INFORMATION

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Concept for a European Register of Products Containing Nanomaterials

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A. Key points concerning a European register of products containing nanomaterials

1. Due to the particular uncertainties concerning evaluation of the possible risks of nanomaterials for human health and the environment, the German Federal Environment Agency (*Umweltbundesamt – UBA*) supports the establishment of a European register of products containing nanomaterials as a precautionary measure.
2. The objective of such a product register is the creation of an overview of products containing nanomaterials that have applications in the consumer area and in an open environment. This enables public authorities to set priorities in enforcement and monitoring, to estimate exposure for humans and the environment and, in the case of adverse effects, to ensure traceability. For actors in the supply chain a product register creates transparency.
3. The establishment of such an electronic product register should take place at the EU level und be managed centrally. A national product register would result in overlaps with varied EU legislation and in varying obligations and regulations in individual EU Member States, which would mean increased costs for authorities and stakeholders subject to notification.
4. Elaboration of such a product register should have the objective of avoiding duplicate obligations and maintaining a reasonable cost-benefit ratio. At the same time, there are substance-related regulatory bases (REACH and CLP Regulation) and also product-related regulatory bases (Cosmetics Regulation and Novel Food Regulation) in European law. Both legal bases should be utilized for a product register, since both contain appropriate points of departure (for example, registration and notification requirements). For the purpose of consistent legal implementation, enactment of a European product register regulation is to be recommended, which would lay down general provisions in the form of an umbrella regulation, amend existing substance- and product-related provisions, adapt or create notification requirements and consolidate generated information.
5. Substances and mixtures (manufactured or imported) that comprise or contain nanomaterials are subject to notification. Furthermore, articles that intentionally or unintentionally release nanomaterials (analogous to Article 7 (2) in connection with (3) REACH) should be subject to notification. Notification should basically be restricted to product name / description, characterization and concentration of the respective substance, manufactured or imported tonnage bands as well as application and functionality. It has to be ensured that products that are no longer on the market are removed from the register, and that article variants do not have to be individually registered. The register comprises a "public" part that is generally accessible and a confidential part to which only authorities have access. In order to guarantee protection of confidential information, certain data is only contained in the confidential part.
6. Regarding the practicability of the product register, it has to be ensured that the cost for stakeholders subject to notification and for public authorities is limited. As far as concerns products with nanomaterials, according to industry representatives several hundred nanomaterials in up to 100,000 mixtures have to be expected with further development of nanotechnology. The number of articles containing nanomaterials that are subject to notification is unlikely to be greater than this figure, since with a large proportion of such

articles the release of nanomaterials can be ruled out. Reliable figures on nanomaterials in products are presently not available, however, and should be established within the scope of an "impact study". Mechanisms have also to be developed for cost-effective monitoring of provisions, since experience shows that with imported articles, in particular, a significant rate of non-compliance with notification requirements is to be expected.

7. Products should be assigned a notification number, which should be displayed on the respective product in order to facilitate research, without it being regarded as a warning.
8. A product register substitutes neither further developments in the elaboration of the REACH Regulation nor necessary, nano-specific provisions in substance-, product- and environment-related legislation, which is currently being discussed; it is merely a component thereof.

B. Objective of a European register for products containing nanomaterials

Nanomaterials (NMs) pose new legal challenges. Up to now, special regulations for NMs have been established only in isolated cases. The large projects that are currently being considered are an adaptation of central substance-related provisions as well as creation of transparency with regard to applied nanomaterials by means of a register of products containing nanomaterials (hereafter: nanoproduct register: NPR). This report concerns itself merely with an NPR. Ideas on adaptation of substance-related provisions are being separately developed.

A prerequisite for any regulation is the definition of nanomaterial. The European Commission published in October 2011 a recommendation on the definition of nanomaterial.[1] We regard this recommendation as basically appropriate for regulation of NMs in different sectors of law.

Up to now, no comprehensive information has been available concerning the form in which NMs come onto the market, and in particular, concerning the NMs that are used in particular products as well as the function they fulfil. Solely in the case of the EU Cosmetics Regulation[2] have cosmetics containing nanomaterials, as from 2013, to be notified six months before placement on the market and the nanoscale ingredient indicated on the packaging with the word "Nano". Nanomaterials should also be regulated within the scope of the EU Novel Food Regulation.[3] After around three years of negotiations between the European Parliament (EP), the Council and the European Commission, however, this regulatory proposal foundered on other issues in the subsequent conciliation procedure. The EP and the Council decided in July and September 2011, respectively, on a Regulation concerning the labelling of food ingredients with the word "Nano", which will be applicable with effect from 13 December 2014.[4]

Lack of knowledge of the use and concentration of nanomaterials concerns, due to largely failing declaration and registration obligations, not only consumers but also authorities. Here, the REACH Regulation[5] cannot provide an adequate remedy, since it primarily regulates substances and mixtures. The Regulation also contains practically no registration requirements concerning the composition of individual products. The specific substance-related provisions in the REACH Regulation, without adaptation, do not guarantee adequate information on nanomaterials.

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1 Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial (2011/696/EU).

2 Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products.

3 Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and Novel Food Ingredients.

4 Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers [...].

5 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 Chemical Substances (REACH), establishing a European Chemicals Agency [...].

Due to failing transparency concerning the type, amount and applications, estimation of exposure and thus evaluation of the potential risk for human health and the environment emanating from nanomaterials is possible only to a very limited extent. In this respect, an NPR could provide a remedy. In this report, we present proposals for the possible structuring of an NPR.

The purpose of an NPR, with its accompanying notification obligation, is to offer public authorities an overview of products containing nanomaterials that are manufactured in Europe or available on the EU internal market. An important question, which has to be answered, concerns the information that should be contained in the NPR and for whom it should be accessible. At the same time, in elaboration and realization of the NPR the scope of a meaningful overall regulation of nanomaterials has to be considered. Existing regulations have also to be determined, and the question resolved as to how they can be further elaborated for the desired purpose.

The users of an NPR would primarily be public authorities. On the grounds of transparency, however, part of the stored data should be accessible to the general public; while to ensure protection of confidential information the general public should be denied access to certain data.[6] A register has thus to be established, which, in part, is accessible only to the responsible public authorities, but which in certain areas also allows public access to information for consumers.

6 Where appropriate, further legal aspects of data protection should be examined.

From the point of view of the State an NPR could produce the following benefits:

1. A general market overview for estimation of the relevance of nanotechnology and, where appropriate, individual nanomaterials for the purpose of deciding on the setting of priorities in enforcement and law-making / regulation.
2. Enhancement of risk assessment of nanomaterials through differentiated information on application and exposure.
3. Improved responsiveness to adverse effects of products containing nanomaterials.

For consumers, an NPR could provide the following benefits:

1. More transparency concerning nanomaterials on the market.
2. Depending on its structure, freedom of choice concerning the purchase of products containing nanomaterials.

For manufacturers, importers and traders the following benefits could arise:

1. Less stringent market intervention compared to other regulatory options (authorization requirement, labelling obligation or moratorium). Enhanced knowledge on the part of the authorities also allows differentiated evaluation, with the effect that the need for further precautionary measures is reduced.
2. Transparency for all market participants. Product responsibility can only be perceived with knowledge of the composition of a product. The provisions of an NPR, appropriately designed, ensure communication in supply and processing chains.

Sensible structuring of an NPR depends on the information that is to be obtained and on how integration in existing regulative instruments is to be effected. The regulations have to further attainment of the set objectives, and at the same time to avoid excessive costs. The latter implies avoidance of unnecessary duplicate regulations, observance of the proportionality of requirements relating to the set objective as well as consideration of available regulative alternatives. In addition, the regulation must be enforceable. The regulation's addressees must have a clear perception of his obligations, and administrative control must be possible.

An NPR involves a certain cost both for the stakeholders affected and the bodies responsible for management of the register. Initial estimations concerning the products affected are to be found in Section D. The Federal Environment Agency plans further investigation of the costs.

C. Concept for precise legal structuring of a European register of products containing nanomaterials

a) Regulatory system

All substances, mixtures and articles in terms of chemicals law as well as all products in terms of product-related law (for example, cosmetics products, biocidal products, plant protection products and medicinal products) that are or contain nanomaterials as defined in the Recommendation of the European Commission should be covered.[7] The level of NM concentration at which obligations should arise, and how NMs are dealt with whose release is largely ruled out, has still to be clarified. This is particularly relevant for articles.

Existing general national product registers[8] (of which none are NPRs) have up to now excluded articles. Studies of the Federal Environment Agency during the period 1998 – 2002 concerning the design of a comprehensive German or European product register for chemicals also excluded articles.[9]

On the other hand, the inclusion in the regulation of nanomaterials in articles is required for the stated objective of the NPR.[10] It has to be assumed that nanomaterials will be used in future in a large number of the most varied articles. The objective of transparency would therefore not be attained were nanomaterials in articles to be excluded from a requirement for notification in an NPR. For considerations of exposure, too, information concerning articles is required. It has to be clarified, however, whether all or merely particular articles should be covered by the regulation.

European chemicals law distinguishes, with regard to requirements for substances, between three situations:

1. In the case of intended release, a registration obligation exists pursuant to Article 7 (1) REACH with effect from 1 t/a, as well as a classification obligation pursuant to Article 4 (2) (a) of the CLP Regulation.[11]
2. When exposure of humans or the environment during normal or reasonably foreseeable conditions of use, including disposal, cannot be excluded, a notification obligation exists in

7 Cf. Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial (2011/696/EU).

8 Switzerland, Denmark, Finland, Norway and Sweden.

9 UFOPLAN Project: "Comparative investigation of various European product registers for chemicals (ingredients) as basis for the forthcoming decision on establishment of a German register for chemicals" (Research Project No. 299 67 292, duration 9/99 – 5/01).

10 Concerning the need for regulation of articles Cf. Öko-Institut: Legal Feasibility Study on the Introduction of a Nanoproduct Register; Berlin, Freiburg 2010.

11 Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and [...].

respect of substances of very high concern (SVHC) pursuant to Article 7 (2) REACH with effect from 1 t/a and with a concentration > 0.1% in the respective article, as well as a classification obligation pursuant to Article 4 (2) (b) of the CLP Regulation.

3. No registration or notification obligations arise pursuant to REACH when, in the case of normal or reasonably foreseeable conditions of use including disposal, exposure of humans or the environment can be excluded.

A notification requirement in an NRP for the third group of articles (situation 3 above) would be very difficult to justify, and could be problematical with respect to WTO law.[12] This is also not necessary, however, for attainment of the above-mentioned objectives of an NPR.[13] So far as a general market overview is concerned, this leads to a restricted picture, but this is not critical, since such additional knowledge is not a prerequisite for action on the part of the state. When release does not occur, no state action would be derived from knowledge of such a product. Furthermore, this would lead to problems in enforcement, since analytical proof of nanomaterials in such constellations would be possible only in isolated cases.

It is therefore appropriate to restrict an NPR to articles that release nanomaterials intentionally, or to articles with which release of nanomaterials cannot be excluded in the case of normal or reasonably foreseeable conditions of use including disposal.

It should be examined, to what extent notification of frame formulations in the case of mixtures and consolidation of product variants in the case of articles are possible.

12 It needs to be pointed out that compatibility of the concept with WTO law has not been thoroughly examined.

13 France thus also dispenses consequentially with obligations for this area in its proposed regulation on a national product register (Ordinance on annual registration of nanoscale substances in application of Article L 523-4 of the Environmental Protection Act [cf. Notification with the EU: 2011/0307/FJ].

b) Stakeholders subject to notification

The stakeholders stated below should be subject to notification in respect of the following objects of regulation:

		Substance manufacturer / importer	Initial distributor of a mixture[14]	Article producer / importer
Substances		X		
Mixtures			x	
Articles	intended release			X
	unintended release			X
	no release			[x]

X = subject to registration; [x] = subject to registration when registration requirement is laid down in the respective regulation (for example, food and feed, medicinal products, cosmetics and biocidal products) for substances in articles in general (that is, also when release does not occur).

Table 1: Stakeholders subject to notification of information concerning products containing nanomaterials

c) Scope of notification

Notification should contain data on the quantity manufactured or imported, the concentration of nanomaterials in the respective product, the use, characterization and functionality of the nanomaterials used, product and trade name as well as the name and address of the registrant.

At the same time, an obligation to update should be provided for in the case of modification of information required or withdrawal from the market. The scope of notification for an NPR is displayed in Table 2, whereby data that should be accessible to the general public is indicated.

Information in an NPR	Accessible to the public
Name and address of the registrant	
Product and trade name	x
Application	x
Functionality of the nanomaterial(s) employed	x

14 Repackaging, re-labelling and marketing for an area other than that registered by the initial distributor triggers an independent registration obligation.

Characterization of nanomaterial(s)	partially
Volume manufactured or imported	
Nanomaterial concentration in the respective product	
NPR notification number (product-/substance-specific)	x (possibly on the product)

Table 2: Scope of notification for an NPR

d) EU regulation *versus* national regulation

An NPR can only be structured cost-effectively at the EU level. Were individual or all EU Member States to establish a national NPR, and were, for example, varied information to be demanded or even different regulatory content exist, an uneven picture would arise from which one could not deduce measures for the European Union as a whole. Even if the same regulatory content were to be laid down in all countries, unnecessary additional costs would arise from creation of a large number of national systems.

In certain EU member States action has already been taken towards introduction of a national NPR. In France, for example, a registration requirement for nanomaterials was introduced by the "Grenelle 2“ Act of 12 July 2010, according to which manufacturers, importers and distributors of nanomaterials are required to regularly submit data to the competent authorities on substance identity, volumes applied and the identity of commercial users. The registration requirement is intended to come into force in 2013. Other countries (for example, Belgium and Italy) are also considering national regulations.

A further national regulative measure in Germany would, in our view, be largely disadvantageous. It would result in overlaps with various European requirements and in duplicate provisions and thus in duplicate obligations. This could apply, too, for the national registers in other countries, whose experiences will, however, be advantageous for the structuring of an EU register. The establishment of a national register should therefore be examined as an alternative, in the event that realization at the EU level is not expected in the foreseeable future. Furthermore, it is advantageous, in terms of the "Europeanization" of substance- and product-related legal regulations, when the overview of and information on products containing nanomaterials exist not only in Germany but in the European Union as a whole.

e) Existing product-related regulatory bases

An NPR can be established on the basis of product law. Product law is basically strongly orientated towards the existence of a hazard; that is, towards a situation in which possible occurrence of damage to a legally protected good is in all probability substantiated. Flexibilization of preconditions, however, already arises from the fact that where particularly valuable legal interests are endangered the threshold for state action can be lower.

Here, Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on General Product Safety provides an appropriate legal basis. The Directive applies to all

products defined in the Directive. In order to enshrine an NPR in the Directive, however, the directive would have to be fundamentally modified.

However, in certain more particularized regulations of product law (for instance, plant protection products, biocidal products, medicinal products, novel foods, food packaging and cosmetics) a regulatory basis exists that can be utilized.

The EU Cosmetics Regulation, for example, already contains notification requirements for nanomaterials in cosmetics.

f) Existing substance-related regulatory bases

The EU REACH Regulation and / or CLP Regulation could provide a substance-related basis for an NPR.

Generally, through adaptation of the information required for registration of nanoforms of substances pursuant to REACH nanomaterials on the market could be covered.

Regarding the information on substances and substances in mixtures the notification requirement pursuant to Article 45 of the CLP Regulation could be extended and applied. The use of relevant data for an NPR would have to be legally based, and the Europeanization of the process expedited. Up to now, a national procedure has been involved (in Germany pursuant to Article 16 e of the Chemicals Act), whereby this data could previously only be used for the purpose of processing inquiries concerning medical issues.

g) Legal structuring

We can basically imagine two regulatory models:

1. A separate European nanoproduct register regulation (EU NPR Regulation) is enacted, which is structured independent of existing EU product- and substance-related regulations.

   The main disadvantage of such an NPR regulation is the creation of unnecessary duplicate obligations in comparison to existing regulations (for instance, the EU Cosmetics Regulation), and thus of increased costs for stakeholders subject to notification and public authorities. At the same time, such a regulation would hamper acceptance of further necessary nano-specific provisions in individual product- and substance-related regulations, when industry had already been burdened with far-reaching, possibly duplicate obligations through an NPR regulation.

2. An EU NPR Regulation, based on and supplementary to existing regulations, which regulates consolidation of information from existing regulations, avoids the disadvantages mentioned under option 1 above. Though it would involve a highly complex legislative process, in which different legal regimes would have to be modified by means of an umbrella regulation. In our view, however, the advantages predominate.

   The key aspects of this solution are outlined below:

   An EU NPR regulation is established, which is based on existing substance-related regulations (REACH and CLP Regulations) and particular product-related regulations (for example, medicinal products, biocidal products, plant protection products,

cosmetics and novel foods), and which supplements and adapts such regulations in accordance with a notification requirement for nanomaterials and for mixtures and articles containing nanomaterials. This process is displayed schematically in Figure 1.

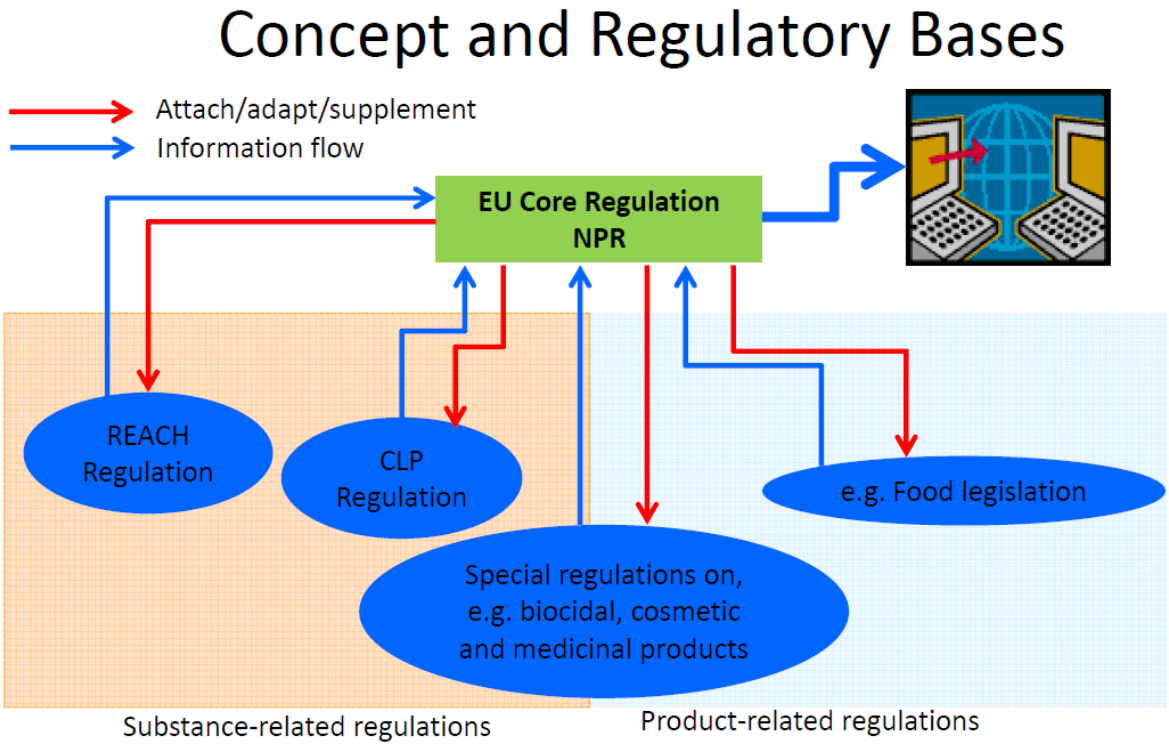

Figure 1: Concept and regulatory bases for an EU NPR regulation

The formulation of notification requirements for nanomaterials as substances should be based on the registration requirement of the REACH Regulation, with necessary adaptation for nanomaterials. Information on areas of application could also be based on adaptation of obligations of registrants and downstream users pursuant to REACH.

Information on mixtures containing nanomaterials could be obtained through extension of the notification requirement pursuant to Article 45 of the CLP Regulation. The use of data relevant for an NPR would have to be legally based, and Europeanization of the process expedited. Up to now, a national procedure has been involved (in Germany pursuant to Article 16 e of the Chemicals Act, whereby this data could previously only be used for the purpose of processing inquiries concerning medical issues). European harmonization of notification systems is in any case intended through the CLP Regulation.

Insofar as special regulations for product classes exist that go beyond REACH requirements (such as, for example, authorization of biocidal products) NPR requirements should be based on adaptation of such product regulations.

Concerning the introduction of a notification requirement for articles containing nanomaterials, it has to be decided whether the notification requirement for articles is laid down in the REACH Regulation, by means of extension of Product Safety Directive 2001/95/EC, or as a separate provision in an EU NPR Regulation. Supplementing existing provisions on

articles in the REACH Regulation, notification requirements could be provided for products for which special EU regulations do not exist. The alternative would be to include a separate provision for articles in an EU NPR regulation. In so doing, the concentration limit for nanomaterials in products would have to be determined, above which a notification requirement is necessary.

In any case, information obtained from different regulatory areas by the notification requirement in an EU NPR regulation should be consolidated in an NPR.

h) Information for consumers

Where provisions exist, which require that ingredients have to be declared on the respective product, this should also apply to nanomaterials. EU Cosmetics and Food Regulations contain such provisions. For biocidal products and articles treated with biocidal products the future EU Biocidal Products Regulation[15] contains labelling requirements for nanomaterials contained in biocidal products. An analogous provision should be included for substances and mixtures in the labelling requirement in the CLP Regulation. For areas in which no such labelling obligations are provided for (in particular, articles and nanomaterials in mixtures that are not classified as hazardous) a labelling obligation can be established by way of an EU NPR regulation.

For consumer information there are basically four conceivable options:

1. NPR for passive information. No declaration on the product. Consumers can check whether the product contains nanomaterials via the product name.
2. Declaration of NM-specific NPR notification numbers on the product or packaging. With such numbers the nanomaterials contained can be researched.
3. Declaration of a product-specific NPR notification number. With this number, information on nanomaterials in the respective product can be researched.
4. Declaration of the product-specific NPR notification number. With this number Information on nanomaterials in the respective product can be researched. In addition, nanomaterials are declared on the product or packaging.

Option 1 has the result that the consumer can find out only at considerable cost whether nanomaterials are contained in the respective product; provided, that is, he is aware of the possibility. At the same time, changes in composition or the product name lead to uncertainties. For this reason, this option is not recommended. Option 2 quickly becomes confusing in the case of complex products. Option 3 is basically appropriate. One would achieve a maximum in transparency if, additionally, nanomaterials had also to be declared on

15 In accordance with the position of the European Parliament adopted at Second Reading on 19 January 2012 with a view to the adoption of Regulation (EU) No. ../2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products. The Council approved on 10 May 2012. The Regulation shall apply from 1 September 2013.

the product (Option 4). Option 4, however, would arouse the suspicion, much more so than other options, of a particular risk from nanomaterials. In order to rule out discrimination we therefore favour Option 3, insofar as specific regulations do not require more extensive labelling.

D. Practicability

a) Preliminary remark

Not only national guidelines (in Germany: Joint Rules of Procedure of the Federal Ministries (*GGO*) and the Act on the Establishment of the German National Regulatory Control Council (*NKRG*)) but also European guidelines provide for analysis of the effects of new legal regulations. At the present stage of developments a comprehensive analysis of the effects of an NPR is not possible. An initial rough analysis concerning practicability and cost is undertaken, however, in this section.

Unfortunately, definitive statements on the future scope of required NPR notification cannot be made. The cost can therefore not be reliably estimated at the present time. Statements have been published by industrial associations[16] to the effect that the nano definition pursuant to the recommendation of the European Commission covers a large number of materials.

b) Substances and mixtures

In the case of mixtures a wide range of experiences can be drawn on concerning hazardous ingredients. The extension of existing requirements to cover mixtures containing nanomaterials is generally regarded as acceptable. Existing provisions on communication (labelling, safety data sheet and information pursuant to Article 32 REACH[17]) can be expanded in such a way that, without undue difficulty, necessary information is made available to stakeholders.

Certain problems can arise in the case of mixtures and substances imported into the EU. Importers do not always have adequate information on the nanomaterials the substances and mixtures contain. This problem concerns in particular (not only in the case of imports) nanomaterials that are not intentionally added.

Independent of an NPR, importers and manufacturers must already dispose of information on nanomaterials contained in substances and mixtures in order to fulfil their obligations under REACH.

It is established, however, that significant non-compliance with notification requirements pursuant to Article 16e of the German Chemicals Act[18] occurs. A specific investigation in the State of North Rhine Westphalia in 2010 showed that with 15% of 760 examined products no notification had been made, and with a further 8% delays in notification had occurred.[19]

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16 Cf., for example, VCI press release of 18.10.2011; EU declares just about all everyday products to be "nano".

17 Obligation to inform downstream users in the supply chain in the case of substances as such and of mixtures for which no safety data sheet is required.

18 Notifications for poison treatment and information centres.

19 Rosemarie Greiwe; Chemikaliengesetz: Einhaltung der Mitteilungspflichten durch Unternehmen und Folgerungen für den Vollzug; StoffR 2011, p. 153-158.

A significant level of non-compliance has to be expected with nanomaterials that are not to be classified as hazardous, since in this case existing requirements cannot be drawn on. Monitoring of requirements is difficult, and only in the case of specific suspicion is there the possibility of analytical control of whether nanomaterials are contained. The notification requirement is nonetheless still considered to be monitorable.

Estimations of the number of notification to be expected cannot be made on the basis of available information. Several million mixtures must be assumed on the EU internal market.[20] In the medium term, depending on the concentration limit for nanomaterials in mixtures, it has to be assumed that 100,000 mixtures will be subject to notification in an NPR. The actual number will ultimately depend on the market penetration of nanomaterials.

c) Articles

From the discussion on REACH requirements for articles it is known that generally only very limited knowledge exists on their chemical composition. This applies, in particular, to imported articles.[21] This problem will also occur with regard to articles containing nanomaterials. In this case there is the additional problem that analytical proof of nanomaterials in an article is barely possible. With highly complex articles, in particular, and with articles imported into the EU in general, compliance with notification requirements will involve considerable problems.

In addition, one can draw only in certain areas on existing information requirements in chemicals and product law. There are an almost unmanageable number of different articles that, in part, are brought onto the EU internal market by different importers. It has therefore to be expected that even with an optimum structure an NPR will still have significant information gaps concerning nanomaterials in articles.

The demands of the Federal Environment Agency for further development of requirements for articles under the REACH Regulation would also contribute to improved compliance with notification requirements for an NPR. Yet even then, it must be expected that a complete overview of relevant articles containing nanomaterials actually on the EU internal market will not be provided. A marked improvement in knowledge of the main areas of application and of approximate volumes will, however, be possible.

Although no reliable figures are available on articles on the EU internal market, estimates show that considerable more articles than mixtures are on the market. The share of articles, however,

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20 In estimating the cost resulting from the transitional regulation in the CLP Amendment Act (Bundestag Doc. 17/6054 (No. 27 and 49) a total of 3 million required safety data sheets is assumed. In addition there are mixtures for which no such obligation exists. There is also the problem of varied product names in different EU Member States. In the impact assessment for the CLP Regulation the Commission assumed, on the basis of a CEFIC estimate, a total of 2 million mixtures on the EU Internal Market.

21 On the topic of problems in meeting REACH obligations for articles, see, for example, Ökopol, Umco; Analysis of the Realisation of Obligations from Article 7 and 33 under REACH for imported Articles; (UFOPLAN FKZ 3707674005), Hamburg 2010.

which can release nanomaterials, will probably be small. One can therefore expect a manageable number of notifications.

All in all, we believe it is necessary to carry out an impact analysis of the scope of an NPR and the consequences of its establishment.

E. Conclusion

Due to the particular uncertainties concerning evaluation of the possible risks of nanomaterials for human health and the environment, as well as on the grounds of precaution, the German Federal Environment Agency supports the establishment of a European register of products containing nanomaterials. Reflections on the possible structure of such a nanoproduct register are presented in this report. Together with the experiences made by other EU Member States, a useful contribution can be made by Germany towards closing safety and communication gaps concerning nanomaterials.

An NPR is merely one component in the overall regulation strategy for nanomaterials. An NPR cannot substitute other adaptations in chemicals, product and environmental law that are being discussed.