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Legal appraisal of nano technologies

Existing legal framework, the need for regulation and regulative options at a European and a national level

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Dedication

The authors dedicate this legal appraisal; also on behalf of the Society for Institutional Analysis and Öko-Institut; to Professor Eckard Rehbinder, doyen of German and European chemicals law, on the occasion of his 70th birthday on 15 December 2006.

For the authors

Darmstadt, 12 December 2006

Martin Führ

Overview

Index of Contents

List of Tables

1 Introduction

Nano technology is regarded as a key technology of the 21st century, which will be used in a large lumber of industries and technical applications. On the one hand, completely new products are being developed, and on the other hand, existing technical solutions are being replaced with "nano solutions". Possible application fields for nano technology are interesting from an economic point of view, but they also have the potential to improve aspects of sustainability (for instance, increased efficiency and resource protection).

A typical feature of a key technology is that, due to the large number of actual and potential applications, its form is also heterogeneous and complex. This is shown not least by the problems that arise in demarcating the field of nano technology (see Section 4.1).

There are also, however, considerable uncertainties concerning the possible risks that occur or can occur in the life cycle of nano-technology products. These uncertainties have to do, among other things, with the fact that, due to small particle size, particular properties of nano materials are to be expected, or have already appeared, such as a particular mobility of individual particles, special agglomeration and cohesion properties as well as new functionalities and effects. Despite the rapid development of nano technology little is known about the threat to man and the environment from nano particles. There are specific indications, however, that there is interaction between nano particles and biological systems. Moreover, a number of scientific publications show that due to their particular properties nano particles can involve a risk for human health and the environment (see Bibliography under 8.2). Admittedly, the particle geometry of a substance in the nanoscale form itself says nothing about the properties of a substance, or whether it is a hazardous substance. Irrespective of the results of future analyses, it can be said that particularly small particles can overcome barriers that are unsurpassable for larger particles. Particularly relevant barriers of this kind are those of human and other organisms. So far as human barriers are concerned, it is known that the so-called endothelium – the inner lining of veins and other vessels, which are responsible for the exchange of nutrients, electrolytes and hormones between blood and tissue – are permeable for particles in the nanoscale form (Lippert 2000, 52). This endothelium includes the blood-brain barrier as well as the cells surrounding liver and kidneys, which provide important protection against inflammation. Against this backdrop, the production and use of such particles represent an abstract risk of these barriers being overcome. It therefore appears appropriate to talk about "nano-specific risks".

Beyond that, there is the possibility that a substance in the nanoscale form has other properties than the same substance in another form. Present knowledge already supports this suspicion (Umweltbundesamt 2006), which has became a certainty in the case of titanium dioxide (CAS-Nr. 13463-67-7), a substance that has been known for many years. This substance, which is produced in large quantities and used as a white pigment, was regarded as unproblematic before its appearance in these small particles, since tests conducted provided no relevant indications. The results of tests on titanium dioxide in the nanoscale form now show, however, that these particles can have ecotoxic effects (Hund-Rinke/Simon 2006, 225 ff.). The observation that the properties of a substance in the nanoscale form differ from those of the same substance in a non-nanoscale form was also made with regard to other substances (Nel et al. 2006, 622 ff.). The cause of this varied behaviour of one and the same substance is still unresolved. Besides particle size, other possibilities are surface quality and

surface size. Against this background, and as a result of the specific effects on organisms and biocenoses that can derive from nano materials, it makes a difference, considering the problem to which legislators have to react, whether a substance is in the nanoscale form or of another size.

2 Objective of the appraisal

On the basis of an analysis of the present state of "nano technologies" and a review of existing national and European environmental legislation, including legislation that will come into force in the near future (in particular REACh) regarding nano technologies, it is the objective of this appraisal

- to identify gaps in legislation at both a national and a European level regarding nano technologies,
- to point out possible regulatory approaches and
- to formulate recommendations for further regulatory action.

Tabulated overviews at the end of each section offer a summary of results (see the List of Tables on page VI). The results presented flow into considerations concerning a regulatory multi-step concept in Chapter 7.

3 Methodical approach

A process for the formulation of political demands on the issue of nano technologies has not been concluded, and defined control concepts, which would be required as point of reference for deficit analysis, are therefore lacking. Normative orientation has therefore to be achieved in another way (see Section 3.1).

The task of further investigation is initially to mark out, in a two-step analysis, areas

- in which regulatory deficits exist (the question has therefore to be asked: "Are there nano-specific or nano-appropriate guidelines in existing environmental law?" – see Chapter 5), and
- to point out regulative options to reduce these deficits ("Are there points of departure for filling gaps?" – see Chapter 6).

It has to be emphasized to begin with that neither the existence of a regulatory gap nor the description of a regulative option implies that there is a *need* for regulation. Instead a search has to be made for an – if necessary stepwise – approach on the part of administrators and legislators as an adequate answer to the societal problem situation (Section 3.2).

On the basis of an intermediate report, which summarized initial results, a discussion took place on 28 September 2006 at the Federal Environmental Agency (Umweltbundesamt) in Berlin. The authors would like at this point to express their thanks to all participants for their co-operation and the constructive discussion. Discussions at this meeting and comments subsequently made all flowed into the final version of this legal appraisal.

3.1 Regulatory objectives

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, or
- legislative objectives in similar regulative contexts can be drawn on in a kind of parallel consideration.

In Community law, Article 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 Article 2 and the cross-sectorial clause in Article 6 of the EC Treaty.[1] In German Basic Constitutional Law (*Grundgesetz*), from the perspective of protection, it is primarily fundamental rights in Articles 2 II, 12 and 14 as well as Article 20a that are relevant. But Basic Law can also be cited for the use of nano materials. From the perspective of promotion, different uses of nano technology can also serve issues of the common good and fundamental rights under Basic Law (including those in Articles 2 II, 12 and 14 as well as Article 20a).

Parallel consideration of other regulations is based in the end on the "assumption of the rationality of law" (see Führ 1999), which aims at fundamental consistency, that is the absence of contradiction, in the legal system.[2] It has therefore to be assumed that – as in other regulations – the principle of precaution also finds application in the case of nano materials. The normative "benchmark" could therefore lean on the material protection objectives of legislation on installations or water (see Section 5.2 and 5.2.2). Since risks are based on the specific substance-related properties of nano materials, it appears to be sensible to take as a basis the material objectives of the REACh Regulation,[3] 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" (Article 1 (3) REACh).

In implementation care should be taken that the obligation to act does not primarily lie – as with the present law on existing substances – with the authorities (Führ/Merenyi et al. 2005), but rather, in application of the principle that "environmental damage should as a priority be rectified at source" (Article 174 (2) EC Treaty), with the companies that handle nano materi-

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1 For the resulting demands see Calliess 2003, Köck 2003 as well as Führ/Merenyi et al. 2005 and Calliess/Lais 2005.

2 However, the embodiment of this – weak – demand in the constitutional principle and the resulting inference in decisions of the Federal Constitutional Court on municipal charges for waste and charges for hazardous waste levied by the Länder goes too far; see the detailed comments in Führ 1998.

3 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACh), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, EC OJ Dec. 30, 2006, page 1 – 847.

als. Such a regulative approach is in line with the basic principle of REACh, namely that of direct responsibility (Führ/Heitmann/Koch/Ahrens et al. 2006).

3.2 Choice of regulative options

For the purposes of prospective analysis of the consequences of a law, but also in application of the principle of reasonableness, those regulative options (with the resulting incentive mechanisms) should be preferred that by equal attainment of objectives encroach to the least extent on the freedom of action of stakeholders as protected under constitutional (and Community) law.

This requires, also within the scope of a legal appraisal, that other institutional options be considered that on the basis of legal criteria[4] could also be preferred as a "milder method". For regulative recommendations it is therefore not only a matter of the existence or absence of legal guidelines, but rather of whether the incentives resulting from regulations and the institutional context will be sufficient to influence the behaviour of those targeted in a way that corresponds with the control concepts of the regulatory authorities.[5] The results of considerations in this regard are discussed in Chapter 7.

[4] On the "responsive regulation" approach, see Bizer/Führ/Hüttig 2002. On the resulting demands on a precautionary strategy for action see Section 7.1, p. 53.

[5] Detailed incentive analysis was not intended within the scope of this legal appraisal. Nevertheless, legal analysis requires an "analytical pattern" as a methodical basis, see Führ/Bizer 2007.

4 Description of the problem and conflict situation

Nano technology distinguishes itself through its versatility with regard to existing research and development approaches as well as possible areas of application. Just about all industrial sectors are involved, but particularly the automobile industry, energy and environmental technology, mechanical engineering, chemicals, pharmaceuticals, medicine, cosmetics and foodstuffs. Due to the heterogeneity of technological approaches and areas of application it is therefore better to speak of *nano technologies* than of nano technology.

4.1 Definition of nano materials

Nano materials are the subject of investigation in this report. In line with other definitions[6] these are understood to include:

- Structures of anthropogenic origin (for example, particles, layers[7] 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 realizable in the macro form and be specifically used for the development of new products and applications.

In this connection it should also be pointed out, with a glance at the substances from which nano materials are derived and their particularly small particle size, that the following distinction can be made: On the one hand, substances can be involved that have been known and in circulation for a long time, for which, however, particular types of application in the nanoscale form have only recently been know 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. On the other hand, substances can be concerned that have been known for a long time also in this particularly small particle size (for example, carbon black). At the same time, fundamentally new substances are being produced, which are only available and in use in this particularly small particle size (for example, CNTs).

4.2 Nano-technological products and developments

Recently conducted research[8] has shown that a great many products with different nano materials are already on the German market. Moreover, this market for nano products and materials is distinguished by dynamic growth, since a new product comes along almost daily. However, manufacturers of nano products often do not present them as such, particularly as there is no identification requirement for nano materials.[9]

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

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

8 Cf. In Annex III of the German version.

9 On the other hand, it can happen that the designation "nano" is used although, according to the above definition, no nano materials are present.

4.3 Foreseeable emissions into environmental media

On the basis of available information it has to be assumed that the emission of nano materials is basically possible at every stage of a product life cycle. More specific statements are only possible on the basis of further investigations in particular cases, whereby the type of nano material as well as its size and application play a significant role.

According to initial estimates, (uncontrolled) emissions have to be expected in the current boom, especially during research and development, as a result of explorative and experimental modes of operation and the use of open plants (for example, during grinding, filling and finishing). It is also not clear whether occurring waste flows are professionally treated and disposed of.

Besides the type of manufacturing process (open or closed systems), the way nano materials are embedded in the product matrix is an important limiting condition for the emissions and exposure situation. This way it is ultimately determined how easily nano particles can be released into the environment. Furthermore, the degradability of nano materials plays an important role in this connection. In the post-consumption phase it should also be examined how nano materials behave in waste incineration plants and waste-water purification plants.

In principle, mobilization effects can be assumed for nano materials, which have great adsorption potential due to their surface. They can act as a carrier and as a result discharge nutrients and contaminants from soil into groundwater.

Partial completely uncontrolled release of nano materials can presently be observed with consumer products. With paints and varnish, cleaning and sealing agents, cosmetics and disposable items it is a matter of particularly urgency that the nano materials used should be tested for nano-specific risks. Consumer protection is of immediate importance, but nano materials can also enter the environment (for instance, sunscreens in recreational waters, or nano particles from textiles in domestic waste water).

5 Analysis of the existing legal framework

The description of the existing legal framework follows the "life-cycle approach", beginning with research and development (Section 5.1), and continuing with the manufacture and industrial use of nano materials (Section 5.2), the marketing of substances and products (Section 5.3), transport (Section 5.4), use (Section 5.5) and disposal (Section 5.6).

The individual sections conclude with a tabular summary, in which the most important results are clearly arranged. Regulative options are treated in Chapter 7.

Due to the Community dimension of the issue, which derives not least from EC legislation on chemicals, this report primarily examines Community law. Where national law has no special features it is not discussed. The tabulated summaries, however, also mention national regulations.

5.1 Research and development activities

In a market economy innovation is the motor for business success. Research and development, with the pursued goal of "invention", are the source of innovation.[10] The legal framework is accordingly designed, as a rule, to provide research and development with the greatest possible scope. From an environmental perspective,[11] R & D activities are the subject of legal regulation only in exceptional circumstances, as in the area of genetic engineering.

Special regulations in legislation on industrial installations take effect only when the laboratory scale is overstepped and the sampling phase in pilot plant facilities is reached. Installations on a laboratory or pilot plant scale have been generally exempt since 1997 from licence requirements in accordance with Article 1(6) of the 4th Federal Immission Control Decree (BImSchV).[12] Beyond that, installations listed in the Annex to the 4th BImSchV are subject to licensing; however, according to Article 2 (3) of the 4th BImSchV, a simplified licensing procedure (without public participation) applies in the case of "testing installations". Material demands on testing installations do not differ from those on actual production installations, which is why reference can be made to comments in the following section.

Where a licensing obligation according to Articles 4 ff. BImSchG is not effective, laboratory and pilot-plant installations require planning permission. In the planning approval procedure the demands contained in Articles 22 ff. BImSchG have also to be examined.[13] In examining whether adverse effects on the environment from air impurity are to be expected, reference must be made to "TA Luft" (technical instructions for the maintenance of air purity) and its specifications in No. 4 (Chapter 1, TA Luft). Here, reference is also made to the comments in the following section.

In the R & D area, regulations in legislation on water and waste have also to be observed, but there are no peculiarities from a legal point of view. On the other hand, it could be difficult to register inputs of nano materials from research and development.

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10 Concerning the concept of innovation and its elements, see Schumpeter 1950 and Klodt 1995.

11 The situation in the area of industrial safety is different, since here the health of employees in R & D departments is the prime concern.

12 See Böhm in GK-BImSchG, Art. 4, marginal note 83 ff.; Hansmann in Landmann-Rohmer, 4. BImSchV Art. 1, marginal note 13a.

13 Roßnagel in GK-BImSchG, Art. 22, marginal note 161 ff.

5.2 Production

5.2.1 Legislation on installations

The production and industrial use of nano materials falls under the jurisdiction of the Federal Immission Control Act (BImSchG). Other than the title of the Act suggests, it is not merely an air purity act, but has rather – for installations subject to licensing – the character of a comprehensive law governing the licensing of industrial installations, and thus continues the tradition of trade regulations.[14] In recent years the focus has been on an integrative approach. IPPC Directive 96/61/EC is responsible for this development, which, together with other aspects of Community law, has determined the legal situation in Germany.[15] The following description is therefore largely restricted to the ICCP Directive.

5.2.1.1 Authorization requirement

The IPPC Directive applies to all installations mentioned in Annex 1 of the Directive. The Annex is arranged – similar to the 4th Federal Immission Control Decree (BImSchV) – by industry. Articles 4 and 12 of the IPPC Directive make clear that both new installations and changes in installations made by operators are covered.

Production of nano materials

The production of nano materials is subject to authorization pursuant to Annex 1 (4) to the IPPC Directive whenever this is carried out in an "installation" and the outcome is the "production on an industrial scale by chemical processing of substances or groups of substances listed in Sections 4.1 to 4.6".[16]

The definition of installation – just as that of substance[17] – is met entirely.[18] What is therefore decisive is whether the manufacture of nano materials is carried out by way of "chemical processing". This question can be answered in the affirmative in the case of most manufacturing processes. Only purely mechanical manufacturing methods are not covered.

Further industrial use

Besides manufacturing, the further use of nano materials in other stages of production is subject to authorization. This concerns, for instances, surface treatment processes, as detailed in Nr. 4 of Annex I to the IPPC Directive.

The decisive criterion, however, is not the "nano property" of surface coating, but rather the type and quantity of solvent used. When, for instance, nano particles are used during surface treatment, the authorization requirement takes effect only with the overstepping of the quantitative thresholds of the respective solvent. There is no authorization requirement directed specifically at the risks of nano materials.

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14 See *Führ* in GK-BImSchG, Art. 1 marginal note 9 ff.

15 See – for changes to installations – *Führ* in GK-BImSchG, Art. 16 marginal note 85-134.

16 The listed substances and groups of substances should be taken as examples. The production of such nano particles, which are not covered by the listing in the letters of No. 4.1 to 4.5, is therefore also subject to licensing according to the IPPC Directive as soon as an industrial scale is reached.

17 Article 2 no. 1 IPPC Directive defines "substance" as "any chemical element and its compounds".

18 Article 2 no. 3 IPPC Directive: "stationary technical unit"; Art. 3 (5) BImSchG: "Operating plants" and "other stationary facilities".

5.2.1.2 Material demands

The IPPC Directive lays down in Article 3 – analogous to Article 5 BImSchG – basic obligations ("general principles governing the basic obligations of the operator"). Installations should be operated in such a way that no "significant environmental pollution" is caused and preventative measures are taken through "application of the best available techniques".

Emission-side demands

These demands are to be implemented by competent authorities in the form of "conditions of the permit" in accordance with Article 9 IPPC Directive, and emission limit values should be laid down for all relevant pollutants, based on "best available techniques".[19] Beyond that, the conditions of the permit should contain provisions on the minimization of long-distance and transboundary pollution and ensure a high level of protection for the environment as a whole. Finally, according to Article 9 (5) IPPC Directive the permit should contain suitable release monitoring requirements.

Immission-side demands

Article 10 establishes a relationship between permit content and environment quality standards.

- Here, the limit value for fine particles and ultrafine particles and very fine dust, as laid down in Community air quality law, is a possibility. This is still several times the size of nano particles, and is therefore not appropriate for coping adequately with the specific risks of nano particles.
- Article 2 (7) of the IPPC Directive defines *environmental quality standard* as "the set of requirements which must be fulfilled at a given time by a given environment or particular part thereof, as set out in Community legislation". Whether such legislation will in future also include PNEC[1] values, which are to applied according to REACh within the scope of substance-related risk management, remains to be seen.[2] After all, it concerns quality values that have been deduced on the basis of an EC Regulation according to a procedure laid down in Community law.[3]

Prevention of industrial accidents

Requirements aimed at the "control of major-accident hazards involving dangerous substances" are contained in Directive 96/82/EC (Seveso II Directive)[20]; adopted in Germany in the 12th Federal Immission Control Decree (BImSchV).

The directive is applied when certain quantitative thresholds in "operational areas" can be exceeded. It is characterized – in great contrast to its earlier connection with installations – by its primary substance-related orientation. Quantitative thresholds are set so high (mostly in the four- to six-digit kilogram range), however, that they do not cover nano materials. This applies both to quantitative thresholds linked to hazard characteristics and to thresholds laid down for individual substances.

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19 Cf. the exchange of information according to Article 16 as well as the reference documents ("BREF") issued on this basis by the Sevilla Office" (European IPPC Bureau); cf. the overview at http://eippcb.jrc.es/pages/FActivities.htm.

20 OJ L 10, 13, as amended by Directive 2003/105/EC (OJ L 345, 97).

The essence of the directive is the demand for a "major action prevention policy" (Article 7 Seveso II Directive). This policy has to be drawn up in writing by the operator before the installation is put into operation, properly implemented and – if a business is involved that is subject to basic obligations – made available to the competent authorities. Businesses subject to extended obligations have to document compliance with this requirement in the area of safety.

Updating the permit (subsequent conditions)

According to Article 13 of the IPPC Directive, competent authorities have to "periodically reconsider and, where necessary, update permit conditions." The reason for this could be the need to revise emission limit values or include new values in the permit, or also new developments in emission reduction technology.

Should the regulation have a practical effect, concretization is necessary not only of immission specifications but also of requirements concerning the latest developments in technology.

National level

The basic obligations of the law on immission control, as contained in Article 5 BImSchG, apply to installations subject to licensing. Decrees according to Article 7 as well as administrative regulations issued according to Article 48 implement these basic obligations. Subsequent orders can be based on Article 17 BimSchG.

The basic obligations of Article 5 cover the effects of an installation on rights protected by law. Where air-borne emissions are involved, the requirements of the implementation order on the Federal Immission Control Act[21] as well as of TA Luft (technical instructions for the maintenance of air purity) take effect, which, however, contains no special requirements at all regarding nano particles.

In the case of an installation for the production of different nano powders, which was the subject of a judgement of the Higher Administrative Court of the State of Baden-Württemberg,[22] the competent authority adopted much more stringent requirements in its decision than those in TA Luft. Whether it was obliged by law to do so is unresolved even after the judgement of the Higher Administrative Court, since the permit was objected to by an affected third party whose action was unsuccessful because he could not prove that "adverse effects on the environment", pursuant to the law, emanated from the nano powders. It was shown during the court hearing, with the help of a expert opinion from Professor Greim (Munich), that immission exposure would remain less than 1% that of the immission value of diesel soot regarded as tolerable by the LAI.[23] The resulting restriction – which was reduced in a disclaimer by the operator by a factor of 100 during appeal proceedings – remained unchallenged in the decision of the Federal Administrative Court (Bundesverwaltungsgericht – BVerwG):[24]

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21 For instance, the immission-related demands of the 22nd BImSchV as well as demands on the operation of installations in the 13th, 17th and 31st BImSchV.

22 Judgement of 18 December 2001, file number: 10 S 2184/99 (juris). See also the appeal decision of the Federal Administrative Court: BVerwGE 119, 329; more on this in Section 7.1, page 53.

23 Länderausschuss für Immissionsschutz [Länder Committee on Immission Control], Krebsrisiko durch Luftverunreinigungen, Düsseldorf 1992.

24 Federal Administrative Court, BVerwG of 11.12.2003 - 7 C 19/02 -, E 119, 329/334.

> "Where a scientifically ascertainable effect threshold is lacking, it is free of arbitrariness, in the absence of better knowledge, when consideration of irrelevance is based for the purpose of orientation on the criteria for judging the carcinogenic effects of comparable substances evolved in the LAI study on "Cancer risks from air impurities" (1991). Beyond such an irrelevance threshold, which marks the area of inevitable residual risk, the immission-control-related legal obligation of protection and preclusion is meaningless."

The outcome was that violation of the protection and preclusion obligation deriving from Article 5 (1) no. 1 BImSchG (which merely protects third parties) had to be denied. It would be a mistake, however, to deduce from the judgement that present knowledge of the effects of nano materials are satisfactory or that the formulation of legislation on installations is not in need or capable of improvement. The Federal Administrative Court merely observed that the decision of the authority was "free of arbitrariness". Possibly, emission-limiting measures were either too stringent or even, measured on the obligation for precaution (that excludes third-party protection), not far-reaching enough.

It can therefore be maintained that, on the basis of material obligations on the part of installation operators, the authorities are quite able to respond to the specific dangers of nano particles released into the environment. However, they must determine and evaluate the risk independently. As yet, no support is to be found in non-statutory regulations. Authorities can merely use the interpretive support of the LAI on carcinogenic air pollutants ("TA Krebs" – [technical instructions concerning cancer]). These allow – risk-based – analogous consideration without, however, addressing more precisely the specific effects of nano materials. This is problematic, since the effects of nano materials on human health must by no means be restricted to their carcinogenic potential.[25]

5.2.1.3 Installations not subject to licensing

As mentioned in Section 5.1, the Federal Immission Control Act (BImSchG) also lays down demands for installations that are not subject to licensing under emission-control law. Requirements according to Articles 22 ff. BImSchG have then to be observed within the framework of planning approval. As yet, there is no corresponding regulation at the EC level.[26]

5.2.1.4 Other regulations at the EC level

Community legislation on installations is not restricted to the IPPC Directive. On the one hand, there are regulations for specific groups of substances, such as the VOC Directive, which regulates not only the production but also the further use of VOC substances, provided that the respective installation size or quantitative thresholds laid down in this directive – which do not correspond with those of the IPPC Directive – are achieved. At the same time, there are further special installation-related standards in Community law, such as those for large fossil-based incinerating plants or waste processing plants.[27]

5.2.1.5 Conclusion

It can therefore be observed that, besides a licensing obligation for specified installations, the IPPC Directive also lays down that requirements on emission limitation take effect and that

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[25] Umweltbundesamt [Federal Environmental Agency] 2006, 12 ff.

[26] See also Führ/Merenyi 2005 (UBA-Texte 04/05, *http://www.umweltdaten.de/publikationen/fpdf-l/2953.pdf*) and Führ/Merenyi 2006.

[27] See Führ, in: Koch/Scheuing 2003 (GK-BImSchG), Art. 16 marginal note 116 ff.

environmental quality standards be complied with. Largely unregulated in Community law are installations beyond the field of application of the IPPC Directive.

The Seveso II Directive contains substance-related requirements for the prevention of major industrial accidents.

All the regulations mentioned, however, are not addressed at the specific risk situation of nano materials, as can be seen from the following overview.

5.2.1.6 Overview of legislation on installations

Subject matter	Status quo D	Status quo EC	Deficit/ need	Options	Comments
Initial control (incl. changes) – Production	Art. 4 + 15/16 BImSchG 4th BImSchV*:	Art. 4 +12 IPPC Dir. Annex I:	Instruments themselves exist		
– Application	No. 4	No. 4	"Chemical processing"? / other processes?	Clarification of definition / production of nano materials without chemical processing subject to licensing?	
– Waste processing installations not covered by 4th BImSchV*	No. 5.1, 5.2 among others	No. 6.2, 6.7 among other	Not nano-specific	Introduce specific licensing obligation?	Surface activity as threshold value?
	No. 8	No. 5	Not nano-specific	Ditto?	Ditto?
	Art. 22 ff. BimSchG*	VOC Directive	Not nano-specific	Ditto?	Ditto?
Requirements on immissions	22nd BImSchV* Analogous to LAI "TA Krebs"	Air-quality Directive: fine particles	Not nano-specific	Specific regulations - Link to chemicals law: indicative effect of PNEC* (in Directives, ordinances/decrees, VwV*) - Technical standards?	Surface activity as immission value?
Requirements on emissions-	State-of-the-art, concretized in decrees/ordinances and TA Luft*	BAT, concretized in BREFs*	Not nano-specific	Draw up specifications: - risk-controlled (→ chemicals law) - Precaution according to BAT?	Retention technically possible (pure air filter); cost-benefit analysis: bases for this?
Preclusion of industrial accidents	Basic obligations derived from Art. 5; 12th BImSchV	Seveso Directive	Not nano-specific	Introduce nano-specific thresholds	Surface activity as threshold value?
Monitoring - Emissions /immissions	Art. 26 ff. BimSchG	Art. 14 IPPC Directive	Not nano-specific	General requirements	Measuring methods available?
Subsequent conditions	Art. 17 ff. BimSchG	Art. 13 IPPC Directive	Nano-specific grounds necessary	Link to chemicals law?	Cost-benefit analysis: bases for this?

*__Explanation__: BimSchG: Federal Immission Control Act – BImSchV: Federal Immission Control Decree – BREFs: Best available technique reference documents – PNEC: Predicted no effect concentration – TA Krebs: Technical instructions concerning cancer – TA Luft:: Technical Instructions on air – VwV: Administrative Regulation on the Road Traffic Act

Table 1: Overview of results for legislation on installations

5.2.2 Legislation on water

When nano materials are manufactured or used industrially, water-law requirements on the discharge of substances into water bodies (point sources) have to be observed. However, nano particles can also enter waters from diffuse sources, for instance during the use of products including nano materials (see the examples in Section 5.5).

5.2.2.1 Initial control

Emissions of nano particles from industrial activities into waters listed in Annex I to the IPPC Directive are subject to licensing according to Article 8 IPPC Directive. There is no licensing obligation at an EC level for the discharge of nano particles into water bodies through activities or diffuse sources not listed in the IPPC Directive.

The indirect discharge of List II substances into groundwater is the exception, for which a licensing obligation exists according to Article 4 of the Groundwater Directive.[28]

According to German legislation, a permit is required under water law for every direct and indirect discharge of nano particles into a water body.

5.2.2.2 Material demands

With regard to the discharge of pollutants specified in a non-definitive list[29] in Annex VIII of Water Framework Directive 2000/60/EG (WFD)[30], Member States have to limit emissions, in accordance with Article 10 WFD, on the basis of best available techniques or relevant emission limit values. In addition, Article 16 WFD includes the obligation to comply with quality standards with respect to certain prioritized substances specified in Annex IX.[31] Neither Annex VIII nor the list of prioritized substances, which has to be updated every four years, currently takes account of nano-specific substances or substance properties.

In the case nano particles are not included among prioritized substances in the WFD, limit values for List II substances in Water-quality Directive 76/464/EEC[32] have to be observed, which will be repealed by the WFD by 2013 at the latest. List II contains limit values for "classical" pollutants, such as metalloids, metals and their compounds, but does not explicitly take nano particles into account. The description of pollutants listed in Annex VIII to the WFD – for example, as substances and preparations or their degradation products, whose carcinogenic or mutagenic properties in water have been proven (No. 4), persistent hydrocarbons (No. 5), metals and metal compounds (No. 7) or suspended materials (Nr. 10) – is in such general

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28 Directive 80/68/EEC of the Council of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances (OJ No. L 20, p. 43), as amended by Directive 91/692/EEC (OJ L 377 of 31.12.1991, p. 48).

29 The list in the WFD (see Footnote 32) replaces List I substances in Article 6 of Water-Quality Directive 76/464/EWG, cf. Article 22 (2) and (3) WFD.

30 Directive 2000/60/EC of the European Parliament and the Council of 23. 10. 2000 on the creation of a framework for Community action in the field of water policy (Water Framework Directive (WFD)); OJ L 327 of 22. 12. 2000, p. 1.

31 Up to now, 10 of the 18 substances specified in List I of Directive 76/464/EEC have been adopted in the list of prioritized substances. Quality standards and emission limitations for the remaining 8 substances in List 1will presumably be abolished; cf.: http://www.umweltbundesamt.de/wasser/themen/stoffhaushalt/wrrl.htm.

32 Directive 76/464/EEC of the Council concerning water pollution by discharges of certain dangerous substances of 4 May 1976 (OJ L 129, p. 23); last amended on 31 December 1991 (OJ L 377, p. 48)

terms that nano particles could also be covered.[33] Concretization of limit values for these pollutants is to be found at the EC level in Directive 91/271/EEC[34] on the treatment of municipal water bodies for the parameters "phosphate" and "nitrate", however without nano-specific characteristics being covered.

Specifications for indirect drainage – that is, through soil and subsoil – of groups and families of substances specified in List II of Groundwater Directive 80/68/EEC also contain no nano-specific requirements. The Directive will be annulled at the latest 13 years after the Water Framework Directive (cf. Article 22 (2) WFD) comes into force and should be replaced by a daughter directive[35] of the WFD. But also the planned groundwater quality standards in Annex I and threshold values for groundwater pollutants in Annex III to the proposed directive do not take nano-specific characteristics into account.

It can be regarded as a deficit that for the discharge of nano particles there are either no limit values for nano materials or existing limit values and quality standards for pollutants do not cover nano-specific characteristics (the examination of corresponding German regulations produces the same result). Furthermore, available technologies for restricting the discharge of nano particles must either be adopted in BREFs or newly developed.

[33] The prioritized substances mentioned are identical with substances listed under "water" in Annex III to the IPPC Directive.

[34] Directive 91/271/EEC on urban waste-water treatment of 21.05.1991, OJ L 135, p. 4; amended by Directive 98/15/EC of the Council of 27.02.1998, OJ L 67, p. 29.

[35] Proposal for a Directive of the Council on the protection of groundwater against pollution of 19.9.2003, COM (2003) 550 final.

5.2.2.3 Overview of legislation on water

Subject matter	Status quo (D)	Status quo (EC)	Deficit	Options	Comments
Initial control (incl. changes) in the case of direct discharge (sewage disposal)	Only a permit, Articles 2,6,7 WHG* (Licensing obligation, Art. 18b and c WHG*)	Only for existing industrial activities according to Article 9 IPPC Directive	Lack of requirements for activities that do not fall under the IPPC Directive are caught in Germany by the WHG*	-	-
Initial control (incl. changes) in the case of indirect discharge	Permit or approval, Articles 2,6,7,8 WHG*		Lack of threshold values for indirect dischargers	Requirements for mixing and for the place of occurrence	-
Immission requirements	Judgemental latitude: management objectives, Art. 25a I, 33a, 34 WHG* (deterioration, preservation and development requirement)	Immission standards of future daughter directives of the WFD in accordance with Article 16	Not nano-specific	Specific regulations through link to chemicals law. Indicative effect of PNEC*.	-
Immission requirements (direct discharge)	- Art. 1a II, 7a WHG*: state-of-the-art concretized in Waste Water Ordinance (AbwV)	- Art. 10 WFD*, BAT* concretized in BREFs* - Limit values concretized for phosphate and nitrate in Directive 91/271/EEC	Not nano-specific	See above	Retention technically possible up to 1 nm; diaphragm filter but then possible problems with waste-water quantities
Emission specifications (indirect discharge)	Art. 7a (4) WHG*, LWG* + indirect-discharger ordinance (Länder level)		Not nano-specific		See above
Monitoring of emissions	Self-control, Art 21 ff, WHG*; auth. representative	Article 6 (1) and 14 IPPC Directive (self-control)	Not nano-specific		Need for research
Monitoring of immissions	Water quality (Art. 4 II, No.1 WHG*) Measurement/ analysis (Art. 4 AbwV*, Annex)	Article 9 (V) IPPC Directive	Not nano-specific		Need for research
Subsequent conditions	Article 5 WHG*	Article 13 IPPC Directive	Nano-specific grounds necessary	Link to chemicals law	Cost-benefit-analysis necessary

*__Explanation__: AbwV: German Ordinance on the discharge of waste water into water bodies – BAT: Best Available Technique – BREFs: Best Available Technique Reference Documents – PNEC: Predicted no effect concentration – WFD: Water Framework Directive – WHG: German Water Management Act – LWG: Water laws of the German Länder

Table 2: Overview of results for legislation on water

5.2.3 Legislation on waste

5.2.3.1 Disposal of waste

The basic obligation to avoid or reduce waste according to Article 3 (1a) of Waste Directive 2006/12/EC applies to the production and use of nano materials within the scope of industrial activities specified in Annex I to the IPPC Directive (cf. the reference in Article 3 (c) IPPC Directive).[36] Where waste cannot be avoided it has primarily to be recycled or[37], when recycling cannot be carried out properly and safely, disposed of:[38] Where the composition of waste from the production and processing of nano materials is unknown, the possibility of proper and safe recycling has to be examined in each individual case. Should safe recycling in accordance with Article 5 (3) of the Closed-cycle Substance and Waste Management Act (KrW-/AbfG) not be possible, such waste has to be disposed of in accordance with Article 10 (1) KrW-/AbfG in a manner compatible with the common good.

Further comments on the control of waste flows and the depositing of waste with nano materials are to be found in Section 5.6.

5.2.3.2 Recycling of waste

Where waste containing nano materials is disposed of in a waste incineration plant, the provisions of both the IPPC Directive and Waste Incineration Directive 2000/76/EG[41] have to be observed.

Operators of waste incineration plants and "co-incineration plants" for the thermal recycling of household waste as well as other waste (for example, sewage sludge, used tyres and clinical waste) and hazardous waste that is excluded from the scope of Directive 94/67/EG (such as waste oil and solvents), require a permit for which the requirements of the Waste Incineration Directive have to be observed. In the case of emissions to the atmosphere, and in accordance with Article 7 of the Waste Incineration Directive, waste incineration plants have to meet limit values in Annex V and co-incineration plants must meet limit values in Annex II. In the case of emissions into water, according to Article 8 of the Waste Incineration Directive the specifications in Annex IV have to be met.

In the case of material demands, there are regulatory gaps in the Waste Incineration Directive. For instance, limit values apply only to known ("classical") pollutants. Emissions from substances that, due to their nano-specific properties, have to be classified as pollutants are not considered. Furthermore, the measurement of emissions to the atmosphere and water, which according to Article 10 has to be carried out by plant operators, is conducted on the basis of mass concentration, which leads to inadequate results with nano particles due to their low mass.

For nano materials, one could additionally lay down the measurement of particles per cubic metre, provided the emission of nano particles is involved and there is concern about ad-

[36] Directive 2006/12/EC of the European Parliament and the Council on waste of 5 April 2006 (OJ L 114, p. 9):

[37] Cf. Article 5 (2) sentence 2 KrW-/AbfG.

[38] Cf. Article 5 (3) KrW-/AbfG.

[41] Directive 2000/76/EC of the European Parliament and the Council of 4 December 2000 on the incineration of waste, OJ. L 332 of 28.12.2000, p. 91.

verse effects on human health. The availability and efficiency of air and water filters for the retention of nano particles has to be investigated.

5.2.3.3 Overview of legislation on waste

Production-related regulations are described together with those on post-consumption and disposal in Section 5.6.3.

5.3 Marketing

Those wishing to place nano materials on the market have to comply with the provisions of chemicals law, provided chemicals law is applicable to the particular case.[42] The following considerations concentrate on environment-related elements of "primary chemicals law". The following comments define "primary chemicals law" as regulations, such as Articles 7, 9 and 9a German Chemicals Act,[39] which, by means of special mechanisms (for instance, specific test specifications), are aimed at systematic identification of substance-related risks. The reason for this is the intention of legislators to register substances at an early stage, directly after production.[40] "Derived chemicals law" is distinguished from "primary chemicals law" (directed at data collection) by the fact that, based on data from primary chemicals law, it includes specifications for identifying and – through appropriate action – "preventing" dangers in subsequent individual use (Article 8 GefStoffV (Dangerous Substances Decree)) and controlling risks (so the formulation in the REACh Regulation). In future, specifications in the REACh Regulation will have to be observed (see Section 5.3.2). At present, registration as a new substance is a possibility (Directive 67/548/EEC[41]). Existing substances are dealt with in Regulation 793/93/EEC.[42]

5.3.1 Nano materials under prevailing law

Whether a substance in the nanoscale form falls under the legal regime for existing or new substances depends on whether the respective substance is listed in the EINECS[43] register of existing substances.[44] According to the latest formulation in the Manual of Decisions, "substances in nanoform, which are in EINECS (e. g. titanium dioxide) shall be regarded as exist-

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42 Excluded, for instance, is the use of substances in medicinal products for humans and animal.

39 The quoted standards of the German Chemicals Act result from implementation of Article 7 (1) in connection with Annex VII A (2) in connection with Annex VIII 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 L 196 of 16.08.1967 p. 1-98, last amended by Directive 1999/33/EG, OJ L 199 of 30.07.1999, p. 57-58.

40 Cf. Rehbinder/Kayser/Klein Article 3 (1) (German Chemicals Act), marginal note 4.

41 Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 196 of 16.08.1967 p. 1-98, last amended by Directive 1999/33/EG, OJ L 199 of 30.07.1999, p. 57-58.

42 Regulation 793/93/EEC of 23 March 1993 on the evaluation and control of the environmental risks of existing chemical substances, OJ L 84 of 05/04/1993 p. 1 – 75.

43 European Inventory of Existing Commercial Substances: lists all substances traded on the European market between 01.01.1971 and 18.09.1981 (number: 100,195).

44 The existence of a substance in this register results, in accordance with Article 2 (e) of the regulation on existing substances, in its treatment as an existing substance, non-existence in the register to its treatment as a new substance.

ing 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".[45]

One substance in the nanoscale form that would have to be treated as an existing substance is carbon, which is listed in EINECS as "Symbol C, CAS-No. 7440-44-0, EINECS No. 231-153-3" when manufactured or marketed in the nanoscale form (that is, with a particle size in the nm range). Carbon in this special form is presently manufactured and sold as "nano powder".[46] On the other hand, carbon compounds produced in the nanoscale form that are not listed in EINECS (for example, fullerenes such as C-60 or C-70 compounds) would have to be treated as new substances. It is argued[47] that substances belonging to the group of carbon nanotubes are synthetic graphite, having the layered structure characteristic of the existing substance graphite (CAS 7782-42-5), and have to be treated accordingly as the existing substance graphite. In the following sections, current demands on both variants are explained, following which substance-specific information relevant to the assessment of risk is described – based on the example of specific substances – that would have to be notified by manufacturers under both legal regimes.

5.3.1.1 The definition of substance in prevailing chemicals law

The above-mentioned assignment of substances in the nanoscale form to existing and new substances is based on information contained in the Manual of Decisions[48]. This assumes that the occurrence of a chemical in the nanoscale form does not independently satisfy the description of substance, namely that irrespective of the particle size of a chemical a single substance is involved (for example, titanium dioxide in both the nanoscale form and another form is to be treated as an existing substance). It is questionable whether this corresponds with the definition of substance in prevailing chemicals law.

The regulatory object of prevailing chemicals law is "the substance", which is defined in Article 3 (1) of the German Chemicals Act and in Article 2 (1a) of Directive 67/548/EWG[49] as a "chemical element or substance 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". On this basis, substances are initially distinguished with regard to their natural occurrence as elements (for example, carbon C) or compounds (for example, naturally occurring carbon compounds such as methane), and then, however, as substances that are manufactured (for example, fullerenes C-60).

As chemical elements and chemical compounds in the form of nano particles these generally fall initially under this definition.[50]

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45 Manual of Decisions for implementation of the 6th and 7th amendments to Directive 67/548/EEC of 03.07.2006, EUR 22311, Section 5.1.3, p: 64. „Substances in nanoform which are in EINECS (e. g. titanium dioxide) shall be regarded as existing substances. Substances in a nanoform which are not in EINECS (e.g. carbon allotropes other than those listed in EINECS) shall be regarded as new substances“.

46 For instance, by Sigma-Aldrich under the designation, catalogue number 633100, "Carbon nanopowder: Amorphous materials formed by laser techniques“; source: www.sigma-aldrich.com, 04.06.2006.

47 Kitzinger 2006, Chapter 4, p. 7.

48 Cf. Footnote 47.

49 Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 196 of 16.08.1967 p. 1-98, last amended by Directive 1999/33/EG, OJ L 199 of 30.07.1999, p. 57-58.

50 Thus clarified in Kitzinger 2006, at Nr. 5.3.2.2, p. 10.

The answer to the question whether the occurrence of these individual substances in the nanoscale form *independently* satisfies the definition of a substance is not to be found in the definition itself.

Beyond the criteria mentioned in the above definition, substances have always been distinguished primarily on the basis of their chemical and physical properties, for these are characteristic and invariable for a substance.[51] This means, on the other hand, that if different properties can be observed different substances are involved.

Up to now, one has generally assumed that the chemical properties of a substance are independent of the size and form of the particles it is composed of.[52] On the basis of this assumption, it was irrelevant for the definition of a substance whether a chemical existed in the nanoscale form or in some other form.

As soon, however, as different manifestations involve special properties (as in the example of titanium dioxide with the property of ecotoxicology, which was observed in the nanoscale manifestation but in no other manifestation of titanium dioxide), from the point of view of chemical law two different substances have to exist, and this because their different risks call for appropriately varied treatment (for instance, classification and labelling).

The following description is initially orientated towards statements contained in the Manual of Decisions, which do not make this distinction, but rather stick to the traditional view that "substance identity is independent of form of manifestation". Comments that take up this distinction are to be found in Section 6.1.1.2.

5.3.1.2 Nano materials as existing substances

If nano materials are treated as existing substances they are subject to the requirements of Regulation 793/93 on existing substances, also known as the Existing Substance Regulation (ESR). Article 7 (1) ESR requires the spontaneous submission of certain information, in particular when a substance experiences new uses that substantially change the type, form, magnitude or duration of exposure man or the environment to the substance (letter a).

Where a substance already listed in EINECS, which has previously not been used in the nanoscale form, is now applied in this particularly small particle size, it has to be assumed that due to the resulting special surface/volume ratio – that is, its greater surface energy – such a new application exists that essentially changes the type, form, extent and duration of exposure on the part of man and the environment.[53] This supposition is supported, above all, by the enormous surface expansion of the substance used, which can give rise to completely different reactions than the previous non-nanoscale form, particularly when the substance

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51 Cf. Rehbinder/Kayser/Klein 1985, Article 3 (1) German Chemicals Act, marginal note 7. On the basis of, inter alia, different properties, different substances can also be identified, which have the same empirical formula (a formula that merely indicates how many atoms of the same kind are present in a molecule) but different structural formulae (a formula in which the atoms of a molecule are individually named, and in which atoms connected to each other are indicated with a hyphen. An example of an empirical formula: C_2H_6O. This applies to two different substances, which have the following different structural formulae: C_2H_5-OH (ethanol) and CH_3-O-CH_3 (methoxymethane).

52 Rehbinder/Kayser/Klein 1985, Article 3 (1) Chemical Act, marginal note 7.

53 The Manual of Decisions (see Footnote 45) makes only general reference, p. 64: “New information on existing substances, ‘including those with nanoforms’, shall be submitted in accordance with Art. 7 of Regulation (EEC) No 793/93“.

should react as a catalyst.[54] With regard to exposure on the part of the environment, particular mobilization effects of the substance are to be expected on account of such a reaction within and between individual environmental media, so that also under this aspect the prerequisites of Article 7 (1a) ESR would exist.

Nevertheless, the Existing Substance Regulation has not created an adequate basis for requiring unsolicited submission of data on the part of manufacturers of existing substances in the nanoscale form. For according to Article 7 (1) ESR this updating requirement applies only to those manufacturers and importers that have already submitted information on a substance in accordance with Articles 3 and 4. The initial submission of data according to these requirements is effective at the earliest, however, when a manufacturer has produced a substance in a quantity exceeding 10 tonnes per year (Article 4 (1) ESR). Under the regulatory regime for existing substances, the possibility therefore remains that every substance listed in EINECS is manufactured and marketed in the nanoscale form in quantities of up to 10 tonnes per year, without resulting risks for human beings and the environment being closely examined. According to the wording of Article 7 (1) ESR (see above), manufacturers are also not obliged to submit information to the effect that they are now producing and marketing existing substances in the particular particle size of the nanoscale form.

In addition, attention has to be drawn to a further basic limitation in the Existing Substance Regulation: Annex II to the Regulation lists a number of substances, which are exempt from the requirements of Articles 3 and 4 ESR, as a consequence of which they are also exempt from those of Article 7 ESR (requirement for spontaneous updating on the part of manufacturers). Among such exemptions is carbon, as already mentioned, and graphite.[55] The background to the exemption of the listed substances from the demands of the ESR is the assumption that "on the basis of their intrinsic properties they involve only risks generally recognized as minimal".[56] Since the regulation was adopted in 1993, the existence of substances in the nanoscale form might not have been considered, at any rate not to the extent that they are now manufactured on an industrial scale in defined particle sizes. Against this backdrop it has to be asked whether this assumption can remain unchanged, or whether it should be adapted to new developments.

Another situation arises where the manufacturer or importer of a substance is informed "that the substance in question may present a serious risk to man or the environment". In this case, according to Article 7 (2) ESR, he should *immediately* report such information to the Commission and the Member State in which he is located. Accordingly, such immediate notification is also required for existing substances in the nanoscale form when it becomes obvious that they could present a serious risk to man or the environment.[57] The regulation contains no particular specifications, however, on the collection of data on such risks (for instance, the conduct of appropriate tests).

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54 When it does this, or when this can be excluded, would have to be clarified by the manufacturer in documents to be submitted.

55 ESR Annex II, OJ L 84 of 05.04.1993 p. 70.

56 See Recital 7 to the ESR.

57 Whereby the formulation, "substance in question" can be interpreted in several ways and therefore raises the question, whether this obligation according to Article 7 (2) ESR should cover all existing substances, or only those that are already subject to the requirements of Articles 3 and 4 ESR. Without further knowledge regarding this question: Rehbinder 2003, Article 61 marginal note 88, who in this connections writes of the "concerned substance".

The requirements of Article 7 (1) and (2) are basically distinguished by the period of time during which they have to be fulfilled. Article 7 (1) mentions that information has to be "updated", whereby "in particular" such changes mentioned under the letters a) to c) have to be submitted. Information regarding production and import volumes has to be updated every three years. Viewed as a whole, information to be notified according to Article 7 (1) concerns such that can be located in the usual period of time applicable for existing substance procedures. On the other hand, Article 7 (2) requires that information be reported "immediately".[58] Here, however, active data collection is not demanded; a substance supplier has merely to pass on such information of which he becomes "aware".

There is thus "no quantitative threshold" for the obligation according to Article 7 (2) ESR.[59] The notification requirement extends accordingly to all existing substances, that is all 100,195 substances listed in EINECS. In application of this interpretation – irrespective of every produced or imported quantity – information has to be reported immediately to the Commission and the respective Member State on existing substances in the nanoscale form, should it turn out that they could represent a serious danger to human health and for the environment.

5.3.1.3 Nano Materials as new substances

Under the regulative regime for new substances, nano materials are subject to the requirements of Directive 67/548/EEC. According to Article 5 of this Directive, Member States have to take all necessary measures to ensure that substances as such or in preparations can only be placed on the market when they have been registered with the competent authority of a Member State in accordance with this Directive. According to Article 7 (1) of the Directive, complete registration must include the following information:

- A technical description with details necessary to evaluate the predictable immediate or subsequent dangers that the substance can represent for human health and the environment, and with all data relevant for this purpose.
- A declaration on unfavourable effects of the substance with different foreseeable types of application.

Depending on the annual manufactured quantity of a substance per manufacturer, varied demands are made on the content, extent and depth of detail of this technical description (according to Article 8 of this Directive fewer demands on registration are made, for example, when the substance is produced in quantities of less than 1 tonne per year).

According to Article 13 (2) of the Directive, substances are regarded as registered when they are produced in quantities of less than 10 kilogram per year and manufacturer, provided that the manufacturer/importer fulfils all the conditions of the Member State in which the sub-

[58] In so far as this shows the actual difference between these requirements, it appears to be correct to regard only such a "substance in question" as is clearly in the focus of the existing substance directive due to obligations in accordance with Articles 3 and 4 ESR. The registration requirements in Article 7 (1) and (2) would therefore only affect such existing substances as are manufactured or imported in quantities in excess of 10 tonnes per year and per manufacturer/importer. Following the result of a discussion of experts on 28 September 2006 at the Federal Environmental Agency (with the appraisal of the history of the standard that was presented on this occasion), separate application of the notification requirement in paragraph 2 can be assumed..

[59] VCI 2006, Section 3.1.1.2, p. 3.

stance is placed on the market. These conditions do not go beyond those foreseen in Annex VII C Nos. 1 and 2.

As a result, under the new-substance regime the prerequisite for a start being made at all on the testing of substances in the nanoscale form, according to primary chemicals law, is that they are produced in a volume of at least 10 kilograms per year and manufacturer. In so far as substances are presently manufactured and distributed in the nanoscale form, which are not listed in EINECS and are therefore subject to new-substance law, this occurs to a certain extent in very small quantities, at any rate with regard to the size of the package.[60] For instance, in the case of substance catalogue no. 482994 "buckminsterfullerenes C-70" registration only then takes effect when 200,000 units of the 50mg package and 1.000,000 units of the 10mg package have been placed on the market.

Where an already registered new substance should perhaps be produced in the nanoscale form only at a later point in time, this would be a change pursuant to Article 14 (1) of the directive, which would require corresponding notification. Article 14 (1) sentence 2 lays down that the registrant in this case has to provide information on this fact, effects and other circumstances, in so much as this can be expected of him in exercising necessary care. It is not clear to what extent detailed tests of a new substance in the nanoscale form can be demanded on this basis.

5.3.1.4 Results with regard to legislation on existing and new substances

It can be said, to begin with, that in the legal treatment of nano compounds both under existing-substance and new-substance law a systematic evaluation of the risks for human health and the environment emanating from these substances is only demanded when certain quantitative thresholds have been reached. Even when this threshold is much lower in new-substance law (10 kilograms) than in existing-substance law (10 tonnes), the question is raised, regarding the very small volume placed on the market, whether this standard is adequate. Here, one could consider the introduction of nano-specific quantitative thresholds (see also the comments on regulative options within the scope of the REACh Regulation).

Furthermore, the criteria need to be clarified, according to which a substance is assigned to the existing-substance or new-substance regime (see Section 6.1.1.2).

5.3.2 Nano materials under REACh

In future, the demands of REACh will have to be complied with for the marketing of nano materials. If the assignment of substances in the nanoscale form to existing and new substances remains as laid down in the Manual of Decisions (see Section 5.3.1), nano compounds assigned to existing substances will become so-called phase-in substances according to Article 3 No. 20 (a) REACh, for which, as far as the registration requirement is concerned, the special transition provisions of Article 23 ff. REACh will apply.[61]

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[60] Sigma-Aldrich offer, for example: Catalogue No. 482994, [5,6] Fullerenes C 70, (price for 50 mg: 173.00 euros); source: www.sigma-aldrich.com, 26.10.2006.

[61] Regarding the registration myth of new substances with a marketing volume of under 10 kg, it should be explained whether this mythical effect should be covered by Article 24 (1) REACh, according to which notification in accordance with Directive 67/548/EEC is to be regarded as a registration for the purposes of this title. However, this question can remain undecided, since REACh only requires the submission of substance-related data for a production volume of 1 tonne and over per year and manufacturer.

In detail, REACh-relevant demands on nano compounds – subject to possible realization of EP Amendment No. 217 as introduced in the Environment Committee (see Section 5.3.2.5) – are as follows. They proceed from the definition of substance under REACh.

5.3.2.1 Definition of substance under REACh

Article 3 No. 1 REACh defines substance as "a chemical element or substance 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", thus corresponding with the definition in the previous regulation (see Section 5.3.1.1).

Should the above-mentioned demarcation of nano materials between existing and new substances be maintained, mention has to be made to this effect in the REACh Regulation, since demarcation between existing and new substance, as previously found in all chemicals-related regulations, is no longer explicitly maintained in REACh. REACh talks only of notified substances (Article 3 No. 21) and phase-in substances (Article 3 No. 20), which besides the substances listed in EINECS (according to the previous definition "existing substances") also include other substances.

5.3.2.2 Registration requirement

To match the principle of "no data, no market", established in Article 5 REACh, a manufacturer or importer who manufactures or imports a substance as such or in one or more preparations in a quantity of at least 1 tonne per year must submit a registration dossier to the Agency in accordance with Article 6 (1) REACh. This obligation applies, according to Article 7 (1), also when articles are produced in which the substance is present in quantities totalling over 1 tonne per year per producer or importer, provided the substance is intended to be released under normal or reasonably foreseeable conditions of use. This obligation applies therefore to nano materials only when they are the subject of regulation under REACh and are manufactured or imported as such or in one or more preparations or articles in the quantity mentioned.

5.3.2.3 Updating requirement

Article 22 (1) REACh requires that a registrant "spontaneously" update his registration without undue delay with relevant new information (such as changes in the composition of the substance, or a change in the annual quantity manufactured or imported etc.). This obligation exists, according to the wording of the standard ("after registration"), only for new substances, since they alone are subject to registration. Notification – likewise only of new substances – according to Directive 67/548/EEC, which in accordance with Article 24 (1) REACh is regarded as a registration for the purposes of this title, would be a sufficient prerequisite for the obligation to update.

Subject to possible transition periods, it has to be assumed that the updating requirement for existing substances in Article 7 (2) ESR (cf. Section 5.3.1.2) will no longer exist one year after the coming into force of the REACh Regulation (repeal of the ESR in accordance with Article 139 (2) REACh).

5.3.2.4 Determination of risk

Beyond these fundamental conditions, in particular after the quantitative threshold of 1 tonne per year and manufacturer has been reached, and in so far as the regulatory mechanisms under REACh take effect, the question remains whether these are appropriate to recognize and preclude possible risks to human health and for the environment from nano materials. It has to be borne in mind, as far as that goes, that the degree of detail of data submitted within the registration process rises with increasing production volume in accordance with Article 12 REACh. A detailed chemical safety report in accordance with Article 14 (1) REACh is required only with a production or import volume of 10 tonnes per year and manufacturer/importer. In the case of substances in the nanoscale form it takes correspondingly longer to reach this threshold. With individual substances – such as carbon black and titanium dioxide – the threshold could well already have been exceeded.

Apart from this, there currently appear to be no adequate testing methods with which specific risks from nano compounds could be determined.[62]

5.3.2.5 Authorization obligation according to EP Amendment No. 217

With their Amendment,[63] the Members of the European Parliament pursued their demand in the Environment Committee that nano particles be adopted as letter f a) under Article 56 REACh, that is, in the list of substances subject to authorization. The Amendment justification stated:

> "According to 'Science', the very small size of nanomaterials can modify the physico-chemical properties and create the opportunity for increased uptake and interaction with biological tissues. This combination can generate adverse biological effects in living cells that would not otherwise be possible with the same material in larger form. According to SCENIHR, information about the biological fate of nanoparticles (e.g. distribution, accumulation, metabolism and organ specific toxicity) is still minimal. Nanoparticles should therefore fall under authorization."

No account was apparently taken of this amendment in the course of the "trilogy" proceedings.

5.3.3 Results and the need for regulation

Gaps in the statutory treatment of nano materials exist not only in existing law but also – subject to the granting of the above-mentioned amendment in its present or modified form – with regard to REACh, where it is particularly questionable whether the quantitative thresholds necessary to trigger registration will be attained, in view of the extremely small individual quantities in which nano materials are, in part, currently placed on the market.[64]

Due to the fact that one and the same substance can have different properties in the nanoscale form than in another form, it has to be said that particularly in the determination of risk

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62 Confirmed by SCENHIR 2006, p. 59, 60. Initial attempts may evolve from a new project of EMPA, Switzerland, in which a cell culture test should be developed (http://www.chemlin.de/news/mai06/nanorisk.htm).

63 Amendment No. 217 to Article 56 REACh from Carl Schlyter, Caroline Lucas and Hiltrud Breyer, adopted by the Environment Committee of the European Parliament on 10.10.2006.

64 This applies at any rate to the fullerenes under consideration.

appropriately differentiated consideration of these different "substance variants" has to take place.[65]

5.3.4 Regulation under the Dangerous Substances Decree?

The above-mentioned regulatory gaps were mentioned as such in the Draft Final Report.[66] During the discussion of experts on 28. 9. 2006 it was mentioned in individual contributions[67] that provisions of the German Dangerous Substances Decree (GefStoffV [68]) were able to compensate these deficits. A prerequisite, however, would be that regulations in the Dangerous Substances Decree were able to fulfil the following functions ascribed to chemicals law with regard to the subject matter of this legal appraisal:

- Ascertainment of the properties of a substance in the nanoscale form and
- in so far as dangerous properties are concerned, transference into appropriate risk information and measures for the control of substance-related risks, whereby
- protection would have to cover not only employees but also all persons that could be subject to the effects of nano materials as well as all environmental media.

A more precise examination of the regulatory approach and individual provisions makes clear, however, that these functions are not covered by the Dangerous Substances Decree (and the EC regulations thus adopted[69]).

The reason for this, to begin with the last-mentioned function, is that the Dangerous Substances Decree essentially serves industrial safety in the sense of occupational health[70] and – other than the formulation in Article 1 (1) of the decree, according to which the decree also applies "for the protection of the environment against substance-related degradation", might lead one to believe – only secondarily and very selectively environmental protection. Exemplary reference is made to Article 8 (6) and (7) of the decree, which specifically concerns the response to threats to the environment that can arise from the depositing of dangerous substances.[71] The Dangerous Substances Decree does not cover the protection of the environment comprehensively, as is intended by the REACh Regulation.

Existing requirements concerning the ascertainment of information and the assessment of danger as contained in Articles 7 ff. Dangerous Substances Decree primarily address – as

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65 So also SCENHIR, Section 3.8.5, p. 34: "… the safety evaluation of nanoparticles and nanostructures cannot rely on the toxicological and ecotoxicological profile of the bulk material that has been historically determined." Cf. the discussion of regulative options in Section 6.1.1.2.

66 Führ et al. 2006.

67 See also VCI 2006, p. 2, 4; VCI-statement, p. 1 as well as Kitzinger 2006, p. 8 f.

68 Verordnung zum Schutz vor Gefahrstoffen (Gefahrstoffverordnung) (Dangerous Substances Decree) of 23.12.2004, Fed. Gazette I, p. 3758, last amended on 23 December 2004 (Fed. Gazette I, 3855) as well as by Article 2 of the 10th Chemicals Law Amending Decree of 11.7.2006 (Fed. Gazette I, 1575).

69 The last amendment served "adaptation to EC Directive 98/24/EG and other EC Directives", thus the title of the amendment of 2004. Concerning the Community-law background see also the official justification,1 ff.

70 Official justification to the Amendment of the Dangerous Substances Decree (GefStoffVO), p. 1 ff.; also the Committee for Industrial Safety and Safety Technology of the German Länder (LASI 2006, 5): the Dangerous Substances Decree serves the "protective objectives of the Industrial Safety Act" (see also the comments on the area of application on p. 8 ff.). Cf. also Schäfer, StoffR 2005, 35 ff.

71 See also the Amendment Resolution of the Bundesrat (under A 1), to which the new version of Article 1 Dangerous Substances Decree goes back (Federal Government Document 413/04, 1).

already mentioned in the intermediate report[72] – occupational health,[73] which arises from authorization laid down in Article 19 (1) sentence 1 German Chemicals Act ("Measures for the protection of employees") and Article 3 and 5 Industrial Safety Act (ArbSchG[74]). The resulting obligations to protect are therefore for the benefit of employees (and similar persons), and these represent only a very small and, moreover, very specific area of the regulatory situation to be examined by this report. As a result, they are not appropriate to accomplish the extensive tasks intended by Article 1 German Chemicals Act, namely, to generally protect human health and the environment – also beyond the circle of employees – against the adverse effects of dangerous substances, to make such effects particularly recognizable, to avert them and to prevent their occurrence.

In so far as the demands of Article 5 (classification and labelling) and Article 6 (safety data sheet) of the Dangerous Substances Decree are based on authorizations in Article 14 German Chemicals Act and therefore – at any rate not exclusively – in the relationship between employers and employees, they lack, similar to requirements under Articles 7 ff. of the decree, a basic prerequisite for closing the identified regulatory gaps: They lack an requirement pursuant to primary chemicals law to examine substances in the nanoscale form systematically and extensively with regard to their possible danger for human health and the environment. The absence of this obligation cannot be compensated by the standards of the Dangerous Substances Decree, which, on the contrary, is based on the results of primary chemicals law.

This shows itself, for example, within the framework of Article 5 (1) sentence 4 of the Dangerous Substance Act, according to which the manufacturer or importer of a substance has to take account in the course of classification of all those dangerous properties that exist on account of

1. results of tests according to Articles 7, 9 and 9a German Chemicals Act or
2. well-founded scientific knowledge through assignment to the characteristic features of danger in Article 4 Dangerous Substances Act or
3. obtained in an authorization procedure.

Application of the provisions of the Dangerous Substances Decree therefore requires knowledge of substance-related properties and the hazardous properties deriving from them, which has first to be gained on the basis of primary chemicals law – such as Articles 7, 9 and 9a German Chemicals Act – or is available in the specific case as "well-founded scientific knowledge".

At this point reference should be made once more to the distinction made at the beginning of this Chapter. It is the application of primary chemicals law that guarantees that at first such data is obtained that is necessary to implement the provisions of the Dangerous Substances Decree in business operations, so that these can also be described as secondary or derived chemicals law. Up to now, however, primary chemicals law does not guarantee systematic registration of the properties of substances in the nanoscale form.

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72 Führ et al. 2006, p. 21 Footnote 57.

73 So also LASI 2005, p.5.

74 Act on the conduct of industrial safety measures for the improvement of the safety and health protection of employees at their place of work (Industrial Safety Act) of 07.08.1996 (Fed. Gazette I p. 1950), last amended by Article 11, No. 20 of the Immigration Act of 30. 7. 2004, (Fed. Gazette I p. 1246).

The Dangerous Substances Decree attempts to partially compensate the weaknesses of "primary" chemicals law – especially with respect to existing substances – through independent requirements, and obliges the employer to use not only marketing-related data but also "other freely accessible sources" (Article 7 (2) GefStoffV). It contains, however, no substance-specific testing programme. When no data is available or accessible, the requirements of "derived chemicals law" have no effect.

To sum up the following may therefore be said: Regulations with regard to classification and labelling (Article 5 Dangerous Substances Decree – GefStoffV)), safety data sheet (Article 6 GefStoffV) as well as the ascertainment of information and assessment of danger (Articles 7 ff. GefStoffV) apply irrespective of quantity; they fall back, however, on the insights of primary chemicals law, which recognizes quantitative thresholds and does not so far address substances in the nanoscale form. Requirements with respect to protective measures (Articles 7 ff. GefStoffV) are directed at the "employer" and are largely restricted to the "assessment of working conditions" or "dangers to the health and safety of employees". The Dangerous Substances Decree is therefore unable to develop an adequate compensation effect regarding indicated deficits in environmental law and, especially, in primary chemicals law.

5.3.5 Overview of chemicals law

The following table summarizes once more the results of the analysis.

Subject matter	Status quo D	Status quo EC	Shortcomings / need	Options	Comments
Initial control A) Notification [+]	Art. 4, 5 German Chemicals Act from 10 kg new substance	Art. 7 in connection with 3, 5 Dir. 67/548/EEC from 10 kg	Unclear whether nano compounds are subject of separate regulation	Adopt nano compounds in definition of terms (Art. 3 REACh) Separate SIEFs* (Art. 29 REACh)	Basic analysis of definition of substance necessary Nano manifestations: separate substance?
B) Registration [+]	Does not exist on account of GefStoffV* (and the corresponding EC Directive)				
	In future: Art. 5-7 REACh from 1 tonne				
C) Authorization [+] [+associated in each case with the obligation for systematic data collection]	for chemicals currently (-) for biocides: Art. 12 ff. German Chemicals Act / Biocide Directive		Dependent on work on the definition of "substance" and "nano compound"		
	In future: Art. 54 ff. REACh, if substance CMR*, *PBT or vPvB* or just as alarming or Amendment 217				
Updating requirement regarding existing substances	Article 7 II ESR* irrespective of quantity		Not covered by Article 22 REACh	Also extend obligation in Article 22 REACh on this	See above
Immission specifications	Partially related to individual substances (PNEC*/DNEL*), but usually not from chemicals law but from other sectorial environmental law		Not nano-specific	See above	See above
Emission specifications	See above		See above	See above	See above
Monitoring	See above		See above	See above	See above
Subsequent restrictions	According to Title VII REACh		Not nano-specific	See above	See above

*__Explanation__: CMR: carcinogenic, mutagenic and reprotoxic – DNEL: Derived No Effect Level – ESR: Existing Substances Regulation – GefStoffV: Dangerous Substances Decree – PBT: persistent, bioaccumulative and toxic – PNEC: Predicted No Effect Concentration – REACh. Registration, Evaluation and Authorization of Chemicals – SIEF: Substance information exchange forums – vPvB: very Persistent and very Bioaccumulative

Table 3: Overview of results under chemicals law

5.4 Transport

Transport law largely governs the classification and labelling of substances and is therefore not dealt with here in detail.

The distribution of nano materials from the place of manufacture or from transitional storage to fixed-site warehouse or consumer can take place in mobile enclosures by road or rail, by sea or through pipelines.

Safety demands on transport technology and secure enclosure are laid down in the European Convention on the International Transport of Dangerous Goods.

5.5 Use

Nano materials can also be released to the environment in many different ways during their use. Presumably the most important emission paths concern products in which nano particles are not integrated into a solid product matrix. Nano materials from cosmetics and sun creams can enter the environment – recreation waters, for example – through washing or rubbing off. Emissions into domestic waste water are possible from widely differing sources: Non-degradable nano materials from medicinal products can be excreted from the body; washing powder can contain selectively active nano materials. As far as concerns nano materials released into domestic waste water or refuse, reference is made to comments in Sections 5.2.2 and 5.6.1.

Regulations affected during the period of use of nano materials encompass the most varied consumer protection regulations, such as Directive 2001/83/EC[75] on medicinal products for human use, Regulation 178/2002/EC[76] on the general principles and requirements of food law, and Directive 76/768/EWG[77] on cosmetic products. These regulations are not examined, since they do not fall within the focus of this report: pollutant emissions into environmental media.[78] The regulations rather have the aim of promoting the protection of consumer health, for example through the prohibition and restriction of substances for product contents and labelling requirements for products. It applies also to these substances (such as, food additives, materials and objects that can come into contact with foodstuffs, medicinal products and certain contents of cosmetic products) that risks for the environment can emanate from them, even when they have been tested for risks to human health.

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75 Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, p. 67, and in Germany the *Gesetz über den Verkehr mit Arzneimitteln* of 24 August 1976 (Fed. Gazette I 1976, p, 2445). Newly formulated by promulgation of 12.12.2005, Fed. Gazette I, p. 3394,

76 Regulation 178/2002/EC of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; OJ L 031 of 1.2.2002, p. 1. Cf. the German *Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)* of 1 September 2005, Fed. Gazette I 2005, p. 2618.

77 Directive 76/768/EEC of the Council Rates of 27 July 1976 concerning cosmetic products, OJ L 262 of 27.9.1976, p. 169. Cf. the German *Verordnung über kosmetische Mittel* of 16. December 1977 (Fed. Gazette I 1977, p. 2589). Newly formulated by promulgation of 7.10.1997 (Fed. Gazette I, p. 2410); last amended on 13.12.2005, Fed. Gazette I, p. 3479.

78 Questions of inadmissible advertising with the term "nano" have also not been examined.

An overview of possible nano products and corresponding European regulations, which find application in the period of use, is to be found in the study carried out by Chaudhry et. al.[79] Regulations for detergents as well as for fuel and fuel additives are examined, since emissions of nano particle from these two product groups are probably among the most important uncontrolled emission paths (see Section 4.3).

5.5.1 Detergents

As far as the use of nano materials in detergents is concerned, Regulation 648/2004/EC on detergents (hereafter: EC Regulation) and the German Detergents Act (WRMG)[80] have to be observed.[81] In so far as nano materials are detergents, certain surfactants for detergents or other products that belong to detergents,[82] the EC Regulation has to be observed. The draft WRMG[83] should also be applicable to surfactant-based cosmetic products for cleansing pursuant to Article 2 (5) LFGB (code on food, consumer products and animal feed) (for example, soaps and shampoos). Nano materials as detergents are subject to the EC Regulation and should also be covered by the draft WRMG when substances or preparations are involved that contain surfactants and are intended for washing and cleaning processes (Article 2 No. 1 EC Regulation). The important definitions of substance and preparation in connection with detergents as defined in Article 2 Nos. 4 and 5 of the EC Regulation are more or less identical with those in REACh. Corresponding to the findings of this study on the applicability of the term substance to nano materials (see Section 5.3.2), nano materials are subject as surfactants in detergents to the EC Regulation and the draft Detergents Act (WRMG). It therefore also applies to nano materials as surfactants, that they may be placed on the market in detergents when the criteria in Annex III on ultimate aerobic biodegradation are fulfilled (Article 4 (1) EC Regulation). Where the level of ultimate aerobic biodegradation is lower than that stipulated, derogation may be granted under certain circumstances for "classical" detergents as well as for such nano materials as industrial or institutional detergents (Article 4 (2) and Article 6 (2) EC Regulation). Finally, the EC Regulation contains no specifications for nano materials when organic contents of detergents are involved that are not surfactants, or when substances are involved that are subject to anaerobic biodegradation.[84]

Where there are justifiable reasons for believing that a nano material in a detergent constitutes a risk to the health of humans or animals or for the environment, the competent national authority may temporarily prohibit or restrict the placing on the market of this detergent in accordance with Article 15 of the EC Regulation.[85] The final decision on the placing on the

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79 Cf. Chaudhry, Q. et. al. 2006, p. 92.

80 Gesetz über die Umweltverträglichkeit von Wasch- und Reinigungsmitteln (Wasch- und Reinigungsmittelgesetz – WRMG (Detergents Act) of 5.3.1987; newly formulated by promulgation of 5.3.1987, Fed. Gazette I, p. 875, last amended by decree of 25.11.2003, Fed. Gazette. I, p. 2304.

81 Regulation 648/2004/EC of the European Parliament and the Council of 31 March 2004 on detergents (OJ L 104, p. 1) has been in force and applied directly in Germany since 8 October 2005. The legislative procedure with respect to the WRMG is presently taking place (draft of 10.10.2005 – hereafter "draft WRMG"), with the aim of adapting it to the EC Regulation by way of an abandonment act.

82 For example, washing powder, fabric softener, agent for cleaning surfaces or other washing and cleaning agents as defined in Article 2 of the EC Regulation.

83 See the draft on the Website of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety: http://www.bmu.de/chemikalien/downloads/doc/35500.php .

84 Cf. Recital 31 of the EC Regulation.

85 According to Article 14 (2) of the draft WRMG this authority would be the Federal Environmental Agency (Umweltbundesamt UBA).

market of the detergent would, however, be taken in a comitology procedure at the EU level. In order for the competent authority to be able to take action, however, it must have knowledge of detergents on the market that contain nano materials and of the respective outline recipes. In Germany, according to the still-valid Article 9 (1) WRMG, the outline recipe and a registration number must be notified to the Federal Environmental Agency at the time when certain detergents are first placed on the market. This information is stored in a detergent register at the Federal Environmental Agency. Since this requirement, due to specifications in the EC Regulation, is no longer contained in the draft WRMG, the issuing of such restrictions for detergents with nano materials by the Federal Environmental Agency would be made difficult. The register could, however, be maintained, on the basis of a voluntary commitment on the part of industry.

5.5.2 Fuels and fuel additives

Directive 98/70/EEC on the quality of petrol and diesel fuels[86] (incorporated into German law by the 10th BImSchV[87]), which has to be observed in the case of nano materials in fuel or fuel additives, contains no nano-specific requirements. According to the directive, in order to protect the environment and the health of consumers petrol and other fuels may only be placed on the market when they comply with technical requirements specified in the annexes to the directive. Petrol that is intended for the German market, for instance, must at least satisfy the demands of DIN EN 228 (edition March 2004) or a corresponding standard of another Member State. The minimum standards concern the most varied substances that are contained in fuel – for example, sulphur and lead – but include no specifications for nano materials.

5.5.3 Results and regulatory gaps

Where nano materials are detergents, surfactants intended for detergents or other products belonging to detergents, EC Regulation 648/2004 on detergents, supplemented by the WRMG, is applicable. As with all "classical" surfactants, nano materials as surfactants have to be ultimately biodegradable in accordance with the requirements in Annex III to the EC regulation. It has to be examined whether test methods for "classical" surfactants in accordance with Annex III to the Regulation as well as the level of biodegradability (mineralization) measured according to one of five specified tests (at least 60% within 28 days) also adequately cover the possible risks of nano materials. If nano materials are the organic contents of detergents, which do not belong to surfactants, these are not covered by the EC regulation. Where there are reasons for believing that nano materials in detergents give rise to an unforeseen risk for the environment, the Federal Environmental Agency can take action to avert risks for the environment through the prohibition or restriction of access to the market of the detergent in question. It would be helpful in this connection for the detergent register to be continued and the outline recipe to be registered at the Federal Environmental Agency should it indicate the use of nano materials.

[86] Directive 98/70/EC of the European Parliament and the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Directive 93/12/EEC of the Council des Rates, OJ L 350 of 28.12.1998, p. 58; last amended by Directives 2003/17/EC (OJ L 76, p.10) and 2003/30/EC (OJ L 123, p. 42).

[87] 10. BImSchV (10th Federal Immission Control Decree) of 24 June 2004 (Fed. Gazette I, p. 342).

Should the risk assessment of nano materials in fuel additives show that risks to the environment could arise, the minimum standards of Directive 98/70/EEC should be adapted to apply to the nano materials used.

5.6 Post-consumption / disposal

With regard to the post-consumption phase and the disposal of products for the manufacture of which nano materials were used, there is a lack of knowledge concerning many scientific issues; for example, whether and in which form and size nano materials can escape from a product (for further points see Section 4.3).

The analysis focuses on legislation on waste, in particular waste-flow control and the disposal of waste as well as immission-control demands on waste incineration plants. As far as legislation on water is concerned, reference is made to comments in Section 5.2.2.

5.6.1 General legislation on waste

Legislation on waste is substantially determined by Community regulations, which is why these are in the foreground of the following analysis. Where German legislation fills the gaps in Community law or contains important concretization, these are dealt with.

5.6.1.1 Control (monitoring) of waste flow

It has not yet been resolved whether and how individual nano materials in the form of liquid, solid or sludge waste are to be classified as hazardous or non-hazardous waste according to European law. According to the European Waste List,[88] which was adopted in Germany in the Waste List Decree (AVV),[89] normative classification of every single waste has to be carried out. Wastes listed in Annexes I and II of Directive 91/689/EEC are regarded as hazardous throughout the EU. In the lists in Annexes I and II (wastes classified as hazardous on account of their constituents or the activities that generated them, or wastes having properties listed in Annex III, such as medicinal products or printing ink) nano-specific properties are as yet not considered. This is not alarming, however, since the classification of wastes refers to the Directive on Hazardous Substances (see no. 5 in the Annex to Decision 2000/532/EC concerning a Waste List).[90] Test methods to be applied are therefore contained in the most current version of Annex V to Directive 67/548/EWG[91]. According to Article 1 IV of Directive 91/689/EEC hazardous waste must demonstrate one of the hazard properties (H

[88] 2000/532/EC: Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1 (A) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1 (4) of Council Directive 91/689/EWG on hazardous waste, OJ L 226 of 6.9.2000, p. 3.

[89] Verordnung über das Europäische Abfallverzeichnis (Abfallverzeichnis-Verordnung – AVV) (Waste List Decree) of 10 December 2001 (Fed. Gazette I p. 3379) last amended on 24 July 2002 (Fed. Gazette I, p. 2847).

[90] Cf. also Article 6 (7) of Decision 2000/532/EC: "The classification as well as the R numbers refer to Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196 of 16.8.1967, p. 1) and its subsequent amendments. The concentration limits refer to those laid down in Council Directive 88/379/EEC of 7. June 1988 on the approximation of the laws, regulations and administrative provisions of the member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 187, 16.7.1988, p. 14) and its subsequent amendments". Cf. for German law the comments in No. 3 of the Annex to the AVV.

[91] Directive 67/548/EEC of the Council of 27 June 1967 on the approximation of laws, regulations and administrative provisions for the classification, packaging and labelling of hazardous substances, OJ L 196 of 16.8.1967, p. 1.

1 to H 14) listed in Annex III to the Directive; they must, for example, be mutagenic or ecotoxic. Nano-specific hazards can be considered in classification, since the substances / constituents in Annexes I and II demonstrate hazard-relevant properties listed in Annex III to Directive 91/689/EWG. This can also be the case for production waste with nano materials. It will be decisive in this case that nano-specific hazards are determined under chemicals law, in order that they can also be considered in classification according to waste law.

If assessments according to the law on dangerous substances or classification according to the law on waste do not exist, or waste from nano materials occurs that cannot be assigned to an existing waste code, there is the possibility to subsume these under "back-up" Chapter 16 of the Waste List. Separate listing with a specific waste code and safe disposal appear to be necessary, in particular, for waste from nano materials giving cause for considerable concern, as long as there is no corresponding classification under the law on dangerous substances.

According to the German Closed-cycle Substance and Waste Management Act (KrW-/(AbfG)[92], a separate storage order can be issued for waste for recycling in accordance with Article 5 (2) sentence 4 KrW-/AbfG. The standards that have to be met are laid down in Articles 4 and 5 KrW-/AbfG and have, in particular, the objective of ensuring proper and safe recycling.[93] An order for separate storage arises in respect of waste for disposal from Article 11 (2) KrW-/AbfG), which refers to the standards in Article 10 KrW-/AbfG regarding the extent and limitation of the separate storage order. An order for separate storage of waste that cannot be recycled is accordingly required in so far as it is necessary for permanent exclusion of wastes from closed-cycle management and for the maintenance of waste disposal compatible with the common good (Article 10 (1) KrW-/AbfG). Moreover, the Federal Administrative Court (BVerwG)[94] has approved a so-called "intercategorical separate storage order". This concerns the mixing of waste for disposal and waste for recycling in accordance with Articles 11 (2) and 10 KrW-/AbfG. If nothing is known about the composition and danger of wastes from the manufacture or use of nano materials (in particular in research and development, see comments in Section 4.3) and at the same time there is considerable cause for concern, such waste should be separately stored not only at the place of occurrence but also in further disposal. This way, appropriate wastes can be excluded from the substance cycle until such time as relevant knowledge is available and, depending on the cost-effectiveness of the disposal path, disposed at a landfill site in such a way that, should a risk for groundwater arise, they can be disposed of more safely. What is more, special requirements for hazardous waste disposal at specified hazardous waste dumps or plants could be considered in accordance with Article 41 (1) and (2) KrW-/AbfG.

92 Gesetz zur Förderung der Kreislaufwirtschaft und Sicherung der umweltverträglichen Beseitigung von Abfällen (Kreislaufwirtschafts- und Abfallgesetz - KrW/AbfG) of 27 September 1994 (FG I p. 2705); last amended by Articles 2 and 3 (3) of the Act of 1 September 2005 (FG I No. 55, p. 2618).

93 Cf. Kunig, in: Kunig/Versteyl/Paetow, Article 7 KrW-/AbfG, marginal note 11. See also the corresponding provisions of the Gewerbeabfallverordnung – GewAbfV (decree on the disposal of industrial waste and certain building rubble and demolition waste) of 19 June 2002 (FG I p. 1938); last amended by Article 2 of the act of 25.July 2005 (FG I, p. 2252).

94 BVerwG, judgement of 15.06.2000.

5.6.1.2 Waste deposit sites and waste acceptance procedures with landfill disposal

The setting up and operation of waste deposit sites are subject to authorization in accordance with Article 9 of Landfill Directive 1999/31/EC[95], according to which a special authorization procedure has to be conducted for all landfill categories in accordance with the general authorization requirements in Article 9 of Directive 2006/12/EC[96] and Article 9 of the IPPC Directive 96/61/EC.[97] According to the landfill directive, different landfill categories have to be distinguished for hazardous waste, non-hazardous waste and inert waste. The assignment of waste to a landfill category takes place on the basis of certain criteria, which are laid down in Council Decision 2003/33/EG.[98] These criteria are based on leaching limit values for certain substances and limit values for the total content of organic parameters (LOI or TOC). Whether these criteria cover the potential dangers of nano materials, however, and therefore enable disposal of nano materials compatible with the common good, is not clear.

5.6.1.3 Monitoring of emissions / immissions

Nano materials that enter groundwater from a landfill body are not covered by the measuring and monitoring programme carried out by landfill operators during the operation (Article 12 Landfill Directive) and after the final closure of a landfill (Article 13 Landfill Directive). For the specifications in Annex II to the Landfill Directive contain no nano-specific requirements. In so far as nano materials lead to a mobilization of pollutants in waste or soil as a result of landfill leachate – for example, with non-degradable nano carrier materials such as C-60 fullerenes, these are covered by the existing measuring and monitoring programme. Research has to be carried out into appropriate parameters, in order that measuring and monitoring programmes also cover nano materials that give rise to a danger for groundwater. These could be laid down for groundwater measurement in No. 4 B of Annex III to the Landfill Directive.

5.6.2 Recycling of sewage sludge (Sewage Sludge Decree)

Nano materials in sewage sludge from domestic waste-water treatment plants can become a problem. A large part of sewage sludge in Germany is incinerated, and depositing on agricultural land is diminishing.[99] However, so long as there is no general ban on depositing – as, for instance, in Switzerland[100] – and the composting of sewage sludge is still possible, nano materials from cosmetics and detergents can enter domestic waste water and subsequently,

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95 Directive 1999/31/EC of the Council of 26 April 1999 on the landfill of waste, OJ L 182 of 16.7.1999, p. 1.

96 Directive 2006/12/EC of the European Parliament and the Council on waste of 5 April 2006 (OJ Nr. L 114, p. 9). The Directive came into force on 17 May 2006 and replaces Directive 75/442/EEC (OJ Nr. L 194 of 25.7.1975, p. 39).

97 The requirements of the Landfill Directive were implemented in the German Landfill Decree and the Decree on the depositing of waste.

98 Decision of the Council 2003/33/EC of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC, OJ Nr. L 11 of 16.01.2003, p. 27.

99 In Germany in 2003, 56% of sewage sludge was utilized in agriculture and landscaping, 3% was deposited, 38% incinerated and 3% utilized in other ways; see the results of the DWA Sewage Sludge Survey 2003, Durth, A., 2005, Tagungsband DWA-Klärschlammtage, Würzburg.

100 By the autumn of 2008, at the latest, sewage sludge may no longer be used as fertilizer and will have to be incinerated; see: http://www.umwelt-schweiz.ch/buwal/de/medien/presse/artikel/20030326/01205/index.html.

by way of sewage sludge, groundwater.[101] Research has not yet been made into the behaviour of nano materials in sewage treatment plants and the resulting degradation products (see comments in Section 4.3).

The German Sewage Sludge Decree (AbflKlärV), which implements the EC Sewage Sludge Directive[102], makes it possible to confront the possible dangers of nano materials in sewage sludge from domestic waste. The specific demands of the Sewage Sludge Decree have shortcomings, however, in as much as the sampling of sewage sludge for the investigation of soils used for depositing (Article 3 II to VI AbflKlärV) and for the limitation of maximum pollutant content in sewage sludge (Article 4 VIII to XIII AbfKlärV) does not take nano-specific properties into consideration. Here, possible carrier effects of nano materials, such as fullerenes, should be borne in mind, which can discharge nutrients and pollutants from soil into groundwater (see Section 4.3).

[101] The EU plans to amend Sewage Sludge Directive 86/278/EC. With this in mind, the Commission prepared a working paper (of 18 December 2003) entitled, "Sewage sludge and biowaste", according to which the utilization of sewage sludge in agriculture and in landscaping should remain possible, but with more stringent limit values, for heavy metals for instance.

[102] Directive 86/278/EEC of the Council of 12 June 1986 on the protection of the environment and in particular of the soil, when sewage sludge is used in agriculture, OJ L 181 of 4.7.1986, p. 6.

5.6.3 Overview of post-consumption / disposal

Subject matter	Status quo (D)	Status quo (EG)	Shortcomings	Options	Comments
Initial control (incl. material demands)	Permit requirements for transport; waste disposal plants (Art. 27 I 1 KrW-/AbfG*)	Directive 2006/12/EC, IPPC Directive	-	-	-
– Waste flow (Manufacturing)	- Art. 41 I and II KrW/AbfG*, - Art. 3 AVV classification in waste requiring supervision and waste requiring special supervision – linked to R nos. depending on concentration - Assignment AVV (origin-related): e.g. No. 1;No. 6,7; No.12 AVV	Directive 2006/12/EC, Directive 91/689/EEC (Annexes I to III),	- Absence of legal classification of nano materials - No nano-specific waste code	- Undertake legal of nano materials to enable classification according to Annex III Directive 91/689/EEC - In "back-up"-Chapter 16 AVV*	-
– Waste flow (post-consumption)	Assignment AVV (origin-related) No. 18,19,20 AVV	See above	See above	See above	-
– Waste disposal (landfill disposal)	- Art. 31 ff. KrW-/AbfG*, Art. 4 AbfAblV* (municipal waste) landfill category II - Landfill Decree (inert waste, waste requiring special supervision) - Demands concretized in TA-Abfall* and No. 10 TaSi* (assignment criteria in Annex B TaSi*	- Permit for landfills, Art. 9 Landfill Directive - Assignment criteria Decision 2003/33/EC	- No nano-specific assignment criteria, - Sampling and analysis procedures according to Annexes A and B TaSi*	Disposal indications analogous to TaSi* and TRGS* 519	-
– Waste utilization (sewage sludge)	- AbfKlärV*, VwV*-sewage sludge, - Restrictions, prohibitions (Art. 4 AbfKlärV*); e.g. sewage sludge from domestic waste water treatment plants	- Sewage Sludge Directive 86/278/EEC	No nano-specific limit values	- nano-specific limit values for nano materials in sewage sludge - Ban on depositing sewage sludge with nano materials	Need for research on the behaviour of nano materials in sewage sludge after depositing
– Waste utilization (incineration plants)	Article 31 I KrW-/AbfG* and Article 4 BImSchG* in connection with17th BImSchV*	Waste Incineration Directive 2000/76/EC (Art. 6 and Annexes II and V)	No nano-specific emission limit values	Nano-specific limit values for nano material in sewage sludge	Need for research on the behaviour of nano materials during incineration
Monitoring of emissions / immissions during incineration	Article 26 BimSchG*	Article14 IPPC Directive	Not nano-specific	Nano-specific limit values in TA-Luft*	Need for research on measuring and test methods as well as evaluation
Subsequent conditions	Article 17 ff. BimSchG*	Regular examination of conditions, Art. 13 IPPC Directive	Nano-specific justification necessary	Link to chemicals law	Cost-benefit analysis

*__Explanation__: AbfKlärV: Sewage Sludge Decree – AVV: Waste List Decree – BImSchG: Federal Immission Control Act – BImSchV: Decree supplementing the BImSchG – KrW-/AbfG: Closed-cycle substance and Waste Management Act – TA-Luft: Technical Instructions on Air – TASi: Technical Instructions on Municipal Waste – TA-Abfall: Technical Instructions on Waste – TRGS: Technical Regulations for Dangerous Substances – VwV-sewage sludge: Administrative Regulation supplementing the sewage Sludge decree.

Table 4: Overview of results for legislation on waste

6 Regulative options

Analysis of individual legal areas has clearly shown that there are gaps at many points in sectorial environmental law regarding the specific properties of nano materials. It must once more be emphasized that the mere existence of a gap in a regulation does not mean that regulations should be enacted to fill such gaps. Legislators enjoy considerable judgemental latitude in this respect (see Section 7.1).

Against this backdrop, the task of the following sections is to indicate available regulative options. This is not to say that legislators should either now or later make use of an option. The options take into consideration not only legislative action at a European or national level, but also administrative activities and non-statutory standards (for instance, in the form of technical rules and regulations[103] or other non-governmental activities). Recommendations for a stepwise approach are to be found in Chapter 7.

6.1 Chemicals law

6.1.1 Separate "nano regulation"?

Against the backdrop of gaps in chemicals law (see Section 5.3) the general question arises of whether one should amend existing chemicals law or draw up a separate regulation for nano materials. The following points can be made against separate regulation: Chemical elements and chemical compounds in the form of nano particles[104] are covered by prevailing chemicals law 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. Where new risks arise from the occurrence of a known substance simply because it is now handled in the nanoscale form (as in the case of titanium oxide), it has to be ensured that this is recognized by the regulatory system and a distinction made between the two forms. Bearing in mind the general assignment of existing substances in the nanoscale form to the substance group of existing substances, it is questionable whether such recognition could be made possible.

6.1.1.1 Differentiation of existing substances and new substances

Should one want to retain the demarcation criterion of the EINICS[105] listing, as laid down in the Manual of Decisions,[106] it would be a good idea to adopt the relevant definition in the list of definitions in Article 3 REACh. This way, the specific connection for nano materials between previous rules and REACh would be clear, particularly since with REACh the familiar concept of existing and new substances is abandoned in favour of phase-in substances and notified substances. Such a definition would further

[103] Both at the ISO level (TC 229) and within the scope of CEN (TC 352) one has begun with the standardization of basic aspects (incl. classification, terminology and nomenclature, measuring calibration methods; see the description in Lottes 2006.

[104] As clarified in Kitzinger 2006 to 5.3.2.2, p.10.

[105] Thus the proposal of the "Working Group on Nano-Materials" for the Manual of Decisions, p. 4

[106] Cf. Footnote 45.

make clear that substances in the nanoscale form also fall under "primary chemicals law" (REACh), so that compliance with all corresponding provisions on the part of respective substance suppliers has to be examined.[107]

6.1.1.2 Nano manifestations as a separate substance?

The legal issues to be analysed within the scope of this appraisal relate to the specific properties that can exist in materials in the nanoscale form, which one would like to utilize for certain functions or applications. As with all technical developments, however, undesired effects can occur. For the purposes of the principle of precaution it is therefore advisable to systematically record corresponding data in advance. Against this backdrop the question arises how nano materials should be integrated into the systematics of (primary) chemicals law.

The central point of reference of chemicals law is the substance (see Section 5.3.1.1). Its legal form thus determines at the same time the content and scope of corresponding obligations. A substance is defined in terms of its characteristic physical and chemical properties, whereby one has up to now assumed that these were independent of its size and shape.[108] Bearing in mind existing knowledge of substances in the nanoscale form – in particular the greatly changed ratio of surface volume and, where applicable, the resulting specific features – this assumption would appear to be outdated.[109] It seems very likely that the varied behaviour of one and the same substance in the nanoscale form, on the one hand, and in a non-nanoscale form on the other hand necessitates appropriately differentiated consideration, in order to be able to determine systematically these different properties.[110] It should therefore be generally examined whether the special particle size in the nm range has the result that a substance in this particular manifestation demonstrates other properties than in its "previous" manifestation (non-nanoscale form). Where this is the case, a substance in the nanoscale form should be regarded as a separate substance that is automatically subject to new chemicals law.[111] If one wanted to make this quite clear, explicit reference to this connection would be useful.[112]

When it is argued against this position that the starting point of prevailing legislation is not the physical but rather the dangerous properties of a substances,[113] this is doubt-

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107 Such an approach could be dispensed with, were the amendment to be adopted (cf. 5.3.2.5), according to which all nano particles should be subject to authorization, since then the requirements of the authorization procedure would have to be observed.

108 For the definition of substance according to Article 3 No. 1 German Chemicals Act: Rehbinder/Kayser/Klein 1985, Art. 3 (1) ChemG, marginal note 7. For the definition of substance in REACh see Section 5.3

109 Thus also SCENHIR 2006 (see the quotation in Footnote 65). See also the results of Hund-Rinke/Simon (2006, 225 ff.) as well as Nel et al. (2006, 622 ff.); see about that already in Chapter 1.

110 The necessity for separate consideration is emphasized also in SCENHIR 2006 and Hund-Rinke: "For nano particles as such toxicological tests are not prescribed, however, since in principle the basic chemical substances are known," VDI-Nachrichten of 19.05.2006.

111 Should, for instance, the nano powder mentioned have fundamentally different properties than carbon in the previously-known form, it would again match the definition of substance, and would then have to be considered a separate substance and subject to the law on new substances.

112 This need for clarification also remains should the REACh Regulation comes into force in its present form.

113 VCI 2006, Chapter 3, p. 2.

less true. However, physical properties can be the determining characteristic of danger. For instance, the dangerous property (Article 3a (1) No. 3, German Chemicals Act) of high inflammability is attached, inter alia, to the physical properties of flash point and boiling point (cf. Article 4 sentence 2 No. 3 Dangerous Substances Decree[114]).

In so much as the objection is intended to indicate that the particle geometry of a substance in the nm range on its own says nothing about the properties of the substance in question, nor about whether it is a hazardous substance, there is agreement on this point, which also underlies this legal report.[115] Nevertheless, as the findings of Hund-Rinke and Nel et al show, a change in particle size can evidently have the result that the characteristic properties of a substance change. Where this is the case with a substance in both the nanoscale and a non-nanoscale form, these manifestations have different properties. According to the systematics of chemicals law, a specific programme of tests and action is required for each of the manifestations; a consequence that previous chemicals law linked to the definition of a substance. That is the reason for considering the option of regarding each manifestation as a separate substance. The objections put forward[116] give cause for a closer look at this point.

The fact that the definition of substance is the key definition of chemicals law stems from the assumption that harmful effects on human health and the environment can be assigned to specific substances.[117] To be consistent, substances that give rise to different hazards for human health and the environment have to be viewed "in a legal sense"[118] as different substances. Where one and the same substance occurs in different manifestations and has different properties depending on the manifestation, the objective of chemicals law – "to protect human beings and the environment from the adverse effects of hazardous substances and, in particular, to make such effects perceptible" (Article 1 German Chemicals Act) – can be achieved with the least possible systematic infringement by viewing different manifestations as separate substances. This objective of recognizability, as laid down in German law, is not found explicitly in REACh, but the recognizability of different risks is a prerequisite for the attainment of the objectives of protection and precaution in Article 1 (3) REACh.

If one does not pursue this path, but rather unites the manifestations of varied danger under the generic term for a substance, the aforementioned objectives can also be achieved by carrying out a splitting within the same substance, and this way enabling the required separate consideration of different manifestations. This is shown by the example of phosphorus,[119] which merely has an EINECS number (231-768-7) and is therefore recorded only as one existing substance in the relevant register, despite its varied manifestations as red (P_n) and white phosphorus (P_4). Its different properties, depending on its manifestation (white phosphorus: highly inflammable, highly toxic,

[114] Verordnung zum Schutz vor Gefahrstoffen (Dangerous Substances Decree) of 23.12.2004, FG I, p. 3758, last amended on 23 December 2004 (FG I S. 3855).

[115] Cf. Chapter 1.

[116] Kitzinger 2006, p. 7 ff.

[117] Rehbinder/Kayser/Klein 1985, Art. 3 (1) German Chemicals Act, marginal note 3.

[118] This does not mean, however, that this has to be so in the systematics of chemistry. It rather concerns – as in the case of the term "organism" in the law on genetic engineering (Art. 3 No. 1 GenTG) – something laid down by law. Many a misunderstanding could stem from the varied viewpoints of the disciplines involved.

[119] Kitzinger 2006, p. 10.

caustic, environmentally hazardous; red phosphorus: highly inflammable), are distinguished in the existing-substance system with the aid of two index numbers.[120] Necessary separate consideration thus takes place below the level of the generic term. From that point of view, the existing-substance system is inconsistent, since in other cases it has treated isolated allotrope modifications of a particular chemical element as different substances. This is evidenced by different EINECS entries for carbon, graphite and diamond, which incidentally, so far as "their dangerousness"[121] is concerned, are by no means as strongly distinguished as the different phosphorus allotropes.

The existence of such inconsistencies from the past does not prevent legislators from pursuing other – better – paths in the future regulation of substances in the nanoscale form. Based on the protective purpose,[122] it is a matter of ensuring the selective controllability of different risks from the same substance in its nanoscale and non-nanoscale forms. This requires that regulatory structures guarantee correspondingly differentiated consideration of a substance in the nanoscale and non-nanoscale forms, which in a system-compliant manner can best be achieved by regarding them as separate substances.

Were one, on the other hand, to create "sub-categories" of a substance (as in the example of phosphorus), legal and implementation issues would arise. From a legal point of view it would first have to be clarified, who – and under which circumstances – is authorized or obliged to create such categories, and how these should be designated and differentiated. The obligations, which would have to be fulfilled for sub-categories, would then have to be defined. In practical implementation one would face the task of describing system extension with sub-categories in the database systems with which the vast majority of affected companies internally record their substance-related legal obligations.

From the point of view of legal systematics and practical implementation, the variant of appropriate modification of substance definition would therefore appear to be preferable. This way, it would at the same time become indubitably clear that the properties and effects of a substance in the nanoscale form have to be separately recorded and assessed.

The proposed solution at the level of the generic substance term would have the following additional advantage under REACh: In the interests of secrecy, manufactures and importers of substances in the nanoscale form could have an interest in avoiding the disclosure of their nano-specific information in a SIEF (Substance Information Exchange Forum), in accordance with the demands of Article 29 REACh, through collaboration with manufacturers or importers of the same substance in a non-nanoscale form. According to previously intended regulations, SIEFs would have to be formed for every phase-in substance – that is for each existing substance – without a distinction being made between the existence of this substance in the nanoscale or other form. Since it is the objective of each and every SIEF to avoid duplication of studies (Article 29 (2a)

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

121 Since none of these substances demonstrates a dangerous property in accordance with Article 3a German Chemicals Act, one should better say that they cannot be distinguished with regard to "their harmlessness".

122 See on this point the objectives in Article 1 German Chemicals Act or Article 1 REACh as well as the comments in Section 3.1.

REACh), the setting up of such forums makes little sense if, in this connection, different studies have to be conducted anyway. This is another reason why substances in the nanoscale form should be regarded as separate substances.

In summary it can be said that the regulation of substances in the nanoscale form can be seen in two ways: Either one sees in the nanoscale form[123] a separate substance, or one creates – as in the case of phosphorous – sub-categories. A lot is to be said for the first solution on the grounds of systematics and practical implementation, which, incidentally, also apply if one decides on a voluntary system of data collection (for instance, for the purposes of a multi-step concept – see Section 7.2).

6.1.1.3 Nomenclature for substance identity

The departure point for legal consideration of substances is unequivocal identification of nano materials. Two constellations can be distinguished:

- Where a particular molecular structure is involved (for example, with fullerenes), there is the possibility of designation (for instance, in the form of the CAS number).[124]
- Where, on the other hand, it involves merely a nanoscale manifestation of a substance, which is also used in a macro form (without a separate structure), the situation is more difficult. SCENHIR, the Scientific Committee on Emerging and Newly Identified Health Risks, has put forward two suggestions in this connection (SCENHIR 2006, p. 55): To begin with, a separate CAS number could be issued for the substance in the nanoscale form. As an alternative, SCENHIR 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 nano materials (for example, CAS-**NP 50** for a substance with a nano particle size of 50 nm). With this approach, carbon with this particle size would be assigned the designation CAS 7440-44-0-**NP 50**.

Whichever solution one chooses, a standardized nomenclature is in any case necessary.[125]

6.1.2 Modifications in REACh

In order to provide those affected with a clearly perceptible indication that nano materials are also covered by REACh, reference to them in the definition of substance would be advisable, even if it were merely in a declaratory manner.

Should one want to retain the demarcation criterion of the EINICS[126] listing, as laid down in the Manual of Decisions,[127] it would be a good idea to adopt the relevant definition in the list of definitions in Article 3 REACh.

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123 Further differentiation is a possibility should different properties occur within the nanoscale form. The different nano manifestations would then be designated, in accordance with SCENHIR proposals (see Section 6.1.1.3), according to size.

124 See Footnote 60; the [5,6]-Fullerenes C_{70} mentioned have the CAS-Nr. 115383-22-7.

125 In standards committees one has already recognized this need for clarification (Lottes 2006).

126 So the proposal of the „Working Group on Nano-Materials“ for das Manual of Decisions, S. 4

127 Cf. Footnote 45.

6.1.2.1 Quantitative thresholds

The requirement for registration laid down in Article 6 (1) REACh applies from a production volume of one tonne per year and manufacturer. It is questionable, however, whether this volume will be achieved with nano materials, which are presently placed on the market in very small quantities.[128] It therefore has to be assumed that the standard principle in Article 5 REACh: "No data, no market", which in any case applies to new substances,[129] is ineffective as far as many nano materials are concerned. Whether the neglected systematic collection of data – required under primary chemicals law – on the risks of such substances for man and the environment is acceptable, or whether a much lower quantitative threshold could be standardized, above which registration would be mandatory, is a question of proportionality(?) and interpretation of the principle of precaution mentioned in Article 1 (3) sentence 2 REACh. Since there are already indications that nano particles can overcome the blood-brain barrier, and that harmful effects on human health have to be expected (UBA 2006, 14 f.), a reduction in the quantitative threshold for nano materials, at which mandatory registration applies, does not appear to be unreasonable for the purpose of protecting human health.

With regard to the specific properties of nano materials, it would be possible to deviate from the previous "kg/t logic" and to give preference to an approach that makes immediately perceptible the overall risk caused by manufactured nano materials. Insofar as this risk can be represented by the physical property of surface activity, registration-free manageable quantities of nanoscale substances could be determined on the basis of this property.[130] This brings with it, of course, the need for a standardized method for ascertaining this property, which could possibly be satisfied at the level of technical standards.

6.1.2.2 Exemptions

It has further to be borne in mind that certain substances are intended to be exempted from the basic demands of the REACh regulation; for example, according to Article 2 (7a) REACh), "substances listed in Annex II, since sufficient information is available concerning these substances, so that it can be assumed that due to their inherent material properties they give rise to an insignificant risk." Annex IV of the REACh regulation thus corresponds with Annex II of the previous existing substances regulation. Accordingly, carbon (symbol C, CAS No. 7440-44-0, EINECS No. 231-153-3) remains exempt from relevant data collection requirements and, in particular, from mandatory registration under the terms of REACh. Differentiation of carbon in the nanoscale form and in other forms cannot therefore take place. Even in the case of a reduction in quantitative thresholds for nano materials that trigger the registration obligation, carbon in the nanoscale form would not be affected. A solution could be found in "retrograde ex-

[128] See, for example, the substance of manufacturer Sigma-Aldrich, catalogue no. 519308 Carbon nanotube, single-walled Carbo-Lex AP-grade 50-70 % purity as determined by Raman spectroscopy, tubes in bundle of length about 20 µm, which is sold in quantities of 0.25 g or 1 g v (price for 1 g: 250.70 euros); source: www.sigma-aldrich.com, 04.06.2006.

[129] That is, those that are not phase-in substances.

[130] In the end, both data can be converted into each other, however, so no basic differences exist.

ception": The list in Annex IV would then not apply for substances in the nanoscale form.[131]

6.1.2.3 General mandatory authorization of nano particles?

General mandatory authorization of nano particles, as demanded in proposed modification put forward by the Environment Committee of the European Parliament (see Section 5.3.2.5), assumes that these should be considered as substances giving rise to particular concern pursuant to Article 54 REACh. Insofar as their adoption in Article 56 (f-a) was proposed, this obviously has the purpose of viewing their effect on human health and the environment as such that pursuant to Article 56 (f), they "cause the same concern as other substances listed under the letters a to e". It is questionable whether present knowledge on the effects of nano particles is sufficient to back up such an opinion. The positive vote of the Environment Committee gives voice to the view, however, that systematic data collection is necessary in accordance with the requirements of the previous law on hazardous substances (under the Existing Substance Regulation).

6.1.2.4 Testing and monitoring methods

Present toxicology testing methods are obviously not able to adequately describe the effects of substances in the nanoscale form.[132] Testing specifications in REACh have therefore to be extended. The same applies to monitoring methods.[133]

In the development and standardization of methods, industrial safety bodies as well as consumer and environmental protection authorities are also faced with a challenge. In view of the vast number of different users of substances, the associated tasks can hardly be managed within the framework of direct responsibility. All the same, user expertise should be considered. One could commission a pluralistic body with the formulation of corresponding testing standards (perhaps under the umbrella of CEN). Specialized international bodies, such as SETAC[134] or FECS[135] would also be a possibility.

REACh could provide the basis for a corresponding standardization mandate.

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131 This change would be superfluous were substances in the nanoscale form to be regarded as separate substances and thus subject to new substance law (cf. Section 5.3.1.4).

132 SCENHIR 2006, Section 3.8.4, p. 33.

133 So also SCENHIR 2006, Section 3.9.3, p. 41.

134 Society of Environmental Toxicology and Chemistry.

135 Federation of European Chemical Societies and Professional Institutions.

6.1.2.5 Overview: Regulative options under chemicals law

The following overview summarizes once more regulative options under chemicals law:

		Term	Threshold	Toxic testing methods	Monitoring	Nm-specific. RMM [136]	Prevailing law
		A	B	C	D	E	F
EC level	1	REACh Annex IV: substance (e.g. C) is only exempted when C IS NOT in the nanoscale form (if it is in nanoscale form, it has to be tested) Definition of the nm: separate substance? Assignment: existing or new substance.	Nano-specific thresholds taking account of overall risk → data not based on kg-logic, but rather, for example, on produced total surface tension, which is exempt from registration (cf. Section 6.2)	If necessary, establish standardization mandate	C 1	Develop criteria	A1 and B1 should also apply in ESR* and new chemicals law
National level	2			Studies	C 2	Co-operation E1	
Admin. Level	3	Transposition → sectorial regulation		A 3	A 3	Co-operation E1	A3
Technical standards	4	Own systematic. E.g. CAS NP 50 (cf. SCENHIR*) CAS/ISO: "NP 50" Nomenclature of properties	Standard methods for generally understandable determination of surface activity Sigma	CEN/ISO (preliminary work of the VDI-KRdL*); specialized bodies	C4	Develop definitions and standardized methods	A4, B4, C4, D4 (E4)

***Explanation**: ESR: Existing Substances Regulation – REACh: Regulation, Evaluation and Authorization of Chemicals; RMM: Risk Management Measures – SCENHIR: Scientific Committee on Emerging and Newly Identified Health Risks – VDI-KrdL: Commission on the Maintenance of Air Purity of the Association of German Engineers

Table 5: Regulative options under chemicals law

[136] RMM stands for risk management measures.

6.2 Law on installations

The results of the analysis of legislation on installations (see Section 5.2 with the overview in 5.2.1.6) can be summarized as follows: The IPPC Directive explicitly addressed neither the manufacturers nor the users nor the release of nano particles. The manufacture of nano materials is subject to authorization when this takes place by means of "chemical processing" Further industrial use – for instance, in surface treatment or incorporation into other products – is subject to authorization when the installations are subject to authorization for other, nano-unrelated reasons. Here, the handling of nano materials as such could be made subject to authorization. At the same time, an appropriate parameter for the definition of threshold value would have to be sought. This could be a unit – as in chemicals law (See Section 6.1.2.1) – that describes the surface activity of nano materials.[137]

From a material point of view the basic obligations of installation operators also cover the plant-related risks of nano materials. Up to now, however, there has been non-statutory concretization neither of emission demands nor of emission-side environmental quality standards that have to be met. Both would also be a prerequisite should updating obligations be effective.

With regard to emission-side concretization, one could adopt information on the retention of nano particles in reference documents on best available techniques (BREF). This would initially have a recommendatory character, since Member States are not strictly obliged to adopt information from BREF documents in authorization requirements.

In a further step one could evolve immission-related guidelines. In view of the great variety of possible nano materials, this could hardly occur in the foreseeable future in a substance-specific form; one would rather have to search for an appropriate general parameter, taking up perhaps the specific potential danger of nano materials. Here, a property could possibly be considered that covers "surface activity". On the other hand, mass-related specifications (mg/m^3) would be just as unsuitable as a property related to the number of particles, since it is not the number but rather the specific properties of particles that constitute the danger for protected rights.

The following overview summarizes once more the regulative options (lower-level options are shown in *italics*):

[137] A departure point for this could be the physical property of surface tension Sigma, measured in Newton per metre. Surface energy, know also as surface tension, is a characteristic value for the interaction of a condensed phase (solid or liquid) with its environment.

		Obligation to obtain a permit	Immission values and monitoring	Safe use	Supplementary conditions	Installations not subject to authorization
		A	B	C	D	E
EC level (IPPC Directive)	1.	Industrial manufacture and use of NP (with threshold value)	Air quality requirements until then: Indicative effect of the PNEC*	BREFs*: Adoption or creation / Seveso Directive: nano-specific threshold values	Examination and updating according to Article 13; but reference values necessary in B1 and C1	BREF*-analogous demands (apart from Annex I)
National level (Federal Immission Control Act - BImSchG*)	2.	Industrial manufacture and use of NP (with threshold value)	Immission values (22nd BImSchV*) Reference: I Indicative effect of the PNEC*	*If necessary adoption in an implementing ordinance*	Supplementary order according to Art. 17 BImSchG; but reference values necessary in B2/3 and C2/3	Application of immission values
Administrative level	3.	Clarification in VwV*: concept of manufacturing	Immission values in " TA-Luft* " Reference: Indicative effect of the PNEC*	Adoption in " TA-Luft*"	Specification in Part 6 "TA-Luft*"	Analogous application "TA-Luft*" (No. 1 (4))
Technical standards	4.	Operationalization of units for surface activity If necessary, calculation of threshold value	Immission measuring (monitoring)	Immission measuring (monitoring)	See B4/C4	See B4/C4

*__Explanation__: BimSchG: Fedarel Immission Control Act – BImSchV: Federal Immission Control Decree – BREFs: Best Available Technique Reference Documents – PNEC. Predicted No Effect Concentration – TA-Luft: Technical Instructions on Air – VwV: Administrative Regulation on the Road Traffic Act –

Table 6: Regulative options under the law on installations

6.3 Water law

Water law lays down guidelines from the perspective of this medium that have an effect on the operation of industrial plants. Water law does not take effect only when certain threshold limits are exceeded, but rather demands initial control on the part of all those who discharge substances into a water body from point sources, whether directly (discharging pollutants as a "direct discharger", or in other ways (as "indirect discharger through municipal sewage plants). "Diffuse sources" of pollutant input are more difficult to get a grip on under water law, irrespective of whether they are from households or conveyed by other means (for instance, in the air or soil, from installations or through the use of products (such as cosmetics, fertilizers or crop protection agents)).

Possible installation-related, water-borne point sources of nano materials are covered in Germany by installation-related aspects of water law, even when the plant is not subject to the IPPC Directive.

In a material sense, the basic obligations of installation operators also cover installation-related risks of the manufacture and use of nano particles. Up to now, however, there has been a lack of non-statutory concretization not only of emission standards, but also of binding immission-side environmental quality objectives. Against this back-

ground it appears to be necessary for potential dischargers of nano particles and nano materials to be known to water authorities, who can form an impression of the kind and extent of such discharges. Where municipal sewage treatment plants are unable to treat waste water from the manufacture and use of nano particles or nano materials (and this has initially to be assumed), the authorities can lay down demands on indirect discharges with respect to waste water quality before mixing or the place of occurrence. Where the danger from the discharge of nano particles is measurable, limit values for necessary parameters can be introduced at a later point in time in the annex to the AbwV (decree on demands on the discharge of waste water into water bodies).

To be able to lay down emission- or immission-side threshold and target values (for instance, in authorizations under water law), appropriate parameters have to be found. At the same time, suitable parameters have also to be laid down for measuring and testing procedures.

Regarding both diffuse and point sources for nano particles that are a considerable potential danger for or through the aquatic environment, the Commission can also fall back – bearing in mind the principle of proportionality – on process or product restrictions (see Article 16 (6) of the EU Water Framework Directive).

Conceivable regulative options under water law are summarized in the following table, with secondary options shown in italics:

		Subject to approval Direct dischargers	Subject to approval Indirect dischargers	Diffuse sources	Immission values and monitoring	Emission values	Supplementary regulations
		A	B	C	D	E	F
EU level	1.	-	-	Where necessary, combination of product and procedural restrictions according to Art. 16 (6) WFD*	Water quality specifications until then: Indicative effect of the PNEC*	- *BREFs: Adoption or creation according to IPPC*	No regulation in WFD*, reference to IPPC
National level	2.	-	Nano-specific threshold value for waste water quality before mixing or for the place of occurrence	Corresponding implementation of the above proposals	See above	*Where necessary adoption in the manufacturing section of the AbwV**	
Administrative level	3.	-	-	*Taking account of possible burdens with nano particles in drawing up management plans*	-		VwV* with nano-specific explanation for existing nano materials
Technical standards	4.	Operationalize parameters for threshold and target values	Operationalize parameters for threshold and target values		Investigation of appropriate parameters for monitoring as well as measuring and testing procedures	Investigation of appropriate parameters for monitoring as well as measuring and testing procedures	

***Explanation:** AbwV: Decree on the discharge of waste water into water bodies – BREF: Best available technique Reference document – PNEC: Predicted No Effect Concentration – WFD: Water Framework Directive – VwV: Administrative Regulation.

Table 7: Regulative options under water law

6.4 Waste law

So far as the disposal of waste from the manufacture or use of nano materials is concerned, it has to be stated that such waste is not assigned its own waste code. This is not critical, however, since the classification of waste refers to the law on dangerous substances (in future: REACh). What is essential, however, is that nano-specific dangers are actually determined under chemicals law, so that they can be classified under waste law. If evaluations according to the law on dangerous substances or classification according to waste law are not available, or waste from nano materials arises that cannot be assigned to an existing waste code, there is the possibility to subsume such waste under "back-up" Chapter 16 of the waste list. For waste from nano materials with considerable concern potential, in particular, separate registration under a specific waste code and secure disposal appears to be necessary so long as appropriate classification under the law on dangerous substances does not exist. Such a waste code 16 03 07 could be formulated as follows:

"Waste, which emanates from the manufacture or industrial use of nano materials, unless <specification of an appropriate lower threshold value>"

Concerning the depositing of waste with nano materials, it has to be examined whether the assignment criteria according to the Decision of the Council 2003/33/EG[138] are appropriate to determine the risks emanating from the respective nano materials. It has then to be examined, under which landfill category such waste should be deposited. Corresponding landfill disposal under particular landfill categories would certainly be difficult to realize without appropriate disposal of hazardous nano waste from manufacture, or identification and waste-flow control in the case of products with nano materials in household waste (for instance, through an obligation to take back, or separate disposal of products).

With regard to nano particles in landfill leachate, a distinction has to be made between possible mobilization of pollutants in waste or soil through nano particles, which can be registered under the existing measuring and monitoring programme, and dangers that emanate from nano particles themselves. In the latter case, it has to be clarified whether this can be registered under the existing measuring and monitoring programme. There is the legal possibility to regulate nano particles as a parameter in the measurement of groundwater (cf. No. 4 B of Annex III to the Landfill Directive). For that, appropriate parameters have still to be investigated.

On account of its objective, the German Sewage Sludge Decree enables the regulative treatment of possible dangers from nano materials in sewage sludge from household waste water. The specific demands of the Sewage Sludge Decree have shortcomings, however, since the sampling of sewage sludge for the investigation of landfill sites and the restriction of maximum pollutant content in sewage sludge or landfill sites does not take account of nano-specific properties. Here, in particular, possible carrier effects of nano particles, such as fullerenes, have to be borne in mind, which can discharge nutrients and pollutants from soil into groundwater.

[138] See Footnote 98.

With regard to the incineration of nano materials, Directive 2000/76/EG on the incineration of waste contains limit values only for "classical" pollutants. So long as the applicability of limit values to nano materials is unresolved, or nano-specific limit values not yet legally regulated, decision-making aids for authorities on the co-incineration of certain nano materials could provide orientation. Moreover, nano-specific air and wastewater monitoring by operators of installations for the manufacture of nano materials should be taken into consideration. The measurement of air and water emissions on the basis of mass concentrations should be supplemented by the measurement of particles per cubic metre for nano particles, where the emission of health endangering nano particles is involved. It should further be examined, whether air and water filters for the retention of nano particles are available on the market, and how efficient they are. Finally, research should be conducted on the behaviour of particular nano materials during incineration.

Possible regulative options under legislation on waste are summarized in the following table, with secondary options shown in italics:

		Classification of waste type	Nano-specific disposal	Utilization (sewage sludge)	Thermal utilization
		A	B	C	D
EU level	1.	Classification of nano materials according to the criteria in Annex I to III (91/689/ EEC). Where necessary, introduction of a separate waste code in "back-up" Chapter 16	Nano-specific assignment criteria for landfills in Decision 2003/33/EC	Introduction of threshold values for nano particles in Sewage Sludge Directive 86/278/EEC	Emission limit values for dangerous nano materials in Directive 2000/76/EC
National level	2.	Corresponding to EC level in AVV* (see above)	*Nano-specific groundwater monitoring by landfill operators*	Introduction of threshold values for nano particles in the AbfKlärV*	Nano-specific air and waste-water monitoring by plant operators
Administrative level	3.	Support for typical places of origin of waste with nano materials	Corresponding to the EU level, assignment criteria in "TA-Abfall*". Information for authorities on the recycling of waste with nano materials in accordance with Article 6 I IPPC Directive	-	*- Decision-making aids for authorities on the permissibility of the simultaneous incineration of nano materials*
Technical standards	4.		Need for research on the behaviour of particular nano materials in the landfill body/leachate + possible parameters for groundwater monitoring	Need for research on the effects of nano particles in sewage sludge	- Measurement of nano particles in waste air in particles per cubic metres - Need for research on the behaviour of certain nano materials during incineration

***Explanation:** AbfKlärV: Sewage Sludge Decree – AVV: Waste List Decree – TA-Abfall: Technical instructions on waste.

Table 8: Regulative options under waste law

7 Elements of a multi-step regulatory concept

In putting forward proposals for regulation it has to be borne in mind that due to the present very rapid innovation process, which runs parallel to the spreading of technology, it is not clear where (that is, in which areas of application, industrial sectors and businesses) substance-related hazards occur, which regulatory proposals and approaches should address. Current research indicates that potential dangers exist, while at the same time there are fears on the part of industry that hasty regulation on the basis of insufficient scientific findings could wreck the technology.

7.1 Legal demands on regulation

Legislative action is possible from the perspective of both the avoidance of danger and precaution. There is no fundamental difference in legal definition.[139] Judicial decisions on the legal classification of nano materials exist as yet only at a national level, and these therefore form the basis of the following presentation.

An approach based on the *avoidance of danger* requires sufficient probability of damage occurrence. According to the classical definition, a danger exists where "certain prevailing conditions will result, according to the law of cause and effect, in conditions and events that give rise to certain other damage" (PrOVG [Higher Administrative Court], judgement of 15 October 1894, PrVBl [Law Gazette] 16, 125/126). This is not the case, as the German Federal Administrative Court laid down in its judgement on nano particles,[140] where damage occurrence is uncertain. For the vast majority of nano materials a situation of danger does not at present exist.

Legislators can rely, however, on the *principle of precaution*, which is also established in Community law (see Section 3.1). In its "nano decision", the German Federal Administrative Court stated in this connection:[141]

> "Potential adverse effects on the environment, a merely possible connection between emission and damage occurrence or general potential concern can give cause for precautionary measures, provided that these are reasonable in terms of their nature and scope. Precautionary measures against adverse effects on the environment thus cover possible damage that cannot be ruled out, since, based on the present state of knowledge, certain causal connections can be neither confirmed nor denied, which is why danger does not exist, but rather a suspicion of danger or potential danger (BVerwGE 72, 300 <315>). Where sufficient grounds exist for the assumption that emissions might possibly lead to adverse effects on the environment, it is the purpose of precautionary measures to minimize such risks below the danger level."

According to the findings of the Federal Environmental Agency (Umweltbundesamt) (UBA 2006), as well as the results reported on in Chapter 1 and the possibilities of release referred to in Section 4.3, in view of the special properties of nano materials such potential concern should be accepted (indications of causal connections already exist). Official authorities (of the EC and Member States) are committed to the principle of precaution and are therefore called on to act.

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139 See the bibliographical references in Footnote 1.

140 BVerwG of 11.12.2003 - 7 C 19/02 -, E 119, 329/332; see also Footnote 24.

141 Cf. Footnote 140.

Regarding the weight that should be attached to potential concern and the choice of possible action, state authorities – and legislators in particular – have considerable judgemental latitude,[142] covering not only the definition of the regulative objectives under consideration, but also the assessment of what they regard to be appropriate and necessary for the achievement of these objectives. The Federal Constitutional Court can examine this decision "to only a limited extent, depending on the specific character of the matter in question, the possibilities of forming a sufficiently secure judgement and the protected rights at stake."[143] According to the Federal Constitutional Court, the judgemental latitude of legislators is overstepped only "when the considerations of legislators are so flawed that they cannot reasonably provide a basis for such measures".[144] Independent of – largely withdrawn – constitutional demands in their function as "control standard", precaution-related guidelines in the EC Treaty and German Basic Law have also to be regarded as a "pervasive or permeating standard" [German: *"Maßstabsnorm*".][145] The same goes for the principles of equal treatment and reasonableness. For the purposes of consistent governmental or supranational risk regulation, legislators should not fundamentally deviate from decisions in other areas.

According to these principles there are good reasons for looking for suitable ways to support and – where necessary – stimulate independent action on the part of stakeholders.[146] Since the risks of nano materials have primarily to do with their material and structural properties, it is obvious that these properties should first be precisely analysed, on the basis of which a regulative approach should then be chosen, which leans on the new EU REACh Regulation on chemicals. It has to be borne in mind, however, that up to now there has been a partial lack of testing methods appropriate for determining the risks of nano materials and for ensuring monitoring.

Moreover, not only the risk side (that is, undesirable effects) has to be examined, but also the socially desirable effects that can result from the use of nano materials (UBA 2006). These effects reflect matters of the common good, but also constitutional rights that have to be taken into consideration by state authorities in deciding their strategy for action.

Against this backdrop, the regulatory challenge lies in drawing up a regulation that accompanies and supports the innovation process and at the same time establishes nano-specific risks and evolves strategies for their "control",[147] but without impeding the chances for development of the technology as a whole.

7.2 Elements of the multi-step concept

Regulatory gaps and options have been described in detail in Chapters 5 and 6. To avoid repetition, but also in view of the still necessary societal process of clarification,

142 See Führ 1999 on the constitutional demands on "rational regulation".

143 BVerfGE 110, 141/157 f. (*Dog Decree*) under reference inter alia to E 77, 170/214 f.; 90, 145/173.

144 BVerfGE 110, 141/158 under reference to E 30, 292/317; 37, 1/20; 77, 84/106.

145 Details disputed; see Führ 2003, 372 ff.

146 More stringent regulations are, as already mentioned (see Footnote 144), quite possible, in so far as an understandable justification is not completely lacking.

147 The term is used here pursuant to Community law, where it is used not only in the REACh Regulation, but also in the Seveso II Directive..

the description of a stepwise regulative procedure is confined to a generally brief description of individual elements of altogether five steps:

Step 1: Initial measures to cope with the problem of information

a) Communication requirements for already existing information:

- Clarification: on a voluntary basis or obligation to notify?
  - In the latter case: modification of REACh (see Section 6.1.2, page 42).
  - If required, adaptation of the definition of substance.
- Subject and procedure of communication (Who? What? When? To whom?: threshold values, properties of substances, [provisional] testing programme)

b) At the same time:

- Standardization of nomenclature for the designation of nano substances.
- Development and evaluation of testing procedures and monitoring methods[148]

Step 2: Systematization and assessment of information on risk

a) Develop mechanisms for the gaining, merging and assessment of information (administrative or civic: discourse on risk in which institutional context?).

b) Definition of (provisional) measures to cope with risk (based, for instance, on classification of the application/release of nano materials according to the "traffic-lights principle"):

- Green: unproblematic in terms of the present state of knowledge. Application possible, but long-term monitoring necessary for unforeseen effects.
- Yellow: concern potential exists; examination in isolated cases; in particular, benefits for the environment and socio-economic advantages have to be measured against concern potential. Where benefits are not predominant, release must be avoided. In the contrary case, protection and minimization principles have to be developed.
- Red: considerable concern potential up to suspicion of danger: avoid release.

c) Prepare and test support for stakeholders in implementation of a)/b).

Step 3: Clarification of further regulation requirements

a) Depending on the results of Step 2, decisions on further regulative elements could be taken (for instance, within the framework of chemicals law:

- Specific determination of life-long risk (analogous to REACh?)
- Labelling (analogous to chemicals law)
- Risk communication in the chain (specific demands on safety data sheets)

b) At the same time, continuance of activities mentioned under 1 b) (with the participation of civic stakeholders and, if applicable, in the context of international standardi-

[148] Both points are already the subject of activities at ISO and CEN levels (see Footnote 103).

zation organizations), which are, in part, the prerequisite for rating risk management measures.

c) Ensuring "safe application" by overcoming problems at the interface between chemicals law and other sectorial regulations, such as the law on installations, water and waste. Besides environmental law, aspects of industrial safety and consumer protection have also to be considered.

Step 4: Implementation and monitoring of risk management measures

Establishing a risk-adequate concept for determining and controlling the undesirable effects of nano particles, and

a) incorporation of experiences gained in the previous steps in
   - non-statutory regulations and administrative regulations and
   - standards and norms, such as ISO/OECD, CEN, DIN and VDI (Association of German Engineers)

b) toxicological and ecotoxicological monitoring programmes, as far as applicable to nano particles within the framework of existing programmes. Otherwise, it should be examined to what extent monitoring programmes should be set up by manufacturers of nano materials within the scope of product responsibility.

Step 5. Modification of the regulative framework

Observation of technical developments, the real burden on protected rights and the incentive effect of measures adopted in the previous steps, with the aim of possible adaptation of the regulative framework.

7.3 Conclusion

National and EU authorities are faced with the question of whether and in which way they can initiate a regulative framework for the use of nano technologies.[149] At the same time – as mentioned at the beginning of the report – they have to cope with a balancing act that is not wholly untypical for "new" technological developments; namely one that allows the desired effects of new technology, but at least observes and, where possible, overcomes undesirable effects preventatively.

The idea that the state by means of a strict “command and control” approach can comprehensively intervene in private research and development departments appears – in both a practical and a legal sense – to offer little promise. Nevertheless, the state can influence the research objectives (also from the point of view of precaution) of programmes that it wholly or partly finances and impose accompanying risk research programmes. In the case of private research it will be a matter of encouraging independent action on the part of stakeholders by means of a broad regulative framework. To what extent it will be enough to rely on voluntary co-operation, or whether a modified legal framework will be necessary, depends essentially on the incentive situation in which the leading stakeholders in industry and research find themselves. As an "intermediate step", standardization will anyway play an important role. This applies, for instance, to nomenclature as well as to testing and measuring methods. It is also conceivable, however, that additional elements of the multi-step concept will be created; for instance, the operationalization of a "traffic-lights" system or application support for industrial stakeholders.

Investigation of the incentive situation of stakeholders would exceed the framework of this report. One would have to formulate normative behavioural expectations for specific courses of action and then compare these with the behavioural contributions of stakeholders that are actually to be expected.[150] This would require, however, a process of clarification – which would have to be performed at least within the government, or even in the parliamentary sphere – to determine which behavioural contributions would be expected by society from which stakeholders (individually and/or collectively) at which point in time. On the basis of such detailed normative behavioural expectancy, the need for supplementary motivational impetus would have to be determined scientifically within the scope of "delta analysis". On this basis, appropriate institutional measures could be identified.

[149] It has to be mentioned – should possible regulatory action be geared to the particularly small particle size – that at the same time a statement would be made – at least implicitly – on the regulation of particles of an even smaller size. For the nanoscale form is not the smallest of all possible manifestations. Occurrence at a pm (picometer = 10^{-12} m) or fm (femtometer 10^{-15} m) size is conceivable.

[150] For such incentive analysis in the area of stakeholder co-operation for substances subject to registration under REACh see Führ/Heitmann/Koch/Ahrens et al. 2006. See also Führ/Bizer 2007.

8 Bibliography

8.1 Legal sources

Amtliche Begründung zur Novelle der Gefahrstoffverordnung 2004	Begründung zum Entwurf einer Verordnung zur Anpassung der Gefahrstoffverordnung an die EG-Richtlinie 98/24/EG und andere EG-Richtlinien. Kabinettsache Datenblatt-Nr. 15/09036 (download unter http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Rechtstexte/Gefahrstoffverordnung.html__nnn=true; so am 27.9.2006)
Bizer/Führ/Hüttig 2002	Bizer, Kilian/Führ, Martin/Hüttig, Christoph (Hrsg.): Responsive Regulierung - Beiträge zur interdisziplinären Institutionenanalyse und Gesetzesfolgenabschätzung, Tübingen 2002 (Mohr Siebeck).
BMU 2004	BMU (Referat IG I 4), Vollzugshilfe zur Störfall-Verordnung (März 2004)
BMU 2005	Synthetische Nano-Partikel – Entwicklungschancen im Dialog, 25. Oktober 2005, Dessau.
Calliess 2003	Calliess, Christian 2003: Zur Maßstabswirkung des Vorsorgeprinzips im Recht - Dargestellt am Beispiel der geplanten Reform des europäischen Chemikalienrechts durch das Weißbuch der EU-Kommission zur zukünftigen Chemikalienpolitik - VerwArch 2003, 389
Calliess/Lais 2005	Calliess, Christian/Lais, Martina 2005: REACh-revisted - Der Verordnungsvorschlag zur Reform des Chemikalienrechts als Beispiel einer neuen europäischen Vorsorgestrategie, NuR 2005, 290 – 299
Chaudhry, Q. et. al 2006	Chaudhry, Q. et. al., A scoping study to identify gaps in environmental regulations for the products and applications of nanotechnologies, 2006
Denninger 1990	Denninger, Erhard 1990: Verfassungsrechtliche Anforderungen an die Normsetzung im Umwelt- und Technikrecht, Baden-Baden (Nomos).
ETC Impact Agriculture 2004	ETC Group, Down on the Farm - The Impact of Nano-Scale Technologies on Food and Agriculture, November 2004
ETC NanoGeoPolitics 2005	ETC Group, NanoGeoPolitics - Surveys the Political Landscape, July/August 2005
ETC Nanotech 2004	ETC Group, Nanotech: Unpredictable and Un-Regulated, 2004
Europäische Kommission 2000	Mitteilung über die Anwendbarkeit des Vorsorgeprinzips, NVWZ 2001, Beilag zu Heft 4.
Führ 1998	Führ, Martin: Widerspruchsfreies Recht im uniformen Bundesstaat? - Zum Sonderabfallabgaben-Urteil des Bundesverfassungsgerichts, KJ 1998 (31), 503 - 517.
Führ 1999	Führ, Martin: Rationale Gesetzgebung - Systematisierung verfassungsrechtlicher Anforderungen, in: Gawel/Lübbe-Wolff 1999, 193 - 226 (als pre-print: sofia-Diskussionsbeiträge zur Institutionenanalyse 98-2, Darmstadt).
Führ 2003	Eigen-Verantwortung im Rechtsstaat, Berlin 2003 (Duncker & Humblot).

Führ et. al. 2006	Führ, M; Hermann, A.; Merenyi, S.; Moch, K.; Möller, M.; Rechtsgutachten Nanotechnologien – ReNaTe, FKZ 363 01 108, Zwischenbericht (Entwurfsfassung des Abschlussberichts) - Stand 04.09.2006.
Führ/Bizer 2007	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), 327-334, Elsevier, Exeter (UK).
Führ/Heitmann/Koch/Ahrens et al. 2006	Risikominderung für Industriechemikalien nach REACh - Anforderungen an eine Arbeitshilfe für Hersteller, Importeure und Stoffanwender, UBA-Texte 05/06.
Führ/Merenyi 2006	Führ, Martin/Merenyi, Stefanie 2006: Mind the Gap - Interface Problems between EC Chemicals Law and sectoral environmental legislation, Review of European and International Environmental Law (RECIEL) 15 (3), 281-292.
Führ/Merenyi 2005	Führ, Martin/Merenyi, Stefanie 2005: Schnittstellenprobleme zwischen gemeinschaftlichem Stoffrecht und anderem sektoralen Umweltrecht (Umsetzungshemmnisse bei der Risikominderung von Altstoffen nach 793/93/EG – „Instrumentenlücke“), UBA-Texte 03/05, ISSN 0722-186X.
Gawel/Lübbe-Wolf 1999	Gawel, Erik/Lübbe-Wolff, Gertrude: Rationale Umweltpolitik - Rationales Umweltrecht. Konzepte, Kriterien und Grenzen rationaler Steuerung im Umweltschutz, Baden-Baden 1999.
Kitzinger 2006	Kitzinger, G.; zugleich Stellungnahme der Bayer Material Science AG zum Entwurf (Stand: 04.09.2006) des Rechtsgutachtens „Nano-Technologien“ vom 16.10.2006
Klodt 1995	Klodt, Henning: Grundlagen der Forschungs- und Technologiepolitik, München 1995 (Verlag Vahlen)
Köck 2003	Köck, Wolfgang: Das System „Registration, Evaluation und Authorisation fo Chemicals“ (REACh) – Rechtliche Bewertung am Maßstab des Gemeinschaftsrechts, in Rengeling (Hrsg.) 2003.
Kommentator, in: Kunig/Paetow/Versteyl	Kunig, Phillip/Paetow, Stefan/Versteyl, Ludger-Anselm, Kreislaufwirtschafts- und Abfallgesetz – Kommentar, 2. Auflage, München 2003
LAI 1992	Länderausschuss für Immissionsschutz (LAI), Krebsrisiko durch Luftverunreinigungen, Düsseldorf 1992.
LAI 2005	Länderausschuss für Immissionsschutz (LAI), Bewertung von Schadstoffen, für die keine Immissionswerte festgelegt sind, vom September 2004 in der Fassung vom 21. Januar 2005, auf der Grundlage des Beschlusses auf der 108. Sitzung des LAI vom 21. bis 22. September 2004 in Leipzig (http://www.lua.nrw.de/gesundheit/pdf/LAI2004.pdf).
LASI 2005	Länderausschuss für Arbeitsschutz und Sicherheitstechnik (LASI), Leitlinien zur Gefahrstoffverordnung, Düsseldorf/Wiesbaden 2005.
Lottes 2006	Lottes, Ralph: ECOS Information about standardisation work on nanotechnologies in CEN; Papier für das Fachgespräch im Rahmen des ReNaTe-Projektes am 28.9.2006 in Berlin
Lübbe-Wolff 1998	Lübbe-Wolff, Gertrude: Präventiver Umweltschutz – Auftrag und Gre-

	muem des Vorsorgeprinzips im deutschen und im europäischen Recht, in: Bizer, Johann/Koch, Hans-Joachim (Hrsg.), Sicherheit, Vielfalt, Solidariät – Ein neue Paradigma des Verfassungsrechts?, Baden-Baden 1998.
Moch/Stephan 2002	Moch, Erika/Stephan, Thomas: Entwicklung von Arbeitshilfen zur Erstellung und Prüfung des Konzeptes zur Verhinderung von Störfällen, UBA-Texte 15/02
Rehbinder 1991	Rehbinder, Eckard: Das Vorsorgeprinzip im internationalen Vergleich“, Düsseldorf, 1991
Rehbinder 2003	Rehbinder, Eckard: Allgemeine Regelungen – Chemikalienrecht, in: Hans-Werner Rengeling (Hrsg.), Handbuch zum europäischen und deutschen Umweltrecht (EUDUR), 2. Aufl. 2003, Bd. II, 1. Teilband § 61, S.547 - 625.
Rehbinder/Kayser/Klein 1985	Rehbinder, Eckard/Kayser, Detlev/Klein, Helmut 1985: Chemikaliengesetz – Kommentar und Rechtsvorschriften zum Chemikalienrecht, Heidelberg 1985.
Rengeling 2003	Rengeling, Hans-Werner (Hrsg.) 2003: Umgestaltung des deutschen Chemikalienrechts durch europäische Chemikalienpolitik, Köln 2003.
Risikokommission 2003	Risikokommission [Hrsg.] (2003) Abschlussbericht der Risikokommission. Adhoc-Kommission „Neuordnung der Verfahren und Strukturen zur Risikobewertung und Standardsetzung im gesundheitlichen Umweltschutz der Bundesrepublik Deutschland“. Salzgitter
Royal Society/Royal Academy 2004	The Royal Society & the Royal Academy of Engineering, Nanoscience and Nano-Technologies: opportunities and uncertainties. London: 2004. http://www.nanotec.org.uk/finalReport.htm
SCENHIR 2006	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 vom 10.03.2006
Sieder/Zeitler/Dahme	Sieder, Frank/Zeitler, Herbert/Dahme, Heinz, Wasserhaushaltgesetz – Abwasserabgabengesetz, Kommentar, München, Stand: Juli 2005
TAB Arbeitsberichte 2003	TAB Büro für Technikfolgenabschätzung [Hrsg.]; Paschen, Herbert; Coenen, Christopher; Fleischer, Torsten; Grünwald, Reinhard; Oertel, Dagmar; Revermann, Christoph (2003) Nano-Technologie. TAB-Arbeitsberichte Nr. 92. Berlin: Eigenverlag. (Auch als Bericht des Ausschusses für Bildung,Forschung und Technikfolgenabschätzung des Deutschen Bundestages, unter Drucksache 15/2713 veröffentlicht.)
Theuer 1996	Theuer, Andreas: Risikobewertungsmodelle als Grundlage von Stoffverboten? Zur Anwendung des Vorsorgegrundsatzes im Chemikalienrecht, NuR 1996, 120 – 130.
Umweltbundesamt 2006	Nanotechnik: Chancen und Risiken für Mensch und Umwelt, Hintergrundpapier, Dessau August 2006
VCI 2006	Verband der Chemischen Industrie e.V.: Positionen und Empfehlungen des VCI zum Umgang mit Nano-Partikeln und nano-skaligen Stof-

	fen unter rechtlichen Gesichtspunkten vom 01. 02.2006.
VCI-Stellungnahme	Stellungnahme des VCI zum Entwurf (Stand: 04.09.2006) des Rechtsgutachtens „Nano-Technologien“ vom 10.10.2006
Working Group on Nano-Materials	Doc JM/06/2006 zum „13th Joint Meeting of the competent authorities for the implementation of Directive 67/548/EEC (New Substances) and Council Regulation 793/93/EEC (Existing Substances)“ vom 24.04.2006.
	Stellungnahmen und Vorträge im Rahmen des Dialogs http://www.dialog-Nano-Partikel.de/index.html
Schäfer 2005	Schäfer, Heinz-Günter: Die neue Gefahrstoffverordnung, StoffR 2005, 35-40.

8.2 Scientific sources

AdNano® Ceria	AdNano® Ceria; http://www.advanced-nano.com/webapps/adnano.nsf/downlo-ad/121945E028411E32C12570F9004EF733/$File/pi%20adnano%20ceria%2011%202005.pdf [abgerufen am 12.06.2006]
AdNano® Zink Oxid	AdNano® Zink Oxid; http://www.advanced-nano.com/webapps/adna-no.nsf/download/9C09730E6DEE6BC7C12570F900510A5B/$File/pi%20adnano%20zinc%20oxide%2011%202005.pdf [abgerufen am 12.06.2006]
AG Cilander	AG Cilander ; http://www.cilander.com
Automobil-Produktion 2005	Struktur-Klebstoffe – Kleben mit Magnetfeld. In: Automobil-Produktion, S. 78, Februar 2005 http://www.advanced-nano.com/webapps/adnano.nsf/download/0FA658B92E35C86DC1256FE8004787FB/$File/Automobil-Produktion.pdf
BASF 2006a	BASF, Unser Beitrag zur öffentlichen Debatte über Nanotechnologie. http://www.corporate.basf.com/de/sustainability/dialog/nanotechnologie/dialog/?id=k6eIO8sEFbcp*6V
BASF 2006b	Im Dialog: Nanotechnologie bei der BASF. http://www.corporate.basf.com/de/sustainability/dialog/nanotechnologie/dia-log/?getasset=file1&name=Im+Dialog+060503+mit+Layout.pdf&MTITEL=Nanotechnologie+bei+der+BASF&suffix=.pdf&id=V00-Dnhtq8sEGbcp324
Bayer 2006	Bayer; Taking a Step into the future with carbon nanotubes. 2006 http://www.bayermaterialscience.com/internet/global_portal_cms.nsf/id/Nanotechnologie_en
Bayer Bayblend	Bayer Bayblend; http://plastics.bayer.com/plastics/emea/de/products/

	description/43/index.jsp?pid=43 [abgerufen am 29.06.2006]
Baytubes® C150P	Baytubes® C150P; Multi-Wall Carbon Nanotubes – Preliminary Data Sheet for Product Development http://www.bayermaterialscience.com/internet/global_portal_cms.nsf/files/datenblaetter/$file/Baytubes-C150P.pdf
Bioactive	Bioactive; http://www.trevira.de/mode/de/p0028_Produkte.shtml?navId=17 [abgerufen am 20.06.2006]
Brinkmann 2005	Brinkmann, M.; Hightech in der Haut. Autolack von morgen. In: SPIEGEL online 01. Dezember 2005.
Bugatti	Bugatti: http://www.bugatti.de
Cabot/Siemens Axiva	Cabot/Siemens Axiva http://pcs.khe.siemens.com/efiles/pronews/2003_02_de.pdf
CNI 2006	CNI – Center of Nanoelectronic Systems for Information Technology. http://www.cni-juelich.de/index.php?index=87
Degussa 2004	Degussa; Winzige Rußpartikel machen Reifen leistungsfähiger. Tanz im magischen Dreieck. Presseinformation Nr. 3 vom 15.6.2004 http://downloads.degussa.de/downloads/de/produkt_stories.Par.0001.downloads.0003.myFile.tmp/Carbon_Black.pdf [abgerufen am 20.06.2006]
Degussa 2005	Degussa Corporate Citizenship Report 2005, S. 24-27 http://downloads.degussa.com/downloads/en/additional_reports.Par.0002.downloads.0005.myFile.tmp/Degussa_Corporate_Citizenship_Report_2005_en.pdf
Degussa 2006	Degussa Ceramic membranes. Separion® Safety and Performance.
Dufte Bären	Dufte Bären ; http://www.dufte-baeren.de [abgerufen am 19.06.2006]
Erlus	Erlus; http://www.erlus.de [abgerufen am 20.06.2006]
Eusolex®	Eusolex®; T-Produkte für kosmetischen Sonnenschutz: http://www.sachtleben.de/include/3_9_4_0_DE.html [abgerufen am 20.06.2006]
Fraunhofer 2003	Produktion von und mit Nano-Materialien. Untersuchung des Forschungs- und Handlungsbedarfes für die industrielle Produktion. http://www.isc.fhg.de/german/improfil/presse/publikationen/media/nanotechnologie.pdf [abgerufen am 12.06.2006]
Fraunhofer 2006	http://www.fraunhofer.de/fhg/press/pi/2006/05/Mediendienst52006Thema3.jsp
Gaskell et al. 2006	Gaskell, G.; Allansdottir, A.; Allum, N.; Corchero, C.; Fischler, C.; Hampel, J.; Jackson, J.; Kronberger, N.; Mejlgaard, N.; Revuelta, G.; Schreiner, C.; Stares, S.; Torgersen, H.; Wagner, W.; Europeans and Biotechnology. In 2005: Patterns and Trends. Eurobarometer 64.3. A report to the European Commission's Directorate-General for Research. May 2006.

	http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf
Genthe-X-Coatings GmbH	Genthe-X-Coatings GmbH; http://www.gxc-coatings.de/cms.py?module=content&page=35&node=2 [abgerufen am 14.06.2006]
Golem 2005	Nanotech-Unternehmen verspricht Akku-Revolution; http://www.golem.de/print.php?a=36525 [abgerufen am 28.02.2005]
G-PRO	G-PRO; http://www.g-pro.com/Deutsch/index.htm
Hansaplast	Hansaplast – Geschichte von Silber; http://www.hansaplast.de/wunden/silber_info.asp [abgerufen am 12.06.2006]
Hartchrom AG Steinach	Hartchrom AG Steinach; http://www.hartchrom.com/index_de.php?TPL=105000&x105000_ID=11 [abgerufen am 14.06.2006]
Hegemann 2006	Hegemann, D.; Funktionale Textilien dank Nanotechnologie. Beitrag zum BfR Expertengespräch „Nanotechnologie, ihre Produkte und Risiken für den Verbraucher“ vom 28. März 2006. http://www.bfr.bund.de/cm/232/funktionale_textilien_dank_nanotechnologie.pdf [abgerufen am 14.06.2006]
Henkel	Henkel; http://www.henkel-waschmittel.de/produkte/reinigen/spezialreiniger/?inc=sidolin
Heubach et. al 2005	Heubach, D.; Beucker, S.; Lang-Koetz, C.; Einsatz der Nanotechnologie in der hessischen Umwelttechnologie. Hessisches Ministerium für Wirtschaft, Verkehr und Landesentwicklung. Erstellt von Fraunhofer IAO, März 2005. http://www.bum.iao.fraunhofer.de/nano/ [abgerufen am 23.06.2006]
Holleman-Wiberg 1985	Holleman, A. E.; Wiberg, E.; Lehrbuch der anorganischen Chemie, 91. – 100. Aufl., Berlin, New York 1985.
Hombitec RM	Hombitec RM, Holzschutz der Zukunft http://www.sachtleben.de/include/3_7_4_0_DE.html [abgerufen am 20.06.2006]
Hombitec RM 110	Produktinformation Hombitec RM 110 http://www.sachtleben.de/publications/0264d072.pdf [abgerufen am 20.06.2006]
Hombitec RM 130 F	Produktinformation Hombitec RM 130 F http://www.sachtleben.de/publications/0094d072.pdf [abgerufen am 20.06.2006]
Hombitec RM 200/220	Produktinformationen Hombitec RM 200 und RM 220 http://www.sachtleben.de/publications/0237d072.pdf http://www.sachtleben.de/publications/0238d072.pdf [abgerufen am 20.06.2006]

Hombright S	Hombright S http://www.sachtleben.de [abgerufen am 20.06.2006]
Hund-Rinke/Simon 2006	Hund-Rinke, K.; Simon, M.; Ecotoxic Effect of Photocatalytic Active Nanoparticels (TiO2) on Algae and Daphnids. In: Environ. Sci. Pollut Res 13, 225-232 (2006).
Innovationsreport 2002	Innovationsreport 2002; http://www.innovations-report.de/html/berichte/biowissenschaften_chemie/bericht-8952.html
Inomat GmbH	Inomat GmbH; http://www.inomat.de/ [abgerufen am 20.06.2006]
ItN Nanovation a	ItN Geschäftsbereiche und Produkte http://www.itn-nanovation.com/main.asp?page=produkte
ItN Nanovation b	ItN Nanocat - Keramikbeschichtung http://www.itn-nanovation.com/main.asp?page=produkte&subpage=nanocat
ItN Nanovation c	ItN – Einsatzmöglichkeiten von Nanocat http://www.itn-nanovation.com/main.asp?page=produkte&subpage=nanocat_einsatz
ItN Nanovation d	ItN – Nanopore. Keramische Filtermembrane http://www.itn-nanovation.com/main.asp?page=produkte&subpage=nanopore
Levasil®	Levasil®; http://www.spezialchemikalien.bayer.de/SC/download/LEVASIL.pdf
Lippert 2000	Lippert, H.; Lehrbuch Anatomie, 5. Aufl., München/Jena (2000).
MacDonald 2005	MacDonald, V.; Nanotechnology finds some growing applica-tions.(personal care). In: Chemical Week 167 (16) Mai 2005, 35-38.
MagSilica®	MagSilica® http://www.advanced-nano.com/webapps/adnano.nsf/frametest/englischframe?opendocument&C53FA10720E9226FC1256FE800495A71 [abgerufen am 20.06.2006]; http://www.advanced-nano.com/webapps/adnano.nsf/download/0FA658B92E35C86DC1256FE8004787FB/$File/Automobil-Produktion.pdf [abgerufen am 20.06.2006]
Nanit®active	Nanit®active; http://www.nanit-active.de/ [abgerufen am 12.06.2006]
Nano S GmbH	Nano S GmbH; http://www.nano-s-gmbh.de/
NanoLux	NanoLux; http://www.bmbf.de/de/338.php
NanoMat 1	NanoMat 1; http://www.nanomat.de/datenblaetter/22000.htm
NanoMat 2	NanoMat 2; http://www.nanomat.de/datenblaetter/32000.htm
NanOp 2004	NanOp 2004¸Competence Centre for the Application of Nanostructures in Optoelectronics.http://www.nanop.de/

NanoPore	NanoPore; http://www.nanopore.com
nanoRoad 2005a	Nano-Material Roadmap 2015. Overview in Promising Nano-Materials for Industrial Application. September 2005. http://www.nanoroad.net/download/overview_Nano-Materials.pdf [abgerufen am 12.06.2006]
nanoRoad 2005b	Nano-Material Roadmap 2015. SWOT Analysis Concerning the Use of Nano-Materials in the Energy Sector. September 2005 http://www.nanoroad.net/download/swot_e.pdf [abgerufen am 12.06.2006]
nanoRoad 2005c	Nano-Material Roadmap 2015. SWOT Analysis Concerning the Use of Nano-Materials in the Automotive Sector. September 2005 http://www.nanoroad.net/download/swot_ai.pdf [abgerufen am 12.06.2006]
nanoRoad 2006	Nano-Material Roadmap 2015. Roadmap Report Concerning the Use of Nano-Materials in the *Aeronautics* Sector. March 2006 http://www.nanoroad.net/download/roadmap_as.pdf [abgerufen am 12.06.2006]
Nanosphere	Nanosphere; http://www.schoeller-textil.ch/default.asp?cat1ID=115&cat2ID=133&pageID=268&emotionstate=0&emotionID=8&langID= [abgerufen am 14.06.2006]
Nanotol	Nanotol; http://www.nanotol.de
Nano-X GmbH 1	Nano-X GmbH 1 http:// www.nano-x.de/html/nano-x.html [abgerufen am 14.06.2006]
Nano-X GmbH 2	Nano-X GmbH 2 http://www.nano-x.de/html/x-formr.html [abgerufen am 14.06.2006]
Nel et al. 2006	Nel, A.; Xia, T.; Mädler, L.; Ning, L.; Toxic Potential of Materials at the Nanolevel. In: Science 311, 622-627 (2006).
Nohynek 2006	Nohynek, G.J.; Nanoparticles and the Skin - A Health Risk for the Consumer?. Beitrag zum BfR Expertengespräch „Nanotechnologie, ihre Produkte und Risiken für den Verbraucher“ vom 28. März 2006. http://www.bfr.bund.de/cm/232/nanoparticles_and_the_scin.pdf [abgerufen am 14.06.2006]
Oberdörster et. al. 2005	Oberdörster, Günther/Oberdörster, Eva/Oberdörster, Jan: Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles. In: Environmental Health Perspectives. 2005 (113) Nr. 7 S. 823-839.
OECD 2005	Report of the OECD Workshop on the Safety of Manufactured Nano-Materials: Building Co-operation, Co-ordination and Communication. Washington D.C., United States, 7th-9th December 2005. http://appli1.oecd.org/olis/2006doc.nsf/43bb6130e5e86e5fc12569fa005d004c/b69b32217944d8a1c125715e0038d403/$FILE/JT03208175.PDF

	[abgerufen am 29.06.2006]
Padycare	Padycare; http://www.texamed.de/tex/neurodermitis.php [abgerufen am 14.06.2006]
Paschen et al. 2003	Paschen, H.; Coenen, C.; Fleischer, T.; Grünwald, R.; Oertel, D.; Revermann, C.; Nanotechnologie. TAB Arbeitsbericht Nr. 92, 2003
Percenta	Percenta; http://nano-products.info/nanotechnologie-leder-versiegelung.php [abgerufen am 14.06.2006]
Peter 2005	Peter, P.; Umwelt- und Gesundheitsrisiken nanotechnologischer Applikationen. ETH Zürich NSSI Nr. 29/2005.
Pilkington Active	Pilkington Active http://www.pilkington.com/resources/pilk_ekbrosch_ansichtspdf.pdf
POLO 2006	POLO Fraunhofer Verbund Polymere Oberflächen http://www.polo.fhg.de/polo_Site.pdf [abgerufen am 12.06.2006]
Protectosil, Dynasylan	Protectosil, Dynasylan http://www.protectosil.com/protectosil/en/easytoclean/downloads.Par.0005.File.tmp/Clean_Einzelseiten.pdf [abgerufen am 12.06.2006]
Royal Society 2004	The Royal Society & The Royal Academy of Engineering; Nanoscience and nanotechnologies: opportunities and uncertainties. July 2004 http://www.nanotec.org.uk/finalReport.htm [abgerufen am 22.06.2006]
Sachtoperse	Sachtoperse: Bariumsulfat Nano-Partikel für PCB-Coatings http://www.sachtleben.de/include/3_7_3_0_DE.html
Sarastro GmbH	Sarastro GmbH; http://www.sarastro-nanotec.com/ [abgerufen am 12.06.2006]
Schmid et al. 2006	Schmid, G. ; Brune, H. ; Ernst, H. ; Grunwald, A. ; Günwald, W. ; Hofmann, H. ; Hrug, H. ; Mayor, M. ; Rathgeber, W. ; Simon, U. ; Vogel, V. ; Wyrwa, D. ; Nanotechnology - Assessment and Perspective. Springer-Verlag, Berlin- Heidelberg 2006
Siegner 2006	Siegner, A.; Neue Nahrungsergänzungsmittel durch Nanotechnologie. Beitrag zum BfR Expertengespräch „Nanotechnologie, ihre Produkte und Risiken für den Verbraucher“ vom 28. März 2006 http://www.bfr.bund.de/cm/232/neue_nahrungsergaenzungsmittel_durch_nanotechnologie.pdf [abgerufen am 14.06.2006]
Steinfeld et al. 2004	Steinfeldt, M.;, von Gleich, A.; Petschow, U.; Haum, R.; Chudoba, T.; Haubold, S.; Nachhaltigkeitseffekte durch Herstellung und Anwendung nanotechnologischer Produkte. Schriftenreihe des IÖW 177/2004. http://www.innovationsanalysen.de/de/download/endbericht_nano_nachaltigkeit.pdf [abgerufen am 27.06.2006]
Sto AG	Sto AG; http://www.sto.de [abgerufen am 12.06.2006]
SusTech	SusTech; http://www.sustech.de [abgerufen am 12.06.2006]
SusTech a	SusTech; Das Biokomposit Nanit®active.

	http://www.sustech.de/biokomposite.htm
SusTech b	SusTech; Partikuläre Systeme – Nanopartikuläres Zinkoxid http://www.sustech.de [abgerufen am 12.06.2006]
SusTech c	SusTech; Das Biokomposit Nanit®active – Wirkung gegen schmerzempfindliche Zähne. http://www.sustech.de [abgerufen am 12.06.2006]
SusTech d	SusTech; Bond-on-Command. Technologie und Anwendungsgebiete. http://www.sustech.de [abgerufen am 12.06.2006]
SusTech e	SusTech; Bond-on-Command. Ferromagnetismus, Superparamagnetische Mikrowellenabsorption. http://www.sustech.de [abgerufen am 12.06.2006]
Swiss Re 2004	Swiss Re; Nanotechnologie. Kleine Teile – große Zukunft? 2004 http://www.swissre.com/INTERNET/pwsfilpr.nsf/vwFilebyIDKEYLu/ULUR-5YNGCZ/$FILE/Publ04_Nanotech_de.pdf/ [abgerufen am 29.06.2006]
TEGO SUN Z 500/800	TEGO SUN Z 500/800; http://www.advanced-nano.com/webapps/adnano.nsf [abgerufen am 14.06.2006]
Tinoderm	Tinoderm; http://www.cibasc.com/index/ind-index/ind-per_car/ind-pc-m.htm [abgerufen am 12.06.2006]
Tinosorb	Tinosorb; http://www.cibasc.com/tinosorb-s_brochure.pdf [abgerufen am 12.06.2006]
VDI 2004	VDI; Technological Analysis - Industrial application of Nano-Materials - chances and risks. Band 54, 2004.
VDI 2006	Luther, W.; Zweck, A.; Nanotechnologie in Architektur und Bauwesen. Innovationsbegleitung Nanotechnologie. Zukünftige Technologien; VDI Consulting Band 62; April 2006. ISSN 1436-5928.
VDI Nachrichten 2006	Ungiftiges kann in Nanoform giftig sein; In: VDI-Nachrichten v. 19.5.2006 http://www.vdi-nachrich-ten.com/vdi_nachrichten/aktuelle_ausgabe/akt_ausg_detail.asp?source=volltext&cat=1&id=28002 [abgerufen am 23.10.2006]
WING 2006	WING (Werkstoffinnovationen für Industrie und Gesellschaft); Wunderwelt Werkstoffe. Neue Materialien verändern unseren Alltag. http://www.fz-juelich.de/wing/datapool/page/6/Wunderwelt_Werkstoffe.pdf [abgerufen am 28.06.2006]
Wolter 2006	Wolter, H.J.; Die Welt der Winzlinge. In: AKTIV – Chemie in Baden-Württemberg. Wirtschaftszeitung. 7/24.6.2006, S. 4-5.
X-Static	X-Static; http://www.x-static.com/index2.html [abgerufen am 12.06.2006]