MARTINUS NIJHOFF PUBLISHERS

*JEEPL 9.2 (2012) 113–135*

JOURNAL FOR EUROPEAN ENVIRONMENTAL & PLANNING LAW

brill.nl/jeep

# Precautionary Principle and Nanomaterials: REACH Revisited

**Christian Calliess and Heidi Stockhaus***

*europarecht@fu-berlin.de; heidi.stockhaus@fu-berlin.de*

**Abstract**

Throughout 2011 several institutions endorsed the concept of establishing a European nanoproduct database,[1] which would enable consumers and government officials alike to determine which consumer products contain nanomaterials. In keeping with the precautionary principle this would allow measures to be taken in the event of the recovery of a potential risk in the future.[2] For while the scope of EU regulatory activities has increased, an instrument is lacking that would across all sectors allow both consumers and government officials to obtain a clear idea of which products contain nanomaterials. This approach would also be in keeping with REACH,[3] which

*) Christian Calliess, Professor of Public and European law at Freie Universität Berlin, is holder of the Jean Monnet Chair for European Integration and a member of the German Advisory Council on the Environment (Sachverständigenrat für Umweltfragen (SRU)). Heidi Stockhaus is a research fellow at SRU and is working toward her doctorate at Freie Universität Berlin under ProfessorCa lliess.

1) See for example Press Release No. 19/2011 of the Federal Ministry of the Environment, Nature Conservation and Nuclear Safety, available at: <http://www.bmu.de/english/current_press_releases/pm/47004.php>.

2) See SRU, *Precautionary Strategies for Managing Nanomaterials* (2011), available at: <http://www.umweltrat.de/SharedDocs/Downloads/EN/02_Special_Reports/2011_08_Precautionary_Strategies_for_managing_Nanomaterials_chapter07.pdf;jsessionid=539D79446A6EBA39973EE86AE5402C8D.1_cid137?__blob=publicationFile>; Working group 3 of the NanoKommission, *Review of Nanomaterial and Nanoproduct Regulation* (2011), pp. 54 et seq., available at: <http://www.bmu.de/files/english/pdf/application/pdf/nano_abschlussbericht3_en_bf.pdf>.

3) 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, O.J. 2006, L 396, pp. 1 et seq. (hereafter: REACH regulation).



DOI 10.1163/187601012X639817

also applies regardless of the sector and lays down regulations concerning chemicals and thus also applies to nanomaterials by virtue of their being a specific embodiment of chemicals. However, as all concerned agree, REACH exhibits a certain number of deficiencies when it comes to nanomaterial regulation. The present paper discusses these deficiencies in light of the precautionary principle and at the same time addresses the issue as to whether reforming REACH would obviate the need to establish an online public nanoproduct database.

**Keywords**
precautionary principle, burden of proof, REACH-Regulation, registration and authorisation of nanomaterials, communicationo fi nformation, nanoproductd atabase

## 1. Nanomaterials as a Challenge for Regulation

Nanomaterials are notable not for their specific chemical composition, but for their extremely small size: a nanometer is only one billionth of a meter in size and is thus around 100,000 times smaller than the diameter of a human hair. As the predominant force in the nanometer sphere, quantum mechanical effects alter electron energy states, a phenomenon that can result in different optical, electrical and magnetic properties to the bulk material. The nanometer sphere also displays an extremely enlarged surface to volume ratio. Therefore, a nano surface displays a greater number of atoms or molecules, which can increase surface reactivity.[4] These phenomena are leveraged (via targeted manipulation) by nanomaterial and nanoproduct manufacturers to achieve special effects either by reducing the size of a macroscale material (such as nanoscale titanium dioxide) or by building atom-based molecular structures (such as carbon nanotubes and fullerenes).

These material properties also have ramifications for scientific risk assessment in that the relevant test methods need to be reconsidered[5] and additional data must be gathered. The key consideration in this regard is that knowledge concerning macroscale materials is not applicable to nanomaterials and thus their environmental and health impacts need to be scientifically assessed separately.

---

[4] Royal Commission on Environmental Pollution (RCEP), *Novel Materials in the Environment: The case of nanotechnology* (2008), p. 16, available at: <http://www.official-documents.gov.uk/document/cm74/7468/7468.pdf>.

[5] Organisation for Economic Co-operation and Development (OECD), *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials* (2009), available at: <http://www.oecd.org/document/53/0,3746,en_2649_37015404_37760309_1_1_1_1,00&&en-USS_01DBC.html>.

Hence it is not surprising that nanomaterial risk research has intensified in recent years, although the results so far do not allow for final assessments. For example, the data from various animal studies on the effects of inhaling the emissions of nanomaterials such as carbon nanotubes and nanoscale titanium dioxide show possible carcinogenic effects but are not (yet) enough for a classification as a carcinogen.[6] Besides such first insight into a handful of areas, virtually nothing is known for example about the behaviour of nanomaterials in the environment and their impact on aquatic and soil organisms.[7] Generally, the scientific risk assessment of nanomaterials is complicated by the fact that different research facilities use different testing methods.[8] This in turn complicates the task of assessing the relevant findings and leads to controversial expert opinions. At the same time risks can only be assessed for specific nanomaterials and on a case by case basis.[9] This entails massive efforts in research, also due to the increasing pace at which new nanomaterials are emerging.

This situation is very unlikely to change at any time in the near future. In the interest of ensuring that domestic and international regulations and regulatory authorities can keep up with the pace of nanomaterial development, a number of years ago the Canadian environmental organization, *Environmental Technology Centre* (ETC), called for a moratorium on all nano-research.[10] However, the European Commission termed this a highly counterproductive concept that would deprive society of possible advantages, and referred to the precautionary principle as the guide in case of emerging risks.[11] And the Commission's point is well taken for the precautionary principle allows for differentiated approaches to the challenges posed by nanomaterials and nanoproducts.

---

6) Bundesinstitut für Risikobewertung (BfR)/Umweltbundesamt(UBA), *Beurteilung eines möglichen Krebsrisikos von Nanomaterialien und von aus Produkten freigesetzten Nanopartikeln* (2010), p. 1, available at: <http://www.bfr.bund.de/cm/343/beurteilung_eines_moeglichen_krebsrisikos_von_nanomaterialien_und_von_aus_produkten_freigesetzten_nanopartikeln.pdf>.

7) SRU, *Toxic substances and REACH, Selected Chapters of the Environmental Report 2008, Volume 3*, Item 652, available at: <http://www.umweltrat.de/SharedDocs/Downloads/EN/01_Environmental_Reports/2008_Environmental_Report_Vol_3_selected_chapters.pdf?__blob=publicationFile>.

8) RCEP, op. cit. *supra* note 4, p. 55.

9) BFR/UBA, op. cit. *supra* note 6, p. 1.

10) Nanotechnologie: Die nächste Kandidatin für ein Moratorium, Basler Zeitung, 15 July 2003.

11) European Commission, *Towards a European Strategy for Nanotechnology* (2004), p. 19, available at: <http://ec.europa.eu/nanotechnology/pdf/nano_com_en_new.pdf>.

## 2. The Precautionary Principle and Nanomaterials

The precautionary principle is enshrined in German law via Article 20a of the German Constitution and in European Community law via Article 191(2) of the Treaty on the Functioning of the European Union, and can thus be regarded as a generally accepted legal principle.[12] The European Commission has published a communication on the precautionary principle according to which it can be referred to in case of doubt not only in the area of environment, but also of health and consumer protection.[13] Hence the precautionary principle applies above all in situations where scientific findings do not allow for a definitive conclusion or where such conclusions are unclear, and a preliminary risk assessment raises concerns of negative impacts on the environment or human health. Hence under the precautionary principle government action is legitimate in the presence of risk—i.e. "reasonable grounds for concern"—and thus unlike the sufficient-probability criterion that applies to averting of danger, the mere possibility of a risk allows the State to intervene. This in turn means that the State can intervene sooner and does not have to wait for proof of an actual danger.

### 2.1. *Elements of a Risk Management based on the Precautionary Principle*

To avoid exercising precaution for precaution's sake and to allow for balancing of the risks and opportunities that are entailed by new materials and products and hence increase acceptance, the legislator is bound by specific requirements. To this end the reasonable grounds for concern that allow recourse to the precautionary principle need to be determined via risk data generation and scientific risk assessments on one hand and via normative risk assessments on the other. The difference between the two being that while the former is based on a process whereby all available information is gathered and the potential risk is assessed, the latter involves determining whether a particular risk is

---

12) Calliess, *Rechtsstaat und Umweltstaat* (2001), pp. 179 et seq.

13) European Commission, *Communication from the Commission on the precautionary principle*, COM (2000) 1, 2 February 2000, p. 8 et seq.; also see Rengeling, "Bedeutung und Anwendbarkeit des Vorsorgeprinzips im europäischen Umweltrecht", *Deutsches Verwaltungsblatt* (2000), pp. 1473 (1478 et seq.); Appel, "Europas Sorge um die Vorsorge. Zur Mitteilung der Europäischen Kommission über die Anwendbarkeit des Vorsorgeprinzips", *Neue Zeitschrift für Verwaltungsrecht* (2001), pp. 395 (396 et seq.); Arndt, *Das Vorsorgeprinzip im EU-Recht* (2009), pp. 80 et seq.

acceptable for society.[14] Once reasonable grounds for concern have been identified, measures can be taken to counteract the potential risks. These measures have to take into account the basic right of economic freedom and thus have to be proportionate to the possible adverse effects. To transfer knowledge about potential risks to the administration, supply-chain actors, as well as consumers and to communicate information about handling risks, risk management regulations should include obligations to share information.

### 2.2. *Shifting the Burden of Proof by the "Rebuttable Presumption of Danger"*

Since the precautionary principle is concerned with managing risk scenarios that are fraught with uncertainty, it is crucial that the preventive elements of the principle are enforced so that the state can take adequate measures. The significance and purpose of the precautionary principle implies a shifting of the burden of proof, which, however, cannot be applied generally. A complete shifting of the burden of proof that requires those who cause the risk to prove that the substance or product is not harmful is beyond the realm of possibility. Having its possible positive effects in mind, it is also not desirable in regard to the scientific and economic progress. Finally, a complete shifting of the burden of proof would entail problems in terms of the rule of law and constitutional rights.

However, recourse to the precautionary principle is allowed in the case of reasonable grounds for concern, which require a scientifically established potential risk, or in the case of a *non liquet* scenario, where uncertainty concerning the validity of a potential risk cannot be resolved owing to conflicting expert views. Here the precautionary principle can act to shift the burden of proof by creating a "rebuttable presumption of danger".[15] This means that neither lawmakers, nor regulatory authorities, nor risk originators need to

---

[14] Calliess, "Inhalt, Struktur und Vorgaben des Vorsorgeprinzips im Kontext der Gestaltung des Umweltrechts" in: Hendler/Marburger et al. (Ed.), *Jahrbuch des Umwelt-und Technikrechts* (2006), pp. 89 (111 et seq.); for a more complete account see Calliess, op. cit. *supra* note 12, pp. 214 et seq.

[15] Concerning the derivation and tenets of the precautionary principle see Calliess, "Vorsorgeprinzip und Beweisverteilung im Verwaltungsrecht", *Deutsches Verwaltungsblatt* (2001), pp. 1725 (1728 et seq.); for a more complete account see Calliess, op. cit. *supra* note 12, pp. 153 et seq.; concerning the precautionary principle in general see pp. 223 et seq.; for a discussion of nanomaterials see Calliess, "Das Vorsorgeprinzip und seine Auswirkungen auf die Nanotechnologie", in: Hendler/Marburger et al., *Nanotechnologie als Herausforderung für die*

have complete evidence as to whether the risk in question exists or not. In fact for the implementation of precautionary measures it is sufficient to demonstrate data that indicate a potential risk. Hence if reasonable grounds for concern within the meaning above have been demonstrated, it falls to the risk originator to rebut the presumed cause and effect relationship and show that the resulting concerns are unfounded. In so doing, the risk originator is not required to prove the harmlessness of the substance or product in question, but needs to adduce facts that show that the demonstrated grounds for concern are not likely to occur. Hence the "rebuttable presumption of danger" entails not full-fledged shifting of the burden of proof from government authorities to the risk originator, but rather a reduction of the amount of evidence.

This is consistent with the polluter pays principle and seems justified, since in the final analysis it is the relevant substance or product manufacturers that in effect confront the general public with the risk. It is them from whose sphere of responsibility such risk and the attendant uncertainty stems, and that thus create the cause for concern. Hence any actor whose sphere of responsibility gives rise to such risks and uncertainties is, by virtue of his knowledge advantage obligated to use this knowledge for constructive purposes. Therefore shifting the burden of proof in this manner creates an incentive for risk originators not only to carry out research on innovation but also on risks to be able to rebut the presumption of danger in a procedure that also takes into account the concerns of those affected by such risk.

### 2.3. *Conclusions for Legislators and Competent Authorities*

The precautionary principle or the attendant "rebuttable presumption of danger" legitimizes the legislator to regulate a matter in the face of uncertainty. He can adopt statutes that are based on the precautionary principle and enable the competent authorities to implement measures for precautionary reasons. For example, authorisation procedures that allow competent authorities to take action under the precautionary principle can be implemented. In the absence of an explicit statutory basis for such precautionary action, the competent authorities can only to a limited extend shift the burden of proof themselves. They have to stay within the leeway prescribed by law and follow the legislator's risk assessment and risk allocation. However, this leeway needs to be

---

*Rechtsordnung* (2008), pp. 21 (43 et seq.); for a different view see Arndt, op. cit. *supra* note 13, pp. 286 et seq.

interpreted in light of the spirit rather than the letter of the law, since such statutes are oftentimes somewhat randomly worded.[16] Such interpretations also need to take account of the broader constitutional-rights context of the allocation of the burden of proof. Not only the risk originator's fundamental rights, but also the duty to protect those affected by the risk has to be considered.[17] Insofar as these limits are observed, precautionary measures against new substances and products can be implemented in the absence of firm knowledge concerning their potential risks. Nonetheless, it must be ensured that if a substance or product manufacturer is able to rebut the presumption of danger concerning a new substance or product, he should be entitled to bring it to market.

## 3. Nanomaterial Regulation via REACH in Keeping with the Precautionary Principle

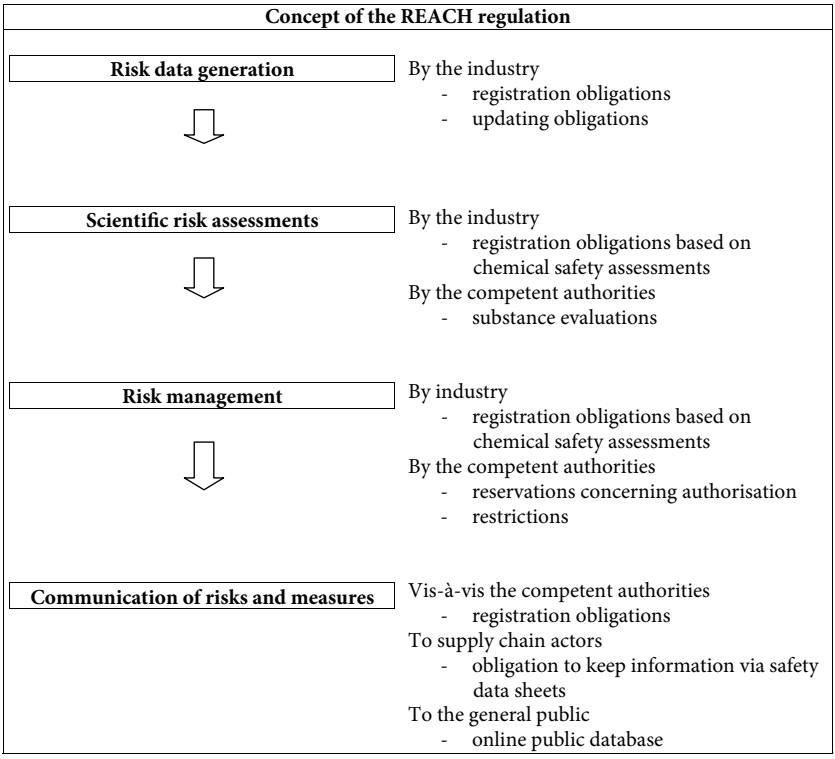
The REACH regulation, which entered into force in 2007 and implemented instruments that allow for registration, evaluation, authorisation and restriction of chemical substances, constituted a far reaching reform of existing regulations and directives in this arena and in so doing claimed to have implemented the precautionary principle.[18] In the interest of achieving a high level of protection for the environment and human health, the REACH regulation lays down substance-specific information compilation obligations that form the basis for the regulation of hazardous substances. Hence chemical manufacturers and importers are required to compile or generate specific data (according to substance volume), carry out risk assessments using the scientific method, and develop the relevant risk management measures. The results are to be conveyed to supply chain actors via safety data sheets, as well as to the European Chemicals Agency (ECHA) within the context of the substance

---

16) Berg, *Die verwaltungsrechtliche Entscheidung bei ungewissem Sachverhalt* (1980), pp. 100 et seq.

17) Calliess, op. cit. *supra* note 15, p. 1725 (1733); for a more complete account see Calliess, op. cit. *supra* note 12, pp. 232 et seq.; Berg, op. cit. *supra* note 16, pp. 99 et seq.

18) See Fleurke/Somsen, "Precautionary Regulation of Chemical Risk: How REACH confronts the regulatory challenges of scale, uncertainty, complexity and innovation", *Common Market Law Review* (2011), pp. 357 (358 et seq.); Calliess, "Einordnung des Europäischen Weißbuchs zur Chemikalienpolitik in das bisherige Chemie- und Umweltrecht" in: Hendler/Marburger et al. (Ed.), *Das Europäische Weißbuch zur Chemikalienpolitik* (2003), pp. 11 (47 et seq.); Calliess/Lais, "REACH revisited - Der Verordnungsvorschlag zur Reform des Chemikalienrechts als Beispiel einer neuen europäischen Vorsorgestrategie", *Natur und Recht* (2005), pp. 290 (294 et seq.).




registration process. The ECHA in turn enters the relevant data in an online public database and coordinates the integration of specific substances into substance evaluation via a rolling action plan where the competent authorities assess the risks of these substances. The findings of these risk assessments in turn form the basis for the ensuing authorisation or restriction procedures, which are intended to promote safe and reasonable use of hazardous substances. Hence substances of very high concern may be subject to an authorisation procedure, while hazardous substances that pose an unacceptable risk to human health or the environment may be subject to restrictions in terms of manufacturing, placing on the market or use.

Although the REACH regulation lays down a comprehensive framework for the regulation of substances, the question arises as to under which circumstances the REACH instruments also promote a precautionary use of nanomaterials.

### 3.1. *Definition of "Substance" According to REACH*

The various instruments of the REACH regulation apply to substances that are defined in Article 3(1) REACH as "a chemical element and its compounds in the natural state or obtained by any manufacturing process." To determine whether a particular element is a substance in its own right, the substance identification criteria pursuant to Annex VI (2) REACH are applied, which, however, make no distinction as to size. There is a general consensus that commercially available nanomaterials qualify as substances under today's chemicals regulations.[19] However, when such substances differ from their macroscale counterpart solely in terms of size, then they do not qualify as substances in their own right. Even if in addition to size, a specific arrangement of the atoms comes into play, some latitude remains. For example, in the final analysis fullerenes and carbon nanotubes are composed of carbon atoms and thus could be considered as carbon.[20] Owing to this lack of robust parameters and descriptors that would allow for clear identification of nanomaterials,[21] they cannot be regarded as substances in their own right under the REACH regulation.[22] This in turn means that the REACH regulation does not apply as a matter of course to nanomaterials, but instead to materials as a whole whether they are produced or imported solely as nanomaterials or as both nanomaterials and macromaterials. Owing to the fact that the REACH regulation links all obligations to "substances", it lacks a catalyst for nanomaterial related action in cases where a substance is manufactured or imported in both its macroscale and nanoscale forms. This lack to capture nanomaterials with the

---

19) Führ/Hermann et al., *Rechtsgutachten Nano-Technologien* (2006), pp. 25, 21, available at: <http://www.oeko.de/oekodoc/334/2006-022-de.pdf>; European Commission, *Nanomaterials in REACH*, CA/59/2008 Rev. 1, p. 5; available at: <http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf>; Köck, "Nanopartikel und REACH. Zur Leistungsfähigkeit von REACH für die Bewältigung von Nanorisiken", in: Scherzberg/Wendorff (Ed.), *Nanotechnologie: Grundlagen, Anwendungen, Risiken, Regulierung* (2008), p. 183 (191).

20) Carbon nanotubes and fullerenes can be regarded as substances in their own right by virtue of now having their own CAS numbers.

21) Rijksinstituut voor Volksgezondheid en Milieu (RIVM), *Nanomaterials under REACH—Nanosilver as a case study* (2009), p. 16, available at: <http://www.rivm.nl/bibliotheek/rapporten/601780003.pdf>.

22) On the own right-status of nanomaterials see Rucireto, "Nanomaterialien" in: Führ (Ed.), *Praxishandbuch REACH* (2011), pp. 105 (109 et seq.).

instruments of the REACH regulation is inconsistent with the precautionary principle. For in order to determine and evaluate the characteristics of nano-substances as opposed to those of their macroscale counterparts and the risks attendant upon such changes, and then devise risk management measures based on these findings, the relevant statutory obligations simply must apply to nanomaterials in their own right. To this end, and in the interest of obviating the need to modify the criteria for the identification of substances, and at the same time establish nano-specific rules, a definition of nanomaterials should be added to Article 3 REACH that requires nanomaterials to be treated as a substance in their own right by way of a legal fiction.

### 3.2. *Registration Procedure*

Title II of the REACH regulation lays down the rules for the registration procedure that require manufacturers and importers of a substance in quantities of 1 ton or more per year to submit a technical dossier containing basic data on the substance, an abstract description of its use and guidance on its safe use. The scope of the information required varies pursuant to Article 12 REACH according to the annual amounts manufactured or imported, whereby the tonnage thresholds are 10, 100 and 1000 tons. The tests that substance manufacturers or importers are required to carry out and the standard data they are required to submit are listed in Annexes VII–X of the REACH regulation. According to Article 14 REACH manufacturers and importers have to submit a chemical safety report requiring information concerning the properties and harmful effects of any substance that is manufactured or imported in amounts exceeding 10 tons. If, according to these findings, the substance meets the criteria for classification as hazardous—for example carcinogenic, mutagenic or toxic to fertility—in accordance with the CLP Regulation[23] or is assed to be persistent, bioaccumulating and toxic (PBT substance), or very persistent and very bioaccumulating (vPvB substance), the manufacturer or importer must then assess the exposure and characterize the risks attendant thereupon for all identified uses. The substances listed in Annexes IV and V of the REACH regulation are exempt from the regulation's registration requirements either because the available information indicates

[23] Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, O.J. 2008, L 353, pp. 1 et seq. (hereafter: CLP regulation).

that they present only a minimal risk or as the registration procedure is deemed inappropriate or unnecessary. Insofar as they have been pre-registered, Article 23 REACH stipulates that phase-in substances—mainly substances that are registered in the European Inventory of Existing Commercial Chemical Substances (EINECS) and thus were placed on the market prior to September 1981—are subject to various transitional periods. The first transitional period ended in December 2010, the remaining two will end respectively in 2013 and 2018. The registration obligation under REACH can be said to be based on the precautionary principle. With regard to nanomaterials, however, shortcomings can be identified.

3.2.1. *RegistrationD ossier*

Inasmuch as nanomaterials are not substances in their own right under the REACH regulation, the decision as to whether such substances should be registered separately is up to their manufacturers and importers. This in turn affects the nature and scope of the information included in the registration dossier, since it only queries information per substance. However, in the view of some, the REACH regulation requires that macromaterial registration dossiers that also encompass nanomaterials should include, at a minimum, nanomaterial information concerning the following: properties, uses, effects, relevant classifications, safety assessment and relevant exposure scenarios.[24] This view is mainly based on Article 1(3) REACH which states that the "regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment". Likewise relevant in this regard is the provision in Article 14(4) REACH to the effect that each chemical safety assessment has to include an exposure assessment and risk characterization for all identified uses of the registrant. However, Article 14(4) REACH only applies to hazardous substances and PBT or vPvB substances, and at the same time presupposes that nanomaterials will open up new uses. Thus the REACH regulation in effect fails to lay down the requisite minimum obligations concerning nanomaterial registration—an omission that is unjustified in view of the altered properties of these materials relative to their macroscale counterparts. That should be remedied in the interest of adherence to the precautionary principle. Moreover, the cause of transparency would be greatly served if separate dossiers were compiled for nanomaterials and their macroscale counterparts.

---

[24] See in particular European Commission, op. cit. *supra* note 19, p. 6.

3.2.2. *Data Requirements and Chemical Safety Assessments*

Although the data requirements in Annexes VII–X of the REACH regulation apply to all nanomaterials that are subject to a registration procedure, these requirements do not address their specific physical and chemical properties. In order for scientifically sound risk assessments to be conducted, it is necessary to adapt the relevant test methods accordingly and gather additional data.[25] If—as is the case with nanomaterials—the requisite data for classification of a substance within the meaning of the CLP Regulation or as a PBT or vPvB substance are lacking, under the REACH regulation neither an exposure assessment nor a risk characterisation need be carried out for chemical safety assessments of substances that exceed the 10 ton per substance and manufacturer limit. Hence for precautionary reasons the REACH regulation should require that such data be developed for nanomaterials without regard for tonnage thresholds so as to set the stage for preliminary risk assessments and the attendant identification of a potential risk.[26] This preliminary risk assessment could trigger the obligation to conduct an exposure assessment and a risk characterisation.

3.2.3. *Tonnage Th resholds*

Any given nanomaterial displays less mass than the bulk material, and owing to its specific surface properties is also more reactive. If solely the nanomaterial variant of a given material were to be manufactured or imported, or if nanomaterials were to be registered separately, the current tonnage thresholds would be unduly high and would not sufficiently take account of the potential risk.[27] This situation could (and should) be remedied by lowering such thresholds or by defining other suitable parameters.

3.2.4. *Transitional Periods for Phase-in Substances*

As nanomaterials are not classified as materials in their own right, they could be folded into the substance registration procedure via a preregistration mechanism and would therefore fall within the scope of the transitional periods for

---

25) SRU, op. cit. *supra* note 7, Item 659; European Commission, op. cit. *supra* note 19, p. 11; RIVM, op. cit. *supra* note 21, p. 17.

26) For a simplified registration procedure for nanomaterials manufactured or imported in volumes amounting to less than 1 ton, see "European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials" (2008/2208 (INI)); for an alternative to the linkage between classifications and exposure assessement and risk assessments see RIVM, op. cit. *supra* note 21, p.58.

27) Führ/Hermann et al., op. cit. *supra* note 19, p. 27; RCEP, op. cit. *supra* note 4, p. 62.

phase-in substances. However, in view of the difference between nanomaterial properties and those of the counterpart bulk material and the possibility that this difference also translates into an altered risk profile, it is unjustified to give the nano version of a bulk material a free pass simply because its macro counterpart has been on the market for years without raising any health or environmental safety concerns.[28] Treating nanomaterials as materials in their own right could potentially solve this problem. Lacking such a solution, application of the transitional periods to nanomaterials should be excluded since otherwise registration of such materials would not be mandatory until 2013 or 2018.

3.2.5. *Exemptions*

The estimates that form the basis for REACH exemptions cannot and should not be applied to nanomaterials since the paucity of the available empirical data concerning nanomaterials does not allow for sound decisions, and neither the appropriateness nor the necessity of a registration can be assessed. It is therefore not justified to exempt also the nanoscale versions of the exempted substances listed in REACH Annexes IV and V from mandatory registration. Inasmuch as, in keeping with the precautionary principle, registration is indispensable for protection of the environment and human health, derogations to the exemptions for nanomaterials should be considered and implemented, as has been done for carbon and graphite in the amended version of REACH Annex IV and V.[29]

3.2.6. *Concluding Assessment of the REACH Registration Procedure*

In terms of exemptions, transitional periods for phase-in substances, and registration dossiers, the root cause of the registration problems discussed above is that REACH's definition of "substance" in effect lumps nanomaterials in with their macroscale counterparts by failing to define nanomaterials as substances in their own right. The problems with the tonnage thresholds and data requirements are also attributable to this definition, but display an

---

[28] Dederer, "Neuartige Technologien als Herausforderung an das Recht—dargestellt am Beispiel der Nanotechnologie" in: Spranger/Dederer et al. (Ed.), *Aktuelle Herausforderungen der Life Science* (2010), p. 71 (85).

[29] Commission Regulation (EC) No. 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V, O.J. 2008, L 268, pp. 14 et seq.

additional dimension of their own in that size complicates reaching the tonnage thresholds and the particularities of scientific risk assessments have an impact on data requirements. In addition, chemical safety reports entailing both an exposure and risk assessment only have to be presented for hazardous substances—reasonable grounds for concern are not a sufficient parameter in such cases. This in turn means that the REACH regulation is limited to classic averting of danger with its relatively high requirements of proof. However, such deficiencies are unacceptable and urgently need to be rectified in view of the fact that the disclosure requirements imposed on manufacturers and importers by the obligation to present information[30] play a pivotal role in implementation of the precautionary principle under chemicals law. And yet, even if these problems are resolved, the fact remains that the REACH registration procedure solely allows for the documentation and evaluation of nanomaterials, and does not provide the competent authorities with a clear picture of the commercially available products containing nanomaterials. Registration dossiers are not required to characterize the application of a specifically identifiable product, but instead merely indicate a general use or use categories.[31] Hence even effecting the relevant changes in the REACH registration procedure would not obviate the need to establish a nanoproduct database.

### 3.3. *Substance Evaluation*

As a basis for later decisions in the authorisation or restriction procedures, a series of registered substances shall be subject to a scientific assessment by competent authorities in the member states that are assigned the substances by the Community rolling action plan.[32] To this end, registrants can be asked via Article 46 REACH to provide information beyond that required for registration. The European Chemicals Agency (ECHA) has been tasked with determining, in cooperation with the member states, the prioritization criteria on whose basis the rolling action plan is to be established.

The current linkage between registration and substance evaluation makes it difficult for nanomaterials entailing reasonable grounds for concern to be

---

30) See Calliess/Lais, op. cit. *supra* note 18, p. 290 (296); Arndt, op. cit. *supra* note 13, p. 316.

31) Also see Hermann/Möller, *Rechtliche Machbarkeitsstudie zu einem Nanoproduktregister* (2010), p. 27, available at: <http://www.oeko.de/oekodoc/1031/2010-083-de.pdf>.

32) On the linkage between registration and substance evaluations see: ECHA, *Guidance on Dossier and Substance Evaluation* (2007), p. 59, available at: <http://echa.europa.eu/documents/10162/13628/evaluation_en.pdf>.

subjected to substance evaluation on their own.[33] However, if the bulk material is to be evaluated the properties of the nanoscale counterpart can be addressed by the responsible competent authorities although no rules for those cases—concerning for example information requirements—have been established so far. To ensure a comprehensive scientific assessment of nanomaterials and to allow transparency throughout the process of substance evaluation, it is justified for nanomaterials to be treated as substances in their own right. What follows is that the prioritization criteria development for future Community rolling action plans should take account not only of nano-specific particularities, but also of the aforementioned reasonable grounds for concern to be factored into decisions concerning which substances are to be evaluated. This should be possible as Article 44(2) REACH allows for inclusion of substances in the rolling action plan in cases where there are "grounds for considering" that a substance constitutes a risk to the environment or human health.

### 3.4. *Authorisation*

The Articles 55 ff. of the REACH regulation provide for a two-phase authorisation procedure aimed at controlling the risks from substances of very high concern, or even replacing such substances. In the first phase substances that are initially placed on the candidate list pursuant to Article 59 REACH can be made subject to an authorisation requirement by listing them in Annex XIV pursuant to Article 58 REACH. In the second phase, manufacturers, importers and downstream users may apply for authorisation of one or several uses of these substances pursuant to Article 62 REACH. Such authorisation can only be granted insofar as "the risk to human health or the environment (…) is adequately controlled," or—if this is not the case—"it is shown that socioeconomic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies" (Article 60(2) and 60(4) REACH). Although making substances subject to an authorisation requirement in the first phase is contingent neither upon prior registration nor on exceeding tonnage thresholds, the Article 57 criteria concerning substances of very high concern have to be satisfied. According to these the substance must meet the criteria for a

---

[33] So far there are three substances proposed for evaluation that could be interesting for the discussion: Silicon dioxide, Silver and Titanium dioxide; see ECHA, *Draft Community Rolling Action Plan* (CoRAP) (2011), available at: <http://echa.europa.eu/documents/10162/13559/corap_2011_en.pdf>.

classification as carcinogenic, mutagenic or toxic to fertility, or they must be a PBT or vPvB substance (Article 57(a–e)), or there must be "scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern" to those other substances (Article 57(f)). Thus, contrary to the European Parliament's position in the REACH legislative process, which pointed to possible altered physical and chemical properties, yet unknown health and environmental effects of nanomaterials and the lack of information concerning their biological dynamics, nanomaterials are not necessarily subject to the authorisation procedure.[34] This is justifiable insofar as no general suspicion must be cast on nanomaterials by equating them with substances of very high concern. However, it now seems highly unlikely that individual nanomaterials will be subject to an authorisation procedure under the REACH Article 57 criteria, as these criteria are limited to classic averting of danger with its relatively high requirements of proof rather than the precautionary principle. Although it would be possible to stipulate an authorisation requirement for nanomaterials solely on the basis of their potential hazardous properties without taking account of the relevant context of use, there is as yet no scientific evidence that nanomaterials actually display such properties. Nor is it possible to determine definitely whether nanomaterials probably have "serious effects to human health or the environment" that "give rise to an equivalent level of concern" to those substances listed in Annex XIV REACH. However, the situation would be different if the criteria of Article 57 REACH could be interpreted in light of the precautionary principle.[35] This however is not an option in terms of the Article 57(a–e) criteria, since the CLP regulation and REACH Annex XIII both reference clearly defined criteria that leave the competent authorities no leeway.[36] Nor is a reading within the meaning of the precautionary principle justified for Article 57(f), according to which substances must give rise to an "equivalent level of concern" to those of the other substances listed in Article 57(a–e). While this allows unknown substance properties to be taken into account,[37] it makes no

---

34) European Parliament, notice of proposed amendment No. 217 to Article 56 of REACH, proposed amendments 208–358 (2004).

35) Concerning all of the criteria mentioned in clauses a–f, see: Bowman/van Calster, "Does REACH go too far?", *Nature Nanotechnology* (2007), p. 525 (526); concerning clause f, see: Köck, op. cit. *supra* note 19, p. 196.

36) Also see: Köck, op. cit. *supra* note 19, p. 183 (196).

37) ECHA, *Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern* (2007), p. 32; available at: <http://www.echa.europa.eu/documents/10162/13638/svhc_en.pdf>.

provision for uncertainty and knowledge or information gaps. Hence in the final analysis the authorisation requirement is a mere instrument to avert the danger caused by hazardous substances.[38] Hence in order for nanomaterials for which reasonable grounds for concern are identified to be subject to authorisation, the REACH Article 57 criteria would need to be supplemented. To this end, a general clause should be added to Article 57 REACH that stipulates an authorisation requirement for substances for which there is "a possibility of serious effects to human health or the environment." This would have the virtue of reducing the amount of evidence needed and would justify an authorisation requirement already in case of reasonable grounds for concern or a *non liquet* scenario. The "rebuttable presumption of danger" hereby implemented would ensure the authorisation requirement to be proportionate. Additional criteria would need to be laid down in order to identify, by way of a preliminary risk assessment, the reasonable grounds for concern according to the precautionary principle.[39]

Not only the current REACH Article 57 criteria but also the procedure for including substances in Annex XIV REACH is not consistent with the tenets of the precautionary principle or the attendant "rebuttable presumption of danger". Article 59 REACH, for instance, stipulates that the ECHA or a member state is to compile dossiers in support of the inclusion of specific substances in the candidate list as an initial step toward authorisation. This in turn means that when it comes to inclusion of a substance in the candidate list, the burden of proof as well as—if neither registration nor the ensuing substance evaluation has been realized—the burden of producing evidence falls to the competent authorities.[40] The burden of proof does not pass to the risk originator until a substance has been included in Annex XIV REACH.[41] In terms of nanomaterials, it is doubtful whether authorisation can be required for them as such since they are not defined as substances in their own right.[42] Nor are nanomaterials likely to be included in the candidate list, owing to the

---

[38] Concerning the European Commission proposal at the time, see SRU, *Umweltgutachten* (2004), Item 1031.

[39] See Scherzberg, "Risikoabschätzung unter Ungewissheit—Preliminary risk assessment im Kontext der Nanotechnologie", *Zeitschrift für Umweltrecht* (2010), p. 303 (310), who also mentions the NanoKommission criteria for preliminary risk assessments.

[40] Also see Foss Hansen, *Regulation and Risk Assessment of Nanomaterials. Too Little, Too Late?* (2009), p. 21, who points out that in the authorisation procedure registration data are deemed to be lacking if the substance in question has not been registered.

[41] Arndt, op. cit. *supra* note 13, p. 317.

[42] Also see Rucireto, op. cit. *supra* note 22, p. 123.

deficiencies in the registration procedure. Until such time as nanomaterial registration is instituted, either the registration and substance evaluation procedures should go their separate ways so that the right to require information that comes into play here can be leveraged or the ECHA or the member states should be granted the right to request additional information from manufacturers and importers within the context of the dossier compilation pursuant to Article 59 REACH. This would shift the burden of producing evidence—if not the burden of proof—to the manufacturers and importers.

Hence the current authorisation criteria and procedure are consistent with neither the precautionary principle nor the attendant "rebuttable presumption of danger". The authorisation requirement can only become a risk prevention instrument if the requisite changes are made in it.

### 3.5. *Restrictions*

Pursuant to Article 67 ff. REACH, restrictions may be placed on the manufacture, use and placing on the market of a hazardous substance that fails the relevant authorisation criteria. Inasmuch as—pursuant to Article 68 REACH—an unacceptable risk to the environment or human health has to be shown, both hazardous properties and exposure are contingent factors in this regard, owing to the REACH definition of a risk. Moreover, socioeconomic considerations and information concerning available alternatives shall support decision-making.[43] As with the authorisation requirement, it is not necessary for the substances to be registered or to have exceeded tonnage thresholds. However, it is highly unlikely at present that nanomaterials will be subject to restrictions since a material must display hazardous properties in order for its manufacture, use and being placed on the market to be deemed an unacceptable risk—and this has yet to be scientifically proven for nanomaterials. Hence the mere fact that a substance with hazardous properties can be presumed to present an unacceptable risk, thus taking into account, to a certain degree, precautionary considerations[44] does not suffice. When it comes to restrictions on the manufacture, use and placing on the market of nanomaterials,

---

[43] ECHA, *Guidance for the preparation of an Annex XV dossier for restrictions* (2007), pp. 69 and 76, available at: <http://www.echa.europa.eu/documents/10162/13641/restriction_en.pdf>.

[44] Ingerowski, *Die REACh-Verordnung* (2009), p. 262, who is referring to the Judgement of the European Court of Justice in Case C-473/98, Kemikalieinspektionen v. Toolex Alpha AB [2001] ECR I-5681 para. 44 et seq.

identifying reasonable grounds for concern via a preliminary risk assessment should be deemed to be a sufficient catalyst for restrictions. This can only be achieved if the restriction criteria are interpreted within the meaning of the precautionary principle (see Article 1(3) REACH) or a provision is introduced that states that restrictions can be established for precautionary reasons.

As with authorisation, the procedure for including restrictions in Annex XVII REACH is not based on the tenets of the precautionary principle and the attendant "rebuttable presumption of danger". Here too the ECHA or member states need to compile dossiers—in accordance with Article 69 REACH—that then serve as a basis for European Commission comitology procedure decisions, which also take account of the positions of ECHA's risk assessment and socioeconomic analysis committees. As with the authorisation procedure, the burden of proof as well as—if neither registration nor the ensuing substance evaluation has been realized—the burden of producing evidence fall to the competent authorities. Hence in order for the restriction procedure to be based on the tenets of the precautionary principle, the observations above concerning the authorisation procedure should also be applied to the restriction procedure. Adhering to the tenets of the precautionary principle is the only way to ensure that restrictions become a full fledged instrument for precautionary action, rather than a mere instrument to avert the danger caused by hazardous substances.

### 3.6. *Safety Data Sheets*

Although other substances are also subject to an obligation to provide certain information, Article 31 REACH stipulates that only suppliers of hazardous, PBT or vPvB substances are subject to an obligation to compile and provide safety data sheets. The latter contain information concerning, among others: manufacturer and substance identification, hazardous properties, environmental impact, effects on human health and measures for responsible use of substances. Hence the purpose of safety data sheets is to disseminate information to the relevant actors and to promote safe substance use within the supply chain.[45]

Owing to the fact that nanomaterials are not substances in their own right under the REACH regulation, it falls to manufacturers and importers to decide whether or not separate data sheets should be compiled for nanoscale

[45] Köck, op. cit. *supra* note 19, p. 189; Dederer, op. cit. *supra* note 28, p. 84.

substances and the equivalent bulk material. And inasmuch as a data sheet needs to be issued for substances with hazardous properties only, it would still remain in the manufacture's or importer's discretion to compile a safety data sheet as long as the relevant information is missing—even if a specific nanomaterial should be regarded as a substance in its own right. While it might be common practice in Germany for manufacturers and importers to *also* use safety data sheets to convey information concerning *non*-hazardous substances to supply chain actors,[46] no such statutory obligation exists in the EU as a whole. In view of the fact that conveying information to supply chain actors is an essential prerequisite for precautionary risk management on the part of downstream users, all nanomaterials should be accompanied by safety data sheets that indicate the nanoscale properties of the substance in question. Also such sheets merely summarize the same information that was previously provided during the registration procedure. There is no requirement to conduct additional tests to raise the quality level of the aforementioned safety data sheet information. For instance, if information concerning a substance's hazard classification is missing, this fact as such needs to be included in the safety data sheet, but manufacturers and importers are not obligated to generate the missing information. Hence it has been correctly asserted that obligating supply chain actors to provide information would yield little benefit when it comes to nanomaterial risk identification, assessment and management.[47] Safety data sheets cannot fulfil their intended purpose as long as it is not possible under a registration procedure to ensure extensive risk assessments.

### 3.7. *Public Database*

Article 119 REACH stipulates that certain information that has been submitted to the ECHA for substance registration purposes is to be made publicly available. This includes among others information concerning substance classification and labelling, the result of each toxicological and ecotoxicological study and guidance on safe use, but—except in cases where a confidentiality request is approved—also information concerning the total tonnage band within which a particular substance has been registered and study summaries. Inasmuch as the information that is to be made publicly available in such cases is contingent upon both the REACH definition of "substance" and on

---

46) Verband der Chemischen Industrie (VCI), *Responsible Production and Use of Nanomaterials* (2008), p. 11, available at: <http://www.nano4m.eu/materiali/vci_nanomaterial_papers.pdf>.

47) Köck, op. cit. *supra* note 19, p. 194.

registration, the problems with both of these elements have implications on the nanomaterial information that is accessible to the public. Since such information is not queried during the registration process, this database provides no information as to which products contain nanomaterials. Hence, effecting the relevant changes in the REACH regulation would not obviate the need for establishing a nanoproduct database.

## 4. Concluding Assessment of the REACH Regulation

Due to the methodological problems involved in testing and the increasing numbers of new nanomaterials that will be introduced in the coming years, the knowledge gap concerning these materials may widen. Against this backdrop, the precautionary principle requires to move risk research forward and allows for making risk originators accountable for it. At the same time, the competent authorities should be empowered to take action concerning nanomaterials even in case of only reasonable grounds for concern. And while the REACH regulation already contains all of the instruments necessary to accomplish both of the foregoing objectives, it needs to be reformed so as to ensure that nanomaterials are used in accordance with the precautionary principle.

The fact that the REACH regulation does not define nanomaterials as materials in their own right creates a ripple effect across the entire REACH framework. This problem has particularly serious ramifications for registration-procedure data compilation and scientific data evaluation. It is compounded by the fact that the tonnage thresholds for a large share of nanomaterials are unduly high and the attendant data compilation requirements have yet to be brought into line with the particularities of nanomaterials. As a consequence, the REACH framework cannot ensure that manufacturers and importers carry out a comprehensive chemical safety assessment. These various registration procedure deficiencies impact other REACH instruments directly or indirectly. In terms of substance evaluation and the publicly accessible database, this is attributable to the formal linkage between registration and these instruments. As for safety data sheet compilation and risk management under the REACH authorisation and restriction procedures, the main problem is the lack of data that are to be compiled and provided for the registration procedure. Here too, not only the REACH definition of "substance" but also the specific properties that qualify a substance as hazardous constitute an additional problematic area in the REACH framework. This deficiency reduces the authorities' risk management to classic

averting of danger with its relatively high requirements of proof and prevents any intervention potentially necessary in situations of uncertainty. Only if the burden of proof can be reduced to demonstrating reasonable grounds for concern and manufacturers and importers are required to provide the information necessary for preliminary risk assessments will it become possible to base authorisation and restriction procedures on the "rebuttable presumption of danger" and to develop these instruments into precautionary instruments.

The aforementioned deficiencies in the REACH regulation can only be resolved by reforming the regulation. However, this would only allow for compilation and scientific assessment of nanomaterial data. Nanoproduct information would still not be compiled, nor would it be made publicly available. Hence efforts should be intensified to require the report of nanoproducts and to establish a nanoproduct database based on the attendant reported data.

## 5. Outlook for a Nanoproduct Database

Establishment of a nanoproduct database would provide both the competent authorities as well as consumers with an overview—the extent of which would need to be determined—over which nanoproducts are placed on the market, and thus ensure their traceability.[48] This traceability is necessary to implement the precautionary principle, particularly when it comes to new technologies that are fraught with uncertainty, and would fulfil the government's statutory obligation to provide a minimum of protection (prohibition of insufficient action).[49] For if products cannot be traced in the event of a *post facto* identified danger caused by hazardous properties, any government action to protect the environment or human health is hardly possible or slow in coming. Moreover, consumers can justifiably expect competent authorities to know which products contain nanomaterials and to take appropriate action if potential risks are reported. By the same token, it is essential that consumers are ensured transparency when it comes to nanomaterial use in products. It is, after all, the consumers who come into direct contact with these products and thus have a legitimate interest in being informed. A nanoproduct database would also

[48] See SRU, op. cit. *supra* note 2; Working group 3 of the NanoKommission, op. cit. *supra* note 2, pp. 55 et seq.; on the tenets and design of registration obligations and a product database see Hermann/Möller, op. cit. *supra* note 31, pp. 57 et seq.

[49] See Calliess, op. cit. *supra* note 12, pp. 322, 451 and 574.

promote the identification of specific demands for regulatory measures concerning individual product groups. All considered, such a database can fill the information gap that would be left by a reform of the REACH regulation, by virtue of its substance rather than product orientation. An amended REACH regulation would *not* obviate the need for establishment of a nanoproduct database, and conversely, establishment of such a database would *not* obviate the need for reforming the REACH regulation.

Achievement of the aforementioned objectives would be furthered if the nanoproduct database proposed here were based on a pan-European and cross-sector approach as used by the REACH regulation. Manufacturers and importers should be required to provide only the information that is necessary to achieve these objectives. In particular, contrary to the REACH approach, manufacturers and importers should not be required, via registration obligations for nanoproducts, to provide extensive information concerning scientific risk assessments of their products and the attendant risk management measures. However, consumer access procedures should be designed in such a way that the nanoproduct database is able to optimally perform its function as an informational instrument that promotes implementation of the precautionary principle.