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Legal feasibility study on the introduction of a nanoproduct register

Final report

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Abbreviations

BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health)
BET	BET theory, BET model (isotherm), named after its developers, Stephen Brunauer, Paul Hugh Emmett und Edward Teller
BfR	Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment)
BGBl. I	Bundesgesetzblatt, Teil 1 (Federal Law Gazette, Part 1)
BGBl. II	Bundesgesetzblatt, Teil 2 (Federal Law Gazette, Part 2)
BImSchG	Bundes-Immissionsschutzgesetz (Federal Immission Control Act)
BMELV	Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (Federal Ministry of Food, Agriculture and Consumer Protection)
BMU	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety)
BUND	Bund für Umwelt und Naturschutz Deutschland e. V. (Friends of the Earth Germany)
BVerfG	Bundesverfassungsgericht (Federal Constitutional Court)
BVerfGE	Entscheidung des Bundesverfassungsgerichts (Decision of the Federal Constitutional Court)
BVerwG	Bundesverwaltungsgericht (Federal Administrative Court)
BVerwGE	Entscheidung des Bundesverwaltungsgerichts (Decision of the Federal Administrative Court)
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety)
CAS	Chemical Abstracts Service
CASG	Competent Authority Subgroup
CE	CE mark(ing) (EU trade “passport”)
CEN	Comité Européen de Normalisation (European Committee for Standardisation)
ChemG	Chemikaliengesetz (German Chemicals Act)
ChemVerbotsV	Chemikalienverbotsverordnung (German Chemicals Prohibition Ordinance)
CLP	EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures
CMR	Carcinogenic, mutagenic or toxic for reproduction
CNT	Carbon nanotubes
Com, COM	Commission of the European Union
DEFRA	Department for Environment, Food and Rural Affairs (UK)
Doc	Document
DÖV	Die öffentliche Verwaltung (German journal of public administration)
DVBl.	Deutsche Verwaltungsblatt (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
EN	Europäische Norm (European Standard)
ENM	engineered nanomaterial

EP	European Parliament
et al.	and others
EU	European Union
ff.	and following pages
GefStoffV	Gefahrstoffverordnung (German Hazardous Substances Ordinance)
GG	Grundgesetz der Bundesrepublik Deutschland (Basic Law for the Federal Republic of Germany)
GPSG	Geräte- und Produktsicherheitsgesetz (Equipment and Product Safety Act)
IEC	International Electrotechnical Commission
IEC/TC	International Electrotechnical Commission / Technical Committee
ISO	International Organization for Standardization
ISO/TC	International Organization for Standardization / Technical Committee
IUPAC	International Union of Pure and Applied Chemistry
LFGB	Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (German Food and Feed Code)
nm	nanometre
No	number
NuR	Natur und Recht (German journal on environmental law)
NVwZ	Neue Zeitschrift für Verwaltungsrecht (German journal on administrative law)
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal of the European Communities
PBT	Persistent, bioaccumulative and toxic (chemical)
PET	Polyethylene terephthalate
PflSchG	Pflanzenschutzgesetz (German Act on the Protection of Plants)
ProdHaftG	Produkthaftungsgesetz (German Product Liability Act)
QSAR	Quantitative Structure Activity Relationship
REACH	EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SiO_2	Silicon dioxide
SIEF	Substance Information Exchange Forum
T	tonne
TFEU	Treaty on the Functioning of the European Union
TS	technical specification
UBA	Umweltbundesamt (Federal Environment Agency)
UV	ultraviolet
VCI	Verband der Chemischen Industrie (the German chemical industry association)
VO	Verordnung (Ordinance in German law)
vPVB	Very persistent, very bioaccumulative
WPMN	Working Party on Manufactured Nanomaterials
ZnO	Zinc oxide

1 Zusammenfassung

Ein Register für Nanoprodukte, die in Deutschland hergestellt oder in Verkehr gebracht werden, ist rechtlich machbar und realisierbar.

Der Zweck eines solchen Produktregisters und einer damit korrelierenden Meldepflicht ist, den Behörden einen Überblick über die in Deutschland hergestellten und auf dem deutschen Markt erhältlichen Nanoprodukte zu ermöglichen. Mit der Erfassung im Produktregister soll dem Entstehen von Gefahren für Leben und Gesundheit von Menschen (insbesondere von Arbeitnehmer/-innen, die bei ihrer beruflichen Tätigkeit verstärkt Nanomaterialien ausgesetzt sind) sowie für die belebte und unbelebte Umwelt in ihrem Wirkungsgefüge im Sinne des Vorsorgeprinzips vorgebeugt werden, und zwar bei der Herstellung, Nutzung und Entsorgung von Nanoprodukten[1] (einschließlich der Nanomaterialien[2] als solche).

Die Analyse der produkt- und stoffrechtlichen Vorschriften zeigt, dass die Behörden in Deutschland (sowie unter Zugrundelegung nur der EG-Vorschriften auch die Behörden in den anderen Mitgliedsstaaten) zurzeit nicht oder nicht ausreichend Kenntnis erlangen können über die in Deutschland (der EU) hergestellten oder in Verkehr gebrachten Nanomaterialien und Produkte, die diese enthalten. Insbesondere hinsichtlich der konkreten Bezeichnung der Nanoprodukte, der Menge an darin enthaltenen Nanomaterialien und der Spezifikation der Nanomateralien haben die Behörden derzeit keinen ausreichenden Überblick. Lediglich bei der Kosmetik-Verordnung der EU werden in absehbarer Zeit verpflichtende Regelungen zu Angaben über die im Produkt enthaltenen Nanomaterialien in Kraft treten, die den Anforderungen des Nanoproduktregisters im Wesentlichen entsprechen. Es ist allerdings zu erwarten, dass auch in weiteren produktrechtlichen EG-Vorschriften Regelungen getroffen werden, die ähnlich der Kosmetik-Verordnung Informationen über Nanomaterialien in Produkten geben werden. Dies zeigt z.B. die Novellierung der Novel-Food-VO.

Eine Regelung für ein Nanoproduktregister sollte zuvorderst auf der europäischen Ebene vorgenommen werden, da dies zur Verwirklichung eines hohen Niveaus beim Schutz von menschlicher Gesundheit und Umwelt in der gesamten EU beiträgt und der freie Warenverkehr weniger beeinträchtigt wird als bei einer nationalen Regelung.

Rechtlich ist die Einführung einer Meldepflicht und eines Registers für Nanoprodukte auch nur (oder zunächst) in Deutschland mit den primär- und sekundärrechtlichen Vorschriften der EU vereinbar. Zu unterscheiden ist dabei zwischen den spezifischen Regelungen, die bereits jetzt oder in Zukunft Informationsanforderungen hinsichtlich Nanomaterialien in Produkten abschließend regeln, und solchen Produktbereichen, in denen solche Regelungen nicht existieren oder nicht abschließend geregelt sind. In letzterem Fall ist in der Regel nicht davon auszugehen, dass eine nationale Regelung in einen von der EU abschließend geregelten Bereich eingreift und damit untersagt ist. Im Fall der Kosmetik-Verordnung, der Verordnung über Lebensmittelzusatzstoffe oder der Novel-Food-Verordnung ist hingegen fraglich, ob darüber hinausgehende Informationsanforderungen in einem Produktregister geregelt werden können. Dies, weil es sich um eine abschließende Regelung auf EU-Ebene handeln könnte, in der dann eine nationale Regelung nicht mehr möglich ist. Nach der hier

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1 On the proposed definition of “nanoproducts” for the purposes of the product register (see Section 8.2.4).
2 On the proposed definition of “nanomaterials” for the purposes of the product register (see Section 8.2.3).

vertretenen Auffassung handelt es sich bei vorgenannten Regelungen nicht um eine abschließende Regelung. In diesem Fall von nicht abschließend geregelten Bereichen ist die Einhaltung der primärrechtlich garantierten Warenverkehrsfreiheit nach Art. 34 (ex-Art. 28 EGV) Vertrag über die Arbeitsweise der Europäischen Union (AEUV) zu gewährleisten. Als Maßnahme gleicher Wirkung i.S.d. Art. 34 2. Alternative AEUV erschwert die Meldepflicht den freien Warenverkehr. Sie ist aber gerechtfertigt, da sie für die zwingenden Erfordernisse des Umwelt- und Verbraucherschutzes notwendig ist und nicht unverhältnismäßig in die Warenverkehrsfreiheit eingreift.

Die für die Umsetzung des Nanoproduktregisters und der Meldepflicht notwendigen Anforderungen an den Regelungsinhalt betreffen insbesondere den Anwendungsbereich der Regelungen, die Definition von „Nanomaterial“ und „Nanoprodukt“ sowie den Regelungsadressaten.

Der Anwendungsbereich der Meldepflicht sollte die folgenden Tatbestände umfassen:

- die Herstellung, den Import und das Inverkehrbringen von Nanomaterialien selbst oder in Gemischen in den Geltungsbereich der Verordnung und
- die erstmalige Herstellung, den Import oder das erstmalige Inverkehrbringen von Erzeugnissen, die Nanomaterialien enthalten, im bzw. in den Geltungsbereich der Verordnung.

Im Hinblick auf die Definition des Begriffs „Nanomaterial“ macht das Gutachten verschiedene Vorschläge, die zu einer unterschiedlich weiten Erfassung von Nanomaterialien führen können. Vor dem Hintergrund des derzeitigen Diskussionsstandes in Fachkreisen und vorbehaltlich der Erfassung u.a. ökonomischer Wirkungen im Rahmen einer Gesetzesfolgenabschätzung wird folgende Definition für das Nanoproduktregister empfohlen:

„Nanomaterialien im Sinne des Produktregisters sind zielgerichtet hergestellte Materialien, die zwischen 0,5 nm und 200 nm in mindestens einer Dimension liegen (Primärteilchen) und daraus abgeleitete Agglomerate und Aggregate.“

Der vorgenannte Definitionsansatz soll zwar möglichst eine große Bandbreite an Nanomaterialien erfassen, erhebt aber nicht den Anspruch einer allgemein gültigen Definition, sondern liefert eine handhabbare Festlegung des Regelungsgegenstandes für ein mögliches Nanoproduktregister.

Der Begriff „Nanoprodukt“ für die Zwecke des Nanoproduktregisters umfasst:

- Nanomaterialien entsprechend der Definition des Produktregisters,
- Gemische, die Nanomaterialien enthalten, nach der Definitionen in Art. 3 Nr. 2 REACH, sowie
- Erzeugnisse entsprechend der Definition in Art. 3 Nr. 3 REACH, sofern sie Nanomaterialien im Sinne des Produktregisters enthalten, und zwar unabhängig von der Konzentration des Nanomaterials im Erzeugnis.

Da eine möglichst weitgehende Erfassung aller auf dem deutschen Markt befindlichen Nanomaterialien, Nanomaterialien in Gemischen und Erzeugnissen mit Nanomaterialien angestrebt wird, muss die Meldepflicht „Hersteller“, „Importeure“ und „Inverkehrbringer“ erfassen.

Die Einführung eines Nanoproduktregisters und einer Meldepflicht in Deutschland sollte durch ein Bundesgesetz erfolgen und nicht im Wege einer Selbstverpflichtung. Der Bund kann durch Gesetz eine Meldepflicht für Nanoprodukte erlassen, da er die konkurrierende Gesetzgebungskompetenz nach Art. 72 Abs. 2 GG i.V.m. Art. 74 Abs. 1, Nr. 1, 11, 19, 20, 24, 29 und 32 GG hat und eine Regelung auf Bundesebene zur Wahrung der Rechtseinheit erforderlich ist.

2 Executive Summary

A register of nanoproducts (nanomaterials, mixtures and articles) produced or placed on the market in Germany is legally viable and is workable in practice.

The purpose of such a product register and a corresponding mandatory reporting requirement is to provide the authorities with an overview of nanoproducts produced or placed on the market in Germany. Following the precautionary principle, the register aims to prevent the emergence of hazards to the life and health of humans (including at their workplace) as well as to the environment as a dynamic complex that may result from the production, utilization and disposal of nanoproducts (including nanomaterials as such).

This is necessary as the analysis of laws and regulations applicable to substances and products shows that currently the use or presence of nanomaterials in consumer products available in the marketplace is not explicitly disclosed to the competent authorities in Germany. At the moment competent authorities cannot obtain a sufficient overview on the precise name of a nanoproduct, the specification of the nanomaterial contained in the product and the amount of nanomaterials in products put on the market.

In the foreseeable future the EU Cosmetics Regulation will contain obligatory rules on the provision of information about nanomaterials contained in products that essentially correspond to the requirements of the nanoproduct register. Moreover, it is possible that similar provision will be introduced in further product regulations, as the discussion on the revision of the Novel Food Regulation shows.

A register of nanoproducts should be introduced primarily on the level of the European Community as this will contribute to a high level of protection of human health, to the improvement of the quality of the environment as well as interfere less with the free movement of goods.

However, the introduction of a mandatory reporting requirement and a register for nanoproducts solely (or initially) in Germany is consistent with primary and secondary EU law. To this aim differentiation must be made between those European product regulations which exhaustively regulate information requirements for nanomaterials and those European product regulations which are not regulating information requirements at all or do not exhaustively cover them. In the first case a national mandatory reporting scheme would not be consistent with EU law in general. In the latter case national mandatory reporting requirements and a register for nanoproducts can be enacted consistent with the specific European product regulation subject to the compliance with primary EU law. However, the answer is complex and depends on the concrete product regulation. For the Cosmetics Regulation, the Regulation (EC) No. 1333/2008 on food additives or the Novel Food Regulation it is the question, whether they cover information requirements for nanomaterials exhaustively or not. With respect to the aims and the definition of nanomaterials in the proposed provisions for a national register for nanoproducts the three Regulations are not seen to regulate the subject exhaustively and therefore would allow the introduction of a national reporting scheme. Since the regulation of reporting requirements for nanoproducts on the level of Member States would affect an area not governed by exhaustive provisions, compliance with the free movement of goods provided for in primary law with Article 34 (ex-Article 28 Treaty of the European Union) of the Treaty on the functioning of the European Union (EFUT) must be ensured. As a “measure having equivalent effect” within the meaning of Article 34 EFUT the mandatory reporting requirement would hinder the free movement of

goods. It is however justified in order to satisfy overriding requirements relating to environmental and consumer protection and does not disproportionately restrict the free movement of goods.

The essential requirements upon provisions governing implementation of the register of nanoproducts and the mandatory reporting requirement concern in particular the scope of the provisions, the definitions of “nanomaterials” and “nanoproducts” respectively and the addressees of the legislation.

The scope of the mandatory reporting requirement should cover the following:

- The production, import or placing on the market of nanomaterials or nanomaterials in mixtures within the legal scope of the regulation;
- The first-time production, importat or first-time placing on the market of semi-finished or end-products containing nanomaterials within the legal scope of the regulation.

For the definition of the term “nanomaterial” the feasibility study develops three different approaches leading to a varying degree of nanomaterials covered by the scope of the regulation. These definitions pursue to regulate environmental, health and safety issues of nanomaterials under a precautionary approach and therefore have a different focus as the definition of nanomaterials in technical standardization, e.g. on the ISO level .Against the background of the current expert discussion on the definition of nanomaterials and prior to an impact assessment of the proposed product register (inter alia the costs for companies to fulfil the reporting duties) the following definition for the purpose of a product register is favoured:

“Nanomaterials for the purpose of the product register are deliberately engineered materials which have at least one dimension between 0.5 nm and 200 nm (primary nanoparticle) as well as agglomerates and aggregates derived from them.”

It must be pointed out that the chosen definition is intended to cover a wide range of nanomaterials within the scope of the regulation. But the definition should not be understood as a universally valid definition of nanomaterials, rather than a legally enforceable description of the object regulated.

For the purpose of the register of nanoproducts the term “nanoproduct” should include the following:

- Nanomaterials in accordance with the definition used in the product register;
- Mixtures as defined in Article 3 (2) REACH containing nanomaterials;
- Articles as defined in Art. 3 (3) REACH containing nanomaterials, irrespective of the concentration of the nanomaterial within the article.

Since the aim is to create a register covering a wide range of all nanoproducts produced or placed on the market in Germany, the mandatory reporting requirement must apply to “manufacturers”, “importers” and “distributors” (for the definition see chapter 8.3).

A reporting requirement and a register of nanoproducts in Germany should be introduced by way of a federal law rather than through voluntary commitment. The German Federal Government is in a position to pass legislation introducing a mandatory reporting requirement for nanomaterials and nanoproducts as it has legislative power in accordance with Article 72, Paragraph 2 of the Basic Constitutional Law (Grundgesetz) in conjunction with Article 74, Paragraph 1 (No. 1, 11, 20, 24, 29 and 32) of the Basic Constitutional Law and since regulation at the federal level is required to maintain legal uniformity.

3 Scope and objectives

In the growing public debate on nanomaterials, their possibilities, uses and risks, the question frequently arises as to which products contain nanomaterials.

The question is asked from a variety of perspectives (e.g. potential hazards to the environment and to consumer and employee health, the need for regulation, consumer freedom of choice, availability of nanoproducts on the German market, etc.) and by a variety of stakeholders (ministries, authorities, consumers, businesses, environmental protection organisations, research institutions, etc.). The possibility of introducing a nanoproduct register is explored for example in the German Federal Government's NanoDialogue project.[3]

The answer to this question can be ambiguous, as it depends to an extent on the definition of "nanomaterial", on the point at which this material is still contained in a product, and primarily on how the players in the manufacturing chain, traders, ministries, authorities and consumers discover that a product contains nanomaterials. This is because the use of nanomaterials – similar to the use of numerous other substances – in a final product does not always entail an obligation to label or provide information. Rather, some legal provisions only 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 instances neither authorities nor consumers necessarily know in which of the intermediate or final products the substances or 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[4]) show that there are numerous products on the German and international markets that contain nanomaterials.[5] 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 in part to a lack of a binding definition, e.g. for nanomaterials or products containing nanomaterials, and also to the lack of an obligation to report the utilisation of nanomaterials.

As early as 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.[6] One of the recommendations of the German Federal Government's NanoKommission is "the creation of an independent form of market overview for consumers in terms of available nanoproducts, so that information relevant to consumers and new

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3 Cf. also "Responsible Use of Nanotechnologies" (*Verantwortlicher Umgang mit Nanotechnologien*): Report and recommendations of the German Federal Government's NanoKommission for 2008, available to download from : http://www.bmu.de/gesundheit_und_umwelt/nanotechnologie/nanodialog/doc/print/42655.php
An English version is available at: http://ec.europa.eu/health/ph_risk/documents/nanokommission.pdf

4 See the database of "The Project on Emerging Nanotechnologies (PEN)" at http://www.nanotechproject.org/inventories/consumer/.

5 See analysis in the Appendix of Führ/Hermann et al. 2007.

6 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, at: http://www.bfr.bund.de/cm/220/verbrauchervotum_zur_nanotechnologie.pdf.

scientific knowledge are collated and presented in an understandable way. Information on contents, function, impact and safety should be grouped together."[7]

Considering the existing and assumed opportunities arising from nanoproducts and the as yet insufficient knowledge of the human toxicology and eco-toxicology of nanomaterials as well as the uncertainty about the degree to which these risks can be controlled by the current statutory framework, the introduction of a binding product register provides clarity on which products contain nanomaterials.[8]

The aim of this study is to assess whether the introduction of a register of nanoproducts and a corresponding mandatory reporting requirement for the manufacture and placing on the market of nanoproducts in Germany is, in principle, legally viable and what form it should take.

Priority must, however, be given to promoting the introduction of a reporting requirement and product register at European level as this would ensure that the internal market could continue to function relatively unimpeded.

Starting with the intended purpose of a register of nanoproducts and a corresponding mandatory reporting requirement (Chapter 4) the study first assesses whether existing legislation satisfies the purpose of a product register or in how far it does so. To this end, the authors examine the contribution made by current legislation to determining information on the chemical substances used for nanomaterials, to passing this information on through the manufacturing and distribution chain, and to the degree to which authorities and consumers are being informed about the presence of nanomaterials in the relevant products (Chapter 5). In a next step, Chapter 6 looks at whether the application of the precautionary principle gives rise to a legal need to provide for the introduction of a product register and a mandatory reporting requirement, and assesses the preconditions under which such provisions are permissible in accordance with the precautionary principle. Following a short examination of comparable regulatory measures in other countries in Chapter 7, Chapter 8 describes essential requirements upon provisions governing a product register. These include in particular the scope of the legislation, key definitions, addressees of the mandatory reporting requirement, details to be reported, and exemptions from the reporting requirement. Chapter 9 examines a number of institutions which could potentially maintain a product register. Chapter 10 conducts a constitutional check of the legal basis enabling the

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7 See "Report and recommendations of the German Federal Government's NanoKommission - Responsible Use of Nanotechnologies, 2008 p. 63. Download at http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanokomm_abschlussbericht_2008_en.pdf.

8 Scientific studies such as Breggin, et al. (2009) *Securing the Promise of Nanotechnologies Towards Transatlantic Regulatory Cooperation* also call for the introduction of compulsory product registers. 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, p. 69, RN 4.71 follows a similar line: "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 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."

introduction of a product register and mandatory reporting requirement and assesses statutes which could potentially be used to make these legally binding. Finally, Chapter 11 assesses whether a national provision for a product register is compatible with European law.

4 Purpose of a nanoproduct register and mandatory reporting requirement

The purpose of the proposed reporting requirement and nanoproduct register is to prevent hazards to human life and health (including in the workplace) and to the environment as a dynamic complex that might occur as a result of the production, utilisation or disposal of nanomaterials[9] and nanoproducts,[10] in line with the precautionary principle.

The reporting requirement is intended to facilitate monitoring of nanomaterials on their own or in mixtures, and of semi-finished and finished products containing nanomaterials, which are produced or placed on the market in Germany. Monitoring in this context is to be understood as the direct, systematic recording and surveillance of nanoproducts and nanomaterials based on reporting and listing in a register.

The reporting requirement is intended to enable clear identification of producers and importers and of any nanomaterials, semi-finished and finished products produced and placed on the market by them. With the aid of this information, the public administration will be better able to estimate and assess potential contamination pathways for the environment and employees, for humans and the animate and inanimate environment, that might arise from the production, use or disposal of a given nanomaterial or nanoproduct.[11] Where there is a report of possible risks to protected resources arising from an “alleged nanoproduct”, the authority can use the register to check whether the product in question is indeed a nanoproduct. In addition, the competent authorities can inform the producer or importer in good time. This authority, or the relevant supervisory authority, can investigate such reports and take appropriate risk management measures where needed. Having products listed in a register will enable more rapid identification of comparable nanoproducts and, where appropriate, their inclusion in risk management measures.

Introduction of a mandatory reporting requirement and register can assist the state in meeting its objective obligation to protect the basic right to life and physical integrity in accordance with Article 2 Paragraph 2 (1) of the Basic Law for the Federal Republic of Germany (GG).[12] The aim is to protect the life and health both of persons employed in the production of nanomaterials and nanoproducts and of the general public.

The term “environment as a dynamic complex” is taken to comprise the environmental media of water, air and soil, animals and plants as well as micro-organisms, both as individual components and in their ecological interdependencies. This object of protection is also taken to include the precautionary and sustainable safeguarding of the integrity of the natural foundations of life. In accordance with the protection mandate set out in Article 20a GG, the

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9 On the proposed definition of “nanomaterials” for the purposes of the product register (see section 8.2.3)

10 On the proposed definition of “nanoproducts” for the purposes of the product register (see section 8.2.4)

11 Cf. also SCENIHR (2009), p. 8: “There is a need to further establish reliable and standardised measurement techniques, to develop measurement strategies, and to further implement screening/monitoring of nanoscale particles in sensitive work areas. Challenges are currently seen, especially in the detection and assessment of manufactured nanoparticles in the environment. Similarly, exposure estimates for consumers from food and consumer products remain difficult. Information on the presence of manufactured nanomaterials solely relies on information (claims) provided by manufacturers. In addition, exposure estimation is also hampered by lack of information on product use and use of multiple products containing manufactured nanomaterials.”

12 Decision of the Federal Constitutional Court (BverfGE) 39, p. 42 ff; 52, p. 57 ff; 77, p. 402 ff.

aim is also to protect future generations and to safeguard the natural foundations of life. Should hazards to human health or the environment only become manifest in the long term or only be recognised in the long term due to complex interactions, the record of nanomaterials and nanoproducts will provide future generations with an initial information basis on which measures can be based.

5 Information on nanomaterials in products under the legal provisions currently in force

As a point of departure for the next stages of this study, we take a look at a selection of legal provisions on substances and products currently in force in Germany. Our aim is to assess how these affect the provision of information on nanomaterials and any risks associated with them, and how they affect communication of this information down the manufacturing and distribution chain of nanomaterials and nanoproducts. We will focus on whether and to what extent producers and traders of mixtures and finished products, relevant ministries and authorities and consumers realise that a product contains nanomaterials. We therefore analyse especially provisions concerning control of market access and reporting and labelling obligations.

5.1 Nanomaterials

In this context the starting point for our investigation is the REACH Regulation[13] as is regulates the production, placing on the market and use of substances on their own, in mixtures or in articles. Although none of the provisions in REACH make specific reference to nanomaterials, it is generally assumed that nanomaterials, like all other substances[14] fall within the scope of REACH.[15]

5.1.1 Substance registration obligations under REACH

As a precondition for market access, registration requires that those responsible for the substance submit basic information on the substance to the ECHA (European Chemicals Agency).[16] Substances on their own, in mixtures or in articles may only be manufactured or placed on the market in the EU if they have been registered (Article 5 REACH). To comply with the “no data, no market” principle enshrined in Article 5 of REACH, a producer or importer manufacturing or importing at least one tonne of a substance either on its own or in one or more mixture(s) must submit a registration dossier to the ECHA (pursuant to Article 6 (1) of REACH). According to Article 7 (1) of REACH this obligation also applies to the manufacture or importation of articles in which substances are present in quantities totalling over one tonne per producer or importer per year, and if the substance is intended to be released under normal or reasonably foreseeable conditions of use. Under Article 10 of

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13 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1.

14 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 stablility of the substance or changing its composition”.

15 Communication of the Commission to the European Parliament, the Council and the European Economic and Social Committee, Regulatory aspects of nanomaterials, 17.6.2008, COM (2008) 366 final, p. 4.

16 A glossary of terms commonly used in REACH is available at: http://www.reach-info.de/glossar.htm (accessed 21 April 2010).

REACH, the registration dossier – as an instrument for assessing and reducing risk – must contain information on the manufacture and use(s) of the substance and guidelines for its safe use.

REACH makes a distinction between registration of "non-phase-in substances" and "phase-in substances":

- "Phase-in substances" are substances that were either already on the market in 1981 and are listed in the EINECS inventory[17] or are on the "No-longer-polymer list" (Article 3 (20) REACH). Under Article 23 of REACH, special transitional provisions apply to the mandatory registration of phase-in substances.[18] In order to benefit from the transitional regime, substances to be manufactured or imported in quantities of at least one tonne per year must have pre-registered with the ECHA before 1 December 2008 (Article 28 (2) REACH). Pre-registration includes especially the name of the substance, its EINECS number and/or CAS[19] number, the name and address of the registrant, tonnage band and envisaged registration deadline. The final registration deadline is set according to tonnage (per manufacturer or importer) or particular categories of hazard:

Tonnage thresholds for registration	Deadline
Substances > 1000 t/a CMR[20] substances > 1 t/a Substances posing an environmental hazard[21] > 100 t/a	01.12.2010
Substances > 100 t/a	01.06.2013
Substances > 1 t/a	01.06.2018

- "Non-phase-in substances" are substances that are not covered by the definition of a phase-in substance. These are primarily substances for which a notification was submitted and which could be placed on the market in accordance with Directive 67/548/EEC, or substances being placed on the market for the first time.

  The transitional provisions applicable under REACH to phase-in substances do not apply to non-phase-in substances. Since 1 June 2008, these substances must be registered if they are to be manufactured or imported in quantities of one tonne or more per year.

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17 EINECS stands for "European Inventory of Existing Commercial Chemical Substances". This EU inventory comprises some 100,000 listings of substances. The list includes all substances that were on the market at the time the obligation to evaluate potential risks posed by chemical substances was introduced (1981).

18 At the end of the transitional period for phase-in substances, the distinction bewteen phase-in and non-phase-in substances is no longer applied.

19 CAS stands for "Chemical Abstracts Service". This is an international organisation that has developed an international standard identification system for chemical substances, in which every substance is assigned a number. Every known chemical substance thus has a CAS number.

20 These are substances that are carcinogenic, mutagenic or toxic for reproduction [reprotoxic].

21 This includes substances classified as R 50/53 ("very toxic to aquatic organisms" and which "may cause long-term adverse effects in the aquatic environment").

In the case of a nanoscale substance, the decision as to whether a substance constitutes a phase-in or a non-phase-in substance is based – exactly like all other substances – on whether it meets the criteria for phase-in status. As a rule, then, this means whether or not it is listed in EINECS. This is because according to the EU Manual of Decisions,[22] substances in nanoform listed in EINECS (e.g. titanium dioxide) are deemed to be existing substances, while substances in nanoform that are not on EINECS (e.g. carbon allotropes other than those listed in EINECS) are regarded as new. This classification does not change even if a substance listed in EINECS is treated differently as a nanoscale substance for the purposes of REACH. The listed substance retains its phase-in status.[23]

In cases where distinguishing between nanoscale and macroscale (bulk) (substance identity or "sameness") is thus irrelevant in terms of a substance's phase-in status, such a distinction is nevertheless relevant in terms of the registration requirements. Depending on whether or not a substance at the nanoscale is regarded as identical to the bulk substance, it may fall into a different tonnage band under REACH and may therefore have to meet different registration deadlines (see above) and different levels of registration requirements.

Registration requirements dependent on tonnage are:[24]

- For volumes of one tonne per year or more the registrant must include all physical-chemical, toxicological and eco-toxicological information relevant and available to him in the registration dossier (Article 12 (1) REACH) (Annex VI No 2 REACH). As a minimum, the registrant must submit the information specified in Article 12 (1) a and b of REACH;
- For volumes of 10 tonnes or more per year, more extensive information must be submitted. Additional basic data must be provided in accordance with the provisions of Annex VII and Annex VIII (Article 12 (1) c REACH). In accordance with Article 14 (1) of REACH, registrants must perform a chemical safety assessment that must be included in the chemical safety report. The chemical safety assessment of a substance must include hazards arising from the physico-chemical properties of the substance, hazards to human health and to the environment, and a PBT[25] and vPvB[26] assessment of the substance (Article 14 (3) REACH). If the registrant concludes that the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB substance (Article 14 (4) REACH), then an exposure assessment and risk characterisation must also be carried out (Annex I, Sections 5 and 6 REACH) addressing all identified uses of the substance:
- For volumes of 100 tonnes or more per year the registration dossier must include, in addition, testing proposals for the provision of the information specified in Annex XI (Article 12 (1) d REACH);

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22 See section 5.1.3 "Substances in Nanoform", of the "Manual of Decisions (MoD) for Implementation of the sixth and seventh amendments to Directive 67/548/EEC on Dangerous substances", available to download at: http://ecb.jrc.ec.europa.eu/DOCUMENTS/New-Chemicals/Manual_of_decisions.pdf.

23 Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) No 1907/2006 (REACH), 15-16 December 2008, Doc. CA/59/2008 rev. 1, p. 9.

24 Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) No 1907/2006 (REACH), 15-16 December 2008, Doc. CA/59/2008 rev. 1, p. 6.

25 "PBT" stands for substances classified as persistent, bioaccumulative and toxic.

26 "vPvB" stands for substances classified as very persistent and very bioaccumulative.

- For volumes of 1000 tonnes or more per year, additional data must be provided in accordance with Annex X if the information available on the substance is insufficient to assess the risk (Article 12 (1) e REACH).

The issue of the chemical identity of nanoscale substances relative to their macroscale counterparts is being intensely debated at EU level in the CASG subgroup.[27] The definition of a substance which serves as the basis for REACH is set out in Article 3 (20). This is defined in more detail in the document "Guidance for identification and naming of substances under REACH".[28] According to this document, substances are defined on the basis of their chemical structure, purity, chemical name (in accordance with IUPAC[29] and CAS) and quantitative composition. Nanomaterials have additional characteristic properties that need to be identified and described. Properties such as particle size and geometry, for example, that are decisive for characterising nanomaterials, must be laid down.[30] The "Guidance for identification and naming of substances under REACH" has so far failed to provide clear rules regarding the question of whether the nanoscale and macroscale forms of a substance should be regarded as the same substance ("sameness") or as two different substances. In principle, the identity of a substance is decided by the registrant(s) in a SIEF[31] in the course of registering the substance with the ECHA. However, until clear rules are in place for deciding whether or not a substance in the nanoscale form is identical to its macroscale counterpart, the registrant has a certain margin of discretion. Depending on how this discretion is used a substance at the nanoscale may be subject to different registration requirements. This discretion is to some extent limited, however, by the fact that the decisions made by registrants in their SIEF can be reviewed by the ECHA in the process of its compliance check for registration of a substance.

According to expectations within the chemicals industry, in the case of most of the nanomaterials currently on the market the 10-tonne threshold is likely to have been crossed already – assuming that they have been registered together with the macroscale version of the substance. It is also likely, however, that many manufactured or imported nanomaterials will fall below this threshold.

5.1.2 Conclusions regarding registration of nanoscale phase-in substances

The last registration in the tonnage band for phase-in substances in volumes of between one and 100 tonnes will be concluded at the latest in 2018. A total of around 145,000 substances have been pre-registered, although only some of these are relevant in market terms. According to European Commission estimates, some 30,000 of these may be phase-in substances.[32] This means that until 2018 no systematic risk assessment will be performed on

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27 CASG stands for Competent Authorities Subgroup. CASG was established at the 3rd Meeting of the REACH Competent Authorities on 28 March 2008 with the aim of assessing the degree to which the legal provisions of REACH also cover nanomaterials.

28 See ECHA (2007), Guidance for identification and naming of substances under REACH, p. 28: "The current developments in nano-technology and insights in related hazard effects may cause the need for additional information on seize of the substances in the future. The current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this TGD."

29 IUPAC stands for International Union of Pure and Applied Chemistry.

30 Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) No 1907/2006 (REACH), 15-16 December 2008, Doc. CA/59/2008 rev. 1, p. 7.

31 SIEF stands for Substance Information Exchange Forum.

32 European Commission (2007), Questions and Answers on REACH, available as download from: http://ecb.jrc.ec.europa.eu/documents/REACH/REACH_PROPOSAL/COUNCIL_COMMON_POSITION_2006/QA_revision_sept2006.pdf (accessed 15.9.2009).

nanoscale phase-in substances to be registered together with or separately from the corresponding macroscale substance in the tonnage band 1 t to 100 t.

5.1.3 Authorisation and restrictions

As a result of the chronological sequence of substance registration in the case of phase-in substances, it may take several years for the ECHA to obtain substance (hazard) information on nanomaterials already available on the market. In the meantime, this gap may be closed in part at least by the rules set out in REACH regarding authorisation and restrictions. Under the provisions of Title VII of REACH, authorisation is required to use or place on the market a "substance of very high concern" (SVHC) on its own, in mixtures or in articles, irrespective of tonnage threshold.

SVHCs are identified on the basis of a complex procedure and are then listed in Annex XIV. This multi-stage procedure comprises the following steps:

- Identification of a substance as a SVHC and submission of a proposal for its listing by an EU Member State or the European Commission/ECHA
- Inclusion of the substance on a candidate list
- Prioritisation of substances on the candidate list, and
- Listing of the substance in Annex XIV.

Under Article 57 of REACH, a substance in Annex XIV is subject to the authorisation procedure if it meets at least one of the following criteria:[33]

- Substances meeting the criteria for classification in the hazard class carginogenicity category 1A or 1B in accordance with Annex 1 Section 3.6 of Regulation (EC) No 1272/2008, point (a),
- Substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with Annex 1 Section 3.5 of Regulation (EC) No 1272/2008, point (b),
- Substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development, in accordance with Annex 1 Section 3.7 of Regulation (EC) No 1272/2008, point (c).

Also included in the SVHC category are substances that are

- persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII point (d) of this Regulation, or
- very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII point (e) of this Regulation.

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[33] The criteria set out in Article 57 points (a) to (f) OF REACH were amended by Article 58 Section 4 of Regulation (EC) No 1272/2008 of the European Parliament and 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 (hereafter referred to as the CLP Regulation; "CLP" stands for Classification, Labelling and Packaging).The new critieria set out in the CLP Regulation enter into effect after a transitional period. Substances and mixtures (the term "mixtures" replaced "preparations" under the CLP Regulation) were hitherto classified on the basis of their properties. This principle remains in place, but classification criteria and limits have been changed for some parameters, and new hazards have been included. As a result, more substances and mixtures will be classified as hazardous in future than hitherto.

Also potentially subject to authorisation under Article 57 (f) of REACH are substances "which give rise to an equivalent level of concern". These are substances that have endocrine-disrupting, persistent, bioaccumulative and toxic properties or substances that are very persistent and very bioaccumulative and which do not meet the criteria set out in Article 57 (d) or (e) of REACH, but for which there is scientific evidence of probable serious effects on human health or the environment which give rise to an equivalent level of concern as those of other substances listed in points a) to e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Under Article 59 Section 3 of REACH, any Member State may prepare a dossier in accordance with Annex XV for substances which in its option meet the criteria set out in Article 57 and forward it to the Agency. Findings from the EU's Existing Substances Program and evidence from the application of QSARs[34] may be used to identify potential "substances of very high concern" (SVHC).[35]

Following the inclusion of a SVHC in Annex XIV, the substance is subject to authorisation; in other words, such substances may not be placed on the market or used unless they have been authorised for the use in question.

5.1.4 Evaluation of authorisation and restriction procedures for nanomaterials

The authorisation and restriction procedures also include nanomaterials classified as "substances of very high concern" or posing a risk that is not adequately controlled (Article 68 (1) REACH). Competent authorities in the EU have the power to prohibit the placing on the market of such nanomaterials or restrict their use irrespective of the volume manufactured or placed on the market. In order to apply these legal instruments, however, there has to be evidence that a particular nanomaterial or class of nanomaterials poses a risk to human health or the environment. Little knowledge is currently available on the effects of nanomaterials in human- and eco-toxicological terms, and methods for monitoring nanoparticles in organisms and in the environment are as yet non-existent or embryonic. Until such a time as this situation changes, these legal provisions will have little practical impact.[36]

5.1.5 Provision of information in the supply chain (Safety Data Sheets)

Here we examine whether Safety Data Sheets (SDB), as a tool for providing information on substances in the supply chain, also conveys information on the presence of nanomaterials all the way down the supply chain to the manufacturer of the finished product.

Since 1 June 2007, REACH requires manufacturers and importers of a substance or mixture to provide relevant safety information concerning the substance or mixture to downstream users in the supply chain. Precise details of obligations relating to communication of information in the supply chain are set out in Title IV of REACH. Under Article 31 of REACH, every supplier in the supply chain (this includes manufacturers, importers and traders) must provide the recipient of a substance or mixture with relevant safety information in the form of a Safety Data Sheet if:

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[34] QSAR stands for Quantitative Structure-Activity Relationship

[35] See instructions on this procedure on the website of the Federal Environment Agency (UBA): http://www.reach-info.de/svhc.htm (accessed 12.9.2009).

[36] RCEP 2008, section 4.38.

- a substance or mixture meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC[37] or
- a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.

The Safety Data Sheet represents the key tool for communication down the supply chain between suppliers and recipients of a substance or mixture. Safety Data Sheets contain safety guidelines for handling dangerous substances. In addition, the expanded Safety Data Sheet required in accordance with REACH must also contain information on risks and risk management measures, and on exposure scenarios.

The obligation to supply a Safety Data Sheet only applies to substances on their own and mixtures, but not to articles. Moreover, the obligation to supply a Safety Data Sheet only applies where a substance or mixture has been classified as dangerous, and only to recipients within the supply chain, not to individual end-users.

In the case of substances not classified as dangerous, a Safety Data Sheet may be prepared and provided on a voluntary basis, but there is no requirement to do so. Under Article 32 of REACH, the supplier in these cases is required to provide only the following information:

- the registration number(s)
- if the substance is subject to authorisation and details of any authorisation granted or denied in this supply chain
- details of any restrictions imposed under Title VIII of REACH, and
- any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.

It is worth mentioning here that in the German chemicals industry it is common practice to communicate information to downstream users by way of a Safety Data Sheet even in the case of products not classified as dangerous according to Directive 67/548/EEC.[38]

In April 2007 a stakeholder dialogue on nanomaterials in the workplace organised by the German Chemical Industry Federation (*Verband der Chemischen Industrie*, VCI) concluded that in the case of nanomaterials too the Safety Data Sheet is a fundamentally vital tool for communicating information in the industrial supply chain. It was also stated, however, in the context of this event that adaptation to specific safety issues relevant to nanomaterials could be required on a case-by-case basis. In particular, the sections relating to physico-chemical properties, safety at the workplace and protection of the environment might need to be amended to include nano-specific considerations.[39]

To provide support for manufacturers of nanomaterials, the VCI has produced guidelines for using Safety Data Sheets to communicate information on nanomaterials in the supply chain ("*Leitfaden zur Informationsweitergabe in der Lieferkette beim Umgang mit Nanomaterialien über das Sicherheitsdatenblatt"*).[40] The VCI recommends that manufacturers of nanomaterials apply a checklist for preparing and using Safety Data Sheets for handling nanomaterials (*Checkliste zur Erstellung und Nutzung des Sicherheitsdatenblattes beim*

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37 This Directive has been replaced by the CLP Regulation, see Footnote 33.

38 VCI 2008 I, p. 4.

39 See presentation on the VCI website: http://www.vci.de/showPDF/showPDF.asp?p=101&docnr=121338&type=xml.

40 VCI 2008 II. These guidelines are in effect a nano-specific supplement to the VCI's general guidelines on Safety Data Sheets, "Leitfaden Sicherheitsdatenblatt des VCI", 28 June 2007.

Umgang mit Nanomaterialien) that is contained in Section II of the guidelines. This checklist basically covers all sections of the Safety Data Sheet.

5.1.6 Evaluation of the Safety Data Sheet as a tool for communicating information on nanomaterials

There are shortcomings as regards communication of the presence of nanomaterials in the supply chain right down to the end user, both in the legal provisions on communication of information on a substance or mixture by way of a Safety Data Sheet and in the VCI guidelines mentioned above:

- as there is no legal definition of nanomaterials, it is not clear to actors in the supply chain whether they are users of manufacturers of a nanomaterial;
- the mandatory obligation to supply a Safety Data Sheet only applies to substances and mixtures classified as dangerous. According to SCENIHR (Scientific Commitee on Emerging and Newly Identified Health Risks), risks relating to nanomaterials have not yet been comprehensively identified. As a result, some nanomaterials cannot be classified due to a lack of appropriate methods of testing. For other actors in the supply chain outside of the chemical industry, most notably importers of nanomaterials, there is no guarantee that Safety Data Sheets will be produced and provided on a voluntary basis;
- if a Safety Data Sheet is produced for a substance, it is not always easy for the user of the Safety Data Sheet to assess which information, if any, relates to the use of the nanoscale form of the substance, or even that the user is dealing with a substance on the nanoscale;
- there are obstacles to the communication of information down the supply chain due, for example, to the absence of a culture of cooperation or the absence of any interest in protecting process-related expertise or customer relations. Particularly susceptible in this regard are actors at the stage just downstream from the primary production stage such as formulators, whose expertise involves using substances and mixtures notably to develop new mixtures that can be used for specific products.[41] This obstacle will also apply to nanomaterials as these materials have particular potential for use in developing products with new functionalities, giving manufacturers an edge over their competitors;
- in addition, supply chains are complex and confidentiality statements and supply contracts can significantly hamper communication.

5.1.7 Provisions on articles in REACH

Here we examine the provisions of REACH with regard to substance information on nanomaterials in articles.

An article is defined in Article 3 (3) of REACH as “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”, e.g. spectacles, a vehicle, or a toy doll. As REACH is a set of legal provisions on substances, the registration of articles containing nanomaterials is not in itself covered by REACH. De facto registration of certain articles is nevertheless possible by

[41] Führ 2008, p. 87 (92).

virtue of the substances they contain. Substances in articles are subject to registration in accordance with Article 7 (1), where:[42]

- the substance is present in those articles in quantities totalling over one tonne per producer or importer per year
- the substance is intended to be released under normal or reasonably foreseeable conditions of use and
- the substance has not yet been registered for the use in question.

Alongside this "standard" mandatory registration for intentional release of the substance in accordance with Article 7 (1) of REACH, the ECHA can also demand the registration of a substance in the case of its unintentional release if there are grounds to suppose that the release of a substance contained in an article poses a risk to human health or to the environment (Article 7 (5) REACH). This can also apply to substances that are not subject to mandatory registration which are present in articles in quantities totalling over one tonne per year and which have not yet been registered for the use in question.

Last, manufacturers or importers must notify ECHA of a substance contained in an article in accordance with Article 7 (2) of REACH, where:

- the substance gives rise to concern in accordance with Article 57 (e.g. it is carcinogenic, mutagenic, toxic to reproduction, persistent, bioaccumulative, toxic, very persistent and very bioaccumulative or endocrine disrupting), or
- the substance is on the candidate list, or
- the substance is present in articles of a manufacturer or importer in quantities totalling over one tonne per year, and
- the substance is present in those articles in a concentration of more than 0.1 % weight by weight, and
- exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal cannot be ruled out.

For the purposes of notification in accordance with Article 7 (2) of REACH, certain information must be submitted to the ECHA in accordance with Article 7 (4) of REACH, including for example the identity of the manufacturer or importer and the identity of the substance(s) and the use(s) of the substance(s) in the article.

5.1.8 Evaluation regarding provision of information on nanomaterials

All in all, the mandatory registration and notification requirements relating to substances in articles described above are inadequate for enabling the competent authorities to obtain a comprehensive overview of products with nanomaterials which are on the market. Current provisions capture primarily nanomaterials that are contained in articles rather than articles containing nanomaterials. Registration of a nanomaterial does not extend to cover description of its use in a specific, identifiable article, but rather an abstract use or use category.

For the purpose of monitoring articles, another limitation is the tonnage threshold. Under the current provisions, articles containing nanomaterials are only captured if they contain more than one tonne of a nanomaterial per year. As this threshold refers only to one specific

[42] See also ECHA "Guidance on requirements for substances in articles", available to download from: http://echa.europa.eu/home_de.asp; (accessed 15.9.2009).

nanomaterial, it is not inconceivable that an article could contain well over one tonne of nanomaterials, albeit a variety of different ones.

5.1.9 The German Hazardous Substances Ordinance / CLP Regulation - compensating for the shortcomings of REACH

Irrespective of the tonnage threshold in REACH, under the German Hazardous Substances Ordinance (GefStoffV)[43] and the EU CLP Regulation, which applies directly in Germany,[44] 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.

Any manufacturer, importer or re-distributor placing hazardous substances or mixtures on the market in Germany is required to supply a Safety Data Sheet in German free of charge to the recipient at the latest by the time the substance or mixture is first supplied (Article 6,GefStoffV - 2005). Manufacturers, importers or re-distributors of non-hazardous mixtures must also supply commercial customers with a Safety Data Sheet on request.

These obligations under the German Hazardous Substances Ordinance do not, however, compensate adequately for the shortcomings of REACH. These shortcomings relate to

- identification of the properties of a nanoscale substance
- where a substance has hazardous properties, translating this into appropriate risk information and measures to control substance-related risks, and
- protection of all persons that could be exposed to the effects of nanomaterials – in other words, not only workers – and protection of all environmental media.

The provisions of the German Hazardous Substances Ordinance relating to classification and labelling (Article 5 GefStoffV), to Safety Data Sheets (Article 6 GefStoffV) and to gathering information and assessing risk (Article 7 ff. GefStoffV) apply irrespective of tonnage. Under the GefStoffV and the CLP Regulation, the objective of classification and labelling is to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for hazardous properties to be properly identified and communicated. Such properties should include both physical hazards and hazards to human health and to the environment.[45] There is no obligation, however, to look at nanomaterials systematically and exhaustively with regard to potential hazards to humans and to the environment that might arise from them. The standards set out in the German Hazardous Substances Ordinance cannot compensate for the absence of this obligation, as this Ordinance itself is based, among other things, on the effects of the original law on substances, which in turn sets out threshold volumes does not to date specifically address nanomaterials.[46] This is made clear by Article 5 of the CLP Regulation, which provides that manufacturers, importers and downstream users of a substance shall identify the relevant available information, and in particular the following:

- epidemiological data and experience on the effects on humans, such as occupational data and data from accident databases

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[43] German Hazardous Substances Ordinance (*Verordnung zum Schutz vor Gefahrstoffen – Gefahrstoffverordnung (GefStoffV*) of 23.12.2004, BGBl. I, p. 3758, as amended by Article 2 of the Ordinance of 18 December 2008 (BGBl. I p. 2768).

[44] See Footnote 33.

[45] Cf. Recital 10 of the CLP Regulation, see Footnote 33.

[46] Führ/Hermann et al. 2007, p. 27.

- any other information generated in accordance with Annex XI Section 1 d) of REACH,
- any new scientific information and
- any other information generated under internationally recognised chemical safety programmes.

Under the CLP Regulation, manufacturers, importers or downstream users have an obligation to identify the "available information". In accordance with Article 8 (1) of the CLP Regulation, they can also conduct new tests to determine whether a substance or mixture entails a health or environmental hazard in accordance with Annex I of the CLP Regulation. New tests may be conducted only if all other means of generating information have been exhausted, including by applying the rules provided for in Section 1 of Annex XI of Regulation (EC) No 1907/2006. Manufacturers, importers or downstream users thus have no *obligation* to conduct their own tests to determine whether a substance or mixture entails a health or environmental hazard in accordance with Annex I of the CLP Regulation (Article 8 (1) of the CLP Regulation provides that such tests "may" be performed).[47]

5.2 Conclusions

REACH has the following shortcomings concerning identification of substance (risk) information concerning nanomaterials, communication of this information down the manufacturing and distribution chain, and possibilities for competent ministries, authorities and consumers to obtain information on the presence of nanomaterials in a finished product:

Registration and thereby systematic identification of risks posed by nanoparticulate substances manufactured or imported in volumes of less than one tonne per year, is not provided for in REACH. Until 2018 no systematic risk assessment will be performed on nanoscale phase-in substances subject to registration in the 1 t to 100 t tonnage band.

All in all, the mandatory registration and notification requirements relating to substances in articles are inadequate for enabling the competent authorities to obtain a comprehensive overview of products with nanomaterials which are on the market.

Even if REACH and voluntary measures to implement it provide for or support the identification and communication of information on nano-specific risks and the presence of nanomaterials in the production chain right down to the end user, there remains considerable uncertainty as to whether and how this information is communicated down the production chain in practice.

5.3 Legislation on products

We now turn to examine whether manufacturers, importers and distributors are required to notify the authorities and consumers of the presence of nanomaterials in articles in accordance with current legislation on products, and what such notification must contain.

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[47] Cf. recital 20 of the CLP Regulation; see Footnote 33: "While a manufacturer, importer or downstream user of any substance or mixture should not be obliged to generate new toxicological or eco-toxicological data for the purpose of classification, he should identify all relevant information available to him on the hazards of the substance or mixture and evaluate its quality."

5.3.1 Scope of study

Since REACH contains provisions on substances in articles, but other legislation also contains provisions on certain products, the question arises as to how these provisions relate to one another. Decisions of the EU Commission show that it seeks to apply the legislation on substances, sectoral product legislation and general legislation on products alongside one another.[48] This approach does not, however, diminish the problem of defining the scope of the different provisions. Since requirements pertaining to substances in products are already set out in the provisions on specific products, and inconsistencies need to be avoided, in the case of certain articles REACH simply removes certain products either from the scope of the REACH regulation as a whole, or from specific provisions. These include:

- medicinal or veterinary products as defined by Directive 2001/83/EC and Directive 2001/82/EC
- cosmetic products as defined by Directive 76/768/EEC,
- medical products and devices as defined by Directive 90/385/EEC and Directive 93/42/EEC which are invasive or used in direct physical contact with the human body, or as defined by Directive 98/79/EC
- food and feedingstuffs in accordance with Regulation No (EC) 178/2002 including use as an additive or flavouring in food or feedingstuffs
- biocidal products, and
- plant protection products.

The number of provisions concerning specific products is very large. In the context of the present feasibility study it is therefore only possible to examine a selection of provisions relating to products or commodities, and general requirements relating to consumer products in Directive 2001/95/EC on general product safety (and the German Equipment and Product Safety Act (*Geräte- und Produktsicherheitsgesetz* - GPSG)).

In accordance with Article 2 (3) of the German GPSG, consumer products are defined as:

- products intended for consumer use
- products not intended for consumer use but which may be used by consumers (e.g. a machine originally intended for professional use but which may be purchased by a consumer in a shop) and
- products made available to a consumer when a service is being provided, or products available on the premises of the provider of a service and which imply active use by the consumer.

General requirements concerning consumer products are set out in Directive 2001/95/EC on general product safety, which is implemented in Germany by the Equipment and Product Safety Act (GPSG). The GPSG does not apply where other statutory provisions make more specific requirements concerning a consumer product, providing these lay down equivalent or more extensive requirements concerning safety and health (Article 1 (3) GPSG, first sentence). An important example of one such sub-category of consumer products are the commodities, foods and cosmetic products for which the German Food and Feed Code (LFBG)[49] sets out more detailed provisions than the GSPG.

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[48] Fischer, K., REACH – das neue europäische Chemikalienrecht, DVBl. 2007, p. 853 (854).

[49] German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch - LFGB) in the version promulgated on 24 July 2009 (BGBl. I p. 2205), as amended by the Ordinance of 3 August 2009 (BGBl. I p. 2630).

Commodities are items intended to come into contact with foodstuffs, cosmetics and in a prolonged manner with humans. The table below contains a list with examples of all such commodities in accordance with Article 2 (6) of the LFGB:

Number in Article 2 (6) LFGB	Examples
1. Articles coming into contact with food	Plates, cups, cutlery, packaging materials (cans, bottles, plastic cups, foils, wine barrels), devices for food manufacturing (e.g. meat grinders, cutters) and food preparation (e.g. pots, toasters, kettles).
2. Packaging for cosmetics	Cans, cartons, jars, pots (only packaging, not repackaging or materials which come into contact with cosmetics in the course of their manufacture).
3. Articles coming into contact with the mucous membranes of the mouth	Toothbrushes, pipes, mouthpieces for musical instruments and cigars, teething rings and teats for infant feeding.
4. Articles intended for body care	Combs, files, shavers, massage devices, sponges, towels, washcloths.
5. Toys and joke articles	Building blocks, toy cars, dolls, soft toys, paints, modelling clay, board games, card games, sneezing/itching powder, stink bombs, and tear gas intended only for use as a joke article and which contains no harmful substances.
6. Articles intended for prolonged contact with the human body	Clothing, bedding, mattresses, masks, wigs, hairpieces, false eyelashes, jewellery, wristbands, spectacle frames, nappies.
7. Cleaning and care products for household use, and commodities within the meaning of No 1	Cleaning agents, furniture care products, car care products, dishwashing detergents, silver polish, limescale removers, stain removers and laundry detergents.
8. Impregnation agents and other finishing agents for commodities within the meaning of No 6, which are intended for household use	Shoe creams, impregnating sprays, optical brighteners
9. Agents and commodities intended for odour improvement in places frequented by humans	Air fresheners, toilet freshener blocks, essential oils for oil burners

Source: German Federal Ministry for Consumer Protection and Food Safety (BVL)[50]

No commodities are articles considered medicines as defined in Article 2 (2) of the German Medicines Act (*Arzneimittelgesetz - AMG*), medical devices or accessories for medical devices as defined in Article 3 of the German Medical Devices Act (*Medizinproduktegesetz -*

[50] See table on commodities in accordance with the LFGB at: http://www.bvl.bund.de/cln_027/nn_490840/DE/03__Bedarfsgegenstaende/bedarfsgegenstaende__bgsNachLFGB.html (accessed 30.9.2009).

MPG), or biocidal products as defined in Article 3b of the German Chemicals Act (*Chemikaliengesetz*), or materials or articles listed in Article 1 (3) of Regulation (EC) No 1935/2004, such as covering or coating materials or water supply equipment.

In the next section we first of all analyse the Cosmetics Regulation and the Novel Food Regulation in more detail. The recast Cosmetics Regulation of November 2009 contains provisions on nanomaterials, in particular market authorisation, introduction of a register and labelling of finished products to indicate the presence of nanomaterials. Similar provisions are under discussion in the context of the revision of the Novel Food Regulation. We then turn our attention to discuss how nanomaterials are covered in statutory provisions concerning other products.

5.3.2 Cosmetics (Cosmetics Regulation)

In Germany, requirements concerning cosmetics are laid down in the Food and Feed Code (LFGB). For the protection of health, in accordance with Article 26 of the LFGB cosmetics must not be manufactured or handled in such a way that their normal or foreseeable use presents a risk to health. Up to now, however, the provisions on cosmetics in the LFGB contain no nano-specific requirements relating to authorisation and labelling.

The requirements concerning authorisation of nanomaterials in cosmetics will change, however, as a result of the new EU Cosmetics Regulation.[51] For the protection of human health, manufacturers, importers and distributors are subject to certain reporting requirements under the new Cosmetics Regulation. Cosmetic products containing nanomaterials must be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market. The information notified to the Commission must contain at least the following information (Article 16 (3) Cosmetics Regulation):

- the identification of the nanomaterial, 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
- the reasonably foreseeable exposure conditions.

On the basis of this information the EU Commission must prepare a catalogue of all nanomaterials contained in cosmetic products, including those used as colourants, UV filters and preservatives (Article 16 (10) (a) Cosmetics Regulation). 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. The

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[51] Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on Cosmetic Products, OJ L 342 of 22.12.2009, p. 59 – hereafter referred to as the “Cosmetics Regulation”. See also: European Parliament legislative resolution of 24 March 2009 on the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast) (COM(2008)0049 – C6-0053/2008 – 2008/0035(COD)).

Commission must produce the first catalogue 48 months after the Cosmetics Regulation enters into force – in other words, it will not be available until late 2013 at the earliest.

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 colourants, 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 is to be presented 54 months after the entry into force of the Cosmetics Regulation.

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 (Article 19 Cosmetics Regulation). 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” in brackets. This obligation does not apply until 42 months after the Cosmetics Regulation enters into force – in other words until mid-2013 at the earliest.

5.3.3 Evaluation of the Cosmetics Regulation with regard to introduction of a nanoproduct register

The future Cosmetics Regulation will essentially impose information requirements concerning nanomaterials in products that would also fulfil the purpose of the nanoproduct register (see Section 8.4). Prior to placing a cosmetic product on the market,[52] distributors[53] of cosmetic products must submit to the Commission information on the nanomaterial(s) contained in the product (identity and specification), an estimate of the quantity and – here the provisions go further than the requirements of the nanoproduct register – the toxicological profile of the nanomaterial(s). This information is entered into a publicly available catalogue. In addition, ingredients in nanoform must be declared on the packaging.

In terms of protective purpose, some differences may be observed between the provisions of the Cosmetics Regulation and those of the nanoproduct register outlined here. The purpose of the Cosmetics Regulation is to protect human health and as such it is not completely identical to that of the nanoproduct register, which also encompasses protection of the environment. Under the nanoproduct register, in contrast to the Cosmetics Regulation, reporting obligations are imposed from the point at which a nanoproduct is manufactured, irrespective of whether or not they are intended to be placed on the market in Germany. Moreover, the definition of nanomaterials under the Cosmetics Regulation excludes soluble nanomaterials and could therefore – depending on the definition of nanomaterials adopted for the product register – be narrower than the definition for the product register (see definition in Section 8.2.3).

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[52] “Placing on the market” means the first making available of a cosmetic product on the Community market (Article 2 (1) (i) Cosmetics Regulation).

[53] In accordance with Article 13 (1) of the Cosmetics Regulation, the obligation to comply with the notification requirements resides with the “responsible person”. Otherwise the obligation to fulfil the notification requirements falls mainly to the distributor, who is responsible in accordance with Article 4 (6) of the Cosmetics Regulation “where he places a cosmetic product on the market under his name or trade mark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.”

5.3.4 Novel foods (Novel Food Regulation)

Foods and food ingredients manufactured using novel processes must – like other foods produced by conventional manufacturing methods – comply with general provisions on foods aimed at protection of consumer health and protecting consumers from deceptive or misleading practices, most notably the provisions of the General Food Law Regulation (EC) No 178/2002 and the German Food and Feed Code.[54]

Where nanomaterials in novel foods and food ingredients are intended to be placed on the EU market, they may be subject to an authorisation procedure in accordance with Regulation (EC) No 258/97 (Novel Food Regulation).[55] In such cases, a safety assessment and authorisation are required for placing such foods or food ingredients on the market. Responsibility for ensuring that a food or food ingredient placed on the market in Germany or within the European Union complies with the relevant statutory provisions on foodstuffs lies primarily with the manufacturer or other person placing it on the market.

Novel foods and food ingredients include those falling into particular categories set out in the Novel Food Regulation. With regard to nanomaterials, foods and food ingredients that come into consideration are those (Article 1 (2) (c) and (f) Novel Food Regulation),

- with a new or intentionally modified primary molecular structure
- to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Any food used for human consumption to a significant degree within the Community prior to 15 May 1997 is not deemed a novel food and is therefore not subject to the provisions of the Novel Food Regulation, even where it falls under one of the categories specified in the Novel Food Regulation. Moreover, food additives, flavourings and extraction solvents falling within the scope of specific sectoral Directives (see Section 5.3.6) are not covered by the Novel Food Regulation where the safety levels laid down in these Directives correspond to the safety levels laid down in the Novel Food Regulation (Article 2 (2) Novel Food Regulation). It is likely to be difficult to determine precisely when precedence of the different provisions is to be applied in practice, especially in the case of nanomaterials, as the “safety level” in the Novel Food Regulation is neither static nor quantifiable.

Foods and food ingredients modified by new production processes such as nanotechnology and nanoscience may fall into the categories in Article 1 (2) (c) and (f) of the Novel Food Regulation referred to above. Ultimately, this is a question that is under discussion among the experts.[56] As it remains unclear to what extent the Novel Food Regulation covers

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[54] German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch - LFGB) in the version promulgated on 24 July 2009 (BGBl. I p. 2205), as amended by the Ordinance of 3 August 2009 (BGBl. I p. 2630).

[55] Regulation (EC) No 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43 of 14.2.1997, p. 1.

[56] See also Breggin et al. 2009, p. 65: “The applicability of category (c) has been questioned recently as the molecular structure of nano-structured food products does not necessarily differ from that of conventional food products.”… “Because the decision to identify nanofoods as ‘novel’ under EU law lies with food producers, any ambiguities with regard to the applicability of the above ‘novel foods’ criteria may therefore prevent a comprehensive regulatory coverage of nanotechnology use in food products.”

nanomaterials, a provision aimed at clarifying the issue has been included in Recital 6 of the Commission proposal for amending the existing regulation.[57]

Insofar as nanomaterials as novel foods or food ingredients fall within the scope of Novel Food Regulation, their access to the market is subject to control by means of an authorisation procedure. According to the proper authorisation procedure, the applicant must submit, among other things, 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. Article 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
- 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." (Article 8 (1) Novel Food Regulation).

As part of the process of revising the Novel Food Regulation, the areas of regulation mentioned above are under discussion between the Commission and the European Parliament. At its 1st reading on the amendment of the Novel Food Regulation, the European Parliament (EP)[58] put forward the following proposals with a view to improving the authorisation procedure and transparency as regards the use of nanomaterials:

- Authorisation for the placing on the market of nanomaterials: The EP sees a need to amend procedures for allowing nanomaterials in novel foods and food ingredients onto the market because the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has established that there are major gaps in the knowledge necessary for risk assessment.[59] These include nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate, and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles; furthermore, the SCENIHR opinion concludes that "existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles."[60] The EP therefore proposes that foods to which production

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[57] Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX of 14.1.2008, COM(2007) 872 final.

[58] Cf. the European Parliament legislative resolution of 25 March 2009 on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No .../2009 [common procedure] (COM(2007)0872 – C6-0027/2008 – 2008/0002(COD)).

[59] Proposal of the European Parliament for a new recital 2d in the European Parliament legislative resolution, see Footnote 58.

[60] Cf. SCENIHR 2005, p. 59 ff: "The safety evaluation of nanoparticles and nanostructures cannot rely solely on the toxicological profile of the equivalent bulk material. In carrying out the risk assessment for products of nanotechnology, new testing strategies will be required that will address the product specification, the intended use and the identification of potential exposure scenarios, both human and environmental. Conventional toxicity and ecotoxicity tests have already been shown to be useful in evaluating the hazards

processes have been applied that require specific risk assessment methods (e.g. foods produced using nanotechnologies) may not be included in the Community list until such specific methods have been approved for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective foods is safe (Article 6 (1)(a) (new)). Likewise, in the Political Agreement of the Council of the European Union of June 2009, the Council sets out in recital 16a that "there is inadequate information on the risks associated with engineered nanomaterials" and "… the Commission … should develop new test methodologies which take into account specific characteristics of engineered nanomaterials".[61]

- Definition of nanomaterials: The European Parliament proposes the following definition of "engineered nanomaterials" in the context of the Novel Food Regulation: "engineered nanomaterial" means "any intentionally produced material that has one or more dimensions of the order of 100 nm or less or 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 to the nanoscale." Properties characteristic to the nanoscale include [1] "those related to the large specific surface area of the materials considered" and/or [2] "specific physico-chemical properties that are different from those of the non-nanoform of the same material."
- Inclusion in the Community list of novel foods: in the Community list, all ingredients present in the form of nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word 'nano' in brackets (Article 7 (2)(d) (new)). The entry in the Community list must also include a specification of the food, the intended use of the food, the name and address of the applicant and a note that only the applicant is permitted to place the novel food on the market, unless another applicant has obtained authorisation for this food without reference to the proprietary data of the original applicant.

  The European Parliament also proposes publishing the Community list on a publicly accessible page of the Commission's website.
- Labelling of novel foods and novel food ingredients: according to the EP proposals, ingredients of novel foods and novel food ingredients in the form of nanomaterials must be indicated on the label. This is a consequence of the requirement that "all specific data on novel foods shall be indicated and labelled to ensure proper consumer information" (Article 7a (new)).[62]

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of nanoparticles. However, some methods may require modification and some new testing methods may also be needed. It appears that nanoparticles can exacerbate certain pre-existing medical conditions."

61 Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX - Political Agreement, 17 June 2009, 10753/09.

62 Proposal of the European Parliament for a new recital 2d in the European Parliament legislative resolution, see Footnote 58.

5.3.5 Evaluation of the Novel Food Regulation with regard to introduction of a nanoproduct register

Under the existing Novel Food Regulation, provisions concerning the designation, precise characteristics of novel foods and specific labelling requirements are laid down in the context of the authorisation procedure. The provisions on labelling do not ensure clarity as regards which specific nanomaterial(s) are being used. So far it has not been sufficiently clear to what extent the Novel Food Regulation encompasses nanomaterials. Up to now there has been no definition of nanomaterials in the Regulation. The European Food Safety Authority (EFSA) therefore rightly highlights the limited state of current knowledge on the use of "engineered nanomaterials" in foods.[63]

If the European Parliament's proposed amendments detailed above are adopted in the revised Novel Food Regulation, the information requirements in terms of a nanoproduct register would be fulfilled insofar as the Community list of novel foods requires that all ingredients in nanoform must be clearly stated, the applicant must be identified and the novel food must be appropriately labelled.

The information requirements of the nanoproduct register are more extensive, however, in that they also impose a mandatory notification requirement on the manufacture of nanomaterials as novel foods or novel food ingredients, irrespective of whether they are placed on the market in Germany. Moreover, in the context of the nanoproduct register, a specification of the nanomaterial and an estimate of the amount of the nanomaterial to be placed on the market are also required (see Section 8.4). The proposed definition currently under discussion in the European Parliament, however, is not completely in line with the definition in the nanoproduct register (see definition in Section 8.2.1). For example, the European Parliament proposal does not envisage any lower size limit. Depending on the binding definition ultimately adopted, then, this may result in some incongruence between the Novel Food Regulation and the nanoproduct register in terms of areas of application.

5.3.6 Food additives, enzymes and flavourings

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.[64] 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 (Regulation (EC) No 1333/2008 on food additives,[65] Regulation (EC)

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63 Cf. also the discussion in EFSA 2009 on "engineered nanomaterials" (ENMs), p. 1 ff.: "Current uncertainties for risk assessment of ENMs and their possible applications in the food and feed area arise due to presently limited information on several aspects. Specific uncertainties apply to the difficulty to characterize, detect and measure ENMs in food/feed and biological matrices and the limited information available in relation to aspects of toxicokinetics and toxicology. There is limited knowledge of current usage levels and (likely) exposure from possible applications and products in the food and feed area."

64 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 of 31.12.2008, p. 1.

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

No 1332/2008 on food enzymes[66] and Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties[67]).[68]

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. (See section 5.3.4 for a comparative discussion of the limits to the scope of these provisions).

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.[69] 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.

5.3.7 Evaluation of the legislation on food additives, food enzymes and food flavourings with regard to the introduction of a nanoproduct register

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 nanoparticulate 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 labelling of the additive as a nanoparticulate 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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66 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 of 31.12.2008, p. 7.

67 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 of 31.12.2008, p. 34.

68 Detailed examination of the Regulations can be found in Breggin et al. 2009, p. 66 ff.

69 See also Recital 13 of Regulation (EC) No 1333/2008.

5.3.8 Articles intended to come into contact with foodstuffs

Articles intended to come into contact with food, such as food packaging or cooking utensils, cannot be used on a commercial basis or placed on the market under Article 31 (1) of the LFGB unless they conform to the manufacturing requirements laid down in the provisions of Article 3 (1) of Regulation (EC) No 1935/2004.[70] In accordance with Article 3 (1) of Regulation (EC) No 1935/2004, 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.

Article 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. We can anticipate the use of nanomaterials in this area, and indeed they are already being used.[71] In the case of both packaging types (intelligent and active materials intended to come into contact with food) the materials and articles used must comply with the requirements for authorisation set out in the Directive on food additives.

In accordance with Article 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 silicon.[72] Under Article 5 (1) (m) of Regulation (EC) No 1935/2004, the Commission can establish and maintain a publicly available Community Register of authorised materials or articles or, under Article 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.[73] 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.[74]

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 nanoparticulate materials too. Furthermore, risk assessment needs to be adapted to the specific risks that arise from the use of nanoparticulate substances.[75] Under Article 7 of Regulation (EC) No 450/2009, the Community list entry for such packaging materials must include the identity of the substance(s), the function of the substance(s), the reference number, and where necessary the conditions of use of the substance(s) or component. Mentioning the nanoform of a substance, however, is not explicitly required.

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[70] 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 of 13.11.2004, p. 4.

[71] See the results of a market research study in: Möller et al 2009, p. 31.

[72] A list of legislation on specific materials can be found at: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm (accessed 20.1.2010).

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

[74] Cf. Recital 14 of Regulation (EC) No 450/2009.

[75] European Commission 2008, p. 22.

One example of a case-by-case assessment of nanomaterials for use in particular food packaging materials can be found in the Scientific Opinion published by EFSA. This document authorises the use of titanium nitride nanoparticles in quantities of up to 20 mg/kg in PET (polyethylene terephthalate) bottles.[76] 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.[77]

As regards labelling, Article 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. As a special requirement, Article 4 (5) and (6) of Regulation (EC) No 1935/2004 additionally stipulates that active and intelligent materials and articles must be labelled in such a way as to enable consumers to identify non-edible parts and to indicate that the materials or articles are active and/or intelligent. There is no provision for 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.[78]

5.3.9 Evaluation of legislation on food contact materials and articles with regard to introduction of a nanoproduct register

The information requirements for placing on the market articles intended to come into contact with food do not correspond exactly to the requirements of the nanoproduct register (see Section 8 on the nanoproduct register). 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.

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[76] On the assessment of titanium nitride nanoparticles see: EFSA, Scientific Opinion: 21st list of substances for food contact materials (November 2008), available to download from: http://www.efsa.europa.eu/en/scdocs/scdoc/888.htm (accessed 20.1.2010).

[77] See also: http://www.fdf.org.uk/responses/fdf_response_nano.pdf (accessed 5.1.2010).

[78] European Commission 2008, p. 23.

5.3.10 Articles

The term “Article” under Article 2 of the German Food and Feed Code (LFGB) encompasses a wide range of products (see Section 5.3.1). Article 30 of LFGB prohibits the manufacturing, marketing and treatment of commodities that could endanger human health. In the case of numerous product groups, however, the legislator imposes neither authorisation nor notification requirements in special laws. Rather, restrictions are imposed on the use of certain substances in consumer-oriented products. In addition, the general provisions of the German Equipment and Product Safety Act (GPSG) (q.v.) apply.

For instance, no mandatory authorisation or notification requirement is laid down by the legislator with regard to textiles. Substances used in manufacturing fall within the scope of REACH and so must comply with the requirements for substances under that Regulation. Also applicable in this regard is Directive 96/74/EC[79] on the names, composition and labelling of textile products.[80] The provisions on labelling under this Directive do not, however, provide any information regarding the use of nanomaterials as starting materials, textile processing or dyeing products. The authorities cannot obtain an overview or comprehensive information on these products, including the use of nanomaterials.

5.3.11 The German Equipment and Product Safety Act (Directive on general product safety)

The scope of the German Equipment and Product Safety Act (GPSG),[81] implementing inter alia the Directive on general product safety,[82] includes the supplying or making available commercially of new or used products intended for consumer use (Article 1 GPSG, first sentence), irrespective of whether these are mass-produced or individually produced, or whether they are products for scientific use or prototypes.[83]

The GPSG prohibits the placing on the market of unsafe products. Article 4 (2) of the GPSG stipulates that:

“A product ... may only be brought into circulation if, under normal or reasonably foreseeable conditions of (mis)use, it does not endanger the safety and health of users or third parties. When assessing a product ... the following in particular must be considered:

1. the characteristics of the product, including its composition, packaging, assembly instructions, installation, maintenance and duration of use
2. its effects on other products, where it is to be expected that it will be used together with other products
3. its appearance, commercial presentation and packaging, labelling, warnings, instructions for use, indications concerning its disposal and any other data or information relating to the product
4. groups of users exposed to greater risk when using the product than others.”

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79 Directive 96/74/EC of the European Parliament and of the Council of 16 December 1996 on textile names, OJ L 032, 03.02.1997 p. 38.

80 On the EU provisions relating to textiles and childrens toys, see Fischer 2005, p. 44 ff.

81 German Equipment and Product Safety Act of 6 January 2004 (BGBl. I p. 2 (219), last amended by Article 3 (33) of the Act of 7 July 2005 (BGBl. I, p. 1970).

82 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, p. 4).

83 Klindt 2004, p. 465 (466).

To establish whether a product meets these requirements, the “new approach” principle applies (Article 4 (2) GPSG, second sentence). If a technical standard is declared universally applicable within the jurisdiction of the European Union (harmonised standard), a product is assumed to be compliant with the basic safety requirements if all the standards applicable to that product have been met in full or a notified body has assessed that this is the case.

The GPSG provides that the following information must be provided to the competent authority and the consumer (Article 5 GPSG):

- Any manufacturer, manufacturer’s authorised representative or importer placing a consumer product on the market must ensure that the user of the product is supplied with the necessary information to enable him to assess and protect himself from any dangers that might arise during the normal or reasonably foreseeable period of use of product and which are not immediately evident without appropriate information. In order to prevent risks, instructions for use in German must be supplied along with the product in accordance with Article 4 (4) point 2 of the GPSG when the product is placed on the market.
- The consumer product or its packaging must bear the name and address of the manufacturer or, if the manufacturer is not based in the European Economic Area, the name and address of his authorised representative or of the importer. In addition, the product must be labelled is such a way that it can be clearly identified, unless it is justifiable to dispense with this information, particularly where the user is already aware of this information, or where labelling with this information would entail unreasonable expense or effort.
- Under Article 5 of the GPSG, manufacturers are required to take “precautions” commensurate with the characteristics of the consumer product they have placed on the market to enable them to initiate appropriate measures to prevent risks, including the withdrawal of the product from the market, the issuing of appropriate and effective warning, and the recall of the product from users. Manufacturers may comply with this obligation by producing a written risk analysis and updating it on the basis of risks that become apparent later as a result of complaints or of their own tests.
- The manufacturer, his authorised representative or the importer must notify the competent authority without delay in accordance with Annex I of the Directive 2001/95/EC, if he knows, or has clear indications based on the information available to him or based on his experience, that a consumer product placed on the market by him poses a risk to human health and safety; in particular he must give notification of measures he has taken to avert this risk. Notification under sentence 1 may not be used to bring criminal proceedings or proceedings under the German Administrative Offences Act against the notifying party.

5.3.12 Evaluation of the GPSG with regard to the introduction of a nanoproduct register

The German Equipment and Product Safety Act (GPSG) contains requirements with regard to the safety of products placed on the market as a “catch-all” clause for all consumer products not covered by specific legislation. In addition, consumers must be informed of any risks arising from the normal or reasonably foreseeable period of use of a consumer product. Obligations to supply information generally enable the authority and consumers to identify the manufacturer or person placing a product on the market, and the product itself. The GPSG does not, however, contain any explicit obligation to supply information to the

authority or the consumer regarding the present of nanomaterials in a consumer product, or regarding the amount of nanomaterials placed on the market.

5.4 Conclusions

At the present time, the use or presence of nanomaterials in the consumer products available on the market which are examined in this study is not explicitly identified. This is also true of the general labelling requirements for foods and food packaging.

In the case of the Cosmetics Regulation, binding provisions regarding information on nanomaterials contained in a product will be introduced in the foreseeable future. These provisions largely correspond to the requirements of the nanoproduct register. It remains to be seen what the result of the legislative process will be with regard to the revision of the Novel Food Regulation.

6 The need for legislation and the precautionary principle

As discussed above, there are weaknesses in the legislation on substances and products as regards provision of information to authorities and consumers on the presence of nanomaterials in products. This suggests that there is a need to examine whether the state can take measures to eliminate them using the precautionary principle. With this aim in mind, we first of all give a general description of the precautionary principle, before moving on to elucidate the conditions and limitations related to its application.

6.1 The precautionary principle

The precautionary principle is a crucial component of international, European and German policy in the field of environmental law and law on the protection of health and on consumer protection. In Germany the precautionary principle is enshrined in the state aim set out in Article 20a of the Basic Law for the Federal Republic of Germany (GG) as a guiding principle for state action, and in the provisions of numerous simple laws in the field of environmental law, e.g. the Federal Immission Control Act and Genetic Engineering Act.[84] At EU level the precautionary principle is mentioned in the context of environmental protection in Article 191 (2) p. 2 of TFEU (formerly Article 174 (2) p. 2 TEC) TFEU.[85] According to a Communication from the Commission of the EU, the precautionary principle is to be applied in practice especially "where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community."[86] The European Court of Justice (ECJ) has ruled in connection with the precautionary principle that "where there is scientific uncertainty as to the existence or extent of risks to human health the Community institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."[87] On this basis, precaution can be understood as overcoming a risk situation which is defined by inconclusiveness and uncertainty.[88] When applying the precautionary principle, a distinction should be drawn between a circumstance arising because grounds for precaution have been identified and assessed (in other words the "whether" of a precautionary measure), and the measure, and its addressee, that may be the legal consequence of this circumstance (in other words the "how" of the precautionary measure).[89]

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84 Calliess 2008, p. 29, and other souces.

85 Article 174 (2) p. 2 of the Treaty establishing the European Community (TEC) states: "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."

86 European Commission 2000, p. 3.

87 ECJ Case C-157/96, National Farmer's Union and Others [1998] ECR I-2211, (cited as NFU judgement), paragraph 63, and ECJ Case C-180/96, United Kingdom v Commission [1998] ECR I-2265 (cited as BSE judgement), paragraph 99.

88 Cf. discussion by Calliess, in: Calliess/Ruffert, Article 174 TEC, paragraph 26 ff.

89 Cf. discussion by Calliess, in: Calliess/Ruffert, Art. 174 EGV, Rn. 29a. On distinguishing between the "whether" and the "how" of the precautionary principle, see also: Rengeling 2000, p. 1473 (1478); Appel 2001, p. 395 (396).

6.2 Grounds for invoking the precautionary principle for nanomaterials

For there to be grounds justifying the application of precautionary measures, there needs to be a situation that entails an abstract potential cause of concern. Evidence of cause and effect relationships for a potential hazard is not required in order to determine that an abstract potential cause of concern is present; it is sufficient for a hazard to be scientifically plausible (initial suspicion has arisen), even it has not yet been substantiated or proven empirically.[90]

In the context of authorising substances to be placed on the market, checking has hitherto been done in general on the basis of the standard requirements for chemicals, in other words, mainly in accordance with the EU Regulation on chemical substances, REACH.[91] It remains to be clarified, however, whether existing methods of measuring and testing adequately cover the risks potentially posed by nanomaterials.[92] For this reason, the European Commission,[93] the OECD[94] and the German Federal Government's NanoKommission[95] have recommended adapting and developing measurement methods to identify and characterise nanomaterials and developing measurement strategies (allowing for background contamination) in the workplace and the environment.[96] A corresponding OECD work programme to review the suitability of conventional testing methods when applied to nanomaterials is also currently under way.

In addition, the OECD has set up a testing programme for a number of nanoparticles that are regarded as representative (including carbon black, SiO_2, ZnO and silver), to determine not only their specific physico-chemical properties, such as agglomeration and specific surface area, but also (eco-)toxicological endpoints and environmental fate of these nanomaterials.[97] The aim is to establish a set of endpoints that may be relevant for exposure and effects assessment of nanomaterials.

6.2.1 Eco-toxicology: potential concerns

Emissions may occur at various phases of the life cycle of nanomaterials – during the manufacture or use of a product or after its use – and may then find their way into the

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90 Calliess 2008, p. 34.

91 Regulation (EC) No 1907/2006 of the European Parliament and of the Council on of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); the text of the Regulation may be downloaded from the website of the Gewerbeaufsicht Baden-Württemberg: http://www.gaa.baden-wuerttemberg.de/servlet/is/16495/.

92 See detailed recent publication of the Royal Commission on Environmental Pollution (RCEP), Novel Materials in the Environment: The case of nanotechnology, November 2008, p. 27 ff. For more in-deprth discussion see the recommendations of the EU's scientific advisory body SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), 2005.

93 SCENHIR (2009), Risk assessment of products of nanotechnologies; Opinion adopted on 19th January 2009, http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf.

94 OECD Working Party on Manufactured Nanomaterials (WPMN), Subgroup (SG) 4.

95 The NanoKommission was created in late 2006 by the Federal Government as a central, national body for dialogue. In it, stakeholders from science and industry, environmental and consumer organisations, trades unions, government ministries and authorities work together to develop concrete approaches for the responsible use of nanomaterials.

96 Cf. also the Report and recommendations of the German Federal Government's NanoKommission for 2008 "Responsible Use of Nanotechnologies", p. 38; available to download at http://www.bmu.de/gesundheit_und_umwelt/nanotechnologie/nanodialog/doc/print/42655.php.

97 OECD (2008): List of manufactured nanomaterials and list of endpoints for phase one of the OECD testing programme. Series on the safety of manufactured nanomaterials, number 6.

environment. More concrete conclusions can only be drawn by examining specific cases, although the type of nanomaterial and its size and purpose play an important role.

As well as the nature of the manufacturing process (open or closed system), the way in which a nanomaterial is embedded in the product matrix is also an important factor for emissions and exposure. These factors ultimately determine how easily nanoparticles can accidentally escape into the environment. Another issue that plays a major role in this context is the degradability of nanomaterials.

Because nanomaterials have a high adsorption potential due to their surface area, it is reasonable to assume that they will exert mobilisation effects. Theoretically they can act as carrier substances and therefore have the potential to transport nutrients and harmful substances into the groundwater.

It is also conceivable that nanomaterials could be released into the environment in a completely uncontrolled manner by products used by private individuals. It is therefore most urgent, especially in the case of paints and varnishes, cleaning products and sealants applied by spray, and for cosmetics and disposable articles, to test nanomaterials for nano-specific risks. Aspects of relevance for consumer protection are a priority in this regard. However, nanomaterials can also enter the environment by this route (e.g. sunscreens in bathing water or nanoparticles from textiles entering household waste water).

As regards the eco-toxicological behaviour of particular nanomaterials, there are some studies that point to impacts on aquatic and terrestrial ecosystems.[98]

Current eco-toxicological studies focus on assessing the toxicity of nanomaterials on aquatic organisms. Relatively few studies have so far been conducted to determine the mechanism of action and effects of nanomaterials in water, soil and in the atmosphere.[99]

6.2.2 Human toxicology: potential concerns

Alongside the dose-response relationship, particle size also plays a major role in terms of toxicity. Research has repeatedly demonstrated that the toxicity of certain particles is related to their size, so that as particle size decreases, their toxicity generally increases.[100] It is not possible, however, to make any generalised statement that all nanomaterials are toxic on the basis of their small size.[101] Nanomaterials represent a diverse group of materials in which other dimensions of particles, such as their length, may also play an important role in determining their toxicity.[102]

Because of their small size, nanoparticles can cross biological membranes, cells, tissues and organs more easily than larger particles. Research into the behaviour of nanoparticles in terms of human toxicology is still in its infancy, but there are indications that these particles can interact with biological systems. If nanoparticles enter the body by way of the circulatory system, they can be transported to the various organs (heart, liver, spleen, kidneys, bone

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98 For an overview of impacts on aquatic and terrestrial ecosystems, see presentation on the website of the German Federal Environment Agency at: http://www.photokatalyse.fraunhofer.de/Images/Leuschner_Rappolder_UBA_tcm24-2810.pdf; for a more detailed account see BT-Drs. 15/2713 of 15.3.2004, p. 162 and BAuA/BfR/UBA 2007, p. 40.

99 RCEP 2008, section 3.27.

100 ENHRES 2009, p. 73.

101 Cf. overview of the current state of knowledge in a presentation by Wim H De Jong, Vice Chair of SCENIHR: (Scientific) Comments on the Public Consultation's Summary, available to download at: http://ec.europa.eu/health/ph_risk/nanotechnology/docs/ev_20091103_co03_en.pdf.

102 ENHRES 2009, S. 73.

marrow).[103] According to current knowledge, biological barriers (such as the blood-brain barrier) present no obstacle to some nanoparticles.[104] Cell experiments have shown that barriers such as the cell membrane, impenetrable to larger molecules, present no insurmountable problem for nanoparticles. Particles smaller than 40 nm in diameter are taken up by the cell by a mechanism as yet unknown.[105] The way nanomaterials are distributed in the body appears to have nothing to do with their size, form or material properties. Biologically degradable nanomaterials such as dextran particles or liposomes are metabolised and excreted. Little is known to date, however, about the behaviour of non-degradable nanomaterials in the body. Initial studies demonstrate that these materials may accumulate in the liver or kidneys, but there is insufficient research so far to establish whether such an accumulation poses a health risk.[106]

In the case of come carbon nanotubes (CNTs) there are indications of acute pathogenic effects related to their specific structure and length, similar to those caused by asbestos fibres. These include reduced elimination capacity of alveolar macrophages, inflammation and fibroses in the lungs (pathological hyperplasia of the connective tissue). Experimental animals receiving an injection of CNTs into their abdominal cavity develop mesotheliomas (tumours of the pleura, the membranes surrounding the lungs) that are typical of asbestos exposure.[107]

6.3 Evaluation of the grounds for invoking the precautionary principle

The examination above shows that the grounds for concern – i.e. initial suspicion – may be justified in the case of some nanomaterials.

It is not possible to affirm that there are grounds for concern in the case of all nanomaterials, as no human or eco-toxicological research findings are yet available on many nanomaterials, while tests conducted to date on other nanomaterials have shown no demonstrable toxicological effects.

As a result, any statement on the human or eco-toxicology of nanomaterials at the present time is fraught with uncertainty.[108] So far there are no standardised nano-specific methods of testing and appraisal and adequate scientific research is not yet available. There is a need for urgent clarification of the many questions that remain open the concerning the human and above all the eco-toxicological impact of nanomaterials.[109]

Whether or not grounds for concern can be affirmed for other nanomaterials for which little or nothing is known as regards the risk of adverse effects is a matter of some controversy. One

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[103] UBA 2009, p. 10.
[104] SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Risk assessment of products of nanotechnologies, 19 January 2009.
[105] UBA 2009, p. 10.
[106] UBA 2009, p. 10.
[107] UBA 2009, p. 9. See also Footnote 101, overview of current knowledge in the presentation by Wim H. De Jong.
[108] Cf. the findings of ENHRES 2009 on four substances studied.
[109] In 2006 the OECD set up a "Working Party on Manufactured Nanomaterials (WPMN)" to promote international cooperation in research into the safety of nanomaterials with regard to the environment and health. A research programme, entitled Safety Testing of a Representative Set of Manufactured Nanomaterials", was launched with the aim of examining a representative set of engineered nanomaterials in terms of their human and ecotoxicological effects, using appropriate testing methods. The 14 nanomaterials under investigation include: silver nanoparticles, titanium dioxids, aluminium dioxide, zinc dioxide and silicon dioxide.

reason is because the question of who should be held accountable for the uncertainties concerning nanomaterials remains open: the risk producer placing the nanomaterials or nanoproducts on the market, the state, or the person potentially affected. If one assumes that a hazard is only present where the probability of an adverse effect is empirically high, then the burden of producing evidence and the burden of proof lies with the state. However, if the producer of the risk is expected to provide evidence that his nanomaterials or nanoproducts are safe, the he carries the burden of producing evidence and the burden of proof.[110] In this situation, in accordance with his fundamental constitutional rights, the legislator can impose a burden of producing evidence and a burden of proof on the producer of the risk.[111] In practice this might be done, for example, by establishing an authorisation requirement or by introducing a mandatory reporting obligation for nanomaterials and nanoproducts.

6.4 Nanoproduct register as a precautionary measure

It must first of all be stressed that any decision to take action on the basis of the precautionary principle and adopt a specific measure is an eminently political decision and will depend on the level of risk that a society considers "acceptable".[112] The legislator may also decide to take no action. If the legislator does decide to act, in principle there is a wide range of options available to him, ranging from legislative measures such as amending existing statutory provisions on substances, products or the environment, to practical measures such as funding parallel research programmes to identify the risks associated with nanoproducts and providing public information on the possible negative impacts of a product.

Up to now the European Commission has sought to ensure that legal requirements relating to risk management concerning nanomaterials are met by means of measures such as

- expanding the knowledge base
- improving enforcement of the statutory provisions
- using existing information options for users
- using existing market surveillance tools and intervention mechanisms.

The Commission's Communication does not, however, contain reflections on introducing a voluntary or compulsory nanoproduct register.[113]

If the legislator decides to take a concrete action such as introducing a nanoproduct register as a precautionary measure, then the nanoproduct register must comply with the general principles of proper risk management. These are:

- proportionality
- non-discrimination
- consistency
- examination of the benefits and costs of action and inaction, and
- examination of the scientific developments.

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[110] Cf. Calliess 2008, p. 40.
[111] For more detail see: Calliess 2008, p. 43 (44).
[112] Communication of the Commission on the Precautionary Principle COM(2000)(1), 2.2.2000, hereafter referred to as the Communication of the Commission.
[113] See European Commission 2008, p. 9 ff.

6.4.1 Proportionality

According to the case law of the European Court of Justice (ECJ), a measure based on the precautionary principle must comply with the principle of proportionality, in other words it must be appropriate, necessary and proportional.[114]

In the first place it must be noted that, in the opinion of the ECJ, the measure must afford an appropriate level of protection of human health and the environment, but it must not be disproportionate to the level of protection chosen, and it must not aim at zero risk.[115] Nevertheless, banning the manufacture of a substance as a far-reaching measure is conceivable under the precautionary principle and is not in itself disproportionate. Rather, a total ban may be a disproportionate response in view of the potential risk in one case, while in another case it may be the only possible course of action.

Any national course of action adopted must be proportionate to the desired goal, and must be sufficient to achieve the desired goal.

The aim of introducing a nanoproduct register and mandatory reporting is to ensure a high level of protection of the environment, human health and occupational safety in the manufacture, use and disposal of nanomaterials. It is very difficult at the present time to state anything with any certainty regarding the human and eco-toxicological risks of nanomaterials.[116] At the same time, a review of the statutory provisions on substances and products is under way to assess whether market access regulations for nanomaterials and nanoproducts adequately cover nano-specific considerations. For example, existing human and eco-toxicological testing methods and evaluation strategies need to be reviewed and optimised as regards their suitability for assessing nanomaterials. Consequently, it may be necessary to adapt or set new limits for nanomaterials in the existing legislation governing market access. It is therefore desirable to record in a product register nanomaterials and nanoproducts already classified as safe and placed on the market in accordance with the current authorisation criteria. If future scientific findings reveal that a nanomaterial or nanoproduct already on the market poses a concrete or potential risk to human health, occupational safety or the environment, then both the competent authorities and – on the basis of information received from the authorities – the manufacturer and distributer of these products would be able to respond rapidly to put in place risk management measures. This register will make it possible to verify whether such a nanoproduct is manufactured or available on the market in Germany, and who manufactured it or placed it on the market. An overview of the market can also help to ensure that unforeseen risks presented by these products are recognised as soon as possible. At the very least, then, mandatory reporting and a nanoproduct register help to ensure a high level of protection of the environment and of human health.

When assessing whether a measure is necessary, all possible alternative options for risk management should be evaluated. A measure is necessary where a more moderate means is not available – with regard to the adversely affected object of protection – to achieve the desired objective. Member States will have to be allowed to exercise a degree of discretion here, as any decision as to the necessity of a measure will depend on an appraisal of the situation.

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[114] Epiney 2005, p. 130 ff.
[115] ECJ Case T-13/99 (Pfizer Animal Health SA v Council) [2002] ECR II-3305, paragraphs 145 and 152.
[116] See discussion in Section 6.2.

Determining whether a measure is more moderate will depend on the measure chosen, but also on the precise design of the measure.

When choosing the most moderate means for protecting human health or the environment, labelling a product with notices and information for consumers may be a more moderate means than product registration or other restrictions applied to the placing of a product on the market. If a state body were to require such notices and information to be provided, this would mean that the distributor of the product would have to supply information on the product to the state body, just as he would for a register. Unless a corresponding reporting requirement is put in place, however, the authority will only be able to obtain an overview of the market by conducting its own comprehensive research.

Instead of providing information to the competent authority, manufacturers and distributors could keep the information within their company, and only make it available to the authority on request. These measures would not be equally appropriate as they would not afford the authority a comprehensive overview of nanomaterials and nanoproducts on the market.

Even existing provisions such as RAPEX, the EU's rapid alert system for non-food consumer products,[117] 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.

Comparison of mandatory reporting, in the form of simply supplying information, with other regulatory instruments[118] that are equally appropriate for achieving the desired objective, reveals mandatory reporting to be the more moderate means. Mandatory reporting is not intended to introduce controls on the marketing of nanomaterials and nanoproducts (e.g. by means of an authorisation procedure, equivalent to a prohibition of all such activities unless permission is granted, or a notification or registration procedure, equivalent to a prohibition of all such activities unless notification is given).

Authorisation requirements – whether in the form of a preventive ban with an authorisation option or a repressive ban with an exemption option – are aimed at hazard prevention and therefore prohibit certain activities prior to appraisal and authorisation by the authorities.[119] The aim of the proposed mandatory reporting requirement in the case of nanoproducts is not to prompt the authorities to check whether the placing on the market of nanoproducts complies with the law or not, with the consequent issuing or refusal (respectively) of an authorisation to place the products on the market. Rather, the legality of placing the products on the market is assessed, and surveillance of the products carried out within the framework of the authorisation procedure set out in the legislation on products and in accordance with the material requirements laid down there.

Hence, the manufacture or importation of nanoproducts into Germany is not subject to authorisation entailing the possibility of prohibition. Trade in nanoproducts in the EU is thus indirectly hampered by the obligation imposed on the manufacturer or importer in the context

[117] See EU website: http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm (accessed 5.2.2010).
[118] Cf. Kloepfer 2004, Article 5 paragraph 37 ff.; Fluck 1998, p. 165 ff.
[119] Cf. Kloepfer 2004, Article 5 paragraph 45 ff.

of the reporting requirement to collect the necessary information and communicate it to the authority. As an instrument, then, mandatory reporting interferes less with trade than prohibition with an authorisation option.

Now we must assess whether the information required for compliance with the mandatory reporting obligation is not necessary in order to attain the desired objective, or whether this information is not the most moderate means as it goes beyond what is necessary. In this case too, trade would be needlessly impeded. In the case of notification or reporting obligations, there is no set typology for forms of notification. A distinction can be drawn between two basic forms, however: notification that accompanies an activity, and notification that permits an activity to be taken up.[120] In the case of notification that permits an activity to be taken up, as the most moderate instrument for controlling the uptake of such an activity the administration should basically be supplied with any information that it might need in order to intervene if required to do so.[121] Depending on how notification is designed, e.g. where rigorous requirements are imposed on the applicant regarding testing and providing evidence, this form of notification may be tantamount to an authorisation requirement in terms of the intensity of its impact on trade. Notification that accompanies an activity on the other hand primarily serves to provide the authority with information for monitoring compliance. It can only be used, for example, to give the authority an overview of the issues within its jurisdiction.[122]

In the context of a mandatory reporting obligation information must be supplied to the authority enabling identification of the distributor and of the nanomaterial and the semi-finished or finished product. In addition, the distributor must provide any human and eco-toxicological information available to him, as well as an estimate of the quantity he wants to place on the market per year.[123] The distributor must update this information regularly.

Setting an information requirement and an obligation to keep this information up to date are the minimum needed to enable the authorities monitor the nanomaterials and nanoproducts on the market in terms of their impact on the environment and on the health of workers and consumers.

Mandatory updating of the information provided enables the development of a database that is regularly updated for long-term monitoring of impacts on the environment, workers and consumers. Having a reporting requirement that applies right down the supply chain also makes it possible to identify anomalies, e.g. unreported nanoproducts.

As discussed above, introducing mandatory reporting of the manufacture and placing on the market of nanomaterials and nanoproducts can also be considered as the necessary action for monitoring these products. In other words, there is no other equivalent course of action that would be less restrictive to trade in nanomaterials and nanoproducts.

A national measure is appropriate unless it is disproportionate for attaining the desired objective. To determine whether this is the case, any disruption of the free movement of goods as a result of the measure must be assessed in relative terms and weighed against the environmental benefits.

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[120] Fluck 1998, p. 165 (168).
[121] Cf. Kloepfer 2004, Article 5 paragraph 38.
[122] Cf. for the purpose of establishing the number of businesses within the jurisdiction of an administration: Badura 2005, Section 3, paragraph 130.
[123] See discussion in Section 8.4.

The ECJ gives Member States broad discretion in this regard. Evidence so far suggests that no health or environmental measure taken by a Member State has yet been declared inconsistent with the obligations of Member States under EU law. In other respects the proportionality principle plays a very minor role in ECJ case law.

A mandatory reporting scheme might be deemed inappropriate because it imposes a standard form of registration on the manufacture and placing on the market of nanomaterials and nanoproducts, making no distinction between different degrees of risk. For example, it is widely assumed that free nanoparticles may present a higher risk to the environment and to human health than nanomaterials which are bound, e.g. in a matrix. This, however, is a plausible assumption that still needs to be assessed on a case-by-case basis for the whole life cycle of a product including its use and disposal. It is therefore not inappropriate to require registration of all nanomaterials and nanoproducts without distinction, especially in view of possible irreversible long-term impacts.

Finally, introduction of a mandatory reporting requirement is appropriate and does not aim at zero risk, as a reporting requirement would not disrupt or prohibit the placing on the market or trade in nanoproducts. The burden on manufacturers and importers is not disproportionate to the possible (and potentially irreversible) human and eco-toxicological impacts of nanomaterials on the environment and on humans. The only burden on manufacturers and importers is that of obtaining information and making it available. Information on the presence and amount of nanomaterials in a product should in any case be available to the manufacturer or importer from conducting his own legal risk assessment (e.g. to identify liability risks). Manufacturers and importers of finished products can also request information suppliers of semi-finished products. State bodies, on the other hand, would be able to gain a comprehensive overview of nanoproducts obtainable on the market. Introducing mandatory reporting and a nanoproduct register are an important step for enabling prompt identification of potential links between adverse health effects and the use of nanoproducts, especially unanticipated effects of particular nanoproducts on human health and on the environment, and to enable those effects to be prevented or reduced. If a nanoproduct presents a hazard to human health or the environment, that product can be identified more easily and taken off the market. In addition, future options for action to protect health and the environment remain open. These might include, for example, requirements regarding proper disposal of nanoproducts.

6.4.2 Non-discrimination

Risk management measures must be non-discriminatory in their application, in other words, comparable situations must not be treated differently unless there are objective reasons to justify doing so.

The proposed mandatory reporting requirement is intended to cover all nanomaterials and nanoproducts, irrespective of their product group or type of nanomaterial they contain, and irrespective of who placed, or wishes to place, the product on the market. The amount of information required is also identical for all nanoproducts.

Exemption from the mandatory reporting requirement may only be granted on objective grounds, for example in cases where another statutory provision already envisages a reporting requirement for nanoproducts, or where the presence of nanomaterials in a product do not give any cause for concern regarding a potential hazard to humans or to the environment.

There is therefore no indication of any arbitrary discrimination resulting from the mandatory reporting requirement.

6.4.3 Consistency

In accordance with the principle of consistency,[124] risk management measures must be of comparable scope and nature to other measures implemented in equivalent circumstances in the past.

To illustrate this comparability, the reporting requirement for detergents and cleaning products set out in the German detergents and cleaning agents Act (*Wasch- und Reinigungsmittelgesetz*, WRMG)[125] provides a useful example. The new WRMG is intended to protect both the environment and the health of consumers using detergents and cleaning products. With this aim in mind, manufacturers of detergents and cleaning agents must submit to the Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung*, BfR) by electronic means the formulation of a detergent or cleaning product prior to placing it on the market. These data are processed at the BfR for the Poison Information and Treatment Database (*Giftinformationsdatenbank*) and made available on a regular basis to the nine Poison Information and Treatment Centres at the level of the *Länder*. This enables the centres to provide advice to doctors, particularly in the event of emergencies involving poisoning.

Compiling a (government) register for reporting and gathering together measures which are associated with risks is an instrument that has been used in other instances where new technologies have been introduced. In Germany, for example, since 2004 it has been possible to access information on the location of transmitters and radio installations from a database on the website of the Federal Network Agency since 2004.[126] The EMF[127] database is the result of a self-imposed obligation by German mobile phone network operators and dates from 2001.

6.4.4 Examination of the benefits and costs of action and inaction

The aim of precautionary measures is to reduce risk to an acceptable level. In this regard, the Commission affirms that affirms that "requirements linked to the protection of public health should undoubtedly be given greater weight than economic considerations." Before measures are taken, the benefits and costs of action and lack of action must be examined (Article 191 (3), point 3 TFEU), including, where appropriate and feasible, an economic cost-benefit analysis. Conducting an economic cost-benefit analysis is beyond the scope of the present study.

6.4.5 Review of scientific developments

As decisions based on the precautionary principle always entail a certain degree of scientific uncertainty as regards the existence or extent of risks for the environment and public health,[128] it is important to call for further scientific research and to evaluate new scientific information. The precautionary measures must then be reviewed and modified or abolished by a particular deadline in the light of new scientific findings. Modification or abolition of a

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[124] For further discussion see Callies, in Callies/Ruffert 2007, Article 1 EUV, paragraph 54 ff.

[125] Act on the environmental impact of detergents and cleaning agents (Gesetz über die Umweltverträglichkeit von Wasch- und Reinigungsmitteln (Wasch- und Reinigungsmittelgesetz – WRMG)) of 29 April 2007 (BGBl. I p. 600). The WRMG applies in addition to Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104 p. 1).

[126] See the website of the Federal Network Agency (Bundesnetzagentur): http://emf.bundesnetzagentur.de/gisinternet/index.aspx?User=1000&Lang=de (last accessed 5.9.2009).

[127] EMF stands for electromagnetic field.

[128] ECJ Case T-13/99 (Pfizer Animal Health SA v Council) [2002] ECR II-3305, paragraph 146.

measure should be linked not to the time factor but to the development of scientific knowledge.[129]

With regard to the nanoproduct register, we can conclude first of all that the need for a register per se and the products (product groups) it contains must be reviewed within a certain time limit. For example the authority responsible for managing the register could conduct period reviews of nanoproducts to be included in or excluded from the nanoproduct register of nanoproducts. These reviews of the register must, however, be based on the latest scientific knowledge on the risks of nanomaterials and products containing them. In this context, it is likely to be much more difficult to decide when scientific knowledge of the risk or level of risk is sufficient to warrant the removal of a product from the register. This, however, is ultimately bound up with a political decision on constitutes an acceptable risk.

[129] Communication of the Commission on the Precautionary Principle, p. 23 ff., see Footnote 112.

7 Regulatory measures in other countries

In January 2009 the French government put a draft act before the cabinet with proposals to include provisions in Book 5 of the French Environmental Code (*Code de l'environnement*) introducing a mandatory reporting requirement for nanomaterials.[130] According to these provisions, persons manufacturing or importing nanoparticulate substances or placing them on the market must notify the competent authority on a regular basis of the identity, quantity and use(s) of these substances. The mandatory reporting requirement extends not only to manufacturers and distributors of such substances, but also to persons using nanoparticulate materials in manufacturing processes. The latter must report to the competent authority the identity and quantity of nanoparticulate material(s) used and the nature of the manufacturing process in question. Explicit reporting of the identity of products containing nanomaterials is not envisaged in these provisions. Furthermore, the draft legislation does not define the term "nanoparticulate substance" ("*substances à l'état nanoparticulaire"*) nor does it refer to another applicable definition. Detailed provisions concerning the reporting requirement will thus be elaborated in subordinate regulations.

Under these provisions, notifiable matters subject to a mandatory reporting requirement include both the manufacture and placing on the market of nanoparticulate substances, and the use of nanoparticulate substances.

In September 2007 the Canadian Ministry of the Environment and Ministry of Health published a proposal for a regulatory framework for nanomaterials.[131] This proposal envisages a mandatory survey of all firms and institutions that produced or imported more than one kilogramme of nanomaterials to collect data on nanomaterials. However, precise details of the design of this survey have not yet been published.[132]

[130] The complete text relating to the proposed amendments can be found in Article 76 of the amending act, accessible at: http://www.developpement-durable.gouv.fr/IMG/pdf/Texte_du_PJL_GE_2_cle21193f.pdf (accessed 3.9.2009).

[131] Proposed Regulatory Framework for Nanomaterials under the Canadian Environmental Protection Act, 1999, see ministry website at: http://www.ec.gc.ca/substances/nsb/eng/nanoproposition_e.shtml (accessed 3.9.2009).

[132] See report by Marc McAree (August 2009) at: http://www.canadianlawyermag.com/Nanotechnology.html (accessed 3.9.2009).

8 Requirements concerning content of legislation on a product register and mandatory reporting scheme

The following sections set out key material and format requirements for fleshing out a mandatory reporting obligation and a nanoproduct register at national level.[133]

8.1 Scope

In this section we describe circumstances that would trigger the mandatory reporting requirement for nanomaterials and nanoproducts with a view to establishing a nanoproduct register.

To ensure that nanoproducts can be more or less completely monitored, it is recommended that a reporting requirement should apply not only to finished products containing nanomaterials, but also to the manufacture of the nanomaterials themselves, in mixtures and to semi-finished products containing nanomaterials, and which are produced or placed on the market in Germany.

Mandatory reporting should be linked to the following circumstances:

- the manufacture, importation or placing on the market of nanomaterials themselves or in mixtures, within the area covered by the regulation
- the production or placing on the market of semi-finished and finished products containing nanomaterials, within the area covered by the regulation, and importation of such products into the area covered by the regulation.

As a general principle the manufacturer, producer, formulator, importer or distributor must report when he, for the first time:

- manufactures, imports or places on the market nanomaterials on their own or in mixtures, and
- manufactures, places on the market or imports semi-finished and finished products containing nanomaterials.

It is also to be anticipated that transitional provisions in the form of deadlines will apply with regard to reporting for nanomaterials and nanoproducts already on the market at the time the mandatory reporting scheme comes into force.

8.1.1 Exclusions from the scope of the provisions

Although it is understood that these provisions should cover the widest possible range of nanoproducts, it should be noted that some substances and products will have to be excluded from the scope of the mandatory reporting scheme on legal grounds. Consideration should be given, for example, to the fact that the EU has already passed – or is increasingly beginning to introduce – legislation on the labelling of nanomaterials in products or on the reporting requirements of manufacturers vis-à-vis the Community. The question that arises in such cases is whether existing EU provisions are exhaustive, which would mean that a national mandatory reporting scheme and product register in these areas cannot be

[133] Cf. Background paper on options for a nanoproduct register at EU level: “Building blocks for an EU-wide reporting mechanism on nanomaterials”, Milieu/RPA 2009, p. 10 ff.

introduced. Examination of this sort needs to be carried out for example in the case of products covered by the Cosmetics Regulation, the Novel Food Regulation and the Regulation on Additives.[134] Checking will also be needed, however, in the case of:

- medicinal or veterinary products as defined by Directive 2001/83/EC and Directive 2001/82/EC and
- medical products and devices as defined by Directive 90/385/EEC and Directive 93/42/EEC which are invasive or used in direct physical contact with the human body, or as defined by Directive 98/79/EC.

Irrespective of the outcome of prior checking, semi-finished products, mixtures and consumer products in which nanomaterials that were not deliberately engineered are present as impurities, should not be subject to the mandatory reporting requirement. This cannot in fact be ruled out and so virtually all products would be subject to the reporting requirement.

Last, nanomaterials manufactured or imported exclusively for the purposes of product or process research and which have not yet reached an advanced stage of development should also be excluded from the scope of the provisions. It would be very difficult and inappropriate to impose a mandatory reporting requirement at an early stage of research and development. On the other hand, however, in the case of nanomaterials that are about to be placed on the market, it is helpful even at this advanced stage of development to know about the uses for which these nanomaterials are intended.[135]

8.1.2 Phased introduction of mandatory reporting

Consideration should be given to introducing mandatory reporting in stages. This could, for example, be done so that the first phase would require reporting by manufacturers and importers that produce or place on the market nanomaterials as raw materials. The next stage would include producers of semi-finished products and modified nanomaterials, formulators and importers, while a final phase would include producers and importers of finished products. If initial reporting is conducted in a structured and systematic manner right down the production chain beginning with starting materials, it will be easier to communicate the presence of nanomaterials down the supply chain. Manufacturers of finished products who are unaware that the semi-finished products or mixtures used by them contain nanomaterials, can obtain information from informed suppliers. Staged introduction of mandatory reporting will not of course deliver the desired effect of simplifying the passing on of information through the manufacturing chain in every case, because in a phased process reporting deadlines are liable to change due to dynamic economic processes (emergence of new products, cessation or modification of production, changes in ownership of manufacturers or importers). Reporting deadlines can also change, however, where mandatory reporting is introduced simultaneously for all parties concerned.

For the competent authority, phased introduction of mandatory reporting could help to ensure that the processing workload is evenly spread, thus helping to prevent overload.

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[134] An initial examination was carried out on the Cosmetics Regulation and the Novel Food Regulation as part of the present feasibility study. See Section 11 of this study.

[135] Cf. Conclusion 10 in: OECD 2009, p. 19.

8.2 Definitions

To introduce a register of nanoproducts and a related obligation to provide information on nanoproducts, the scope of the objects to which the mandatory reporting requirement refers needs to be defined as clearly as possible for reasons of legal certainty. These objects include:

- Nanomaterials as defined in the product register,[136]
- Mixtures as defined in Article 3 (2) of REACH, which contain nanomaterials, and
- Semi-finished and finished products as defined in the product register.[137]

This section sets out recommendations for definitions of some of the key terms used in connection with a nanoproduct register, including "nanomaterial", "nanoproduct", "manufacturer", "importer", "distributor", and "placing on the market". In order to avoid creating contradictions and duplicate provisions, these are based as far as possible on existing definitions, notably those already in place throughout Europe. However, it must also be borne in mind that definitions should always be viewed on the context of the provisions in question and cannot therefore simply be adopted as they stand for the purposes of a nanoproduct register.

8.2.1 Definition of "nanomaterial" for the purposes of the nanoproduct register

Defining a nanomaterial on the basis of the nano size range does not in itself provide more than a description of the scale of the material. Information on scale is often used, however, as a rather imprecise way of designating size relationships. The reason why substances are defined on the basis of size is because nanoscience has established that the properties of a substance can change in the nanoscale due to surface-volume relationships. However, defining particular substances according to their size does not enable conclusions to be drawn regarding the toxicological properties of the substance.

A wide variety of definitions of nanomaterials can be found at both international and national level, put forward by actors such as standardisation bodies, scientific institutions, ministries and authorities, or by environmental organisations. An overview of the various definitions suggested can be found in the annex to this study (see Section 13).[138]

At the EU level the only legally binding definition of nanomaterials currently in existence is that in the Cosmetics Regulation, which applies directly in Germany. Under Article 2 (1) (k) of the Cosmetics Regulation a "'nanomaterial' means 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".[139]

Other legally binding definitions may follow, for example in the Novel Food Regulation, for which the European Parliament has proposed the following definition of "engineered nanomaterials": "any intentionally produced material that has one or more dimensions of the order of 100 nm or less or 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,

[136] See proposed definition in Section 8.2.3.
[137] See proposed definition in Section 8.2.4.
[138] Compiled by Dr Rolf Hertel, Federal Institute for Risk Assessment (BfR).
[139] This definition was devised by higher federal authorities at a workshop for public administrators on 24.09.2009.

including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale.

Properties that are characteristic of the nanoscale include:

- "Properties related to the large specific surface area of the materials considered and/or
- specific physico-chemical properties that are different from those of the non-nanoform of the same material."[140]

There are no legally binding definitions of nanomaterials in the EU or in Germany other than these.

As demonstrated by the proposed definitions for the Novel Food Regulation and the definition in the Cosmetics Regulation, nanomaterials are defined differently in different areas of legislation. Since information on the nanosize range is not in itself sufficient for characterising a material, definitions commonly include references to various material properties. The Cosmetics Regulation for example excludes soluble nanomaterials. However, while nanoscale particles lose their specific nano-properties in dissolution, the case of nanomaterials is not so straightforward. For this reason, the definition of "nanomaterial" – like the definition of "substance" in REACH – should make no reference to properties of substances.

In the field of standardisation, a working definition of a technical standard for defining nano-objects, a sub-group of nanomaterials, in the form of the ISO Technical Specification ISO/TS 27687:2008, "Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate" has been in existence since August 2008. This was produced by the Technical Committee ISO/TC 229 on Nanotechnologies and contains a hierarchical system of definitions. At the core of this Technical Specification is the general concept of the "nano-object". This is defined as a material that has one, two or three external dimensions in the nanoscale. According to ISO/TS 27687:2008, "nanoscale" is defined as the size range from approximately 1 to 100 nanometres.

Also currently in preparation by the Technical Committee ISO/TC 229 on Nanotechnologies is a Technical Specification entitled "Nanotechnologies – Terminology and definitions for nanostructured materials", working paper ISO TS 80004-5. The aim of this document is to provide a set of clear definitions on nanostructured materials. Relevant concepts are arranged in categories and subcategories, and examples illustrating these are included in an annex. In relation to these categories, the current version of the working paper lists and defines the following six terms: nanostructured powder, nanocomposite, nanodispersion nanoporous material, surface structured nanomaterial and nanostructured core-shell particle.

As under the previous ISO/TS 27687:2008, nanoscale is defined as the size range from approximately 1 to 100 nanometres.

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[140] Cf. Article 3 (2) (cc) of the European Parliament legislative resolution of 25 March 2009 on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No .../2009 [common procedure] (COM(2007)0872 – C6-0027/2008 – 2008/0002(COD)). The European Parliament also suggests reviewing the terminology to bring it into line with technological and scientific developments. See: "2a. In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (f) of paragraph 2 to technical and scientific progress and with definitions subsequently agreed at international level."

In a statement published on 29.11.2007, the EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) defines ("engineered nanomaterial") as

"any material that is deliberately created such that it is composed of discrete functional parts, either internally or at the surface, many of which will have one or more dimensions in the order of 100 nm or less."[141]

In another statement published on 19.01.2009, SCENIHR recommends adding to the previous definition based on size a qualifier relating to the specific surface area-mass relationship: "In addition to the size definitions above, add as a qualifier for biological responses a specific surface area of more than 60m²/g."[142]

8.2.2 Proposed definitions of nanomaterial for the purposes of the product register

The proposal for a definition developed in the context of the present feasibility study does not purport to be a universally valid definition of nanomaterials, but rather should be understood as a legally enforceable description of the object regulated. However, the proposed definition should also be as compatible as possible with existing definitions and proposed definitions, and with the scientific debate on these. Defining the object of regulation is ultimately also a political decision and any attempt to address it based on the precautionary principle must not only ensure the broadest possible coverage of nanoproducts but also take in to account the corresponding expense and effort for businesses and responsible authorities (e.g. in an impact assessment of the legislative provisions).

With these considerations in mind, three proposals for a definition were developed in the course of this feasibility study,[143] drawing on current debate and proposals for definitions from national and international bodies, with the aim of making them workable for the purposes of a potential nanoproduct register:

Proposal 1: "Within the meaning of the product register 'nanomaterials' shall refer to deliberately engineered materials composed of discrete functional parts which have at least one dimension between 0.5 nm and 500 nm."

Proposal 2: "Within the meaning of the product register 'nanomaterials' shall refer to deliberately engineered materials which have at least one dimension between 0.5 nm and 200 nm (primary nanoparticle), and agglomerates and aggregates derived from such materials."

Proposal 3: "Within the meaning of the product register 'nanomaterials' shall refer to deliberately engineered materials which have at least one dimension between 0.5 nm and 100 nm, and which belong to one of the substances or groups of substances listed in Annex X."

8.2.3 Discussion of proposed definitions

As a basic principle, it is regarded as appropriate to focus on a relevant spectrum of nanomaterials. If the spectrum is set too broadly, the consequence could be that we would

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[141] In German: "synthetisches nanomaterial", defined as "einen Stoff, der zielgerichtet erzeugt wurde und aus abgrenzbaren strukturellen Bestandteilen besteht, entweder im Inneren oder an der Oberfläche, von denen viele eine oder mehrere Dimensionen von ungefähr 100 nm oder weniger aufweisen".

[142] In German: "Ergänzung zu den größenbezogenen Begriffsdefinitionen sollte als zusätzliches Abfragekriterium für biologische Reaktionen eine spezifische Oberfläche von mehr als 60m²/g hinzugefügt werden."

[143] The proposals also took into account the results of a stakeholder workshop moderated by the authors of this study, which took place on 14 January 2010 in Berlin.

have a very large number of products subject to mandatory reporting, thereby distracting attention from those nanomaterials that pose a potential risk to the legally protected interest.

Bearing this in mind, all of the definitions proposed here envisage defining a lower limit for the primary nanoparticle, as otherwise individual atoms and molecules would also be covered. A lower limit of 0.5 nm was chosen, based on the minimum hitherto used, "in the order of 1 nm", but making it more precise and legally manageable.[144] It is necessary to expand the spectrum to include sizes below 1.0 nm because some nanomaterials that are relevant for a nanoproduct register fall within this size range. The diameter of a C60 fullerene, for example, is 0.7 nm.

By stipulating the characteristic "deliberately engineered", the aim is to exclude naturally occurring nanomaterials (e.g. casein micelles in foods, or dust pollution as contamination) in a product from the scope of the definition. The definition only covers nanomaterials intentionally produced ("engineered") by humans.

It was decided not to limit the definition of nanomaterials to particular aggregation states in which nanomaterials would have to be present, such as "dissolved" or "solid". The proposed definitions therefore encompass nanomaterials (particles, colloids, etc.) in all aggregation states and forms.

The definitions proposed cover not only primary nanoparticles but also agglomerates and aggregates "derived from" those primary nanoparticles. This can be achieved on the one hand (as in Proposal 1) by including agglomerates and aggregates within the term "discrete functional parts" and by deliberately not setting an upper size limit for agglomerates and aggregates, since agglomerates particularly are not very stable. On the other hand, it is also possible (as in Proposal 2) to include agglomerates and aggregates explicitly.

Choosing 500 nm as the upper limit in Proposal 1 does not conflict with the commonly used upper limit of 100 nm, since the definitions refer to a size "in the order of" 100 nm. The fact that nano-specific toxicological effects can also occur in the case of nanomaterials present in a dimension between 100 nm and 300 nm must also be taken into account here. On the other hand, because the term "in the order of" is difficult to define with any clarity, and may be interpreted in different ways, it is not precise enough to provide a clear definition in a legal context. For this reason, in order to provide a clear definition of the object to which the provision refers, a limit of 500 nm was chosen in Proposal 1. This limit takes into account the aforementioned nano-specific toxicological effects above 100 nm, and also includes a safety margin as a precautionary measure. This safety margin is an arbitrary one in the sense that it could have been set higher or lower. While the safety margin is set relatively high in Proposal 1, the upper limit in Proposal 2 has been set at 200 nm in line with the principle of focussing discussed at the start of this section.

In view of the prevailing lack of precision concerning the upper limit of the spectrum to be covered, it is nevertheless clear that size range is merely a more or less useful means of defining the object to which the provision refers. Hence, when introducing a product register it would be useful to review which substances and substance groups should be explicitly included or excluded. A key factor for determining this would be whether a substance can cause nano-specific toxicological effects. This is taken into account in Proposal 3. As regards the precise specifications of Annex X, the legal interpretation of the precautionary principle

[144] Based on the mathematical concept of precision and rules relating to rounding, the validity of the numerical value of 1 with one significant figure begins with the number 0.5. See Bronstein, I.N.; Taschenbuch der Mathematik; Stuttgart / Leipzig 1991.

needs to be borne in mind, namely that causality does not necessarily have to be proven; it is sufficient if there are indications of potential risk. It is questionable, however, whether a manageable and robust list of relevant substances and groups of substances can be drawn up at the present time in view of the prevailing gaps in knowledge relating to toxicological assessment of nanomaterials. Moreover, new materials are constantly being brought onto the market without adequate test data or evidence. These would not be covered by the proposed definitions, and retrospectively it would also be difficult to integrate these products or to trace them.

At present, in a situation fraught with difficulties, Proposal 2 seems to be the definition best suited for the purpose of setting the scope of a product register. Given that methods of measuring particle size have still to be standardised, it should be noted that there is no reliable, generally accepted and hence legally enforceable measurement method available at present. In the meantime, the BET method,[145] a method of analysis for determining specific surface area based on gas adsorption, is recommended for particle size characterisation. As has already been suggested by various actors,[146] the threshold should be set at a specific surface area of 6 x 1/100 nm.[147]

8.2.4 Definition of "nanoproduct" for the purposes of a nanoproduct register

EU-wide definitions introduced through REACH and those set out in the German Equipment and Product Safety Act (*Geräte- und Produktsicherheitsgesetz* - GPSG) and the EU General Product Safety Directive can be drawn upon to define the term "nanoproduct".

In line with the object to be covered by the provisions on reporting and product registration, the term "nanoproduct" must be defined for:

- nanomaterials,
- mixtures containing nanomaterials, and
- semi-finished and finished products containing nanomaterials.

The definition of "nanomaterials" is based on the definition chosen from the proposals in Section 8.2.3 above.

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".

By adopting definitions from REACH we are making use of provisions already introduced and binding throughout Europe, and which are also familiar to the addressees of the legislation in the context of exports and imports into the EU.

The same applies to defining "semi-finished and finished products containing nanomaterials". For this we have made use of the concept of "article" set out in Article 3 (3) of REACH. Under REACH, "article" covers both finished and semi-finished products, although this could make it difficult to distinguish clearly between substance, mixture and article.[148] In accordance with Article 3 (3) of REACH, for the purposes of REACH, "article" means "an object which during

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[145] BET is an acronym formed from the surnames of the developers of the BET model, Stephen Brunauer, Paul Hugh Emmett and Edward Teller.

[146] Cf. SCENIHR Report "Risk Assessment of Products of Nanotechnologies", 19.01.2009, and the German Chemical Industry Federation (VCI) "Positionspapier zur Definition von Nanomaterialien", 3.02.2010.

[147] This refers to the specific surface area of 60 m²/g of a particle with an ideal spherical surface and a density of 1 g/cm³.

[148] Cf. Section 3.3 ff. and Appendix 3 of the European Chemicals Agency (ECHA) document "Guidance on requirements for substances in articles", May 2008.

production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition."

It would also be conceivable to adopt a definition of "finished product" in line with the term "product", already used throughout Europe. In accordance with Article 2 (a) of Directive 2001/95/EC on general product safety, "product" means "any product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned." Reference might also be made here to the definition of a "consumer product" in Article 2 (3) of the German Equipment and Product Safety Act (GPSG), which uses the same wording.

However, both of these definitions – in the EU Directive on general product safety and the GPSG – restrict the meaning of "products" covered by the legislation to "consumer products". Using this definition would bring only some products containing nanomaterials within the scope of the legislation. It would not cover semi-finished products, products used exclusively in industrial production, or products intended for professional use, e.g. by hairdressers. Moreover, limiting the definition to consumer products does not fit the chosen purpose of the product register, namely to prevent the emergence of hazards to the life and health of people, including in their workplace (occupational safety), and to the environment (environmental protection) (see Section 4). By focussing on consumer products, only nanoproducts with which consumers can come into direct contact would be covered by the legislation (consumer protection). All other products that are not consumer products, e.g. medicinal products, semi-finished products or technical work equipment, would not be covered.

In the light of these considerations, we propose the following definition of the term "nanoproduct" for the purposes of the nanoproduct register:

"For the purposes of the product register, "nanoproducts" shall mean:

- nanomaterials within the meaning of the product register,
- mixtures as defined in Article 3 (2) REACH, which contain nanomaterials, and
- articles as defined in Article 3 (3) REACH, which contain nanomaterials within the meaning of the product register, irrespective of the concentration of the nanomaterial present in the article."

8.3 Addressees of the mandatory reporting requirement

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. As the aim of reporting is to cover as comprehensively as possible all nanomaterials that are produced or placed on the market in Germany, the mandatory reporting requirement must apply to "manufacturers" and "importers", producing or placing a nanoproduct on the market. "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 Germany; import shall also be deemed to be placing on the market.[149]

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

The following definitions are proposed for the addressees of the legislation:

- "Manufacturer": means any natural or legal person established within Germany who manufactures a nanoproduct as defined in the nanoproduct register, or has such a product designed or manufactured under his name or trademark."[150]
- "Importer": means any natural or legal person established within Germany who imports a nanoproduct as defined in the nanoproduct register into Germany."[151] Import shall mean the physical introduction into the customs territory of Germany.[152]

8.4 Information to be reported

The content and scope of the information submitted must enable the competent authority to gain an overview of nanoproducts manufactured or available of the market in Germany. To achieve this, the authority must be able to identify the nanoproduct, and the manufacturer or importer. In addition, the information contained in the report must enable the authority to ensure a high level of protection of human health, including in the workplace, and of the environment. To protect human health, including in the workplace, and the environment, the authority must therefore be able to take appropriate risk management measures, where necessary, such as informing the manufacturer of a nanoproduct of any "anomalies" or "adverse effects" that occur in relation to his product, or providing information or warnings to the public. In addition, the authority must be able to assess potential environmental hazards arising from the manufacture, use or disposal of nanoproducts. To fulfil these objectives, the authority responsible for reporting must at least have information enabling clear identification of a nanoproduct, its manufacturer or importer and information on the amount of a given nanoproduct on the market.

As regards mandatory reporting, a distinction needs to be drawn between the placing on the market of nanomaterials and the placing on the market of mixtures and articles that contain nanomaterials. For the purposes of environmental protection and protection of health, the reporting authority needs to have a precise specification of the nanomaterial. However, the passing on of information on the precise specification of a nanomaterial through the supply chain is the subject of concerns relating to protection of trade secrets and confidential business information of the manufacturer or importer of a nanomaterial. To meet these concerns, when a manufacturer or importer first places a nanomaterial on the market, the reporting authority could issue him with a reference number for the nanomaterial placed on the market and only this number would be passed on to downstream users As far as the manufacturer of an article is concerned, only the fact that a product contains nanomaterials is relevant in terms of the objectives of the nanoproduct register, not its precise specification.

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[150] Cf. the corresponding definition of "manufacturer" in Article 2 (1) (d) of the Cosmetics Regulation: "Manufacturer shall mean any natural or legal person established within the Community, who manufactures a cosmetic product, or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark". See also the definition in Article 3 (9) REACH: "Manufacturer: means any natural or legal person person established within the Community, who manufactures a substance within the Community."

[151] Cf. Article 2 (1) (i) of the Cosmetics Regulation: "Importer shall mean any natural or legal person established within the Community, who places a cosmetic product from a third country on the Community market."

[152] Cf. Article 3 (10) REACH: "Import: means the physical introduction into the customs territory of the Community."

Consequently, mandatory reporting to the competent authority by manufacturers and importers first manufacturing or placing on the market nanomaterials within the meaning of the product register should include the following information:

- the name and address of the manufacturer or importer,
- the product name and trade name of the nanomaterial,
- the country of origin, in the case of an imported nanomaterial,
- the specification of the nanomaterial, including particle size and particle size distribution, physical and chemical properties, external form and, where appropriate, any modification(s) made to its surface chemistry (coatings[153]),
- the registration number of the nanomaterial in accordance with REACH and
- an estimate of the quantity of the nanomaterial to be manufactured in or imported into Germany per manufacturer or importer per year.

In addition, the manufacturer or importer shall supply downstream users with the reference number of the nanomaterial in accordance with the nanoproduct register.

Mandatory reporting by manufacturers and importers first manufacturing or placing on the market mixtures or articles containing one or more nanomaterials should include the following information:

- the name and address of the manufacturer or importer,
- the product name and trade name enabling clear identification of the specific article or mixture, and the product category,
- the country of origin, in the case of an imported article or mixture,
- the specification of the nanomaterial(s) used, in accordance with the product register,
- the registration number of the nanomaterial in accordance with REACH and
- an estimate of the quantity of the nanomaterial(s) in the article or mixture to be placed on the market in Germany per year.

In both cases it is also proposed that manufacturers appoint a person to be responsible for dealing with all matters concerning the authority; where a nanoproduct presents a risk to human health, the responsible person shall have an obligation to make available to the authority immediately any further information necessary.[154]

8.5 Exemptions from the mandatory reporting requirement

In order to obtain an overview of the market as regards nanomaterials manufactured or used in mixtures and articles in Germany, any nanomaterial as defined in Proposal 2 above for the purposes of legislation on mandatory reporting requirements, and any mixture or article manufactured or placed on the market in Germany which contains at least one type of nanomaterial, would in principle be subject to the mandatory reporting requirement. It may nevertheless be necessary to allow exemptions for reasons of proportionality or expediency.

[153] Coatings (i.e. deliberate modification of a nanomatieral's surface chemistry) have a major impact on the functional, and in some cases also toxicological, properties of nanomaterials. Working Group 2 of the German Government's NanoDialogue 2006-2008 therfore concluded that coatings constituted one of the "minimum nanomaterial characteristics needed" for comparison purposes (see http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanodialog08_ergebnisse_ag2.pdf).

[154] Cf. also "Obligations of responsible persons" as set out in Article 5 of the Cosmetics Regulation.

It is beyond the scope of the present feasibility study, however, to undertake a detailed examination of whether inclusion of particular product groups or nanomaterials is proportionate, and in any case this would need to be assessed on a case-by-case basis.

General grounds for exemption from the mandatory reporting requirement should be included in legislation on a nanoproduct register for cases where:

- a product or a mixture containing nanomaterials is already subject to a mandatory notification requirement under another law in force in Germany. Of relevance here is notification in accordance with the Cosmetics Regulation (see Section 5.3 above). Avoiding duplication of the notification requirement would limit the effort and expense involved for businesses to meet their reporting obligations. This assumes, however, that the information to be submitted in accordance with notification requirements laid down in other legislation correspond to the requirements of the nanoproduct register concerning content, and that this information is accessible to the competent authority in Germany;
- a nanomaterial has already been registered as a non-phase-in substance in accordance with REACH. Since a nanomaterial cannot be placed on the market unless the required material data have been collected and submitted as part of the registration process, the disadvantages discussed in Section 5.1 with regard to REACH are not relevant here. In contrast to phase-in substances, there are no transitional deadlines for registration;
- a nanomaterial has an internal structure made of homogeneous material which is closed to the outside. In contrast to a nanostructured surface, in the case of a sealed internal structure there is little risk of transporting impurities into an organism, or of reactions or interactions with its surroundings. Hence, nanostructured insulation materials with closed-cell morphology[155] and internal nanostructured surface, for example, could be exempted from the mandatory reporting requirement;
- where the object in question is an integrated electronic circuit based on classical semiconductor technology, but which has an internal structure at the nanoscale made from a homogenous material that is not expected to interact with its surroundings.

In addition, the German Federal Ministry of Defence could be granted exemptions from the mandatory reporting requirement for nanomaterials and nanoproducts. Such exemptions should only be possible, however, where there are compelling defence grounds or exemption is necessary for compliance with intergovernmental commitments.

Regulations on general grounds for exemption should be listed in an annex to the legislation on the mandatory reporting requirement. This would enable the executive to review the rules on exemption on a regular basis and update them in line with scientific findings.

In order to ensure that the content of the register is accurate and up to date, provision should also be made to require manufacturers and importers to renew their registration at regular intervals after their first registration. This could be achieved by requiring manufacturers and importers to verify every three years that the data held by the reporting authority are correct and where appropriate notify the authority of any modification(s).

[155] Closed-cell morphology means that the surface of a product has no open (nanoscale) pores that can interact with organisms or with the environment.

8.6 Obligations relating to testing and evidence

Legislation on a nanoproduct register and mandatory reporting requirement must also include provisions on obligations concerning testing and provision of evidence to assist the competent authority in ensuring that the legislation is properly enforced. This relates particularly to the question of whether a notified nanomaterial or nanoproduct complies with the definition in the legislation on the mandatory reporting requirement. It must also be possible to identify, by means of inspections, nanomaterials and nanoproducts that are subject to the mandatory reporting requirement but have not been notified to the authority.

Official inspection to assess whether the reporting requirement has been fulfilled and whether the information submitted is correct would have little prospect of success if based on measurement of the finished product by the supervisory authorities in the *Länder*. The complexity of the test item (which nanomaterials would one look for?), the lack of reference material for testing and detection of nanomaterials and the costs of carrying out measurement would make it very difficult to carry out an inspection on a point-by-point basis. In this regard the proposed introduction of mandatory reporting in a staged process (see Section 8.1) could also have significant advantages in terms of surveillance. For example, based on the information provided by the manufacturer of the nanomaterial (notably as regards recommended uses), potential users of nanomaterials subject to mandatory reporting can be approached directly. For this reason we recommend placing greater emphasis on a combination of the information already supplied by manufacturers than on specific methods of testing and detection based on measurement.

8.7 Sanctions for infringements of the mandatory reporting requirement

Effective enforcement of the mandatory reporting requirement necessitates imposing sanctions for non-compliance. It follows, then, that circumstances constituting infringements need to be defined. In the case of non-compliance, the infringement would apply to the addressees of the mandatory reporting requirement as defined above (see Section 8.3).

Circumstances constituting infringements should include notably:

- Failure to notify the competent authority of a nanomaterial on its own, or a mixture, semi-finished or finished product containing a nanomaterial, which is manufactured or placed on the market in Germany, or
- Failure to provide information in accordance with the reporting requirement, or provision of information that is incorrect, incomplete or late.

The amount of financial penalties for infringements should be graduated according to the gravity of the misdeed in terms of compliance with the mandatory reporting requirement; they must be proportionate and deterrent.

8.8 Publication of information from the register

We now turn our attention briefly to the question of whether information from the nanoproduct register can or should be published, and if so, how this should take place. This question

arises in connection with the protection of trade secrets and confidential business information and also in connection with public risk perception.[156] Various gradations are conceivable for communicating information:

- a public register in which all the information provided is publicly accessible,
- a public register in which only certain information is publicly accessible, or
- a register which is only accessible to the authority responsible for maintaining the register, but which produces a publicly accessible report on nanomaterials in mixtures and articles on a regular basis (e.g. annually).

As a rule, irrespective of the form chosen for communicating information from the register, the mandatory reporting requirement is contrary to the protection of business interests in the following cases:[157]

- details of the complete composition of a nanoproduct or a mixture within the meaning of REACH,
- the precise use, function or application of a nanomaterial or mixture containing nanomaterials,
- the precise quantity in which the nanomaterial, the mixture containing nanomaterials, or the nanoproduct is manufactured or placed on the market and
- relationships between a manufacturer or importer of nanoproducts or nanomaterials and other actors in the manufacturing chain, such as manufacturers of semi-finished products or mixtures.

As long as only neutral and expert product information on the registered nanomaterials and nanoproducts is made available to the public, e.g. in an internet listing or public report, this is perfectly lawful and does not constitute interference with entrepreneurial freedom.[158] On the other hand, a statutory basis for authorisation is required where information is intended for use in the form, for example, of transparency lists giving so-called quality assurance labelling, as this is deemed to constitute an interference in the occupational freedom of entrepreneurs under Article 12 (1) of the Basic Law for the Federal Republic of Germany (GG) (judgement of the Federal Administrative Court on transparency lists for medicines (BVerwGE 71, 183 Arzneimittel-Transparenzlisten).

[156] Cf. the findings regarding public risk perception concerning nanotechnologies, in BfR 2008, p. 73.
[157] Cf. also Article 118 (2) REACH.
[158] Breuer, 2005, Section 5, paragraph 84.; Lübbe-Wolff, NJW 1987, 2710 ff.; Leidinger DÖV 1993, 930.

9 Institutional framework for a nanoproduct register

In this section we explore the question of which authority or authorities should be assigned responsibility for keeping a nanoproduct register. The question of whether an expert body should be established to support the work of the designated authority or authorities is also addressed.

From the point of view of creating reporting procedure that is efficient and lean, the body receiving notifications and keeping the register should be a high-ranking institution at federal level. There are several institutions in Germany that could be considered for this role, including the Federal Institute for Risk Assessment (BfR), the Federal Institute for Occupational Safety and Health (BAuA) and the Federal Environment Agency:

9.1 Federal Institute for Risk Assessment (BfR)

The Federal Institute for Risk Assessment (BfR) is a public agency of the German federal government with full legal capacity.[159] Reporting to the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV), it advises the ministry on scientific matters concerning food safety, product safety, chemical safety and consumer protection. Some areas of the Institute's activities also fall under the authority of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) and the Federal Ministry of Transport, Building and Urban Development (BMVBS).

The BfR is thus responsible for a wide range of consumer-oriented products such as detergents and cleaning agents, cosmetics, foods, textiles and toys, biocidal products and plant protection products. Nanomaterials are already being used in some of these products. The BfR has the job of analysing and assessing health risks posed by these products and of detecting any new risks. Another of its responsibilities is to develop options for risk reduction measures and recommendations for communicating risks. As an assessment agency, the BfR also has the task of assessing the impact of chemicals on human health. Since the BfR exercises its scientific assessment and research responsibilities independently (Article 2 (2) of the statutes of the BfR (BfRG)), it acts at the interface between politics and consumer protection, conducting its assessment work and making recommendations largely free from the influence of economic, political and social interests.

Locating the nanoproduct register within the BfR would generate synergies in many of the fields outlined above:

- the nanoproduct register would support the existing competence of the BfR in the identification of health risks from consumer-oriented products, and in its assessment and detection of new risks, especially concerning nanomaterials in products. It would also facilitate early detection by the BfR of any problematic applications of nanomaterials or any worrying developments.
- the nanoproduct register would enable the BfR to target its efforts more effectively as regards developing courses of action for risk reduction and recommendations for communicating risks. Finished products and groups of products containing

[159] Act establishing the Federal Institute for Risk Assessment (BfRG) of 6 August 2002, BGBl. I p. 3082, as amended by Article 15 (55) of the Act of 5 February 2009, BGBl. I p. 160.

nanomaterials that pose a significant potential risk could be identified more easily based on knowledge of their starting materials and intermediate products. This would also facilitate the development of options for reducing risk for the whole product group. In terms of communicating risks, the BfR would be able to provide more accurate information on whether adverse effects associate with a product are due to the nanomaterial used or to other ingredients in the product.

- Assessments should be transparent and accessible to the general public, the scientific community and other stakeholders or interested parties. While maintaining the confidentiality of legally protected data, the findings of assessments will be made publicly available. The BfR also has the responsibility of providing scientific advice to the federal ministries involved and to the Federal Office for Consumer Protection and Food Safety.
- Last, the BfR could produce regular reports, e.g. for the Bundestag and the public, setting out its opinion on the use of nanomaterials in products. The BfR is politically independent and serves as source of scientific reference and guidance for consumers, policymakers, for the economy and the media, and for the voluntary sector and scientific community. Regular reporting on the nanoproducts on the German market would enhance transparency on the use of nanomaterials in consumer products and help provide a scientifically nuanced picture of safe and potentially risky uses of nanomaterials.

The scope of the BfR's activities does not, however, cover all areas the nanoproduct register is intended to protect. It is responsible for assessing health-related, but environmental protection and occupational safety are outside its remit. For this reason, cooperation with other federal authorities, notably the Federal Institute for Occupational Safety and Health and the Federal Environment Agency is recommended.

Cooperation among the three authorities – particularly as regards common positions on the assessment of nanoproducts, allocation of responsibilities and information exchange – should be regulated by law (cf. provisions on responsibilities and cooperation among competent authorities for REACH in Germany, in Article 1 (4) of the Act implementing REACH[160]).

9.2 Federal Institute for Occupational Safety and Health (BAuA)

The Federal Institute for Occupational Safety and Health is a specialised federal research institution that advises the Federal Ministry of Labour and Social Affairs on all matters relating to safety and health. According to the new version of the decree establishing BAuA issued on 22.01.2009, one of the tasks of BAuA is to carry out and coordinate research and development aimed at enhancing health and safety at work and improving working conditions. In addition, the BAuA assesses scientific and practical developments in its area of responsibility and monitors the impact of working conditions on the health and safety of employees in industry and administration. The Institute also develops and tests recommendations for preventive approaches to occupational safety and health promotion in the workplace. Additional tasks of BAuA include ensuring that research findings and proposals are translated into practice in the workplace, notably by means of campaigns, publications and events aimed at enhancing the quality of working conditions in Germany.

[160] Act implementing Regulation (EC) No 1907/2008 of 20 May 2008; BGBl. I, p. 922-930.

Alongside its responsibilities in the field of occupational safety, BAuA also has a key statutory role in the context of implementing REACH as the competent federal authority for chemicals in accordance with Article 4 (1) (1) of the German Chemicals Act (*Chemikaliengesetz*, ChemG). The responsibilities assigned to BAuA under Article 5 of ChemG concerning REACH implementation include overarching tasks such as cooperating with the European Commission and EU Member States and providing information to the public in accordance with Article 123 of REACH. In its role as competent authority as defined in Article 123 REACH, the BAuA informs "the general public about the risks arising from substances where this his considered necessary for the protection of human health or the environment." To fulfil this aim, the ECHA, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice, shall provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in mixtures or in articles, with a view to coordinating Member States in these activities."

The responsibilities of the BAuA (notably the obligation to provide information under Article 123 of REACH) are in line with the key objectives of the nanoproduct register, namely to exercise precaution with regard to occupational safety and environmental protection, and precaution with regard to protecting the life and health of the population. In terms of the product register, the BAuA can cooperate with the assessment bodies (BfR and UBA) in a manner akin to its responsibilities under REACH, for example to fulfil its public information obligations in accordance with Article 6 (1), sentence 2 and Article 5 (2) point (5) of the ChemG. For example, the Federal Environment Agency holds special responsibility as an assessment body for assessing risks relating to the environment, including the assessment of risk reduction measures (Article 6 (2) and Article 4 (1) point (2) ChemG), while the BfR, as "assessment body for health and consumer protection" is responsible for health-related risk assessment, including the assessment of risk reduction measures (Article 6 (3) and Article 4 (1) point (3) ChemG). The BAuA can also use the information from the nanoproduct register on the use of nanomaterials to aid its risk assessment work in connection with occupational safety, and for assessment of risk reduction measures. Synergies and cross-fertilisation can take place between the task of keeping the nanoproduct register and the BAuA's existing tasks, not only in its capacity as competent federal authority for chemicals in accordance with REACH, but also for assessment of active biocidal substances, authorisation of biocidal products and notification of biocidal products in accordance with the German Ordinance on notification of biocidal products.

In terms of its legal mandate, the BAuA would be well suited to the task of keeping a nanoproduct register due to its role as competent federal authority for chemicals. However, assessment of risks specifically relating to the environment or to health would necessitate the involvement of the Federal Environment Agency and the BfR.

9.3 Federal Environment Agency (UBA)

In accordance with Article 2 of the Act establishing the Federal Environment Agency (UBA)[161] this body has task of providing scientific support to the Federal Environment Ministry, especially with the drafting of legislation and administrative rules in the field of air quality, waste and water management, soil protection and chemicals in the environment, and in

[161] Act establishing a Federal Environment Agency of 22 July 1974, BGBl. I p. 1505, as amended on 2.5.1996, BGBl. I p. 1416.

matters of health relating to environmental protection, inter alia. The UBA is also involved in enforcement of the German Acts on plant protection and on biocidal products, and in REACH.

The UBA, too, could be considered as an option for hosting a nanoproduct register because of its role and responsibilities with regard to environmental risk assessment including assessment of risk reduction measures for nanomaterials and nanoproducts. Like the BfR and the BAuA, however, the UBA would also only cover a segment of the tasks required – in this case those relating to environmental protection.

9.4 Expert body

In the light of the complex issues surrounding the registration of nanomaterials and nanoproducts in a product register, the question arises whether an expert body should be created to advise the authority in charge of keeping the register. This body could give an opinion on preliminary decisions, especially in disputes over the inclusion of a nanomaterial or nanoproduct in the register and on exemptions from mandatory reporting requirements, and it could play a role in the risk assessment of listed nanomaterials and nanoproducts. To carry out such tasks, this body would have to be very broad in terms of both composition and expertise. Knowledge relating to characterisation of nanomaterials and their human and eco-toxicological assessment would be particularly essential. Because the areas of expertise would vary widely depending on the questions being addressed at any given time, instead of having an expert body with a fixed set of members meeting at regular intervals, it would appear more sensible to consult existing expert bodies on specific issues or, if not available, to convoke an expert panel on an ad-hoc basis. In such cases, however, the problem of confidentiality of data would need to be addressed.

9.5 Conclusions

In terms of their mandate, all three of the institutions examined have areas of activity connected to a greater or lesser extent with the task of keeping a nanoproduct register, and in all three cases synergy effects could be generated with existing areas of activity. However, none of the three covers the protective purpose of the nanoproduct register in its entirety – namely precaution for the protection of employees, consumers and the environment. Assuming that the current remit of the three institutions remains unchanged, it would nevertheless be possible to assign the task of keeping the product register to one of these as lead institution and involve the other institutions by way of agreement or consultation. Cooperation among the three institutions, especially as regards adopting a common position on assessment of nanoproducts, allocation of responsibilities and information exchange would then need to be regulated.

Creating a special, regularly convening expert body is not regarded as appropriate due to the wide range of responsibilities and areas of expertise that such a body would need to cover. Instead, existing expert bodies should be called upon to address particular issues or, if this is not possible, ad-hoc expert bodies should be convened.

10 Basis for authority to introduce a mandatory reporting requirement and nanoproduct register

Concerning federal-level legislation to introduce a nanoproduct register and corresponding mandatory reporting requirement, in this section we examine whether the German Federation has legislative competence in this matter. We also address the question of whether new legislation is needed for a register and corresponding mandatory reporting requirement or whether these can be integrated into existing provisions.

10.1 Regulatory competence of the Federation

Here we examine whether the Federation has the legislative and administrative competence to enact separate legislation on a nanoproduct register and corresponding mandatory reporting requirement.

10.1.1 Legislative competence of the Federation

Under Article 70 (1) of the Basic Law for the Federal Republic of Germany (Basic Law, or GG),[162] the Federation only has legislative power where the Basic Law confers this power on it.[163] Consequently, the division of authority between the Federation and the *Länder* is based on rules and exceptions, whereby the Länder have the right to legislate unless the Basic Law confers legislative power on the Federation.[164] The legislative powers of the Federation may stem from the provisions of the Basic Law or from other competences (referred to as unwritten competences).

Legislating on a nanoproduct register and mandatory reporting requirement does not constitute a matter under exclusive legislative power of the Federation in accordance with Article 73 GG.

However, the Federation can justify its claim to legislative competence on the basis of the following points constituting matters under concurrent legislative powers in Article 74 GG:

Legislative competence of the Federation in matters concerning the reporting of medicines and medical products that are nanomaterials or contain nanomaterials is based on Article 74 (19) GG. Under this provision the Federation has concurrent legislative power with regard to medicines, medical products, drugs, narcotics and poisons. This encompasses all areas relating to the use of these substances, including their manufacture, sale or other means of distribution, and consumption.[165] The Act on medicinal products and parts of the Act on Chemicals are based on this competence.

Based on Article 74 (20) GG, the Federation can enact legislative measures concerning food, recreational products, essential commodities and feedstuffs, and measures connecting with the protection of plants against diseases and pests. While the term “food products” is clearly defined in the German Food and Feed Code (LFGB), defining “essential commodities”

[162] Basic Law for the Federal Republic of Germany (GG) of 23.05.1949, published in the Federal Law Gazette Part III, Gliederungsnummer 100-1, last amended by the Act of 29 July 2009 (BGBl. I p. 2248).
[163] Maunz, Article 70 paragraph 28.
[164] Pieroth, Article 70 paragraph 1.
[165] Maunz, Article 74 paragraph 219.

presents more difficulty due to its broad meaning in common usage. The definition in the LFGB lists particular items such as body care products, packaging, toys and joke articles. The list is not exhaustive, however.[166] For historical reasons relating to its origins, the Code does not include provisions on motor vehicles or buildings, for example.[167] To the extent that reporting relates to nanomaterials or nanoproducts that fall into the aforementioned categories, then, legislation on a mandatory reporting requirement may be based of Article 74 (20) GG.

Insofar as the mandatory reporting requirement is introduced as a precautionary measure to protect employees from potential risks arising from nanomaterials and nanoproducts, the Federation would have the power to legislate under Article 74 (11) GG. This also includes occupational safety as a public law provision aimed at protection of employees from hazards in the workplace.[168]

Since registration in the nanoproduct register and the corresponding mandatory reporting requirement apply to the manufacture, import or placing on the market of nanoproducts and nanomaterials, the Federation may act on the basis of its concurrent right to legislate on "law relating to economic matters" (Art. 74 (11) GG) in addition to the competences referred to above. The term "law relating to economic matters" is interpreted very broadly. It includes "all provisions regulating economic life and economic activity as such and which concern in any way the production, manufacture or distribution of essential economic goods".[169]

Inasmuch as the mandatory reporting requirement is intended as a precautionary measure to protect the environment, the Federation has the power to legislate on the basis of Article 74 (24), (29) and (32) GG. Under these provisions, the Federation has the concurrent right to legislate on waste disposal, air pollution control, protection of nature and management of water resources.

As regards legislating on infringements of provisions on a nanoproduct register, the Federation has the power to legislate on the basis of Article 74 (1) clause 1 (criminal law) GG. On the basis of Article 74 (1) 1 GG the scope of criminal law encompasses all provisions imposing penalty, fine or other punitive or preventive measure as a legal consequence of an illegal and culpable act. It therefore also encompasses law on infringements.[170]

Under Article 72 (2) GG, the Federation has legislative competence in matters falling within Article 74 (1) clauses 4, 7, 11, 13, 15, 19a, 20, 22, 25 and 26 only if and to the extent that the establishment of equivalent living conditions throughout the federal territory or the maintenance of legal or economic unity renders federal regulation necessary in the national interest.

The right of the Federation to exercise its concurrent legislative powers in the case of the nanoproduct register is based on the second alternative referred to in Article 72 (2) GG: enacting legislation on reporting of nanoproducts and nanomaterial serves "the maintenance of legal unity". The objective is to enact uniform legislative provisions on reporting of nanoproducts and nanomaterials and on their inclusion in the nanoproduct register, in order

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[166] Maunz, Article 74 paragraph 227.
[167] von Münch / Kunig, Article 74 paragraph 96.
[168] Maunz, Article 74 paragraph 163.
[169] Decisions of the Federal Consitutional Court: BVerfGE 8, 143/148 f.; BVerfGE 26, 246/254; BVerfGE 28, 19/330.
[170] Pieroth, Article 74 paragraph 4; Decision of the Federal Constitutional Court BVerfGE 109, p. 190 (213); 27, p. 18, (32 f.).

to ensure a high level of protection concerning the manufacture, utilisation and disposal of nanoproducts, thereby enhancing occupational safety and environmental and consumer protection throughout the Federal Republic. This would be in the national interest. If different provisions applied in the different *Länder* regarding which nanoproducts are subject to the reporting requirement, an individual worker or consumer could not be certain of enjoying the same level of protection in all *Länder* concerning the manufacture and utilisation of nanoproducts. Moreover, if provisions varied across the *Länder*, distortions of competition within Germany could result. For example, the *Länder* might enact differing provisions concerning information to be reported or exemptions. A federal-level law is needed because it ensures that those affected by the manufacture or use of nanoproducts in all of the *Länder* benefit equally from a high level of protection in the production and distribution of these products. It also ensures that businesses throughout the Federal Republic have to meet the same reporting requirements for placing nanoproducts on the market.

10.1.2 Administrative competence of the Federation

To the extent that the provisions envisaged for federal-level legislation on a mandatory reporting requirement for nanoproducts and a nanoproduct register are not only substantive provisions but also provisions for an administrative procedure,[171] the consent requirement set out in Article 83 ff. GG shall apply.

As a rule, federal laws are executed by the *Länder* in their own right (*Länder* have separate administration under Article 84 GG). On the basis of Article 84 (1) GG, federal laws require *Bundesrat* consent when they interfere with the organisation and procedures of Land authorities.

However, in line with the proposals for an institutional framework set out in Section 9, the product register and mandatory reporting requirement would not be implemented by a *Land* authority. This task should be assigned to high-level federal authorities accountable to the federal ministries, such as the BAuA and the UBA, which would operate as the central authority for the whole of the Federal Republic. It is therefore necessary to examine to what extent the Federation has its own administrative competence.

The introduction of a mandatory reporting requirement for nanoproducts does not fall into any of the categories mentioned in Article 87 (1) and (2) GG for which separate federal administration is envisaged.

On the basis of Article 87 (3), first sentence GG, “in addition, autonomous federal higher authorities as well as new federal corporations and institutions under public law may be established by a federal law for matters on which the Federation has legislative power. Not only does Article 87 (3), first sentence GG enable the creation of federal higher authorities, it also allows new duties to be assigned to existing federal higher authorities and other legal

[171] Provisions on administrative procedures are “those statutory provisions that regulate the activities of administrative authorities as regards the manner in which they implement the law, inclusive of their forms of action, methods of shaping official opinion, the manner of testing and reaching decisions, the processes by which these are arrived at and implemented, and the conduct of internal participation and monitoring procedures.” (Judgement of the Federal Constitutional Court BVerfGE 55, p. 274, 320 f.; 75, p. 108 (152). These include notably rules of participation, rules concerning formal requirements and deadlines, and provisions relating to administrative costs and enforcement.

entities accountable to the federal government.[172] Such duties must be assigned by enactment of a law; an ordinance is not sufficient.[173]

Article 87 (3) first sentence GG would therefore cover the assigning of responsibilities for implementing the mandatory reporting scheme and keeping the nanoproduct register either to the Federal Institute for Risk Assessment (BfR) as a public agency of the German federal government with full legal capacity, or to the Federal Environment Agency (UBA) and the BAuA federal higher authorities.[174]

In accordance with Article 87 (3) first sentence GG, a prerequisite for assigning a new duty – in this case the duty of implementing the mandatory reporting scheme and keeping the nanoproduct register – is that it must relate to a matter on which the Federation has legislative power. As discussed in Section 10.1.1 above, the Federation has the authority to legislate on this matter on the basis of several of the "matters under concurrent legislative powers" under Article 74 (1) GG, so this prerequisite is fulfilled. For the purpose of assigning these duties on the basis of Article 87 (3) first sentence GG, it is not necessary to establish necessity – as required in Article 72 (2) GG.[175]

Contrary to Article 87 (3) second sentence GG, *Bundesrat* consent would not be required for legislation on administrative procedures relating to mandatory reporting and keeping the product register.

10.2 Legislative framework for provisions on mandatory reporting and a nanoproduct register

Provisions establishing a nanoproduct register and a mandatory reporting requirement could be laid down either in a separate nanoproduct register act or in existing legislative provisions. In this context we examine the German Chemicals Act and the Act on Equipment and Product Safety.

10.2.1 Chemicals Act (ChemG)

Man and the environment are the objects of protection named in Article 1 of ChemG.[176] The purpose of the Act is to protect these objects from "the harmful effects of dangerous substances and preparations". In line with its intended role as an act to bring German law into line with REACH, Section 2 of the ChemG provides for implementation of the substantive provisions of REACH that are applicable in Germany. The scope of the ChemG thus includes nanomaterials as substances on their own or in preparations. Whether the protective purpose of the ChemG also extends to products containing substances is debatable, however, as these are not mentioned in Article 1 of the ChemG. The definition of the term "product" in Article 3 (5) ChemG is identical to the definition of "article" in REACH, however, and Article 2 ChemG (Scope of the Act) excludes products only from certain provisions of the ChemG; moreover, products are regulated in numerous provisions of the ChemG (e.g. in Section 3 on labelling obligations). On this basis, then, one can argue that substances in

[172] Lerche, Article 87 paragraph 175.
[173] Lerche, Article 87 Paragraph 176.
[174] See discussion on the provisions establishing these bodies in Section 9.
[175] Lerche, Article 87 paragraph 179.
[176] Act on Protection from Hazardous Substances (short title: Chemicals Act; *Chemikaliengesetz* - ChemG) of 16.09.1980, as promulgated on 2 July 2008 (BGBl. I p. 1146).

products are covered in conformity with REACH. This would then also apply of course to nanomaterials in products.

The purpose of the ChemG is also to prevent the occurrence of harmful effects to humans and the environment from dangerous substances and preparations. This purpose, rooted in the precautionary principle corresponds to the purpose of the nanoproduct register (see Section 4 above) and the objects it aims to protect. Provisions a mandatory reporting requirement and a nanoproduct register could be incorporated into the ChemG.

Although according to the theory of "legislative reservation" (*Wesentlichkeitstheorie*) the legislator would have to regulate essential questions of this matter in the ChemG itself, rules for implementing the nanoproduct register and mandatory reporting requirement could be issued in the form of an ordinance. A clause authorising the issuing of an ordinance regulating the nanoproduct register and mandatory reporting requirement could be included under Article 28 ChemG. Article 28 ChemG already contains a comparable provision authorising the issuing of an ordinance on reporting procedures for biocidal products.

10.2.2 Equipment and Product Safety Act (GPSG)

Provisions establishing a nanoproduct register and a mandatory reporting requirement could be laid down in the Act on technical work equipment and consumer products (Equipment and Product Safety Act (*Geräte- und Produktsicherheitsgesetz* - GPSG).[177] In terms of scope, the GSPG governs the placing on the market of new and used products intended for consumers (Article 1, first sentence GPSG), irrespective of whether these are mass-produced or individually produced, or whether they are products for scientific use or prototypes.[178] The placing on the market of nanoproducts intended for consumers would thus also be covered by the GPSG.

If provisions on the nanoproduct register were enshrined in the GPSG, it would need to be borne in mind that other more specific statutory provisions on consumer products take precedence over the GPSG where they lay down equivalent or more extensive requirements with regard to safety or health (Article 1 (3) first sentence GPSG). In addition, the regulations of the GSPG do not apply where other statutory regulations on products lay down equivalent or more extensive provisions concerning special obligations of distributors, CE marking, duties and powers of competent authorities, or on the provision of information (Article 1 (3) second sentence GPSG). According to the explanatory memorandum[179] on the GPSG, the Chemicals Act (ChemG) has precedence over the GPSG.

To make use of the umbrella role of the GPSG for all those products that have priority over the GSPG, it would be simpler from a technical viewpoint to enshrine the provisions on mandatory reporting and a register in the GPSG as a kind of basic "template" rather than including a provision in the special legislation in question. Regardless of the question whether the provisions on mandatory reporting and a register constitute a statutory regulation within the meaning of Article 1 of the GPSG, and which would therefore override the GPSG on the basis of the *lex specialis* principle, there are also other reason why the GPSG is not an appropriate home for the nanoproduct register. For instance the GPSG only applies to the placing on the market of consumer products and technical work equipment, not to their

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[177] Act on technical work equipment and consumer products (Equipment and Product Safety Act (*Geräte- und Produktsicherheitsgesetz* - GPSG) of 6 January 2004 (BGBl. I p. 2), as amended by Article 3 (33) of the Act of 7 July 2005 (BGBl. I. No 42, p. 1970).

[178] Klindt 2004, p. 465 (466).

[179] Bundesregierung 2007, Bundestag Printed Paper 15/1620 of 29.9.2003, p. 25.

manufacture. Earlier stages of these products, such as the placing on the market of semi-finished products containing nanomaterials, are not covered. The manufacture and placing on the market of nanomaterials as substances on their own or in mixtures falls within the scope of the ChemG and is not covered by the scope of the GPSG. Consequently, reporting requirements for these cannot be regulated under the GPSG. In addition, the scope of the GPSG does not extend to protection of the environment, so that mandatory reporting aimed at ensuring precaution with regard to environmental protection could not be based on the GPSG.

In conclusion, then, for all the reasons outlined above the GPSG is not a suitable basis for comprehensive regulation of all of the chosen objectives of the mandatory reporting requirement and register. We do not consider it appropriate, on grounds of regulatory fragmentation, to regulate for cases of consumer products falling within the scope of the GPSG.

10.3 Voluntary reporting

Instead of statutory regulation, the nanoproduct register and corresponding reporting obligations could be implemented on the basis of a voluntary commitment on the part of manufacturers, importers and distributors of nanoproducts. Due to the cross-sectoral nature of nanotechnology, however, a broad range of sectors would need to be accommodated within one regime. This is likely to be difficult to achieve by means of voluntary commitment. Given the large number of distributors of nanoproducts (distributors, importers, manufacturers), it is debatable whether the existence of a voluntary reporting scheme would come to their knowledge at all, and they would also have to make a formal commitment before the competent state body. For the chosen purpose of this regulation, however, it is important that there are no gaps in coverage of nanoproducts. Another reason that speaks against opting for a voluntary reporting scheme is that in Germany there is no provision for sanctions in the case of voluntary commitments. If a signatory fails to fulfil his duties/obligations, the competent authority has no possibility of applying coercive measures or imposing sanctions to achieve the agreed behaviour.

Attempts by the public administration in the UK to collect data on nanomaterials by means of voluntary reporting have not proven successful to date.[180] On 22 September 2006 the British environment ministry DEFRA set up a two-year pilot imitative “Voluntary Reporting Scheme for Manufactured Nanomaterials”. Over the course of the two years 11 data sets were submitted (9 from industry and 2 from research institutions). On the basis of this experience the Royal Society concluded that DEFRA’s voluntary reporting scheme for nanomaterials did not work. It therefore recommended introducing compulsory regulations for reporting nanomaterials.[181]

10.4 Conclusions

A reporting requirement and register of nanoproducts should be introduced by means of federal legislation and not by voluntary agreement.

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[180] Defra (2008), Voluntary Reporting Scheme for Engineered Nanoscale Materials, see: http://www.defra.gov.uk/ENVIRONMENT/nanotech/policy/pdf/vrs-nanoscale.pdf (accessed 19.8.2009). Official responsible at DEFRA: Steve Morgan.

[181] RCEP 2009, paragraph 4.74.

The Federation can enact legislation on mandatory reporting of nanoproducts on the basis of its concurrent legislative competence under Article 72 (2) GG and Article 74 (1), clauses 1, 11, 19, 20, 24, 29 and 32 GG, and because legislation at federal level is necessary in order to maintain legal uniformity. Insofar as the corresponding legislation makes not only substantive provisions but also provisions for an administrative procedure, the Federation has the power to legislate on the basis of Article 87 (3), first sentence GG.

Statutory provisions on the mandatory reporting requirement and product register can be incorporated into the Chemicals Act (ChemG), and implementing provisions laid down in an ordinance.

11 Compatibility of mandatory reporting / nanoproduct register with EU law

In this final section we examine the issue of whether national legislation on mandatory reporting and introduction of a register of nanoproducts is consistent with the primary and secondary (provisions on substances and products) legislation of the EU law.

11.1 Harmonised or non-harmonised sector

To assess whether Member States still have competence to regulate in an area when the EU has exercised legislative power, and which requirements under primary law set out in the EC Treaty national legislation must be measured against, a distinction needs to be drawn between two fundamental cases. In the case of non-harmonised sectors the EU has not yet passed any secondary legislation, whereas in harmonised sectors it has.

To the extent that the EU has not yet become active in a given area, or has not regulated on it exhaustively, Member States put national measures in place. In doing so they must take account of fundamental Community freedoms, an important example being the free movement of goods laid down in Article 34 (ex-Article 28 TEC) of the Treaty on the Functioning of the European Union (TFEU).

Nanomaterials are substances that are regulated under REACH. For different products containing nanomaterials, different EU sectoral product Regulations and Directives apply, (see Section 5). The first thing that needs to be examined is whether this legislation is exhaustive with regard to keeping a register of nanoproducts and mandatory reporting of nanoproducts, in other words whether it constitutes legislation in an area of law harmonised by the EU. When legislation is deemed to be exhaustive is not always clear from the case law of the European Court of Justice (ECJ).[182] The scope of the legislation passed by the EU will be a decisive factor in this regard, and so the purpose, scope of application and detail of the provisions must all be taken into account.[183]

If one examines the introduction of a national reporting requirement and register of nanoproducts from the perspective of the purpose, scope of application and detail of REACH, the following picture emerges:

The text of Article 128 (2) REACH in fact contains the assumption that REACH does not exhaustively harmonise the requirements on manufacture, placing on the market or use with regard to protection of workers, human health and the environment. Member States may therefore maintain or lay down national rules in these non-harmonised areas. Closer examination reveals that the scope of REACH is limited by the one-tonne threshold. A substance – which includes nanomaterials – is subject to the registration requirement only where the manufacturer or importer manufactures or imports the substance, on its own or as a component of a mixture, in quantities of at least one tonne per year. Substances present in articles of a manufacturer or importer – this can include products containing nanomaterials – must be registered if they are present in quantities of one tonne or more per year, and if the substance is intended to be released under normal or reasonably foreseeable conditions of use. Where nanomaterials on their own, in mixtures or in articles are manufactured or

[182] See the numerous judgements of the ECJ on this issue in Epiney 2004, p. 121 footnote 139.
[183] Epiney 2004, p. 121.

imported in quantities of less than one tonne, they are not subject to registration (see detailed discussion of REACH in Section 5.1).

If one looks at the detail of REACH as regards protection of human health and the environment in relation to nanomaterials, on their own, in mixtures or in articles, manufactured or placed on the market in quantities of more than one tonne, the provisions are not exhaustive. The information on the substance and its uses that must be submitted for registration under REACH serves the purpose of identification and risk assessment. In the case of nanomaterials, however, parameters for characterising them and assessing the potential hazards they pose to health and the environment have yet to be established. REACH does not yet envisage these. Nanomaterials, like other substances, must undergo all the current human and eco-toxicological tests, but whether and to what extent these tests are suitable for assessing the special properties of nanomaterials has not yet been ascertained.[184] Until this happens, statements on the human and eco-toxicological risks of nanomaterials will inevitably be fraught with uncertainty.

On the basis of the discussion above, it can be argued that the provisions of REACH do not regulate exhaustively in the matter of nanomaterials,[185] irrespective of quantity thresholds, and that therefore the Member States have the right in accordance with Article 128 (2) of REACH to lay down supplementary reporting requirements for nanomaterials.

To assess whether provisions to introduce mandatory reporting and a product register clash with existing EU legislation on products, we shall now examine whether and to what extent EU provisions are exhaustive.

As regards the new EU Cosmetics Regulation, from the point of view of their detail one can list the extensive requirements set out in Article 16 of the Cosmetics Regulation concerning information to be provided by distributors using nanomaterials in cosmetics, publication of the information by the Commission and product labelling requirements (see detailed discussion in Section 5.3.2). In the case of cosmetic products, the EU has set out similar provisions to those envisaged for a national reporting requirement and register of nanoproducts in Germany (see discussion in Section 8). However, the planned mandatory reporting scheme differs from the provisions of the Cosmetics Regulation as regards purpose and scope as well as the object of regulation. Whereas the Cosmetics Regulation aims exclusively to protect human health and ensure the functioning of the internal market,[186] the mandatory reporting scheme is also intended to protect the environment and employees. The definition of nanomaterial for the purposes of the product register is broader than that set out in the Cosmetics Regulation (see Section 8.2.2). Moreover, the notification obligations laid down in the Cosmetics Regulation apply only to the placing on the market of cosmetics that contain nanomaterials. The planned German mandatory reporting scheme would also encompass the manufacture of such cosmetics.

It can therefore be argued that Article 16 of the Cosmetics Regulation does not regulate exhaustively with regard to information on nanomaterials in cosmetic products to the extent

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[184] German Federal Environment Agency 2006, p. 14.

[185] Cf. also RCEP 2008, paragraph 4.35. Here, the Royal Society concludes that “Regulatory instruments like REACH have not been designed with nanomaterial products and their applications in mind, so it is a matter for concern that their risks might not be captured effectively within the current framework.”

[186] Cf. Article 1 of the Cosmetics Regulation: This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.”

that this is deemed necessary to protect the environment and employees in their workplace. Hence Member States retain the power to regulate in this matter.

A similar argument can be made in the case of the Novel Food Regulation – even in the event that the European Parliament's proposed amendments are adopted (see Section 5.3.4), as the purpose of the Novel Food Regulation, too, is to protect the health of consumers, but does not extend to protection of workers or the environment. Hence, harmonisation is only partially implemented.

Furthermore, both the sectoral product regulations and the General Product Safety Regulation (see Sections 5.3.6 to 5.3.11) fail to regulate exhaustively on the provision of information on nanomaterials present in products and on the possibility of official monitoring of these products.

11.2 Interim conclusions

Based on the arguments put forward here, the German Federal Government has the competence to enact national legislation regulating the reporting of nanoproducts and introduction of a nanoproduct register in the sectors covered by the Cosmetics Regulation and the Novel Food Regulation, because these instruments do not regulate exhaustively in terms of the purpose of the nanoproduct register.

As discussed in Section 2 above, the introduction of a European nanoproduct register would be preferable, as the issue of competences outlined here would not arise. If plans to introduce a national product register go ahead, we recommend examining these issues more closely in a legal opinion focussing especially on a more in-depth exploration of the various product regulations at EU level.

11.3 Compatibility with the free movement of goods

We now turn our attention to examine whether a mandatory reporting scheme and product register are compatible with the regulations in the EC Treaty concerning the free movement of goods in accordance with Article 34 (ex-Article 28 ff. TEC) TFEU.

In order to ensure the free movement of goods, Article 34 TFEU fundamentally prohibits quantitative restrictions on imports and all measures having equivalent effect. These prohibitions apply to goods of all sorts, in other words to "all products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions."[187] Article 34 TFEU applies to products originating in Member States, and to products coming from third countries which are in free circulation in Member States (Article 23 (2) TEC). As movables with a commercial value, nanoproducts fall within the category of goods for which free movement is ensured if they are imported into Germany from an EU Member State. The ban on restriction of the free movement of goods does not, however, apply to nanoproducts manufactured in a third country and imported directly into Germany. In the case of these products, there is nothing to prevent restrictive measures from being laid down at national level, subject to compliance with the Community system of competences and international commitments (WTO law).

[187] ECJ Judgment of 9 July 1992, Commission / Belgium (C-2/90, ECR 1992 p. I-4431); Judgment of 28 March 1995 , Evans (C-324/93, ECR 1995 p. I-563).

Quantitative restrictions include any "…measures which amount to a total or partial restraint of, according to the circumstances, imports, exports or goods in transit".[188] Mandatory reporting of nanoproducts is not intended to impose a ban or quantitative restriction on imports of these products (Article 34, first alternative TFEU). Mandatory reporting could, however, constitute a "measure having equivalent effect" (Article 34, second alternative TFEU). Since the landmark Dassonville decision, the ECJ interprets this as meaning "all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade."[189] Article 34 TFEU thus prohibits not only regulations that discriminate de jure or de facto, but all measures in general that hinder imports and thereby restrict the free movement of goods per so.

The introduction of mandatory reporting for nanoproducts is thus deemed to be a measure having equivalent effect within the meaning of Article 34, second alternative TFEU. This is because the reporting requirement applies to the placing on the market of nanoproducts and hence introduces a trade regulation that at least potentially hinders trade in nanoproducts due to the additional requirement to supply the authority with information on the manufacturer and the product.

Consequently, the mandatory reporting requirement fundamentally interferes with the free movement of goods in a manner that can be justified on the grounds explicitly listed in Article 36 (ex-Article 30 TEC) TFEU, or to satisfy mandatory requirements relating to the public interest. The catalogue of grounds set out in Article 36 TFEU is exhaustive[190] and includes public morality, public policy and public security, as well as protection of the health and life of humans, animals and plants. The ECJ's interpretation of the possible justifying grounds in Article 36 TFEU is narrow.[191] For instance, although environmental policy measures generally also fall indirectly within the category of protection of the health and life of humans, animals and plants, the ECJ nevertheless demands that there must be a direct adverse effect on health and hence does not regard indirect preventive measures aimed at protecting health as falling within Article 36 TFEU. Mandatory reporting of nanoproducts is aimed at giving the public administration an overview of products available on the market with a view to protecting the environment, human health, and health and safety in the workplace, and enabling it to put in place risk management measures if necessary. The primary aim of mandatory reporting and the product register, therefore, is not to prevent direct adverse effects on health, but to act as indirect preventive measures for identifying potential risks; preventive measures should then be taken on the basis of other provisions. Justification on the basis of the grounds listed in Article 36 TFEU is not supported.

In the "Cassis de Dijon" case, the ECJ also acknowledged that other government regulatory purposes not explicitly mentioned in Article 36 TFEU might justify restricting the free movement of goods. Thus, for example, "obstacles to movement within the Community resulting from disparities between the national laws relating to the marketing of the products in question must be accepted in so far as those provisions may be recognised as being necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer."[192]

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[188] ECJ 2/73 [1973] ECR 865, parargaph 7 – Geddo.
[189] ECJ 8/74 [1974] ECR 837 – Dassonville.
[190] ECJ 113/80 [1981] ECR 1625 – Commission/Ireland.
[191] ECJ 205/89 [1991] ECR 1361 – Commission/Greece.
[192] ECJ 120/78 [1979] ECR 649 – Cassis de Dijon.

According to the ECJ, then protection of the environment[193] and of consumers are important unwritten grounds that may justify restriction of trade. If the introduction of mandatory reporting is justified on the grounds of environmental and consumer protection, it must also satisfy the principle of proportionality. As the proposed mandatory reporting scheme would not disproportionately interfere with the free movement of goods (see detailed analysis in Section 6.4.1), there is no breach of Article 34 TFEU.

11.4 Conclusions

The introduction of a mandatory reporting scheme and a register of nanoproducts is compatible with the provisions of primary and secondary EU law examined in this study. As the reporting requirement to be introduced in Germany affects an area not exhaustively regulated under EU law, compliance with the free movement of goods guaranteed under primary EU law on the basis of Article 34 TFEU must be ensured. As a "measure having equivalent effect" within the meaning of Article 34 (2), second alternative, mandatory reporting would restrict the free movement of goods. It is justified, however, because it is necessary in order to satisfy the mandatory requirements of environmental and consumer protection and does not interfere disproportionately with the free movement of goods.

[193] For environmental protection as a compelling requirement in the public interest, see: ECJ 302/86 *Commission* v *Denmark* [*1988*] ECR *4607*.

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13 Annex: Definitions relating to nanomaterials (as of December 2009)

13.1 Norio Taniguchi, 1974

"Nanotechnology mainly consists of the processing of, separation, consolidation, and deformation of materials by one atom or one molecule."

(On the basic concept of "Nano-technology" (1974). Proc. Intl. Conf. Prod. Eng. Tokyo, Part II, Japan Society of Precision Engineering)

13.2 German Federal Ministry of Education and Research, 2006

"Nanotechnology in this context refers to the development, analysis or application of functional structures, molecules or internal or external boundary surfaces in the scale of 100 nm or less. At the same time, these structures must possess new functions or properties which are directly linked to their size and hence would not be realisable in the macro form." (http://www.bmbf.de/de/677_7097.php).

13.3 Sofia/Institute for Applied Ecology, 2007

Nanomaterials:

Nanomaterials (NM) are the subject examined in this report (NM). In line with other definitions, for the purposes of this report "nanomaterials" means:

- Structures of anthropogenic origin (e.g. particles, layers, and tubes) which are smaller than 100 nm in at least one dimension.
- These structures must possess new functionalities or properties that would not be realisable in the macro form and be used specifically for the development of new products and applications.

Rechtsgutachten Nanotechnologie (ReNaTe) / Legal appraisal of nanotechnologies: (http://www.oeko.de/forschungsergebnisse/dok/228.php).

13.4 BfR, BAuA, UBA / Research strategy, 2007

Nanotechnology:

"Means the manufacture, study and application of structures, molecular materials or internal boundary structures that are smaller than 100 nm in at least one critical dimension"

Nanomaterial:

"Material that is either a nano-object or nanostructured. In this text the term refers particularly to nanoparticles, nanotubes and nanofibres, etc., and agglomerates and aggregates of these."

Nanoscale:

"Size range between 1 nm and 100 nm."

Nano-object:

“A material with at least one dimension at the nanoscale. Examples include nanoparticles, nanotubes, nanowires and nanoplates.”

Nanoparticles, nanotubes, nanofibres:

“The terms nanoparticles nanotubes, and nanofibres refer to granular particles, tubes and fibres with a diameter <100 nm in at least one dimension. When referring to agglomerates and aggregates of these the more general term nanomaterials is used.”

13.5 Report and Recommendations of the German Federal Government’s NanoKommission, 2008

The term “nanomaterials” refers to engineered materials range which, primarily as a result of their altered surface area-to-volume ratio, develop new properties. There is currently no internationally agreed definition. According to a draft prepared by Technical Committee of the International Standardisation Organisation (ISO Technical Committee 229), nanomaterials may be subdivided into various groups. These include:

“Nano-objects: Materials with one, two or three external dimensions at the nanoscale (approximately 1 to 100 nm). Typical examples are nanoparticles, nanofibres and nanoplates. Nanofibres include electrically conducting fibres (nanowires), nanotubes, and nanorods. Nano-objects are often found in groups.”

“Nanostructured materials have an internal structure in the nanoscale and generally occur in compound systems of nano-objects. Typical examples are aggregates and agglomerates. According to ISO these are not limited in their physical size or form.”

13.6 German Institute for Standardisation (DIN - Deutsches Institut für Normung), 2008

Nanoparticle:

“Nano-object with all three external dimensions in the nanoscale.”

Nanoplate:

“Nano-object with one external dimension in the nanoscale and the other two external dimensions significantly larger.”

Nanofibre:

“Nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger.”

(The text of ISO/TS 27687:2008 was approved by CEN as CEN ISO/TS 27687:2008 without modification).

Nanotechnologies – Terminology and definition for nano-objects – Nanoparticle, nanofibre and nanoplate” (ISO/TS 27687:2008); German version CEN ISO/TS 27687:2008)

13.7 U.S. National Nanotechnology Initiative (NNI), from 1996 on

Nanotechnology:

“Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.

A nanometer is one-billionth of a meter. A sheet of paper is about 100,000 nanometers thick; a single gold atom is about a third of a nanometer in diameter. Dimensions between approximately 1 and 100 nanometers are known as the nanoscale. Unusual physical, chemical, and biological properties can emerge in materials at the nanoscale. These properties may differ in important ways from the properties of bulk materials and single atoms or molecules.”

(http://www.nano.gov/html/facts/whatIsNano.html)

13.8 NIOSH (National Institute for Occupational Safety and Health), USA, undated

Nanotechnology:

“Nanotechnology involves the manipulation of matter at nanometer scales to produce new materials, structures, and devices. Nanotechnology defines a technology as nanotechnology only if it involves all of the following:

1. Research and technology development involving structures with at least one dimension in the range of 1 to100 nanometers (nm), frequently with atomic/molecular precision.
2. Creating and using structures, devices, and systems that have unique properties and functions because of their nanometer-scale dimensions.
3. The ability to control or manipulate on the atomic scale.

Nanotechnology is an enabling technology that offers the potential for unprecedented advances in many diverse fields. The ability to manipulate matter at the atomic or molecular scale makes it possible to form new materials, structures, and devices that exploit the unique physical and chemical properties associated with nanometer-scale structures. The promise of nanotechnology goes far beyond extending the use of current materials. New materials and devices with intricate and closely engineered structures will allow for (1) new directions in optics, electronics, and optoelectronics; (2) development of new medical imaging and treatment technologies; and (3) production of advanced materials with unique properties and high-efficiency energy storage and generation."

Nanoparticles:

"Nanoparticles are particles having a diameter between 1 and 100 nm. Nanoparticles may be suspended in a gas (as a nanoaerosol), suspended in a liquid (as a colloid or nano-hydrosol), or embedded in a matrix (as a nanocomposite). The precise definition of "particle diameter" depends on particle shape as well as how the diameter is measured. Particle morphologies may vary widely at the nanoscale. For instance, carbon fullerenes represent nanoparticles with identical dimensions in all directions (i.e., spherical), whereas single-walled carbon nanotubes (SWCNTs) typically form convoluted, fiber-like nanoparticles with a diameter below 100 nm. Many regular but nonspherical particle morphologies can be engineered at the nanoscale, including "flower" and "belt"-like structures. For examples of some nanoscale structures, see www.nanoscience.gatech.edu/zlwang/research.html."

Engineered nanoparticles:

"Engineered nanoparticles are intentionally produced, whereas incidental nanoscale or ultrafine particles are byproducts of processes such as combustion and vaporisation. Engineered nanoparticles are designed with very specific properties (including shape, size, surface properties, and chemistry), and collections of the particles in an aerosol, colloid, or powder will reflect these properties. Incidental nanoscale particles are generated in a relatively uncontrolled manner and are usually physically and chemically heterogeneous compared with engineered nanoparticles."

(http://www.nano.gov/html/facts/whatIsNano.html)

13.9 OECD Working definition, 2005/2006

Manufactured nanomaterials:

"Nanomaterials intentionally produced to have specific properties or specific composition."

Nanoscale:

"The size range typically between 1 nm and 100 nm."

Nanomaterial:

"Material which is either a nano-object or is nanostructured."

Nano-object:

"Material confined in one, two or three dimensions at the nanoscale."

Nanostructured:

"Having an internal or surface structure at the nanoscale."

13.10 Swiss Federal Office for the Environment (Bundesamt für Umwelt - BAFU), 2007

Manufactured nanoparticles are deliberately produced solid particles which (intentionally or unintentionally) may have at least two dimensions in the nanoscale (between 1 and 100 nm) and can exhibit novel properties as a result of their size.

Nanoparticles may be amorphous or crystalline in structure and consist of one or more elements or phases. They may be dispersed in a gas (aerosol) or in a liquid (suspension). In composites they are embedded in a solid matrix.

Manufactured nanoparticles can also have a coating of organic or inorganic substances that determine their surface properties.

Nanoscale particles that occur unintentionally are referred to as ultra-fine particles and are not included in the definition set out here."

(www.umwelt-schweiz.ch/uw-0721-d)

13.11 European Parliament 2008

Nanotechnology:

"Nanotechnology exploits the fact that nano-size particles have completely different properties from bigger particles of the same substance. The most common definition of nanoparticles is that they are less than 100 nm in dimension. However, nanotechnology also

covers a functional change in the properties of a material owing to its small size where the particles are larger than 100 nm."

(Draft report on regulatory aspects of nanomaterials (PE418.270v01-00))

13.12 Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 2009. Risk Assessment of Products of Nanotechnologies

Nano:

"Currently the definition of what is "nano" is still under debate. Generally nanomaterials are defined as being smaller than about 100 nm in at least one dimension. The currently proposed definitions use the size of the primary particle/structure as a starting point. However, when a nanomaterial is in particulate form, the particles may be present as single particles but might also be present as agglomerates/aggregates. Depending on the nanomaterial, the majority of the particulates may actually be agglomerates/aggregates. This may lead to the misinterpretation that agglomerates/aggregates of nanoparticles that have dimensions well beyond the 100 nm size are not considered nanomaterials. Yet they retain specific physicochemical properties which are characteristic for nanomaterials, most likely due to their relative large specific surface area (SSA). Therefore, when describing a nanomaterial it is important to describe not only the mean particle size but also the size of the primary particles. In addition, information on the presence of agglomerates/aggregates should be presented. When the mean particle size deviates (i.e. is larger) from the primary particle size this would indicate the presence of agglomerates/aggregates. In addition to size the specific surface area as determined by BET method is a good metric to describe particulates as this metric is independent of the primary versus the agglomerated state. Hence, extending the current definition based on physical size by the addition of a limit of the specific surface area to be above 60 m²/g of material volume (the value of 60 m²/g corresponds to the specific surface area of 100 nm solid spheres of unit density) should be considered."

(http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf)

13.13 European Food & Safety Agency (EFSA), 2009

Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety

Nano:

The prefix "nano" specifically means a measure of 1x10-9 units, the nature of this unit being determined by the word that follows, e.g. "nanometre" as a measure of dimension. In this opinion, nanoscale refers to a dimension of the order of 100 nm and below. Since the changes in characteristics that are seen on reducing dimensions do not occur exactly at the 100 nm size, it is important that some latitude is allowed in this definition with respect to the meaning of "the order of" and it is recognised that there will be various borderlines. Generally, we are in the order of 100 nm or less, but there are size-related effects that can appear at larger size."

Engineered nanomaterials:

"An engineered nanomaterial is any material that is deliberately created such that it is composed of discrete functional and structural parts, either internally or at the surface, many of which will have one or more dimensions of the order of 100 nm or less. In this opinion engineered nanoparticles are included in the general use of the term ENMs. The term "engineered" as used in this opinion is equivalent to the term "manufactured" as used in other reports (e.g. SCENIHR, 2009).

Food and feed may contain components that have internal structures that individually could be present at the nanoscale, e.g. naturally occurring molecules, micelles or crystals. However, as said above, "natural" components are considered within the context of this opinion, only if they have been deliberately used or engineered to have nanoscale properties, or used e.g. to encapsulate bioactive compounds.

Micro/macroscale material (i.e. bulk material) refers to a material predominantly in sizes well beyond the nanoscale, while the dissolved chemical describes a size generally smaller than the nanoscale.

An agglomerate is a group of particles (such as primary ENMs) held together by weak forces, such as Van der Waals forces or electrostatic forces.

An aggregate is a group of particles (such as primary ENMs) held together by strong forces, such as those associated with covalent or metallic bonds."

(http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en,0.pdf?ssbinary=true)

13.14 Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No 1331/2008 common procedure) (LA) (First reading)

"Nanomaterial means: any intentionally produced material that has one for more dimensions of the order of 100 nanometers (nm) or less or 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.

The properties that are characteristic to the nanoscale include (i) those related to the large specific surface area of the materials considered and/or (ii) specific physico-chemical properties."

13.15 Cosmetics Regulation (Recast EP 24.03.2009)

'"Nanomaterial" means 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'.

13.16 ISO/TC229

Nanotechnologies Working Group 1 (Terminology and Nomenclature) Project Group 5, proposes the following definitions in ISO/AWI TS 12144 Nanotechnologies - Core terms - Terminology and definitions:

Nanomaterial:

“Material having a geometric or structural feature in the nanoscale.

NOTE Examples include nanocrystalline materials, nanoparticle powder, materials with nanoscale precipitates, nanoscale films, nanostructured objects, nano-porous objects, and materials with nanoscale textures on the surface.”

Nanoscale:

“Size range from approximately 1 nm to 100 nm.

NOTE Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.”