
CNT	Turbine Blades	Complex Objects & Other Products	+
CNT	Golf Shafts	Complex Objects & Other Products	+
CNT	Hulls for Boats	Complex Objects & Other Products	+
CNT	Master Batches	Coatings & Inks	+
CNT	Yarns	Textiles	+
Fullerenes	Anti Ageing Creams	Cosmetics	+
Fullerenes	Tennis Rackets	Complex Objects & Other Products	+
Fullerenes	Golf Balls	Complex Objects & Other Products	+
Fullerenes	Fuel Cells	Complex Objects & Other Products	+
Fullerenes	Batteries	Complex Objects & Other Products	+
Fullerenes	Solar Cells	Complex Objects & Other Products	+
Fullerenes	Protective Eye-Wear	Complex Objects & Other Products	+
Nanosilver	Wound Bandages	Health Care	+
Nanosilver	Shoe Deodorant Spray	Cleaning & Disinfection	+
Nanosilver	Detergents	Cleaning & Disinfection	+
Nanosilver	Soaps (z.B. Acne Products)	Health Care	+
Nanosilver	Shampoo	Cosmetics	+
Nanosilver	Inks	Coatings & Inks	+
Nanosilver	Catalysts	Complex Objects & Other Products	+
Nanosilver	Textile Finishing Agents	Textiles	+
Nanosilver	Anti-odour sportswear	Textiles	-

Nanosilver	Socks	Textiles	-
Nanosilver	Underwear	Textiles	-
Nanosilver	Bed mattresses	Textiles	-
Nanosilver	Towels	Textiles	-
Nanosilver	Refrigerators	Complex Objects & Other Products	-
Nanosilver	Washing machines	Cleaning & Disinfection	-
Nanosilver	Toys	Complex Objects & Other Products	-
Nanosilver	Skin Creams	Cosmetics	-
Nanosilver	Toothpaste	Cosmetics	-
Nanosilver	Fabric softener	Cleaning & Disinfection	-
Nanosilver	Toothbrush	Complex Objects & Other Products	-
Nanosilver	Water Filter	Cleaning & Disinfection	-
Nanosilver	Containers for Contact Lenses	Complex Objects & Other Products	-
Nanosilver	Food containers	Complex Objects & Other Products	-
Nanosilver	Food packaging materials	Complex Objects & Other Products	-
Nanosilver	Solar Cells	Complex Objects & Other Products	-
Nanosilver	Displays	Complex Objects & Other Products	-
Nanosilver	Fuel Cells	Complex Objects & Other Products	-
Nanosilver	Printable Electronics	Complex Objects & Other Products	-
SAS	Food Contact Material	Complex Objects & Other Products	-
SAS	Paper (Coated Products)	Paper Products	-
SAS	Insulation (Aerosols)	Building & Construction	-
SAS	Flocculation Agent (Wine, Fruit Juices)	Food & Feed	+
SAS	Anti-Caking Agent (e.g. Food Powders)	Food & Feed	+
SAS	Carrier Agent (e.g. for Vitamins)	Food & Feed	+
SAS	Agricultural Products	Food & Feed	+
SAS	Food Additive (E551)	Food & Feed	+

SAS	Ketchup	Food & Feed	+
SAS	Coffee	Food & Feed	+
SAS	Milk Powders	Food & Feed	+
SAS	Table Salt	Food & Feed	+
SAS	Icing Sugar	Food & Feed	+
SAS	Baking Powder	Food & Feed	+
SAS	Grated Cheese	Food & Feed	+
SAS	Instant Soup	Food & Feed	+
SAS	Gels	Food & Feed	+
SAS	Gels	Health Care	+
SAS	Chemical-Mechanical Planarisation (CMP) slurries	Complex Objects & Other Products	+
SAS	Paper (SAS as Filling Material, e.g. Envelopes, Cardboard-boxes, Playing Cards)	Paper Products	+
SAS	Coating Agent (e.g. Metal Surface Treatment, Gel Coats)	Coatings & Inks	+
SAS	Paints	Coatings & Inks	+
SAS	Inks	Coatings & Inks	+
SAS	Moulds	Complex Objects & Other Products	+
SAS	Plastics (e.g. Thermoplastic Films)	Complex Objects & Other Products	+
SAS	Other Rubber products (e.g. Cable Sheatings)	Rubber Products	+
SAS	Sealants and Adhesives (Rubber based)	Rubber Products	+
SAS	Composites	Complex Objects & Other Products	+
SAS	Textiles	Textiles	+
SAS	Ready-mixed concrete	Building & Construction	+
SAS	Mortar	Building & Construction	+
SAS	Sealants and Adhesives	Complex Objects & Other Products	+
SAS	Tyres	Rubber Products	+
SAS	Footwear	Rubber Products	+
SAS	Batteries	Complex Objects & Other Products	+
SAS	Catalysts	Complex Objects & Other Products	+

SAS	Face Powders	Cosmetics	+
SAS	Toothpaste	Cosmetics	+
SAS	Flow Conditioner	Cosmetics	+
SAS	Oil Absorbing Agent	Cosmetics	+
SAS	Detergents	Cleaning & Disinfection	+
SAS	Suppositories	Health Care	+
SAS	Pills (e.g. Pain Killers, Contraceptive Pills)	Health Care	+
SAS	Dessicants/Hygroscopic powders	Complex Objects & Other Products	+
SAS	Creme	Cosmetics	+
SAS	Master Batches	Coatings & Inks	+
SAS	Screed	Building & Construction	+
SAS	Tile adhesives	Building & Construction	+
SAS	Cleaning Agents	Cleaning & Disinfection	+
SAS	Polishing Agents	Cleaning & Disinfection	+
SAS	Textile Finishing Agents	Textiles	+
Titanium Dioxide	Plastics (e.g. Packaging Films)	Complex Objects & Other Products	-
Titanium Dioxide	Coated Metal Products (e.g. Tribological Coating in Engines)	Complex Objects & Other Products	-
Titanium Dioxide	Coated Wood Products	Complex Objects & Other Products	-
Titanium Dioxide	Coated Textiles (e.g. for use in Hospitals, Water Repellent Textiles)	Textiles	-
Titanium Dioxide	Coated Dental Impressions	Health Care	-
Titanium Dioxide	Coated Electronic Components	Complex Objects & Other Products	-
Titanium Dioxide	Solar Cells	Complex Objects & Other Products	-
Titanium Dioxide	Windows	Complex Objects & Other Products	-
Titanium Dioxide	Air Purification Systems	Cleaning & Disinfection	-
Titanium Dioxide	Paving stones	Building & Construction	-
Titanium dioxide	Concrete blocks	Building & Construction	-
Titanium dioxide	Bricks	Building & Construction	-
Titanium dioxide	Tiles	Building & Construction	-
Titanium Dioxide	Roofing Tiles	Building & Construction	-

Titanium Dioxide	Food Additive (E171)	Food & Feed	+
Titanium Dioxide	Chewing Gum	Food & Feed	+
Titanium Dioxide	Sugar-Coated Tablets	Food & Feed	+
Titanium Dioxide	Sweets	Food & Feed	+
Titanium Dioxide	Sunscreens	Cosmetics	+
Titanium Dioxide	Coating Agent (e.g. for Plastics, Metals, Textiles)	Coatings & Inks	+
Titanium Dioxide	Paints	Coatings & Inks	+
Titanium Dioxide	Inks	Coatings & Inks	+
Titanium Dioxide	Varnishes (e.g. Wood Preservation)	Coatings & Inks	+
Titanium Dioxide	Catalysts	Complex Objects & Other Products	+
Titanium Dioxide	Ready-Mixed Concrete	Building & Construction	+
Titanium Dioxide	Master Batches	Coatings & Inks	+
Titanium Dioxide	Cleaning Agents	Cleaning & Disinfection	+
Titanium Dioxide	Textile Finishing Agents	Textiles	+
Zinc Oxide	Coated Textiles (e.g. Industry Textiles)	Textiles	-
Zinc Oxide	Ceramics	Complex Objects & Other Products	-
Zinc Oxide	UV nanolasers	Complex Objects & Other Products	-
Zinc Oxide	Liquid Crystal Displays	Complex Objects & Other Products	-
Zinc Oxide	Solar Cells	Complex Objects & Other Products	-
Zinc Oxide	Zinc Ointments	Health Care	-
Zinc Oxide	Zinc Pastes	Health Care	-
Zinc Oxide	Adhesive Tapes	Health Care	-
Zinc Oxide	Wound bandages	Health Care	-
Zinc Oxide	Electronic components	Complex Objects & Other Products	-
Zinc Oxide	Sunscreens	Cosmetics	+

Zinc Oxide	Coating Agent	Coatings & Inks	+
Zinc Oxide	Plastics	Complex Objects & Other Products	+
Zinc Oxide	Paints	Coatings & Inks	+
Zinc Oxide	Varnishes	Coatings & Inks	+
Zinc Oxide	Inks	Coatings & Inks	+
Zinc Oxide	Rubber Products	Rubber Products	+
Zinc Oxide	Ready-mixed concrete	Building & Construction	+
Zinc Oxide	Mortar	Building & Construction	+
Zinc Oxide	Screed	Building & Construction	+
Zinc Oxide	Tile adhesives	Building & Construction	+
Zinc Oxide	Master Batches	Coatings & Inks	+

7.2 Questionnaire "Assessment of a European Register of Products Containing Nanomaterials"

1. General information

Company/Organisation:	
Branch:	
Number of employees:	
Contact person:	
Function / responsibility	
Telephone number:	
E-mail:	

2. Production and import of products containing nanomaterials

Have you manufactured or imported any products (substances, mixtures or articles) containing nanomaterials within the EU-27 during 2012?

If yes, how many different products containing nanomaterials have you placed on the European market (EU-27)?

	Manufacture	Number of products	Import	Number of products
Carbon black	☐	☐	☐	
Fullerenes	☐	☐	☐	
Carbon Nanotubes (CNTs)	☐	☐	☐	
Synthetic Amorphous Silica (SAS)	☐	☐	☐	
Aluminium Oxide	☐	☐	☐	
Titanium Dioxide	☐	☐	☐	
Cerium Oxide	☐	☐	☐	
Zinc Oxide	☐	☐	☐	
Nanosilver	☐	☐	☐	
Other nanomaterials	☐	☐	☐	
Comments				

3. Number of notifications

Under the concept of a European Register of Products containing Nanomaterials (ENPR), subject to notification are:

- Substances and mixtures (manufactured or imported) which comprise or contain nanomaterials. For mixtures, a concentration threshold of 0,001%[141] weight by weight (w/w) applies.
- Articles containing nanomaterials, intended to be released under normal or reasonably foreseeable conditions of use (analogous to Article 7 para 1 of the REACH Regulation).
- Articles containing nanomaterials above a concentration threshold of 0,1%[1] weight by weight (w/w) unless the producer or importer can exclude exposure from his article to humans or the environment during normal or reasonably foreseeable conditions of use including disposal (analogous to Article 7 para 2 and 3 REACH).

Taking these provisions into account, how many of your products do you expect to be notified?

	Substance	Mixtures	Articles
Carbon black			
Fullerenes			
Carbon Nanotubes (CNTs)			
Synthetic Amorphous Silica (SAS)			
Aluminium Oxide			
Titanium Dioxide			
Cerium Oxide			
Zinc Oxide			
Nanosilver			
Other nanomaterials			
Comments			

4. Availability of information

In case a European Register of Products containing Nanomaterials (ENPR) is effectively created, companies need to provide certain information on their products (for more specifics please refer to the attached document on settings and definitions of a European Register of Nanoproducts). Do you have this information readily available? In case information is only partly available, could you indicate what kind of data you would need to collect (please use "comments")?

[141] The threshold refers to the whole substance that is considered as a nanomaterial acc. to the Commission definition and not only to the nano fraction of the substance.

	yes	no	partially
Name and address of the registrant	☒		
Product and trade name	☒		
Application	☐	☐	☐
Functionality of the nanomaterial(s) employed	☐	☐	☐
Characterization of nanomaterial(s)	☐	☐	☐
Nanomaterial concentration in respective products (w/)	☐	☐	☐
Manufactured or imported tonnage bands	☐	☐	☐
Comments (e.g. more information on data gaps):			

5. Administrative burden

How would you estimate the average expenditure of administrative time (working hours) to obtain and submit the required information for each notification?

	Time (hrs)/notification
Name and address of the registrant	
Product and trade name	
Application	
Functionality of the nanomaterial(s) employed	
Characterization of nanomaterial(s)	
Nanomaterial concentration in respective products (w/)	
Manufactured or imported tonnage bands	
Total	
Comments (e.g. do you consider additional aspects important?)	

6. Articles containing nanomaterials (only to be answered if relevant for your company)

As indicated above (question 3), articles containing nanomaterials above a concentration threshold of 0,1% weight by weight (w/w)do not need to be notified if the producer or importer can exclude exposure from his article to humans or the environment during normal or reasonably foreseeable conditions of use including disposal.

Do you have information whether your company can exclude exposure to nanomaterials from your article(s) to humans or the environment during normal or reasonably foreseeable conditions of use, including disposal?

On which information (e.g. life-cycle analysis) do you draw your estimation (please use “comments”)?

Yes	☐
No	☐
Comments	

7.3 Sources of input data for estimating the number of companies affected and number of nanoproducts per sector

There are three main categories of primary sources for estimating the fraction of companies affected and the number of nanoproducts per sector (or number of nanoproducts per company per sector):

- Industry Associations (IA),
- Individual Companies (IC) and
- Desktop Research (DR) which randomly selected companies in the sector and analysed their product portfolio with respect to likely nanoproducts.

As mentioned in the main report, it is often unclear to companies themselves if the material they use would be classified as a nanomaterial according to the COM's definition and therefore all estimates must be treated with a high degree of uncertainty. Nevertheless, a starting point is required.

General procedure for estimating the fraction of companies affected

There are two independent sources used:

a) interviewing relevant industry associations or industry experts,

b) sampling individual companies either by company interview or desktop research.

The former source is limited by the awareness and existing database of the relevant industry association and its individual members (it is not the role of the association to know the number of products, much less the number of nanoproducts). The latter is limited by the statistical validity of interviewing too few companies (45 companies in comparison to a total of approximately 766,000 companies in the concerned sectors). Furthermore, the companies interviewed were more likely to be affected than those not being interviewed. Therefore, desktop research (analysing random company product portfolios from industry service provider websites) provided another way of estimating what fraction of companies were likely to be affected. However, this method is also limited due to statistical validity.

Both methods provide an estimate of the fraction of companies affected per sector. The lower and upper values were taken as a "minimum" and "maximum" value in the study.

General procedure for estimating the number of nanoproducts to be notified per sector

This procedure for estimating the number of nanoproducts to be notified is similar to that used to estimate the fraction of companies affected and used the same independent sources:

a) interviewing relevant industry associations or industry experts,

b) sampling individual companies either by company interview or desktop research (using the same procedure as previously described) to determine the number of nanoproducts likely to require notification per company.

The total number of products to be notified is related to the number of nanoproducts per company by the following formula:

$$= (No.notifiable\ products\ per\ notifier) * (fraction\ of\ companies\ notifying) * (total\ companies)$$

The data for the total number of companies is obtained from Eurostat for the relevant NACE categories (see section 4.1 for a listing of the relevant NACE categories). This formula permits cross-checking of the data sources a) and b) and provide an estimate of the total number of notifiable nanoproducts per sector as well as the number of notifiable nanoproducts per notifier. For example, for some sectors e.g. coatings & inks, industry associations/experts provided an estimated range of the likely total number of notifiable products but not the number of companies having to notify products (notifiers). Therefore, the number of notifications per notifier can be back-calculated. Also for the same sector, estimations for the number of notifications per notifier were obtained from company surveys as well as analysis of company product portfolios. In this way, one arrives at two independent estimates of the number of notifications per notifier and through that, the number of total notifications using the above-stated formula. The lower and upper values were taken as a "minimum" and "maximum" value in the study. Due to the heterogeneity of the data inputs, it is difficult to summarise the different data inputs in a comprehensive manner; however the following table 12 indicates the sources of data that were used for each estimate (refer to section 4.1 for more details).

Table 12: Overview on the source of data used for estimating number of affected companies and notifications.

Sector	Total number of companies in sector[a]	Sources for estimating number of companies affected	Fraction of companies affected [%]	Sources for estimating number of total notifications or notifications per company	Number of products per notifier	Additional Comments regarding sources
1. Substances	3.180	IE, IC, DR	20-40	IE, IC, DR	5-16	Total number of companies affected based on combination of industry specific associations (e.g. pigments), company surveys and DR. Fraction of companies back-calculated. Number of notifications per company averaged from industry-specific IE total notifications, company surveys and DR averages.
2. Cosmetics	4.400	IE, DR	60-80	IE, IC, DR	7-13	Fraction of companies based on national industry experts and DR. Number of notifiers per company averaged from industry-specific IE total notifications, company surveys and DR averages.
3. Health Care	3.800	IC, DR	50-80	IC, DR	23-75	Both, fraction of companies affected and number of notified products per notifier based on company surveys and DR (contacted industry experts unable to provide estimates).
4. Food & Feed	9.170	DR	5-10	DR	2-32	Both, fraction of companies affected and number of notified products per notifier based on DR (contacted industry experts unable to provide estimates).
5. Coatings & Inks	4.400	IE, IC, DR	90-95	IE, IC, DR	350-610	Total number of products containing NM based on VdL publication (2012). Percentage of firms affected based on anonymous national industry association and experts. Number of products per notifier back-calculated and averaged with company surveys and DR averages.
6. Cleaning & Disinfection	4.350	IE, IC, DR	30-60	IE, IC, DR	4-20	Total number of companies affected based on industry specific associations; fraction of companies from company surveys and DR. Number of notifications per company averaged from industry-specific IE total notifications, and company surveys & DR averages.
7. Rubber	8.500	IE, DR	75-90	IC, DR	11-27	Fraction of companies affected estimates from national

Products						industry experts and DR. Number of notifications per notifier averaged from company surveys and DR.
8. Building & Construction	2.600	IE, DR	20-40	IE, IC, DR	3-12	Fraction of companies affected estimates from European industry specific associations. Notifications per notifier averaged between industry expert, company surveys, and DR.
9. Textiles	127.330	IE, IC, DR	5-10	IE, IC, DR	2-31	Fraction of companies affected based on national industry association estimates, company responses, and DR. Notifications per notifier back-calculated based on total notifications from national association and averaged with values from company surveys and DR.
10. Paper Products	18.500	IE, IC, DR	60-80	IE, IC, DR	43-86	Fraction of companies affected based on national industry association estimates, company responses, and DR. Notifications per notifier back-calculated based on total notifications from national association and averaged with values from company surveys and DR.
11. Complex Objects & Other Products	580.430	DR	0.5-1	DR	16-59	

[a] Number of companies obtained from Eurostat according to relevant NACE categories (see section 4.1)

IE= Industry Association/Industry Expert; IC = Individual Company; DR = Desktop Research (analysis of randomly selected company portfolios).