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elni REVIEW

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Editorial

The main topics of this issue are the *enforcement of EU law*, and *criminal law and the environment*. Enforcement of EU law is often prescribed by the national legal framework and therefore depends strongly on national definitions of the findings of the facts. When focusing on criminal environmental law one of the main hurdles to the effectiveness results from the different national implementation practices of European Directives. In this respect, the problems also differ between the different EU Member States.

This issue of elni Review provides valuable insights into selected national law frameworks:

"Environmental penalties in Italy" by Paola Brambilla focuses on the history and actual issues of criminal environmental law in Italy.

"Enforcing EU environmental law outside Europe? The case of ship dismantling" by Thomas Ormond provides a special view on EU law enforcement from an international perspective.

Armelle Gouritin and Paul De Hert critically discuss the recent developments of European environmental criminal law in their article "Directive 2008/99/EC of 19 November 2008 on the protection of the environment through criminal law: A new start for criminal law in the European Community?"

Topics which focus on actual EU-law issues:

The viewpoint of environmental organisations towards the setting of standards of emissions is provided in "Development of harmonised European standards for measuring emissions from construction products in CEN from the perspective of environmental organisations – Part 1" by Michael Riess and Ralf Lottes.

The article "Regulation of nanomaterials under present and future Chemicals legislation - Analysis and regulative options" by Stefanie Merenyi, Martin Führ and Kathleen Ordnung critically reviews REACH under the perspectives of nanomaterials. It also contains information on recent developments on EU level.

Other topics focus on national laws of non-EU countries:

In his article Eugene A. Wystorobets focuses on the "Principle of public participation in environmental law of the Russian Federation" and provides general insights into Russian law.

"A survey of the Vietnamese environmental legislation on water" by Michael Zschiesche and Duong Thanh An focuses on Vietnamese water law and the organisational background of administrative institutions in this context.

The next issue of the *elni review* will focus on the Industrial Emissions Directive (IED). Please send contributions on this topic as well as other interesting articles to the editors by the end of June 2009.

Nicolas Below/Gerhard Roller
March 2009

elni Forum 2009

on 14th May 2009
at FUSL, Facultés universitaires Saint-Louis in Brussels, Belgium.

"The Directive on Industrial Emissions and its implementation in national law - key issues and practical experiences"

The elni Forum 2009 will offer the opportunity to discuss implementation issues of the upcoming European Directive on Industrial Emissions (IED). European and national environmental law experts will comment on this issue.

The **Annual Meeting of the elni Association** 2009 will take place before the elni Forum.

More information is available at:
www.elni.org

Special Announcement

The representative for interested parties of the ECHA Management Board and co-founder of the *Environmental Law Network International* – Marc Pallemaerts – is now member of the ECHA Board of Appeal.

The editors wish him all the best and every success in the future!

In his place Martin Führ, also co-founder of *elni* and editor of the *elni Review* was nominated at 18 December 2008 by the Commission as a new member of the Management Board of the ECHA (European Chemicals Agency) to represent interested parties.

Regulation of Nanomaterials under present and future Chemicals legislation Analysis and regulative options

Stefanie Merenyi, Martin Führ and Kathleen Ordnung

Nanotechnology has already entered our everyday life. It finds application in a large number of industrial areas, for instance in the automobile industry, in energy and environmental technology, mechanical engineering, the chemicals and pharmaceuticals industry, in medicine, cosmetics and the food industry. Nanoscale titanium dioxide in sunscreen products, for example, provides UV protection, car tyres contain – not only recently – nanoscale carbon black, and many scratchproof, antireflection, non-stick and de-misting surfaces are manufactured with the help of nanomaterials. What distinguishes nanomaterials from previously used substances and processes is, above all, their large and active surface in proportion to their volume. The small particle size can result in modified chemical properties and functionalities compared to conventional substance in a non-nanoscale form, which can range from varied melting and boiling points to greater hardness, magnetism and catalytic effects.

Nanotechnology is regarded as a key technology of the 21st century. Considerable economic expectations are attached to its further development. Due to its low consumption of resources and high energy efficiency, nanotechnology also offers potential ecological relief that should be exploited. At the same time, little is presently known about risks to human health and the environment associated with nanotechnology[1]*. The modified properties of nanoscale substances can lead to different risk assessment compared to conventional materials. Early knowledge in this respect has been available for some time.*[2] *As far as titanium dioxide is concerned, the suspicion has been confirmed: This material, which has been manufactured and used as white pigment for many years, was regarded as unproblematic before its appearance in this small particle size, since tests carried out with non-nanoscale particles were negative. Results of tests on titanium dioxide in the nanoscale form showed, however, that these particles could have ecotoxic effects.*[3]

In view of this conflict between expected benefits and potential risks, the question arises as to which legal requirements nanotechnology is subject to. In the spring of 2006 the Federal Environmental Agency commissioned a legal appraisal[4] *of the present framework of environmental legislation with regard to nanotechnologies and the drawing up of proposals for initial action should regulatory gaps be identified. The main focus of this analysis was chemicals law, and its findings are presented below.*

1 The yardstick of the existing legal framework

The review of the existing legal framework serves the purpose of identifying regulatory gaps. From a methodical point of view this presupposes – as a basis for assessment for further investigation – at least a rough definition of a regulatory "benchmark". In a democratic constitutional state its definition is the "chief duty" of parliament. Up to now, however, neither the European Parliament nor the German Bundestag has made binding statements. In this situation, normative orientation can be achieved in two ways:

- One can fall back on primary Community law or national constitutional law,[5] or
- legislative objectives in similar regulative contexts can be drawn on in a kind of parallel consideration.

In Community law, Art. 174(2), Sentence 2 of the EC Treaty – with the precautionary principle and the principles that environmental damage be rectified at source, that the polluter should pay, and that preventative action be taken – should be cited, supplemented by the objectives in Art. 2 and the cross-sectoral clause in Art. 6 of the EC Treaty.

1 Consider the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee (COM (2008) 366 final), download at: http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf; as well as the Report of the Royal Commission on Environmental Pollution: „Novel Materials in the Environment: The case of nanotechnology", November 2008, downloaded at: http://www.rcep.org.uk/novel%20materials/Novel%20Materials%20report.pdf

2 Federal Environmental Agency (UBA), Nanotechnik: Chancen und Risiken für Mensch und Umwelt, Hintergrundpapier, Dessau August 2006. For that matter consider the recently appeared opinion of the Scientific Committee on Emerging and Newly Identified Heath Risks (SCENIHR): Risk Assessment of Products of Nanotechnologies, adopted at its 28th plenary on 19 January 2009, downloaded at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf.

3 Hund-Rinke, K.; Simon, M.; Ecotoxic Effect of Photocatalytic Active Nanoparticels (TiO_2) on Algae and Daphnids. In: Environ. Sci. Pollut Res 13, pp. 225-232 (2006), p. 225 et seqq.

4 Führ, M.; Hermann, A.; Merenyi, S. et al.: Rechtsgutachten Nanotechnologien (ReNaTe)/Legal appraisal of nano technologies; available in German and English at http://www.umweltdaten.de/publikationen/fpdf-l/3198.pdf (as of 9 September 2008).

5 In German Basic Constitutional Law ("*Grundgesetz*"), from the perspective of protection, it is primarily fundamental rights in Art. 2(2), 12 and 14 as well as Art. 20a that are relevant. But Basic Law can also be cited for the use of nanomaterials. From the perspective of promotion, different uses of nanotechnology can also serve issues of the common good and fundamental rights under Basic Law (including those in Art. 2(2), 12 and 14 as well as Art. 20a).

Parallel consideration of other regulations is based in the end on the *"assumption of the rationality of law"*[6], which aims at fundamental consistency that is the absence of contradiction in the legal system. It has therefore to be assumed that – as in other regulations – the principle of precaution also finds application in the case of nanomaterials. The normative "benchmark" could therefore lean on the material protection objectives of legislation on installations or water. Since risks are based on the specific substance-related properties of nanomaterials, it appears to be sensible to take as a basis the material objectives of the REACh Regulation,[7] according to which

> *"This 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. Its provisions are underpinned by the precautionary principle"* (Art. 1(3) REACh).

In implementation care should be taken that the obligation to act does not primarily lie – as with the previous law on existing substances – with the authorities,[8] but rather, in application of the principle that *"environmental damage should as a priority be rectified at source"* (Art. 174(2) EC Treaty), with the companies that handle nanomaterials. Such a regulative approach is in line with the basic principle of REACh, namely that of self responsibility.[9]

Chemicals law must therefore be able to carry out the following functions:

- Determination of the properties of a substance in the nanoscale form and,
- so far as dangerous properties are involved, communication in practical risk information and measures for appropriate control of substance-related risks, whereby
- protection must be provided not only for employees but also for all persons that might be subject to the effects of nanomaterials as well as for all environmental media.

2 Definition of the term "nanomaterials"

Nanomaterials are the subject of investigation in this report. In line with other definitions[10] these are understood to include:

- Structures of anthropogenic origin (for example, particles, layers[11] and tubes, which are smaller than 100 nm in at least one dimension.
- These structures must possess new functionalities or properties, which would not be realisable in the macro form and be specifically used for the development of new products and applications.

So far as the assessment of regulations under chemicals law was concerned, a further criterion was that the nanomaterials under consideration within this context comply with the key definition of *substance*, namely: *"a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition"*.[12]

The nanomaterials under consideration are chemical elements and compounds in the form of nano particles, layers or tubes, and are therefore covered by this definition.

With the requirement of new functionality a special feature of nanomaterials is addressed, to which particular attention will have to be paid from the perspective of chemicals law; namely, the circumstance that nanomaterials can occur in two manifestations that also differ from a legal point of view. It is possible that nanomaterials occur solely in their small particle size and thus exclusively in this manifestation (hereafter: *exclusive nanomaterials*). This is likely to be the case with those substances that, as a result of new research, are manufactured and used exclusively in the nm range (e.g., carbon nano tubes (CNTs)[13] and fullerenes[14]).

From the point of view of chemicals law, a distinction has to be made, however, for nanomaterials that exist in a manifestation with new functionality in addition to an existing non-nanoscale manifestation of the identical – in terms of molecular structure – substance

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6 See Führ, M.: Rationale Gesetzgebung - Systematisierung verfassungsrechtlicher Anforderungen, in: Gawel, E./Lübbe-Wolff, G., Rationale Umweltpolitik - Rationales Umweltrecht, Baden-Baden 1999, pp. 193-226.

7 Regulation (EC) No. 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACh), OJ 29 May 2007, No. L 136/3.

8 See Führ, M./Merenyi, S.: Mind the Gap - Interface Problems between EC Chemicals Law and sectoral environmental legislation, (RECIEL) 15 (3) 2006,pp. 281-292, 283 et seqq.

9 On this concept see: Führ M./ Lahl U.: Self-responsibility as a regulatory concept - as illustrated by the REACh decision-making process, in: Ormond, Th./ Führ, M./ Barth, R.: Environmental law and policy at the turn to the 21st century, Berlin (Lexxion) 2006, pp. 209-220 (download at: http://www.bmu.de/files/chemikalien/downloads/application/pdf/reach_eigenverantwortung_engl.pdf) and Führ, M./Bizer, K.: REACh as a paradigm shift in chemical policy - responsive regulation and behavioural models; in: Journal of Cleaner Production (JCLP), 15, 2007 (4),pp. 327-334.

10 See the definition of the Federal Ministry for Education and Research (BMBF) at http://www.bmbf.de/de/677_7097.php.

11 On the basis of current knowledge there is no concern potential in the case of layers that would give cause for regulatory activity.

12 As defined in Art. 3 No. 1 REACh; see also the parallel definition in Art. 2(1a) of Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances OJ 196 of 16 August 1967 pp. 1-98, last amended by Directive 1999/33/EC, OJ L 199 of 30 July 1999, pp. 57-58.

13 Tube-shaped products with a diameter of between 1 and 50 nm, made up solely of carbon atoms that have a hexagonal, honeycomb structure.

14 Spherical molecules, which are made up solely of carbon atoms and – as for example in the case of the C-60 – have the structure of a football.

(hereafter: *non-exclusive nanomaterials*). Such cases concern a substance that has been used in a non-nanoscale form for quite a long time, for which particular types of application in the nanoscale form have only recently been known and in use. One such new type of application of a long-established substance is that of titanium dioxide of the size of 60 nm in sunscreens.[15] It has to be clarified, particularly in such a case, whether chemicals law offer mechanisms with which varied risks resulting from different manifestations of a substance (such as in the case of titanium dioxide) can be adequately dealt with.

3 Regulatory situation under REACh

REACh standards have to be met when placing nanomaterials on the market. The focus of the following presentation is on the registration requirement.[16]

The question of the extent to which REACh addresses nanomaterials has also being debated continuously by the REACH Competent Authorities and its subgroup on nanomaterials.[17] The question of whether substances in the nano-scale fall under the scope of REACh is answered with "yes" in the frequently-asked-question paper by the European Chemicals Agency ECHA; thus "their health and environment properties must be assessed according the provisions of the Regulation".[18] Although this seems to be a clear-cut statement, a number of application issues still need to be clarified.

3.1 Distinction: existing and new substances

Terminologically, the distinction between existing and new substances is abandoned under REACh. Other than in previous legislation, these terms are not legally defined in the new Regulation. Under REACh, however, a distinction is made between substances listed in EINECS and substances listed in the ELINCS[19] register of new substances. The former – together with two further categories of substances that have to be separately considered – are listed under REACh as so-called "phase-in substances" (Art. 3, No. 20 REACh), while substances listed in ELINCS are listed under REACh as "notified substances" (Art. 3, No. 21 REACh). In addition, there are substances that are subject to registration for the first time. Should it remain by the assignment of nanoscale substances to existing and new substances as prescribed in the Manual of Decisions,[20] nano compounds previously assigned to existing substance become, under REACh, phase-in substances in accordance with Art. 3, No. 20, Letter a REACh. Individual requirements for substances – and thus also for nanomaterials – under REACh are detailed below.

3.2 Regulation of nanomaterials under REACh

3.2.1 Registration obligation

In fulfilment of the principle of "no data, no market", which is embedded in Art. 5 REACh, a manufacturer or importer that produces or imports a substance on its own or in one or more preparations in a quantity of or exceeding 1 tonne per year, has to submit a registration to the European Chemicals Agency pursuant to Art. 6(1) REACh. This obligation also arises, pursuant to Art. 7(1) REACh, when articles are manufactured or imported in which a substance is present in a quantity exceeding 1 tonne per producer or importer per year, and the substance is intended to be released under normal or reasonably foreseeable conditions of use. These obligations therefore apply for nanomaterials when they are manufactured or imported on their own, in preparations or in articles under the conditions and in the quantity mentioned.

Where nanomaterials are treated as existing substances, transitional provisions for phase-in substances apply pursuant to Art. 23 et seqq. REACh. Depending on the volume manufactured or imported as well as on the hazards of a particular substance, transitional registration deadlines apply up to June 2018 at the latest. The sole prerequisite for utilisation of the transitional regime is pre-registration of the respective substance before 1 December 2008. It has to be assumed that when existing substances are pre-registered in time the respective registration deadline pursuant to Art. 23(1) to (3) also applies to their nanoscale manifestation.

It has to be borne in mind that pursuant to Art. 12 REACh the degree of detail of information required

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15 TiO_2 particles of this size are used as UV absorbers (for example, Nohynek 2006, Eusolex®; Tinosorb or TEGO SUN Z 500/800) in sunscreens (for example, the *L'Oreal* brand).

16 The instruments of authorisation and restriction require information on substance properties and effects, which should be obtained, for instance, during the registration process. Concerning the criteria for decision-making within the framework of registration see Winter, G.: Risks, costs and alternatives in EC environmental legislation: The case of REACh, RECIEL 15(1) 2006, p. 56.

17 REACH CASG(Nano)/European Commission, Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH), 16 December 2008, Doc. CA/59/2008 rev. 1;.

18 "Potential registrants should first consider whether they have obligations under REACH, irrespective of the particle size of the substances. Once it is established that the substance falls within the scope of REACH, further investigation of the detailed provisions of REACH may indicate that different provisions apply according to the hazard properties associated with the particle size of the substances.
The evolving science of nanotechnology may necessitate further requirements in the future to reflect the particular properties of nano particles."
http://echa.europa.eu/doc/reach/reach_faq.pdf, p. 6. (ECHA_FAQ_version 2.4_ 2009-03-20 6)

19 European List of Notified Chemical Substances (current number of substances: 4,381).

20 "Substances in nanoform which are in EINECS (e.g. titanium dioxide) shall be regarded as existing substances. Substances in nanoform which are not in EINECS (e.g. carbon allotropes other than those listed in EINECS) shall be regarded as new substances". See Manual of Decisions (MoD) for implementation of the 6th and 7th amendments to Directive 67/548/EEC of 3 July 2006, EUR 22311, section 5.1.3, p. 64 (see also the MoD excerpt which has been added as Annex 2 to the Commission document Doc. CA/59/2008 rev. 1, cf. Footnote 17).

for registration increases in line with production volume. A detailed chemical safety report is required, pursuant to Art. 14(1) REACh, only for substances in quantities of or exceeding 10 tonnes per registrant per year.

The demand made during the second reading of the REACh Regulation to include nanomaterials in the catalogue of substances potentially subject to authorisation[21] was not included in the adopted regulation.

3.2.2 Updating obligation

Art. 22(1) REACh obliges registrants to update their registrations with relevant information on their own initiative and without undue delay when changes occur, for instance, to the composition of a substance or annual production volume. This obligation applies during the "phase-in" period, however, only to new substances, since according to the wording of the standard ("following registration") registration is a prerequisite. In the case of existing substances there is initially – during phase-in for the duration of transitional deadlines – no such registration. However, notification as in the case of new substances pursuant to Directive 67/548/EEC is regarded, pursuant to Art. 24(1) REACh, as registration for the purposes of the Regulation, and would be sufficient for application of the obligation to update.

New information on the nanomaterial treated as an existing substance had also to be notified to the Commission in accordance with REACh – initially up to the end of May 2008 – on the basis of the Existing Substance Regulation (ESR)[22]. Pursuant to Art. 139 REACh the ESR Regulation was repealed with effect from 1 June 2008, so that an updating obligation resulting from this regulation ended at this point in time. Where existing substances are included in the phase-in scheme due to proper pre-registration, the updating obligation pursuant to Art. 22(1) REACh again applies only following registration, which, on account of the transitional regime pursuant to Art. 23 REACh, takes place in the period up to June 2018.

Annex IV of the REACh Regulation should also be mentioned, which is identical with Annex II of ESR, with the effect that the listed substances are also basically exempted from the registration requirements.[23] Should these substances prove to be the cause of great concern – for instance, because they are carcinogenic or genetically harmful – they may also be made subject to authorisation.

3.3 Conclusion on the situation pursuant to REACh

The standardised regulatory mechanisms under REACh also take effect only on attainment of certain quantitative thresholds; namely, for substances of all kinds produced or imported in a quantity of or exceeding 1 tonne per manufacturer or importer per year. It is doubtful whether *exclusive nanomaterials* will generally overstep this threshold. Where they are employed in very small quantities, resulting effects on man and the environment will remain unresearched, at least as far as chemicals law is concerned.[24] Whether a distinction has to be made in determining this quantitative threshold for *non-exclusive nanomaterials* between nanoscale and non-nanoscale manifestations is also unresolved.

A differentiated approach to substances in the nanoscale and the non-nanoscale form lacked not only in the former chemicals law but is also lacking under REACh. As a result, there is no separate analysis of both manifestations. The systematic recording of the material properties and effects of nanomaterials is therefore also not guaranteed under REACh. As a result, there is a lack of legal requirements, which ensure that appropriate risk management measures are developed and communicated along the production chain.

4 Regulative options

Taking identified regulatory gaps as a starting point, basic approaches for possible regulative options[25] are as follow.

4.1 Substances: Nanoscale vs. non-nanoscale form

Regarding the fact that a substance in a nanoscale form can have different properties to the same substance in a non-nanoscale form, there is a need for regulative action for the creation of structures that ensure the separate consideration of these manifestations and thus their different risks. Such structures are conceivable in varied constellations. Since a change in substance properties can lead to a change in substance identity which might necessitate a dialogue between the registration authority and the registrant a possible

21 Amendment No. 217 to Art. 56 REACh from Carl Schlyter, Caroline Lucas and Hiltrud Breyer, initially adopted by the Environment Committee of the European Parliament on 10 December 2006, but disregarded during the course of subsequent "trilogy" proceedings.

22 Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (known as the Existing Substances Regulation, ESR), OJ L 84 of 5 April 1993 pp. 1-75.

23 In the revised version of Annex IV the element "carbon" is not longer mentioned (see on this point the complete version of the ReNaTe-study (footnote 4), section 6.1.2.2, page 43), thus carbon based nanomaterials are covered by the registration process of REACh. For possible further steps in the amendment of Annex IV see http://ec.europa.eu/enterprise/reach/reach/legislation/reviews/index_en.htm.

24 It is also not certain that analysis will be carried out on some other basis. For instance, Part 1 of Annex VII to the Cosmetics Directive of the Council 76/768/EEC of 27 July 1976 on the approximation of laws of the Member States on cosmetic products, OJ L 262 of 27 September 1976, p. 169), lists titanium dioxide with a permissible maximum concentration of 25 % as number 27 in the list of authorised UV filters, without noticeable information on whether the nanoscale or non-nanoscale manifestation is involved.

25 For a detailed presentation of gaps, a survey of regulative options as well as a multi-step concept, which contains not but regulatory and non-statutory elements, see Führ/Hermann/Merenyi et al. (see *supra* note 4), p. 48et seqq. et seqq. and 63 et seqq.

constellation – if not compelling from a chemical point of view then from a legal standpoint – could be the treatment of the nanoscale manifestation as a separate substance. Nothing would of course be gained from such an approach as long as substances in the nanoscale form do not overstep the future quantitative threshold of 1 tonne per manufacturer or importer per year, which triggers off the registration obligation (cf. section 4.2).

As far as *non-exclusive nanomaterials* are concerned, the following circumstance – whose avoidance could be of interest to manufacturers of such nanomaterials – might support this approach. Where the substance in the non-nanoscale form is an existing substance it becomes, following its pre-registration, the subject of a so-called SIEF (substance information exchange forum) pursuant to Art. 20 REACh. In application of the recommendation of the Working Group on Nanomaterials, the nanoscale manifestation also becomes the subject of the same SIEF). This means that manufacturers of the nanoscale manifestation (e.g. titanium dioxide as UV absorber in cosmetics) together with those of non-nanoscale manifestations (e.g. manufacturers of white pigment) unavoidably[26] form a common SIEF. It is questionable, however, whether the objective of legislators (the avoidance of replicated reports, agreement on standardised classification and labelling) can be achieved in such a constellation, since the described circumstances support the view that here things are brought together that do not belong together. Beyond these practical difficulties, interests of manufacturers of these perhaps fundamentally different substances in secrecy could be threatened.

The treatment of nanomaterials as a separate substance is also supported by considerations contained in Recital 45 of the REACh Regulation regarding so-called UVCB. These substances of unknown or variable composition, complex reaction products and biological materials may be registered as a single substance under the regulation provided that their hazardous properties do not differ significantly and warrant the same classification.[27] This also means that where the hazardous properties of varied manifestations differ significantly, with the result that they are differently classified, they each fulfil the definition of a substance and therefore represent different substances from the point of view of chemicals law. Where a substance in its nanoscale and non-nanoscale manifestations have different properties – as in the case of titanium dioxide – these would have to be treated – analogous to the treatment of UVCBs – as separate substances.

Where a nanomaterial is not to be treated as a separate substance, the necessary distinction from its non-nanoscale manifestation has to be established below the level of substance definition. Under the former system, such a distinction was made, for instance in the case of phosphorus. This substance occurs in two basically different forms (white phosphorus: highly inflammable, highly toxic, caustic, environmentally hazardous; red phosphorus: "merely" highly inflammable), but is nonetheless listed as an existing substance under the EINECS number 231-768-7. The distinguishing of both forms, which is necessary because of varied potential risk, is carried out by means of two index numbers.[28] Analogous to this approach, the necessary separate treatment of nanoscale and non-nanoscale manifestations could be effected, for example, by means of a supplement to the CAS number.[29]

Nevertheless, for Carbon Black (the nanoscale manifestation of Carbon) the distinguishing of both forms was realised on the level of substance identification already under the regime of the ESR as the different entries from the EINECS register show (Carbon: EINECS No. 231-153-3; Carbon Black: EINECS No. 215-609-9).

4.2 Optimisation of quantity-related standards

Another aspect of separate treatment is the repeatedly mentioned question, whether quantitative thresholds, which trigger off the registration requirement, should be differentiated with respect to nanoscale and non-nanoscale manifestations. Separate treatment might be supported with the argument that respective production quantities will be an appropriate value for determining the proportionality of regulations under chemicals law on the avoidance of hazards.[30] A prerequisite for each variant is, however, that the production volume of nanomaterials actually accounts for a "noticeable" share of total production.[31] The fundamental question therefore arises, whether an approach based on quantitative thresholds in terms of tons is appropriate to make perceptible the risks deriving from nanomaterials. Since nanoscale substances – as

26 Cf. the unequivocal wording of Art. 29(1) REACh: "shall be participants substance information exchange forum (SIEF)".

27 Recital 45 of the REACh Regulation.

28 Cf. http://ecb.jrc.it/esis-pgm/esis_reponse_self.php?GENRE=ECNO&ENTREE=231-768-7.

29 Cf. Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR): Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, SCENIHR/002/05 of 10 March 2006, which also emphasises the necessity of separate treatment (p. 55), proposes the retention of the already issued CAS number with the addition of a specific nano code that, where applicable, could also reflect the size of individual nanomaterials (e.g., CAS-NP 50 for a substance with a nano particle size of 50 nm), download under: http://www.chemlin.de/news/mai06/nanorisk.htm.

30 This question would be superfluous were nanomaterials to be treated as separate substances.

31 This is questionable in the case of fullerenes, for example [5,6] fullerene C 70, which is marketed by the Sigma-Aldrich company in 50-mg packs at a price of € 173.00; Source: www.sigma-aldrich.com, catalogue No. 482994, on 26 December 2006.

the example of titanium dioxide as an UV absorber shows – are also employed in cosmetics and thus in immediate contact with the human body, legislators should make sure that substances of this kind are tested before use even when, according to REACh, their production does not overstep the quantitative threshold of 1 tonne, particularly as their production below this threshold does not prevent their use in this sector. Similar considerations could apply to environmental effects.

Instead of a "tonne-based philosophy" one could go back, in the case of nanomaterials, to their characteristic properties, surface activity, and grade requirements under chemicals law accordingly[32].

4.3 Separate "nano regulation"?

With the possible introduction of special quantitative thresholds for substances in the nanoscale form, the question arises whether the creation of a separate legal framework for substances of this kind is justified.

The following points can be argued against separate regulation: Chemical elements and compounds in the form of nano particles are covered by REACh, and for the purpose of a uniform regulatory approach this is where they should be dealt with. It is also in the interests of those affected by regulations to dispense with a special "nano regulation", since all requirements and specifications could then be found in a single regulation. Furthermore, REACh serves as the basis of general chemicals law, to whose specifications and regulations other special areas of chemicals law – for example, concerning cosmetics – can fall back on.

5 Summary

Where nanoscale substances occur solely in this small particle size (so-called *exclusive nanomaterials*, e.g. CNTs), they are currently subject to the demands of REACh when their production oversteps the respective quantitative thresholds. However, current standards do not contain tests and risk assessment concepts specially designed for this group of substances.

Where a chemical occurs in the nanoscale, and non-nanoscale form (so-called *non-exclusive nanomaterials*; e.g. titanium dioxide in the nanoscale form as an UV absorber and in the non-nanoscale form as a white pigment), a distinction is not made between these two manifestations in REACh. As a result, there is no systematic treatment of these different manifestations and thus a lack of transparency regarding their potentially varied risks. At all events, the regulatory situation of nanomaterials is inadequate from the point of view of chemicals law.[33]

6 Current legal and standardisation activities

In 2003, the Committee on Education, Research and the Implications of Technology of the German *Bundestag* demanded a systematic and in-depth analysis of the prior legal framework for applications of nanotechnology.[34] In its Communication, "Towards a European strategy for nanotechnology"[35] in 2004 the European Commission also invited Member States to review existing regulation to take into account any specificities of nanotechnology and to adopt a common European approach. Appropriate and timely regulation was essential, so the Commission, also to ensure confidence on the part of consumers, workers and investors. In its 2005 Action Plan[36] the Commission called upon Member States to review and, where appropriate, modify national legislation and to boost and co-ordinate activities in standardisation. It announced that EU regulations would also be examined and, where appropriate, adaptations proposed. Few results have been achieved as yet. While numerous projects exist, which are concerned with present gaps in knowledge from a scientific point of view,[37] legal questions receive only inadequate attention. The Commission has not yet concluded its announced review.[38] In Great Britain, on the other hand, a report commissioned by the Department for Environment, Food and Rural Affairs (Defra) indicated regulatory

32 See the similar results of the Report of the Royal Commission on Environmental Pollution: „Novel Materials in the Environment: The case of nanotechnology", November 2008, pp. 76-79, 156.

33 On regulation in other areas – for instance, product liability law – see van Calster, Geert, Regulating Nanotechnology in the European Union, Nanotechnology Law & Business, September 2006, p. 359, 360.

34 Report of the Committee on Education, Research and the Implications of Technology, TA-Project - Nanotechnology, 15 March 2004, *Bundestag Documents* (*BT-Drs.*) 15/2713, p. 178.

35 Communication of the Commission, "Towards a European strategy for nanotechnology, COM (2004) 338 final, 12 May 2004.

36 Communication of the Commission to the Council, the European Parliament and the Economic and Social Committee – Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009, COM (2005) 243 final, 7 June 2005.

37 E.g., EU projects NanoTox, NanoDerm, Nanosafe, NanoPathology and IMPART. German projects include NanoCare, INOS, Tracer and NANOKER. The Federal Institute for Occupational Safety and Health, the Federal Institute for Risk Assessment and the Federal Environmental Agency have initiated a joint research strategy, *"Nanotechnologie: Gesundheits- und Umweltrisiken von Nanopartikeln"* (Nanotechnology: Risks of nano particles to human health and the environment"), http://www.umweltbundesamt.de/technik-verfahren-sicherheit/nanotechnologie/index.htm.

38 For example, EU projects NanoTox, NanoDerm, Nanosafe, NanoPathology and IMPART. German projects include NanoCare, INOS, Tracer and NANOKER. The Federal Institute for Occupational Safety and Health, the Federal Institute for Risk Assessment and the Federal Environmental Agency have initiated a joint research strategy, *"Nanotechnologie: Gesundheits- und Umweltrisiken von Nanopartikeln"* (Nanotechnology: Risks of nano particles to human health and the environment"), http://www.umweltbundesamt.de/technik-verfahren-sicherheit/nanotechnologie/index.htm.

gaps in prevailing environmental law,[39] as a result of which the British Government introduced a "voluntary reporting scheme", which in the two years of its operation recorded merely nine notifications.[40] The Royal Commission on Environmental Pollution recommended in its twenty-seventh report that the voluntary codes of conducts and reporting schemes "are likely to be most effective if it is backed up at appropriate points by 'harder' legal and regulatory measures". Therefore, Defra should make nanomaterials reporting mandatory.[41] In Germany, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety has initiated the *"NanoDialog 2006-2008"*, within the scope of which politicians, representatives of industry and the scientific community, public authorities and associations discuss the opportunities and risks of nanomaterials for human health and the environment and are expected to draw up guidelines for the responsible handling of nanomaterials. The Nano Commission, which they set up, supported by three working groups,[42] commenced its activities at the end of May 2007. A final report of the work of the Nano Commission was published in November 2008 but contains no noteworthy recommendations in terms of the setting of a regulatory framework with regard to nanotechnology.[43]

The Organisation for Economic Co-operation and Development (OECD) also set up a "Working Party on Health and Environmental Safety Implications of Manufactured Nanomaterials" (WPMN). The working programme 2006-2008 that was adopted at its first meeting in October 2006 in London comprises three fields of activities.[44] One of the six working groups that were set up for this purpose[45] was entrusted with regulatory aspects of nanotechnology, and in particular with the question of voluntary monitoring systems. By now, this project identified similarities and differences of both voluntary and mandatory national information gathering programmes, and prepared recommendations on approaches and elements to consider for information gathering initiatives. Those outputs were recommended to be declassified and are available on the OECD-webpage.[46] In the past years, the programme of work of the WPMN considerably evolved. Two additional projects were set up. These projects are addressing "The Role of Alternative Methods in Nano Toxicology", and "Exposure Measurement and Exposure Mitigation". Already, a new programme of work is under discussion for 2009-2012.[47]

In the area of standardisation, the International Organisation for Standardization (ISO) set up a Technical Committee on Nano Technologies (TC 229) at the end of 2005, in which 28 ISO member states (currently 32) – including Germany – and 9 countries with observer status (currently 8) are represented. It concerns itself – at present in four working groups[48] – among other things with the development of a common terminology and nomenclature.

The first published standards by ISO are the technical specification ISO/TS 27687:2008 on "Nanotechnologies - Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate" (WG 1), and the technical report ISO/TR 12885:2008 on "Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies" (WG 2). Both were published by the end of 2008.[49]

In addition, measurement techniques should be developed that are appropriate for determining the physical, chemical, biological and structural properties of nanomaterials which also serve the purpose of risk assessment.[50]

In the near future, two draft standards will be available: ISO/CD 10801 on "Nanotechnologies - Genera-

39 Chaudhry, Q. et. al., A scoping study to identify gaps in environmental regulations for the products and applications of nanotechnologies, 2006, http://www.defra.gov.uk/environment/nanotech/research/reports/index.htm.

40 See: First quarterly update on the Voluntary Reporting Scheme for engineered nanoscale materials, December 2006, http://www.defra.gov.uk/environment/nanotech/index.htm.

41 Royal Commission on Environmental Pollution, Novel Materials in the Environment: The case of nanotechnology, 27th report, Cm 7468, November 2008, marginal note 4.66 and 4.74.

42 Working Group (WG) 1: Opportunities for the environment and human health; WG 2: Risks and safety research; WG 3: Guidelines for the responsible handling of nanomaterials.

43 See final report of the Nano Commission: "Verantwortlicher Umgang mit Nanotechnologien - Bericht und Empfehlungen der NanoKommission der deutschen Bundesregierung 2008", November 2008.

44 1) Identification, Characterisation, Definitions, Terminology and Standards; 2) Testing Methods and Risk Assessment; 3) Information Sharing, Co-operation and Dissemination. Online source for WPMN publications: http://www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1,00.html

45 1) Development of a database on human health and environmental safety (EHS) research related to manufactured nanomaterials; 2) Development of a global strategy for EHS research on manufactured nanomaterials; 3) Testing of a representative set of manufactured nanomaterials; 4) Evaluation of the suitability of existing OECD test guidelines (chemical safety) for nanomaterials; 5) Information exchange on national regulatory programmes and voluntary regulatory schemes; 6) Co-operation on risk assessment and undertaking exposure measurements.

46 See „Current Developments/ Activities on the Safety of Manufactured Nanomaterials – Tour de Table at the 4th Meeting of the WPMN, Paris" of December 2008, Series on the Safety of Manufactured Nanomaterials, No. 7, ENV/JM/MONO(2008)29, p. 92.

47 See "Manufactured Nanomaterials: Work Programme 2006-2008" of February 2008, Series on the Safety of Manufactured Nanomaterials, No. 4, ENV/JM/MONO(2008)2, p. 7.

48 WG 1: Terminology and Nomenclature; WG 2: Measurement and Characterisation; WG 3: Health, Safety and Environmental Aspects of Nanotechnologies. At the beginning of 2008 an additional working group was formed: WG 4: Material specifications.

49 See online resource: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983

50 See http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983

tion of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method" and ISO/DIS 10808 on "Nanotechnologies - Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing". The next meeting of the committee will take place in June 2009 in Seattle (USA).

At a national level, the *Deutsche Institut für Normung* (DIN) has set up a Working Committee on Nanotechnologies (NA 062-08-17), whose working groups[51] carry out preliminary work for the ISO Committee and its parallel working groups.

The European Committee for Standardisation (CEN) has also set up a Technical Committee on Nano Technologies (CEN/TC 352). Information on specific results from the work of the CEN is presently not available.

On the next occasion further results from CASG(Nano) shall be presented since the work plan of the CA Subgroup includes "[nano]substance identification, further details on how to prepare registration dossiers for nanomaterials and on information requirements and testing."[52] These issues were also part of the debate of the ECHA work programme for 2010 in the Management Board of the Agency,[53] including the need for more specified (interim) guidance on the application of REACh to nanomaterials.

7 Conclusion

In the period before the investigation was commenced, as well as during its conduct, this Federal Environmental Agency project was criticised as being premature. One knew too little about the risks of this new technology, it was said. There was therefore a risk of causing unease among consumers[54] through an unnecessary debate on regulation. This could also irreversibly damage the image of nanotechnologies and considerably impede exploitation of their potentials. Bearing in mind the findings now presented, it would have been wrong to delay examination of legal issues until the question of whether risks are involved with nanomaterials, and if so, of what kind, could be unequivocally answered. On the contrary, legislation should contribute towards attainment of the objectives that REACh has set for this specific group of substances, namely, establishing direct responsibility for the determination of risks and effective risk-management mechanisms.

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51 WG 1: Terminology and Nomenclature; WG 2: Measurement and Characterisation; WG 3: Health, Safety and Environmental Aspects of Nanotechnologies, WG 4: Performance Criteria.

52 See REACh CASG(Nano)/Commission (Doc. CA/59/2008 rev. 1, cf. Footnote 17), p. 18: "Documents to be developed on these issues are envisaged to be published on the same websites after their endorsement. At a later stage, they might also be handed over to ECHA to assist in the preparation of specific guidance documents."

53 See the minutes of the 12th ECHA-MB Meeting, 26/27 February 2009 at http://echa.europa.eu/about/organisation/management_board/management_board_approved_documents_en.asp.

54 See the results of the "*Verbraucherkonferenz Nanotechnologie*" (Consumer Conference on Nanotechnology) conducted by the Federal Institute for Risk Assessment (*BfR*) at: http://www.bfr.bund.de/cd8551, from which recommendations for further regulatory activities arose.

The Öko-Institut (Institut für angewandte Ökologie - Institute for Applied Ecology, a registered non-profit-association) was founded in 1977. Its founding was closely connected to the conflict over the building of the nuclear power plant in Wyhl (on the Rhine near the city of Freiburg, the seat of the Institute). The objective of the Institute was and is environmental research independent of government and industry, for the benefit of society. The results of our research are made available of the public.
The institute's mission is to analyse and evaluate current and future environmental problems, to point out risks, and to develop and implement problem-solving strategies and measures. In doing so, the Öko-Institut follows the guiding principle of sustainable development.
The institute's activities are organized in Divisions - Chemistry, Energy & Climate Protection, Genetic Engineering, Sustainable Products & Material Flows, Nuclear Engineering & Plant Safety, and Environmental Law.

The Environmental Law Division of the Öko-Institut:
The Environmental Law Division covers a broad spectrum of environmental law elaborating scientific studies for public and private clients, consulting governments and public authorities, participating in law drafting processes and mediating stakeholder dialogues. Lawyers of the Division work on international, EU and national environmental law, concentrating on waste management, emission control, energy and climate protection, nuclear, aviation and planning law.

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The University of Applied Sciences in Bingen was founded in 1897. It is a practiceorientated academic institution and runs courses in electrical engineering, computer science for engineering, mechanical engineering, business management for engineering, process engineering, biotechnology, agriculture, international agricultural trade and in environmental engineering.

The *Institute for Environmental Studies and Applied Research* (I.E.S.A.R.) was founded in 2003 as an integrated institution of the University of Applied Sciences of Bingen. I.E.S.A.R carries out applied research projects and advisory services mainly in the areas of environmental law and economy, environmental management and international cooperation for development at the University of Applied Sciences and presents itself as an interdisciplinary institution.

The Institute fulfils its assignments particularly by:
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The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.
The sofia research group aims to support regulatory choice at every level of public legislative bodies (EC, national or regional). It also analyses and improves the strategy of public and private organizations.
The sofia team is multidisciplinary: Lawyers and economists are collaborating with engineers as well as social and natural scientists. The theoretical basis is the interdisciplinary behaviour model of *homo oeconomicus institutionalis*, considering the formal (e.g. laws and contracts) and informal (e.g. rules of fairness) institutional context of individual behaviour.

The areas of research cover
- Product policy/REACh
- Land use strategies
- Role of standardization bodies
- Biodiversity and nature conversation
- Water and energy management
- Electronic public participation
- Economic opportunities deriving from environmental legislation
- Self responsibility

sofia is working on behalf of the
- VolkswagenStiftung
- German Federal Ministry of Education and Research
- Hessian Ministry of Economics
- German Institute for Standardization (DIN)
- German Federal Environmental Agency (UBA)
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sofia

elni

In many countries lawyers are working on aspects of environmental law, often as part of environmental initiatives and organisations or as legislators. However, they generally have limited contact with other lawyers abroad, in spite of the fact that such contact and communication is vital for the successful and effective implementation of environmental law.

Therefore, a group of lawyers from various countries decided to initiate the Environmental Law Network International (elni) in 1990 to promote international communication and cooperation worldwide. Since then, elni has grown to a network of about 350 individuals and organisations from all over the world.

Since 2005 elni is a registered non-profit association under German Law.

elni coordinates a number of different activities in order to facilitate the communication and connections of those interested in environmental law around the world.

Coordinating Bureau

The Coordinating Bureau was originally set up at and financed by Öko-Institut in Darmstadt, Germany, a non-governmental, non-profit research institute.

Three organisations currently share the organisational work of the network: Öko-Institut, IESAR at the University of Applied Sciences in Bingen and sofia, the Society for Institutional Analysis, located at the University of Darmstadt. The person of contact is Prof. Dr. Roller at IESAR, Bingen.

elni Review

The elni Review is a bi-annual, English language law review. It publishes articles on environmental law, focussing on European and international environmental law as well as recent developments in the EU Member States. It is published by Öko-Institut (the Institute for Applied Ecology), IESAR (the Institute for Environmental Studies and Applied Research, hosted by the University of Applied Sciences in Bingen) and sofia (the Society for Institutional Analysis, located at the University of Darmstadt). The Coordinating Bureau is currently hosted by the University of Bingen. elni encourages its members to submit articles to the Review in order to support and further the exchange and sharing of experiences with other members.

elni Conferences and Fora

elni conferences and fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to gather together scientists, policy makers and young researches, providing them with the opportunity to exchange views and information as well as to develop new perspectives.

The aim of the elni fora initiative is to bring together, on a convivial basis and in a seminar-sized group, environmental lawyers living or working in the Brussels area, who are interested in sharing and discussing views on specific topics related to environmental law and policies.

Publications series

- Access to justice in Environmental Matters and the Role of NGOs, de Sadeleer/Roller/Dross, Europa Law Publishing, 2005.
- Environmental Law Principles in Practice, Sheridan/Lavrysen (eds.), Bruylant, 2002.
- Voluntary Agreements – The Role of Environmental Agreements, elni (ed.), Cameron May Ltd., London, 1998.
- Environmental Impact Assessment – European and Comparative; Law and Practical Experience, elni (ed.), Cameron May Ltd., London, 1997.
- Environmental Rights: Law, Litigation and Access to Justice, Deimann/Dyssli (eds.), Cameron May Ltd., London, 1995.
- Environmental Control of Products and Substances: Legal Concepts in Europe and the United States, Gebers/Jendroska (eds.), Peter Lang, 1994.
- Dynamic International Regimes: Institutions of International Environmental Governance, Thomas Gehring; Peter Lang, 1994.
- Environmentally Sound Waste Management? Current Legal Situation and Practical Experience in Europe, Sander/Küppers (eds.), P. Lang, 1993
- Licensing Procedures for Industria Plants and the Influence of EC Directives, Gebers/Robensin (eds.), P. Lang, 1993.
- Civil Liability for Waste, v. Wilmowsky/Roller, P. Lang, 1992.
- Participation and Litigation Rights of Environmental Associations in Europe, Führ/Roller (eds.), P. Lang, 1991.

Elni Website: elni.org

On the elni website www.elni.org one finds news of the network and an index of articles. It also indicates elni activities and informs about new publications. Internship possibilities are also published online.

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