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CONTENTS

Editorial

Water is a precondition for human, animal and plant life as well as an indispensable resource for the economy. Thus, according to the *European Commission* the protection of water resources, of fresh and salt water ecosystems and of the water we drink and bathe in is therefore one of the cornerstones of environmental protection in Europe. Against this background the present issue of *elni Review* focuses on the legal framework for (the protection of) water in Europe and explains, among other things, how far it can cope with possible threats from emerging technologies and to what extent some of the legislation has been implemented in specific member States of the EU. Moreover, insights are provided into some new political or scientific initiatives to further develop the legal framework for protecting water.

First off, *Catherine Ganzleben* and *Steffen Foss Hansen* examine whether Directive 2000/60/EC ('Water Framework Directive', WFD), which aims to reduce and minimise the concentrations of dangerous chemicals in European waters, and related legal requirements include the right instruments to capture nanomaterials. They also consider whether techniques are available to allow for monitoring nanomaterials in surface waters and review data from modelling exercises that estimate concentrations of nanomaterials in EU waters.

Subsequently, *Ana Barreira* provides an overview of the main elements of the Union's Marine Strategy Framework Directive (MSFD) and analyses how Spain, as an EU country with 8000 km of coastal fringe, is complying with the directive and will review its marine governance framework.

The third article is by *Thomas Ormond* and takes another perspective, evaluating how far international and European legal instruments for the regulation of ship dismantling (potentially) ensure the safe and environmentally sound recycling of European ships in regions like South Asia.

Sarolta Tripolszky explains the concept of the term 'water services' in her contribution and outlines the economic and legal consequences of a narrow and broad definition. In this context and with specific reference to a collective complaint started by the NGOs EEB and WWF in 2006 against 11 EU member states to enforce the correct implementation of the WFD, she also describes the development of this legal instrument.

The final article with a focus on water is by *Marga Robesin* and describes current discussions on the question of how to achieve substantial water footprint reduction, focusing in particular on certification and labelling.

A second series of contributions to this issue of the *elni Review* covers a variety of other up-to-date legal issues, including the advancement and legal implementation of the concept of 'sustainable development'. To this end, *Eckard Rehbinder*, who attended the United Nations Conference on Sustainable Development (Rio+20) in Rio de Janeiro in June 2012, shares some critical comments on the summit outcome.

The following contribution by *Peter de Smedt, Hendrik Schoukens* and *Tania Van Laer* examines the anchoring of sustainable development in the Belgian Constitution, discusses the concept's juridical enforceability and subsequently analyses the consequences of this qualification for the application in the jurisprudence.

In a further article *Julian Schenten* and *Martin Führ* present empirical data obtained by several survey methods focusing on companies which manufacture and/or use nanomaterials. They analyse the findings under the perspective of the degree to which REACH (Regulation EC 1907/2006) promotes innovations for sustainability in the field of nanomaterials.

In June 2012 the EU General Court adopted long awaited decisions in two cases in which it interprets for the first time Regulation 1367/2006 ('Aarhus Regulation') – *Anaïs Berthier* examines what real added value these two decisions have with regards to access to justice.

Finally, in a statement by *Almut Gaude* from BUND, the German branch of Friends of the Earth (FoE), the NGO expresses its perspective on the Rio+20 conference outcome.

We hope you enjoy reading the current journal. Contributions for the next issue of the *elni Review* are very welcome and may be sent to the editors by mid-February 2013.

Julian Schenten/Martin Führ

Law and innovation in the context of nanomaterials: Barriers to sustainable development? Results of an empirical study*

Julian Schenten and Martin Führ

1 Introduction

According to Art. 3(3) of the Treaty on the European Union, the Community is working towards the sustainable development of Europe – this constitutes the overriding long-term goal of the European Union.[1] The guiding principle of sustainable development aspires towards the reduced exploitation of natural resources aimed at their long-term preservation and a reduced pollutant burden for protected natural resources.[2] The target for 2020 is that "*chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment*" ('Johannesburg goals').[3] In addition, the guiding principle pursues the safeguarding of the basis for survival and economic production in order to maintain an adequate quality of life.[4] These aims can only be achieved by far-reaching changes to the economic and social structures and also to patterns of consumption and production[5] – consequently innovations are required.[6] This requires specific regulatory strategies – particularly for product or process innovations – in order to create adequate incentives so that actors from trade and industry get innovations for sustainability[7] off the ground.[8] In connection with this the question arises as to how nanomaterials are to be regulated so that the innovation processes linked to these substances are aligned with the guiding principle of sustainable development.[9]

While an internationally binding definition does not exist[10] the European Commission recommends the definition of nanomaterial as "*a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm*".[11] The minute nanoscale materials (1 nm corresponds to 1 millionth of a mm) have special properties which make them fundamentally different from 'normal' macroscopic substances. The specific relationship of low mass to above-average surface area in nanomaterials therefore causes an increased reactivity. In short, using these materials often requires fewer resources than macroscopic substances.[12] In addition, certain nanomaterials can be used to replace hazardous substances.[13] Besides the sustainable development potentials associated with nanoscale materials, there are also nano-specific risks: For example, the high energy input in the production process of certain nanomaterials may counteract expected environmental benefits due to the reduced use of resources.[14] Moreover, harmful effects on human health and the environment have already been shown in relation to individual materials and specific exposure scenarios.[15]

* Parts of the article have been published as Schenten 2012, Recht und Innovation bei Nanomaterialien: Zwischenergebnisse einer juristisch-empirischen Untersuchung, StoffR 2, p. 79 – 87. The text was translated by Lynda Hepburn.

1 European Commission 2009, Mainstreaming sustainable development into EU policies: 2009 Review of the European Union Strategy for Sustainable Development, COM(2009) 400 final, p. 2; see also TFEU, Art. 11 and the preamble to the Treaty on the EU.

2 European Commission 2001, A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development, COM(2001) 264 final, p. 2, 4, Von Hauff/Kleine 2009: Nachhaltige Entwicklung. Grundlagen und Umsetzung, p. 17.

3 United Nations 2002, Report of the World Summit on Sustainable Development, A/CONF.199/20, Johannesburg, p. 19.

4 European Commission 2001 *supra* note 2, 2, Von Hauff/Kleine *supra* note 2, 16, 18.

5 European Commission 2011, http://ec.europa.eu/environment/eussd/ (07.02.2012).

6 United Nations 1987, Report of the World Commission on Environment and Development: Our Common Future ('Brundtland Report'), p. 148 et seq.

7 The concepts of sustainable development and sustainability are used synonymously.

8 Rennings 1998, Towards a Theory and Policy of Eco-Innovation – Neoclassical and (Co-)Evolutionary Perspectives, ZEW Discussion Papers, No. 98-24, http://hdl.handle.net/10419/24575 (27.05.2012), p. 8 et seq.

9 This is one topic addressed by the research project 'Responsive Steuerung von Innovationsverhalten für Nachhaltigkeit' – ReSINa, which is being carried out on behalf of the Bundesministerium für Bildung und Forschung (German Federal Ministry for Education and Research) (BMBF) (FKZ 01UN1014B) as a joint project between the universities of Göttingen and Augsburg and the Darmstadt University of Applied Sciences from 09/2010 to 08/2013; see also www.resina-projekt.de and http://www.sofia-darmstadt.de/resina.html.

10 See Lövestam et al. 2010, Considerations on a Definition of Nanomaterial for Regulatory Purposes, JRC Reference Reports, EUR 24403 EN who discuss the need for a definition as well as which elements are crucial.

11 European Commission 2011, Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, OJ L. 275 of 20 October 2011, 38.

12 Steinfeldt/von Gleich et al. 2010, Environmental Relief Effects through Nanotechnological Processes and Products. Summary, http://www.umweltdaten.de/publikationen/weitere_infos/3777-0.pdf (24.04.2012)

13 Ellenbecker/Tsai 2011, Engineered nanoparticles: safer substitutes for toxic materials, or a new hazard? JOCP 19, p. 483 (484 et seq.).

14 This has been shown for Carbon Nanotubes and Fullerenes, see with further references Greßler//Nentwich 2011, Nano und Umwelt – Teil I: Entlastungspotenziale und Nachhaltigkeitseffekte, NanoTrust-Dossier Nr. 026, November, edited by Institut für Technikfolgen-Abschätzung (ITA), Wien.

15 Overview from Aitken et al. 2009, Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES), http://ihcp.jrc.ec.europa.eu/whats-new/enhres-final-report (27.05.2012), p. 55 et seq.

However, the scale of potential negative effects cannot be assessed at present.[16] The test procedures designed for macroscopic substances are often not suitable for the special properties of nanomaterials.[17] Many of the test methods are still under development.[18] For these and other reasons, leading nano-toxicologists question the validity of existing research results and point to gaps in knowledge which still exist after almost 20 years of research on nanomaterials.[19]

The (EC) Regulation No. 1907/2006 (REACH)[20] provides the legal framework for all chemical substances manufactured in the European Economic Area or imported into it. According to its recitals, REACH also aims to contribute to sustainable development and makes specific reference to the Johannesburg goals.[21] The main purpose of REACH is "*to ensure a high level of protection for human health and for the environment*" (Art. 1(1) half-sentence 1[22]). The registration obligation for quantitatively relevant substances (Art. 5 et seq.) serves a systematic collection of information on substances prior to marketing. In addition, REACH contains basic obligations for those responsible for the substances who, for example, must adequately control the risks arising from their substances (Art. 14(6), Art. 37(5)).[23] The regulation thus forms the basis for product safety and liability avoidance[24] and also for judging whether substance applications are able to make a contribution to achieving corporate social responsibility (CSR) and social sustainability goals.

Nanomaterials are substances in terms of the REACH Regulation and therefore fall within its scope. However, REACH does not contain any provisions directed specifically at nanomaterials. The regulatory omissions arising from this – no definition for nanomaterials; tonnage quantity thresholds may be inappropriate for nanoscale substances; transitional periods for existing substances (phase-in substances, Art. 23) also apply to certain nanomaterials; test procedures are not designed to nanomaterial specifications, etc. – are discussed in depth in the literature.[25]

This article takes a different perspective. It examines to what degree REACH *promotes* innovations for sustainability through nanomaterials. The question of how the regulation affects the manufacturers' approach to nanomaterials was the subject of a survey sent to companies which manufacture and/or use nanomaterials. The survey questioned 37 companies based in Germany. Besides the issues of registering for REACH and carrying out safety assessments, the main focus of interest was on the relationships between substance risks and innovation and between REACH and innovation. The findings obtained from the survey were augmented by telephone interviews on this subject and by the results of a workshop held in Darmstadt, Germany, in December 2011 with representatives from companies and industry associations and experts on the regulation of nanomaterials. Finally, this contribution refers to the results of a study carried out for the European Commission on the innovative effects of REACH on emerging technologies. This document summarises the most important results from the empirical data and, where the data permits, draws some preliminary conclusions for a possible adaptation of the legal framework for nanomaterials.

2 Yardstick for the examination

This article is based on a broad understanding of 'innovation through nanomaterials' which encompasses all (technical) innovations (for example, on the substance or process level) that are made possible through a specific nanomaterial. For the purpose of this examination,

16 EASAC/JRC 2011, Impact of Engineered Nanomaterials on Health: Considerations for Benefit-Risk-Assessment, p. 31, http://ihcp.jrc.ec.europa.eu/our_activities/nanotechnology/nanoreport-10-11/JRC-EASAC-report.pdf (07.02.2012).

17 SCENIHR 2007, The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials, p. 8 et seq., http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf, Aitken et al. 2011, Specific Advice on Exposure Assessment and Hazard/Risk Characterisation for Nanomaterials under REACH (RIP-oN 3), http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon3.pdf (07.02.2012).

18 SCENIHR 2009, Risk Assessment of Products of Nanotechnologies, http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf (07.02.2012).

19 Krug/Wick 2011, Nanotoxicology: An Interdisciplinary Challenge, Angew. Chem. Int. Ed., p. 2 et seq.

20 Regulation (EC) No. 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L. 396 of 29 May 2007, 1, as last amended by Commission Regulation (EU) No 494/2011 of 20 May 2011. OJ L. 134 of 21 May 2011.

21 Cf. recitals 3, 4 and 131.

22 In what follows, unnamed articles, titles and annexes are those in the REACH Regulation.

23 For details see Führ/Bizer 2007, REACh as a paradigm shift in chemical policy – responsive regulation and behavioural models, JOCP 15, p. 327 et seq.

24 According, for instance, to German product safety law, only safe products may be offered for sale. In order to guarantee this, the German Product Safety Act (ProdSG) assigns the responsibility for products to economic actors such as the manufacturers of goods, materials and preparations, see Polly/Lach 2012, Das neue Produktsicherheitsgesetz – was Wirtschaftsakteure beachten sollten, Betriebs-Berater 2, p. 71. In addition, companies must comply with the provisions of the civil product liability law in accordance with the German Civil Code (BGB) and the Product Liability Act (ProdHaftG). According to this, manufacturers are obliged to collect and evaluate information relating to any risks associated with their products and to take account of these results in the design and development phases (design obligation), see German Advisory Council on the Environment (SRU) 2011, Vorsorgestrategien für Nanomaterialien, http://www.umweltrat.de/SharedDocs/Downloads/DE/02_Sondergutachten/2011_09_SG_Vorsorgestrategien%20f%C3%BCr%20Nanomaterialien.pdf?__blob=publicationFile (07.02.2012), margin note 558 et seq.

25 Führ et al. 2007, Legal appraisal of nano technologies. Existing legal framework, the need for regulation and regulative options at a European and national level. Final report, p. 18 et seq., http://www.umweltdaten.de/publikationen/fpdf-l/3198.pdf (26.05.2012), Franco et al. 2007, Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials, Regulatory Toxicology and Pharmacology 48, p. 171 (177 et seq.), Pronk et al. 2009, Nanomaterials under REACH. Nanosilver as a case study, RIVM report 601780003, p. 25 et seq., http://www.rivm.nl/bibliotheek/rapporten/601780003.pdf (26.05.2012).

whenever reference is made to the guiding principle of sustainable development, we focus on its ecological dimension (including human health). In accordance with the manifestation of ecological sustainability under the REACH Regulation, the determination of whether an innovation through nanomaterials is directed towards sustainable development depends in this article on whether such innovation contributes to reduced risks in terms of human health and/or the environment.

3 Design of the company survey

The survey enabled a quantitative analysis of the status quo of the nanomaterial regulation based on standardised questionnaires.[26] The questions comprised:

– information on the company/respondent,
– the registration policy w.r.t. nanomaterials,
– the implementation of safety assessment for nanomaterials,
– the approach to risks for substance innovations and
– statements about the current legal framework for nanomaterials.[27]

The questionnaire was sent in two phases, with the first part sent out in July 2011. A further survey phase took place in September/October of the same year with a slightly improved questionnaire and one additional question.

Companies were contacted by telephone before receiving the document by email in order to establish the correct contact person for the subject of the survey and to find out whether the company was interested in taking part. The data pool of company contacts was supplied by various sector networks and by databases available on the internet.[28] Companies with completely different profiles (size, sector, proximity to the consumer, segment in the value-added chain, etc.) were selected with the aim of using the survey results to portray a cross-section of the prevailing company practice in Germany.

A total of 283 companies were contacted, of which 107 declined to participate. The remaining 176 contacts received the questionnaire and 37 returned the completed survey. This yielded a return rate of 21%.

4 Results

The information obtained from the telephone conversations plus the contributions to the discussion in the workshop have been included in this paper, provided that they were of relevance for the study.

4.1 Survey participants

The companies surveyed included 8 large companies and 29 small and medium-sized companies according to their own statements. The companies vary widely in terms of the sectors under which they fall and the specific relationship to nanomaterials, with the majority of companies (57%, N=21) belonging to the 'chemicals/materials industry' (see Figure 1).

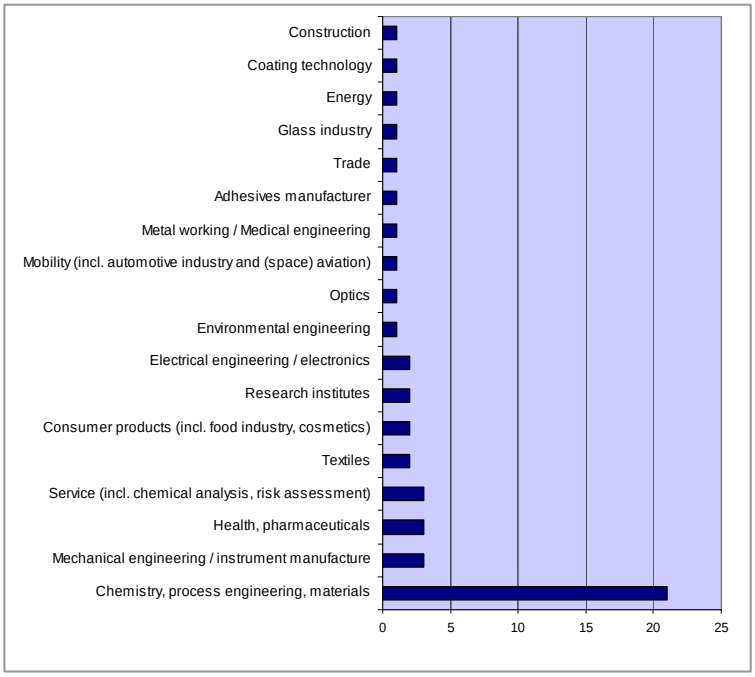

Fig. 1: Sector of origin of participating companies (more than one possible answer)

The questions were mostly answered by members of the R&D departments, sometimes the managers themselves and, in a few cases, employees from the product safety department. It would appear that none of the respondents, amongst which some are apparently assigned as 'REACH representatives', have legal training.

Variety was also displayed in terms of the company's role in the substance value-added chain, with a single company often combining several functions at the same time. The respondents therefore included 17 manufacturers, 15 formulators, 14 final product manufacturers and 2 importers (more than one possible answer).

4.2 REACH requirements

4.2.1 Registration of nanomaterials

In order to determine a cross-section of the practical approach to nanoscale substances adopted by German companies, the first question addressed the number of

26 A Microsoft Word document was used as the survey medium. Questions could be answered either by checking a preset box or by entering free formulations in empty text boxes. A pre-test of the questionnaire with a company showed that it could be completed in 15 minutes.

27 The questionnaire can be accessed at http://www.sofia-darmstadt.de/resina.html.

28 In particular www.nano-map.de, www.nanobionet.de and www.nanoproducts.de.

nanomaterials which a company used.[29] 207 nanoscale substances were mentioned if the information supplied by all the participating companies is combined. The exact number cannot be determined as answers such as "*>1*" were often given.

The next question concerned how many of these substances had a pre-registration or registration in accordance with REACH. The empirical results indicate that only approx. 5% of the nanomaterials (N=10) had been pre-registered or registered (see Figure 2).

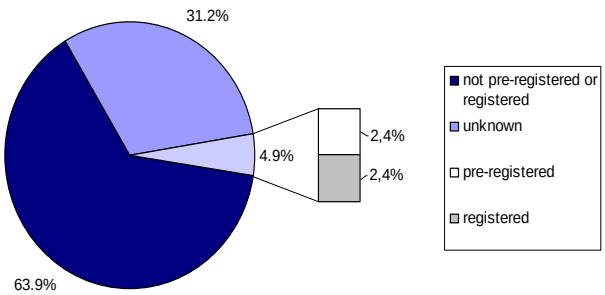

Fig. 2: Percentage of nanomaterials within the study being pre-registered or registered in accordance with REACH

The largest percentage of substances were not registered (approx. 64%, N=131) or it is not known whether they were pre-registered or registered (approx. 31%, N=64).[30] The latter situation occurs frequently where nanomaterials are only purchased and not produced by the company itself.

Of the 207 substances, some (especially what are known as carbon nanotubes [CNT], silver, silicon dioxide, titanium dioxide) were listed by several companies as being manufactured or processed substances. In addition, different forms (e.g. differing sizes) of the same basic material were considered as being separate substances for the purposes of the study.

A further question concerned whether registration of the nanomaterials was made using individual dossiers or as part of bulk material. Two of the 10 companies who had completed a pre-registration or registration claimed to have carried out an individual registration and two companies a combined registration.

Only one company stated that the nanoscale nature of the registered substance is disclosed in the dossier. When making a registration there is the option to use the 'nanoform' box in the IUCLID[31]. The fact that little use is made of this option is confirmed by a glance at the database of registered substances managed by the European Chemicals Agency ECHA. In a Communication published on 3 October 2012 entitled the 'Second Regulatory Review on Nanomaterials' the European Commission states that "*as of February 2012, 7 substance registrations […] had selected 'nanomaterial' as the form of the substance in voluntary fields*".[32] This figure needs to be placed in relation to the total number of registrations submitted. As of August 31 2012 these totalled 27,321.[33]

4.2.2 Safety assessment of nanomaterials

As mentioned in the introduction, various ecotoxicological and toxicological findings point to the harmful effects of certain nanomaterials. In addition, there are large gaps in knowledge regarding possible negative effects on humans and the environment. In view of this, one of the main issues addressed by the survey was the implementation of safety assessments of nanoscale substances by the companies.

Firstly an indication was requested as to whether nanomaterials were generally subjected to a safety assessment as regards potential risks to human health and the environment before being sold to consumers or commercial/industrial users, i.e. independently of a pre-registration or registration and the nature of the test procedure. An affirmative answer was given for almost ¾ (72%, N=130) of the substances covered.

However, if the same results are evaluated in relation to the number of companies participating in the questionnaire, this produces a different percentage: 15 companies generally carry out safety assessments before marketing; however 15 companies do not do this.

This evaluation had to take into account that some downstream users have inadequate information on whether or which safety tests have actually been carried out on the substances by the manufacturer or importer. The sometimes speculative answers from these participants were not included in the evaluation of the results. This leaves information on 30 companies which work with 181 substances for analysis in this section of the survey.

In the month that REACH came into force, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) came to the conclusion that the toxicological and ecotoxicological tests required by the regulation are not suitable for

29 In addition, information could also be supplied on the substances involved.

30 There was no information on the registration status of two substances.

31 Art. 111 states, "The Agency shall specify formats and make them available free of charge [...] on its website for any submissions to the Agency. Member States, manufactures, importers, distributors or downstream users shall use these formats [...] in their submissions to the Agency pursuant to this Regulation. [...] For the purposes of registration, the format of the technical dossier [...] shall be IUCLID." See http://iuclid.eu/index.php?fuseaction=home.iuclidHome.

32 European Commission 2012, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Second Regulatory Review on Nanomaterials COM(2012) 572 final, p. 6. Additionally, "*further assessment [of dossiers] identified three groups of registration dossiers, where a) the registrants recognized nanomaterials (8 dossiers /5 substances); b) substances exist only as nanomaterial (12/9), and c) the assessors identified nanomaterials on the basis of the particle size distribution (5/5)*", see European Commission 2012, Commission Staff Working Paper, Types and uses of nanomaterials, including safety aspects SWD(2012) 288 final, p. 26.

33 http://www.echa.europa.eu/information-on-chemicals/registration-statistics (19.10.2012).

identifying all the potential risks arising from nanomaterials. This judgement was reaffirmed in the autumn of 2011 by an expert committee made up of representatives of the member states, ECHA, the scientific community, industry and NGOs.[34]

Against this background the 15 companies who claimed to carry out safety assessments were asked which procedures they used for this. The aim was to discover whether the assessment methods were designed for the special characteristics of nanomaterials. Answers could be given either by selecting from preset options and/or entering information freely. The assessment methods were then classified by the project as 'nano-specific' if, according to the information provided by the companies, these methods complied with the OECD (ENV/JM/MONO(2010)46) and/or with ISO/TR 13121:2011 (Nanotechnologies - Nanomaterial risk evaluation) and/or other guidelines which appear to treat nano-specific characteristics in an adequate manner (e.g. guidelines on risk assessment for nanomaterials by the German Association of the Chemical Industry e. V., VCI). In addition, the option "*in accordance with the requirements of REACH*" could be selected.[35]

According to the information provided by the participants, 7 of the 15 companies make use of test guidelines designed for nano specifications, 6 companies do not do this and for three no information was available. If the results are evaluated according to how many nanomaterials each of the companies handle, then nano-specific methods were applied to less than 8% of the substances. Of the 130 substances, only 10 were subjected to a test where it can be assumed that the nano-specific properties were treated as such.

4.2.3 REACH and innovation

The REACH Regulation also aims to enhance innovations in the chemicals sector (Art. 1(1) half-sentence 3).[36] This study also looks at how far this is successful in the case of nanomaterials.

At the start of this section of the survey, respondents were asked to evaluate how the legal framework created by REACH affects innovations linked to nanomaterials. Respondents were asked to assign their subjective perception of the effects on innovation to specific categories from positive to negative.[37] Only four companies rated the effects as (fairly) positive while 14 judged them to be (fairly) negative. Most survey participants (N=15) did not perceive that REACH had any effect on innovations using nanomaterials. This evaluation was partially anticipated by the telephone conversations carried out prior to the survey in which many companies were convinced that they were operating outside the scope of the regulation due to production quantities below 1 tonne. What is more, some downstream users were not aware that REACH also places an obligation on them as well as on manufacturers and importers.

Additional comments or reasons could be added to explain why a participant had opted for one or the other category. These included the following explanations:

(Fairly) positive:

"*REACH as it stands does not discriminate against nanomaterials: they are treated like any other substance. This is in accord with the assessment by SCENIHR: 'Nanomaterials are similar to normal substances in that some may be toxic and some may not' (SCENIHR Opinion "Risk Assessment of Products of Nanotechnologies", 2009).*"

"*The only positive thing is that REACH prohibits dangerous substances which can then be substituted by nanomaterials (e.g. organochlorine biocides by nano-silver).*"

(Fairly) negative:

"*The harmlessness of nano-silver has been scientifically well researched. However, the authorities still have to convince themselves of this from the studies produced. Nanomaterials will not be recommended for use as long as any uncertainty about them remains. Companies are therefore not getting involved in the development of new products based on nano-silver. The enormous bureaucratic effort also means that companies prefer to use existing substances for which a REACH approval is provided by the supplier rather than using new products based on nanomaterials and being faced with an incalculable cost (in terms of time and money) to obtain an approval.*"

"*Increased costs for registration and approval at a stage when the product's prospects and options have not been sounded out, where the cost-benefit analysis therefore turns out to be negative.*"

"*Bureaucratic and financial costs which SMEs cannot shoulder.*"

"*Even our suppliers cancel or never even start potential innovative developments due to the risk of a negative image or a possible unforeseeable restriction on use. A lack of innovation on the part of the manufacturer leads to a lack of innovation in the supply chain and finally on the market.*"

In addition the following angle was mentioned several times which, however, has little to do with REACH:

"*Uncertainty – including on the part of the customer – around the word 'nano'.*"

The next question was: How does your company view the current legal framework for nanomaterials? This question

34 Cf. *supra* note 17.

35 Overview of the options: in accordance with the requirements of REACH; in accordance with the OECD test proposals (ENV/JM/MONO(2010)46); in accordance with ISO/TR 13121:2011 (Nanotechnologies - Nanomaterial risk evaluation); other known procedure; own procedure.

36 See Bizer/Führ 2009, Innovationen entlang der Wertschöpfungskette: Impulse aus der REACh-Verordnung, in: Eifert/Hoffmann-Riem, Innovationsfördernde Regulierung and Führ/Bizer 2009, Zuordnung der Innovations-Verantwortlichkeiten im Risikoverwaltungsrecht – Das Beispiel der REACh-Verordnung, in: Eifert/Hoffmann-Riem, Innovationsverantwortung.

37 The following options were available: positive; fairly positive; no effect; fairly negative; negative; unknown.

also required opinions to be assigned to set categories.[38] The companies decided by a clear margin that the legal framework was "*suitable with minor deficiencies*" (46%, N=16), while a high percentage (6 companies) even rated the legal framework as "*optimally suited*". Overall 63% of the participants therefore judged the legal framework to be generally suitable and only 31% as generally unsuitable.[39]

It was again possible to justify the selected categories. The explanations illustrate that participants mostly equate the criterion of the 'suitability' of the legal framework with the question of how far the safety of nanomaterials is guaranteed.

Optimal:

"*As long as a risk assessment of the application is carried out.*"

"*A risk analysis must be carried out for every application of additives, irrespective of the type of substance being used.*"

With minor deficiencies:

"*There is still too little known, particularly about free nanoparticles.*"

Not adequate:

"*Risks associated with nanomaterials lie in the material (chemical) composition on the one hand and in their particle size on the other. Each kind of nanomaterial therefore has an 'individual' risk profile. As far as I am aware the legislation does not take this individual risk profile into account to a great enough degree.*"

"*There is obviously not enough attention paid to research companies like us.*"

"*This depends entirely on the nanomaterial. Nano-silver in particular, a substance that has existed for 120 years (...) should not be viewed as a completely new material. Data which were produced in 1950 should also be included in the discussion on risk. The legal framework is suitable for completely new nanomaterials such as CNTs or C60 (graphene).*"

"*There is not enough known about toxicological properties*"

"*The rules for downstream users are not clear. The time allowances for a proper implementation of the REACH Regulation along the supply chain (from substance manufacturer via various downstream users to the final user) are much too short. ECHA is also unable to cope with the volume of enquiries from substance manufacturers. The non legally binding guidelines are inconsistent and too comprehensive. Applying them can only be done using IT tools which are not yet mature.*"

Not at all:

"*As long as the argument about a definition of what a nanomaterial is continues throughout Europe and the world, this question cannot be given a positive answer.*"

"*Decentralising detailed knowledge is unrealistic.*"

Some comments made by the survey participants also refer to a possible future legal framework. The comment was made that:

"*due to the current negative presentation of nanomaterials by the media in combination with an evolving refinement of the REACH Regulation it is to be feared that it will be made more difficult to market/process nanomaterials.*"

Another company judged a "*tighter*" regulation of nanomaterials to constitute a "*deathblow for SMEs*".

4.2.4 Risk and innovation

Under this heading the first question concerned the degree to which the (potential) risks associated with substances are of importance in making the decision for or against investment in a substance innovation. None of the companies classified the risks as being fairly or completely irrelevant for innovation processes. The majority of 47% (N=16) assessed risks as fairly relevant with 38% (N=13) even rating them as very relevant. Only 15% (N=5) judged them to be almost irrelevant.

Respondents were then asked to state at which phase in the innovation process risks relating to these substances were considered. The main issue of interest here was to find out if risks are important when generating ideas or only at a later point.[40] Only one company claimed not to consider risks in any phase. The vast majority (N=33) considered potential risks in the R&D phase which could be attributed to the fact that product safety and product liability laws[41] require this during the actual product development. It is also no surprise that 19 companies state that they consider risks when putting the product on the market, this corresponding to the general product monitoring obligation (as manifestation of the liability law). However, it is noticeable that a somewhat higher number of participants, 20 companies, even take substance risks into account in the phase of generating ideas.

Although the question was not aimed specifically at nanomaterials, it can nevertheless be assumed that a company does not make a distinction between nanoscale and non-nanoscale substances in its innovation strategy and the decision as to how much attention should be given to substance risks.

5 Discussion

An overall view of the empirical results yields important information as to how far REACH furthers innovations for sustainability using nanomaterials.

First, the results show that only 10 of the 207 nanoscale substances listed by the companies were registered (section 4.2.1). It can be concluded from this that the REACH registration mechanism which includes the aim of obtaining a systematic collection of substance data prior to marketing is clearly not really effective for

38 The categories were: optimally suited; suitable with minor deficiencies; not adequately suited; not suitable at all; unknown.

39 Two companies gave "*unknown*" as an answer.

40 The specified responses were: ideas phase; R&D phase; market launch phase; not at all (more than one possible answer).

41 Cf. *supra* note 24.

nanomaterials. In view of this, an announcement by the European Chemical Industry Council (CEFIC) that 80-90% of all existing nanomaterials should have been registered by the first registration deadline of 30.11.2010[42] appears very doubtful.[43]

The findings on the subject of safety assessment can be summarised to the effect that only around half of the companies who took part in the survey generally carry out safety assessments on nanomaterials and of these approx. only a half use nano-specific test methods. As regards the individual substances, of the 181 nanomaterials available for analysis, just under ¾ were actually tested but in only 5.5% of cases were nano-specific test procedures used (section 4.2.2). In addition, some comments by the respondents point out the inadequate risk assessment mechanism in the REACH Regulation which does not contain any requirements directed specifically at nanoscale substances. In this respect the companies judge the current legal framework for nanomaterials as inadequate (section 4.2.3).

However, there is no clear picture of how the regulation affects innovation. The results show that in many cases companies consider substance-related risks even at the ideas phase of the innovation process (section 4.2.4). If this tendency towards integrated environmental relief is attributed at least in part to the legal framework produced by REACH, conclusions could be drawn about the question as to whether REACH favours a particular line of innovation. Even if there are apparently no comparable values from the period before the regulation came into force, there does seem to be a current trend to include sustainability considerations at a very early stage in the innovation process.

Nevertheless, the majority of participants (N=15) state that they do not perceive any effect of REACH on innovations linked to nanomaterials (section 4.2.3). The reasons for this may lie in the exemptions to the regulation[44] and in the lack of provisions specifically for nanomaterials. It could also be possible that some respondents have failed to appreciate the importance of REACH and the requirements associated with it. For example, there is the principle from Art. 1(3) sentence 1 according to which manufacturers, importers and downstream users have to ensure that the substances they manufacture, offer for sale and use "*do not adversely affect human health or the environment*", irrespective of the quantity of product and the conditions of use. Despite this, it was apparent for example that some downstream users were not aware that REACH also places an obligation on them as well as on manufacturers and importers (section 4.2.3).

Almost as many survey participants (N=14) perceive that REACH has a negative effect on innovation. They base this mainly on the increased bureaucratic and financial input required. Whether this is higher for potentially more dangerous substances or application areas than for potentially lower risk ones cannot be ascertained from the statements. It therefore remains unclear whether or to what degree the direction of innovation is affected. When interpreting the comments in section 4.2.3 it should also be borne in mind that these are not always based on the company's own personal experience.[45]

At the workshop the companies[46] identified the main obstacle for innovations linked to nanomaterials as they see it: this consists of the current *legal* uncertainty resulting from the fact that there is no clear and binding regulations with which to apply the obligation programme in the REACH Regulation to nanomaterials ('grey zones').[47] This in turn creates uncertainty for the commercial buyer which is then passed on as far as the consumer. The consequence is that companies lose their planning confidence. Besides the legal uncertainty, the current prevailing uncertainty about nanomaterials on the part of the authorities and consumers is mentioned as a further aspect which can negatively affect innovation (section 4.2.3). Companies appear to attribute this to the legal framework created by REACH.

To return to the question posed at the start as to how far REACH promotes innovations for sustainability using nanomaterials, the conclusion which can be drawn in this context is that the regulation does not provide an adequate incentive in this respect. First, REACH apparently provides very little incentive to register nanomaterials and to apply safety assessment methods which are specifically designed for them. In addition, in the view of the participants in the survey, innovations using nanomaterials fall outside the sphere of influence of the REACH Regulation, leading to the conclusion that REACH has (so far) not been able to influence the direction of these innovations. The same conclusion is reached by the answers from respondents who associate REACH with negative effects on innovation. The obstacles mentioned in this connection (legal uncertainty, financial and bureaucratic outlay) have an effect on all innovations linked to nanomaterials, therefore making them less attractive, irrespective of the purpose or direction of the innovation.

42 Perenius 2009, How to handle transparency. Cefic's view, Lecture as part of the event NanoImpactNet on 27 March, p. 11, accessible at http://www.nanoimpactnet.eu/uploads/file/Lausanne%20conference%202009/Perenius.pdf (19.03.2012).

43 See also the comparable figures in Section 4.2.1.

44 The registration obligation only applies above 1 tonne per year; there are further exceptions for R&D substances; for certain classes of substances such as biocidal active agents REACH only constitutes subsidiary law; some substance applications are regulated exclusively by specific provisions in the sectoral legislation; there are transitional periods for existing substances, etc.

45 For instance, two of the explanations given for judging the affect of REACH on innovation criticise the increased costs for registration i.e. the bureaucratic effort and financial outlay which SMEs are unable to shoulder. However, the company who supplied these comments is a formulator who has not undertaken registration and is furthermore a large company (not an SME).

46 Four (two large companies, two SMEs) out of five.

47 As an example, in the framework of identifying substances in accordance with Annex VI Section 2, mention is made of the imprecise boundary of independent nanoscale substances compared to their macroscale versions.

It is also questionable whether the empirical findings enable conclusions for improving the legal framework so that it might have a positive effect on the direction of innovation. On the one hand, companies identify the specified obstacles to innovation using nanomaterials but, on the other, the majority of participants judged the legal framework as being suitable with only small deficiencies (section 4.2.3). The comments relating to the future legal framework could permit the conclusion that, from a company perspective, the current uncertain legal situation is still preferable to a clear regulation of nanomaterials ("*deathblow for SMEs*"). The experiences expressed at the workshop, however, are not in agreement with this view. During the workshop the legal uncertainty was identified as the greatest obstacle to innovation and clear regulations demanded, for example, for the definition of nanomaterials but also as regards the extent and type of safety assessments to be carried out.

6 Evaluation of the results in the light of related studies

This study enables comparisons with the results of a study by *Gilbert et al.* on behalf of the European Commission on the effects on innovation of REACH on emerging technologies with particular reference to nanomaterials, which is available as a draft of the final report.[48] The study provides both information on the effects on innovation of the current version of REACH and on specific regulatory options under discussion, based on a review of the literature, a survey and 12 interviews with company representatives.[49] However, it does not make any distinction as to how far REACH and possible alternative regulations affect the *direction* of innovations using nanomaterials.

According to the draft version of the report there are sometimes varying perceptions in view of the effects of the status quo by micro businesses undertaking R&D that are often inadequately informed about the requirements in accordance with REACH and large companies who have, for instance, actually carried out a registration.[50] In summary, the respondents do not associate any of the REACH Regulations with mainly positive effects for innovation using nanomaterials, except for the basic approach to risk regulation associated with the substance life cycle.[51] In addition, it is apparent that uncertainties about the ecotoxicology and toxicology of nanomaterials and their legal classification make the situation for SMEs particularly difficult.[52] The report makes clear that it is less the regulation itself and more the stated uncertainties concerning nanomaterials, the associated reservations of potential customers and generally the current debate on nano risks which have a negative effect.[53]

As regards the current legal framework for nanoscale substances, the preliminary results from *Gilbert et al.* therefore correspond with those in the research results given in this paper. The prevailing uncertainty about nanomaterials is identified as the key obstacle to innovation. At the same time, the *Gilbert et al.* study points out the potentially excessive burden for SMEs caused by REACH – something frequently emphasised by the respondents in this study. It should be noted that both in this study[54] and also in *Gilbert et al.*[55] information on this is sometimes based on mere suppositions rather than experience.

The potential effects of specific regulatory options questioned by *Gilbert et al.* – simplified registration for quantities of less than 1 tonne of manufactured or imported nanomaterials, the treatment of all nanomaterials as new substances, obligations for particular risk information for all registered nanomaterials, etc. – tend to be judged negatively by the companies questioned. However, beyond isolated interesting insights into specific individual cases, the draft report does not endorse any general statements and postpones doing so to the final document which is due to include additional information from a workshop.[56]

7 Conclusion and outlook

Due to their restricted statistical basis, the results presented here only partially exhibit high external validity (the potential to generalise the results to the behaviour of companies which have not been surveyed). Yet some trends are visible. As the results empirically substantiate the omissions discussed in the literature[57] and coincide with the results in the *Gilbert* study on the effects of REACH on innovation through nanomaterials, they also enable recommendations to be made on which modifications of the legal framework could shift the incentive situation for innovation in the direction of sustainable development.

As already established in section 5, REACH apparently does not offer sufficient incentives to register nanomaterials and to apply nano-specific safety assessment procedures. The regulation does not therefore create sufficient incentives in terms of the transparency and safety of nanomaterials. In addition, while REACH as a general substance law also covers nanomaterials, these

48 Gilbert et al. 2011, Study on REACH contribution to the development of emerging technologies (DRAFT), http://www.gaia.fi/files/682/Study_on_-REACH_contribution_to_emerging_technologies_Task_2_DRAFT-_2011_12_03.pdf (07.02.2012).

49 *Id.*, 125 et seq.

50 *Id.*, 140.

51 *Id.*, 169.

52 *Id.*, 137, 147, 152, 169.

53 *Id.*, 170 et seq.

54 See *supra* note 45.

55 See *supra* note 48, 144 et seq.

56 *Id.*, 176, 188.

57 Cf. the references in section 1.

substances have not been addressed by specific provisions to date. This results in uncertainties in the interpretation of legal concepts and obligations. This legal uncertainty and the feeling of uncertainty experienced by the customer and authorities ('nano debate') robs companies of their planning confidence and thus hampers innovations which could make promising contributions to sustainable development.

Against the background of the European Union objective concerning sustainable development, the challenge for the law is that of removing these obstacles. Even the provision of more detailed information on applying the obligations in REACH to nanomaterials conveyed, for example, by associations and help desks, could go some way to contributing to this. This could remedy the lack of knowledge of many an SME about their obligations under REACH.[58] It remains to be seen how far the nano-specific adaptations to the guidance documents[59] on the standard information requirements (Annex VI-X) and on the chemical safety assessment published by ECHA in April 2012[60] can contribute to a change in safety assessment behaviour amongst the companies.

In addition, there is an apparent need for nano-specific legal guidelines which aim to identify, evaluate and control the risks associated with nanomaterials, and furthermore to disseminate information on them. The following additions to the legal framework created by REACH are particularly needed in order to provide legal security for producers and users of nanomaterials and, at the same time, create the necessary incentive towards sustainability:

- Introduction of a (binding) definition for the unambiguous identification of nanomaterials;
- Clarification that nanomaterials are individual substances and as such independently subject to the REACH obligations;
- Clarification that the specific transitional provisions for phase-in substances are not available for nanoscale versions of phase-in substances;
- Specification of triggers for registration or notification obligations which are adapted to the particular size or mass characteristics of nanomaterials;
- Implementation of nano-specific test standards as part of registration or notification for physicochemical, ecotoxicological and toxicological properties of the substances which also take adequate account of the existing methodological difficulties for chemical analysis.

However, this only involves a list of examples of the changes which appear necessary. Moreover, a research question still requiring study is which combination of regulations will achieve the goal of promoting innovations for sustainability through nanomaterials.[61]

It remains to be seen whether the revision of REACH in 2012 (Art. 138(6), (3) in conjunction with Art. 117(4), 'REACH Review') will lead to the specified or comparable regulatory options being put into practice and, if so, in what form. After all, in its 'Second Regulatory Review on Nanomaterials' the European Commission concludes that "*more specific requirements for nanomaterials within the [legal] framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013.*"[62] Then again, "*as regards registration thresholds and timelines for registration based on volume, the Commission considers REACH appropriate*" with regard to nanomaterials.[63]

Thus, in the interim concerned companies are advised that, despite its exemptions and 'grey zones', REACH allows a proactive approach to nanomaterials: a substance may also be registered below the threshold of 1 tonne per year. Some of the information contained in the dossier is made available by ECHA to the general public in an online database and authorities have more extensive access.[64] If the dossier were to contain results from all the safety assessments which appear necessary, in particular those specific to nanomaterials, then this information would also be published. The 'toxic ignorance' about nanomaterials would then be reduced. Furthermore, using the standardised information requests provided by REACH results in legal security and prevents liability claims, including the negative publicity linked to it.

58 In the context of advice of this kind it should be made clear that the use of a registered substance can be of benefit due to the associated gain in transparency. The figures presented in Section 4.2.1 on registration practice show that, up until now, downstream users in many cases (approx. 1/3) do not know whether the nanomaterial they are using is pre-registered / registered or not.

59 This refers to the guidelines issued by ECHA which provide explanations of the REACH obligation programme but are not binding.

60 ECHA 2012, Press Release ECHA/NA/12/16 from 30 April.

61 With this object in mind, the ReSINa research association is carrying out an experimental game with company representatives on the regulatory options under discussion. The results of this will be available at www.resina-projekt.de and www.sofia-darmstadt.de/resina.html in the near future (see also *supra* note 9).

62 European Commission 2012, *supra* note 32, 11.

63 *Id.*, 8.

64 See also Art. 119 and 118 on the exceptions.

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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.
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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. 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

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.

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The first issue of the elni Review was published in 2001. It replaced the elni Newsletter, which was released in 1995 for the first time.

The elni Review 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).

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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.

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elni publishes a series of books entitled "Publications of the Environmental Law Network International". Each volume contains papers by various authors on a particular theme in environmental law and in some cases is based on the proceedings of the annual conference.

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