REVIEW OF NANOMATERIAL AND NANOPRODUCT REGULATION

WORKING GROUP 3 OF THE NANOKOMMISSION

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Contents

1 Preliminary considerations

The present paper on regulation of nanomaterials and nanoproducts was prepared by Working Group 3 of the German Federal Government's NanoKommission in the 2009–2010 dialogue phase. It is the product of discussions that took place over four sessions, along with contributions from a variety of units and organisations.

This paper on regulation presents the current state of debate as of August 2010. Because legislative procedures are currently under way in the European Union (EU), some of the statements made in this paper may no longer be accurate at the time of going to press.

Due to the short time available to it, the Working Group was unable to discuss some specific regulatory issues, including questions relating to liability.

1.1 Purpose of the paper and target audience

The purpose of this paper is to analyse and deliberate on issues relating to the regulation of nanomaterials so as to provide a basis for debates on such regulation. Special attention is given in each case to the question of how rigorously the precautionary principle is applied. In particular, this paper

- presents the objectives of precaution-based regulation of nanomaterials as agreed jointly by the Working Group
- identifies aspects potentially presenting a need for regulation (either in areas where it would be expedient to introduce nano-specific regulation, or based on particular characteristics of nanomaterials that call for regulation) and
- discusses the appropriateness of particular regulatory concepts and instruments.

The paper is aimed at the German Federal Government as the national regulatory authority and as a stakeholder in the EU-wide debate on regulation and in international debates and standardisation processes. In this sense, any statements and recommendations may be applied both to national and to European and international activities, debates and procedures.

Regulation concerning medical applications of nanomaterials and nanotechnologies was excluded from the Working Group's deliberations due to the special methods of assessment that apply in the medical context (risk-benefit considerations).

In the present paper, "regulation" is understood not only in the narrow sense, as a legislative act, but also in its broader meaning which includes secondary legislation and implementation instruments as part of the picture.

1.2 How the paper is organised

The paper is divided into seven sections and three annexes:

- Preliminary considerations
- Definitions of nanomaterials
- Explanation of the precautionary principle
- Examples of existing legislative provisions
- Regulatory instruments
- Concluding remarks
- Abbreviations
- Annexes: Explanation of key concepts (I), List of provisions to be examined (II), Members of the Working Group (III)

With a few exceptions, the sections on the current legislation are structured identically. The first two subsections of each section provide a description of the field covered by the legislation in question and a brief explanation of how nanomaterials are regulated under the existing provisions (status report).

The subsection headed “Deficiencies in existing provisions” sets out the points on which Working Group members agreed. There then follows a brief outline of the divergent opinions among the stakeholders. In the interest of transparency, we show which stakeholder groups or individuals on the Working Group held which positions. Stakeholders that did not express an opinion on a particular issue are given no separate mention.

The subsection “Instruments to eliminate deficiencies in existing provisions” contains details of stakeholders’ suggestions for tackling weak points in the current legislation.

The final subsection in each section presents the conclusions and recommendations of the Working Group. Here too, the consensus positions are presented first, followed by the divergent opinions, identified according to stakeholder group.

1.3 Role of government bodies in the Working Group

As the German Federal Government is the recipient of the NanoKommission’s recommendations, representatives of the various government bodies have a different role to that of the stakeholders in the Working Group. Participants from the Federal ministries and institutions within the ministries’ remit were mandated to provide expertise and advice to support the work of the Working Group. Expert input provided by these individuals does not necessarily represent the official position of the ministry concerned.

The higher federal authorities were also involved in the preparation of this paper on regulation in their capacity as implementing agencies or specialised independent scientific authorities. Their expert opinions are documented accordingly.

2 Definitions of nanomaterials

At the present time there is no general definition of nanomaterials that applies throughout the European Union. Work is, however, currently under way at EU level to produce such a definition. In July 2010 a public consultation on the scientific basis for such a definition[1] was launched at EU level. The European Commission is unlikely to present its initial proposal before the end of the NanoKommission's current dialogue phase.

Below we cite the definitions used in the Cosmetics Regulation (in force) and in the Regulation on Novel Foods (currently being debated) and present the positions of the stakeholders in the Working Group concerning a definition of nanomaterials.

2.1 Definition under the EU Regulation on Cosmetic Products[2]

The following definition is valid under current EU law:

Nanomaterial: '"Nanomaterial" means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.'

2.2 Definition under the EU Regulation on Novel Foods

The Proposal for a Regulation of the European Parliament and of the Council on novel foods (Novel Food Regulation) is still being debated within the EU. According to the position of the Council as of 15 March 2010,[3] the following definition is envisaged, but is not yet in force. It remains to be seen how the legislative process will progress. It is not expected that the Regulation will be passed before 2011.

The term "**engineered nanomaterial**" means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the

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1 Consultation document: Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): Scientific Basis for the Definition of the Term "Nanomaterial"; July 2010

2 Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on Cosmetic Products, OJ L 342 of 22.12.2009, p. 59; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF

3 Position (EU) No 6/2010 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (OJ C 122 E of 11.5.2010, p. 38)

surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

Properties that are characteristic of the nanoscale include:
i) those related to the large specific surface area of the materials considered; and/or
ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.

2.3 Positions concerning a nano-definition

The positions of the different stakeholders and the expert opinions of the higher federal authorities are set out in the following tables.

Stakeholders	How should size be covered in the definition?
German Chemical Industry Federation (VCI)	"Nanoscale" means 1 to 100 nm. The scope of the definition should cover so-called "nano-objects" and their aggregates and agglomerates.[4]
Hermann (Öko-Institut – Institute of Applied Ecology)	Within the meaning of the product register "nanomaterials" shall refer to deliberately engineered materials which have at least one dimension between 0.5 nm and 200 nm (primary nanoparticle), and agglomerates and aggregates derived from such materials.
German Federation for Food Law and Food Science (BLL)	1-100 nm.[5]
Friends of the Earth Germany (BUND)	The definition should encompass all deliberately engineered materials which have a primary particle measuring between 0.3 and 300 nm on average in at least one dimension.[6]
Prof. Scherzberg	I think the proposal of the Federal Institute for Occupational Safety and Health (BauA) and others is preferable because it reflects international debate. However, it might be useful to make provision for an analogous regulation to apply on a case by case basis for larger particles, as in the BUND proposal.
Federation of German Consumer Organisations (vzbv)	The definition should not be framed too narrowly, so we advocate specifying a size of up to 300 nm.

Authorities	How should size be covered in the definition?
Federal Institute for Occupational Safety and Health (BAuA)	The primary particle size must be clearly defined and circumscribed, in other words, upper and lower limits must be stipulated (e.g. 1 – 100 nm). Aggregates and agglomerates should be included in the definition, but without size specification.[7]
Federal Environment Agency (UBA)	See below (additional remarks). From a materials science perspective, nanomaterials are materials < 100 nm with corresponding nano-properties. Based on (eco-) toxicological

[4] Based on the ISO definitions of "nanoscale" and "nano-object".

[5] This corresponds to international conventions (including ISO standards such as DIN EN ISO 27687)

[6] The majority of size-related changes in characteristics that are relevant in terms of toxicology occur at sizes below 200 nm. However, above this size and up to a size of approx. 300 nm at least, new characteristics can occur (affecting bioavailability, for example), that may change the toxicological profile of a material.

[7] If size is not clearly specified, the definition is of no use in regulatory terms. Size is the decisive criterion for determining whether a substance is a nanomaterial.

Authorities	How should size be covered in the definition?
	findings, however, (ability to cross a cell membrane) regulation should also cover particles with a size of up to 300 nm.[8]

Stakeholders	Should "nano-properties" be included in the definition and if so, which?
Prof. Scherzberg	Properties should not be included in the definition, but be identified by means of (where possible nano-specific) tests.[9]
German Chemical Industry Federation (VCI)	"Nano-properties" per se are non-existent.
German Federation for Food Law and Food Science (BLL)	Where appropriate, include a description of nano-specific physico-chemical properties that are different from the properties of the non-nano form of the same material.
Friends of the Earth Germany (BUND)	Materials which have an average size larger than 300 nm should be included if they have new size-specific properties.[10] [11]

Authorities	Should "nano-properties" be included in the definition and if so, which?
Federal Institute for Occupational Safety and Health (BAuA)	Properties should not be included in the definition, but be identified by means of (where possible nano-specific) tests.[12]
Federal Environment Agency (UBA)	See below (additional remarks, second phrase of sentence 2), reference to (general) nano-specific properties, to avoid creating exceptions to the nano-definition.

Stakeholders	How should aggregates and agglomerates be included in the definition?
German Chemical Industry Federation (VCI)	The scope of the definition should encompass aggregates and agglomerates of so-called nano-objects.
German Federation for Food Law and Food Science (BLL)	No, not necessarily.[13]
Friends of the Earth Germany (BUND)	Aggregates and agglomerates of nanomaterials should also be included in the definition.[14]
Prof. Scherzberg	I believe it is necessary to include aggregates and agglomerates in

[8] There are nanomaterials which are smaller than 1 nm. Then, however, one is in the realm of "normal" molecules, and so a second sentence should exclude certain areas from the nm definition.

[9] Including properties in the definition makes it unnecessarily complicated. The definition should be kept as general as possible. Properties are not included in the definition of substances under REACH. Substances are defined solely according to their chemical composition.

[10] One could also approach the definition the other way round, taking nano-functionalities (in other words nano-properties) as the starting point, and then the size range at which these occur. Anything that possesses a new functionality at a size of, say, less than 500 nm (or 1000 nm) and more than 1 nm (or a known functionality that is particularly enhanced at this size), would then be deemed a nano(material).

[11] It is not possible to list here all the properties that are typical of nanomaterials. Rather, one could list physical and chemical parameters and test whether, on a case by case basis, a property of a material at a particular size differs from larger particles that have the same chemical composition. If this is the case, the material in question should be considered a nanomaterial within the meaning of the legislation. Test parameters would include physico-chemical properties such as size, shape, surface structure, polarity, etc., but also other parameters such as absorption, distribution, metabolism, excretion, etc.

[12] Including properties in the definition makes it unnecessarily complicated. A definition should be kept as general as possible. Properties are not included in the definition of substances under REACH. Substances are defined solely according to their chemical composition.

[13] The subject of the definition should be isolated nanoparticles; agglomerates and aggregates can be assessed on the basis of the given application.

[14] As a precautionary measure, aggregates and agglomerates of nanomaterials should be included within the meaning of the definition, as it is well known that they may possess similar properties to those of their primary particle.

Stakeholders	How should aggregates and agglomerates be included in the definition?
	the definition.

Authorities	How should aggregates and agglomerates be included in the definition?
Federal Institute for Occupational Safety and Health (BAuA)	Aggregates and agglomerates should be explicitly included in the definition.[15]
Federal Environment Agency (UBA)	See below (additional remarks). Aggregates and agglomerates should be included.

Stakeholders	Should there be a single definition or a definition in each legislative text?
German Chemical Industry Federation (VCI)	If possible there should be a single, uniform definition.[16]
German Federation for Food Law and Food Science (BLL)	Definitely only one definition![17]
Friends of the Earth Germany (BUND), Federation of German Consumer Organisations (vzbv), Hermann (Öko-Institut)	Ideally there should be only one definition so as to prevent a situation arising where a material is dealt with differently in different legislative provisions. It may, however, transpire in the course of the more detailed debates on specific legislation that there are good and well-founded reasons for using different definitions of nanomaterials in different areas of application.
Prof. Scherzberg	It may already be too late to establish a uniform definition (see footnote for BAuA)

Authorities	Should there be a single definition or a definition in each legislative text?
Federal Institute for Occupational Safety and Health (BAuA)	The most desirable outcome would be to have a single, generally applicable definition to which one could refer in all the different legislative provisions. In practice this is unlikely to be achievable.[18]
Federal Environment Agency (UBA)	A single definition of "nano" would certainly be helpful. To achieve this, various exemptions could be established depending on the area of application.[19]

Stakeholders	Additional remarks concerning the definition
German Federation for Food Law and Food Science (BLL)	We refer to the existing legally valid definition contained in the EU Cosmetics Regulation – '"Nanomaterial" means an insoluble or biopersistent and intentionally manufactured material with one or

[15] Agglomerates are not very stable and the primary particles can exert an effect on humans and the environment. In addition, aggregates and agglomerates still possess nano-specific properties due to their nano-structure (large surface area) and should therefore be investigated specifically.

[16] To facilitate compliance with the relevant legislation by businesses, it is important to avoid divergence between definitions. Having several different definitions creates uncertainty and undermines confidence.

[17] Failure to ensure a uniform definition can have disastrous consequences in terms of substance classification (e.g. TiO2 as a constituent for cosmetic applications, or TiO2 as a constituent in plastics) and in terms of communication.

[18] The Cosmetics Regulation already contains a specific definition that is not applicable in other areas of law as it is based on properties. This is also the case with the definition envisaged for the Novel Food Regulation.

[19] This allows a degree of flexibility while ensuring that the definition is fundamentally consistent. This provides the possibility of creating a broader or narrower area of application depending on the purpose of regulating on this matter in a given area of law.

Stakeholders	Additional remarks concerning the definition
	more external dimensions, or an internal structure, on the scale from 1 to 100 nm.'[20]
Friends of the Earth Germany (BUND), Federation of German Consumer Organisations (vzbv)	The definition should encompass all materials that have new, size-specific properties and may therefore have a different toxicological profile.[21]

Authorities	Additional remarks concerning the definition
Federal Institute for Occupational Safety and Health (BAuA)	Proposal of the Federal Office for Chemicals (BfC) for a possible definition under REACH: nanomaterials are deliberately engineered substances in nanoscale form which have one, two or three external dimensions at the nanoscale, meaning in the size range between 1 – 100 nm, and any structures derived from them.[22]
Federal Institute for Risk Assessment (BfR)	Nanomaterials are substances deliberately engineered in the nanoform and which have one, two or three external dimensions in the nanoscale, meaning a size range between 1 – 100 nm, and any structures derived from them.
Federal Environment Agency (UBA)	"Nanomaterials are engineered materials which have one, two or three dimensions in the size range 300 nm or smaller, and their aggregates and agglomerates." Organic and inorganic molecules are not included in this definition unless they possess (novel) properties as a result of the nano-dimension. The definition does, however, encompass materials in which substances in the nanoscale ≤ 300 nm exceed 5 per cent by weight.[23]

[20] Source: European Parliament legislative resolution of 24 March 2009 on the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast) (COM(2008)0049 – C6- 0053/2008 – 2008/0035(COD))

[21] The aim here is to take account of the precautionary principle.

[22] BfC strategy: nano definition (chemical composition + particle size), additional nano-specific assessment programme

[23] The loose term "novel properties" needs to be more clearly defined. (The properties in question in a sense have simply been newly discovered, and in fact in some cases have been known for some time. For this reason, the definition must make it clear that these are properties that are different from those of the material in its bulk form. This is more problematic in the case of nanomaterials for which no bulk form exists.)

3 The precautionary principle – an explanation

3.1 Working definitions relating to the precautionary principle

Given that Working Group 3 is concerned with issues relating to regulation, the considerations in this paper are guided by the definitions set out in the Communication from the Commission on the precautionary principle[24] as integrated into most legislative texts in German law and as implemented and applied in both German and European legal practice – even though there are separate, legally binding definitions that apply in specific areas of regulation. Divergent definitions are discussed separately later in this paper[25] (concerning the various concepts and terminology see also: *SRU, Umwelt und Gesundheit – Risiken richtig abschätzen, 1999, p. 49 ff.*). In this case the key feature of this approach is that it means that the concepts of hazard and risk are interpreted not according to their scientific definitions, but according to their legal definitions. They serve to legitimise action on the part of the state, in other words to determine whether the legislator must or can take action. Action on the part of the legislator must, however, always be distinguished from action on the part of the administration enforcing the law.

Hazard: A hazard is present when there is sufficient likelihood that, if an objectively expected event is allowed to take place unrestricted, it will cause harm, in other words significant impairment of an asset that is protected by law. The concept of hazard here is relative. The greater the potential harm or consequences of harm, or the more important the protected resource under threat, the less knowledge is required regarding the degree of likelihood attached to the hazard.

Risk: If the occurrence of harm is possible or cannot be ruled out, this is referred to as a risk. While a hazard assumes sufficient likelihood of harm occurring, the mere possibility of harm occurring is enough for a risk to be deemed present. The concept of “risk”, then, in contrast to “hazard”, specifically covers cases characterised by uncertainty and subjective lack of knowledge of individual factors or cause-and-effect relationships.

Residual risk: Residual risk is present where the possibility of an adverse event occurring in the future can be ruled out in practical terms, but not with absolute certainty. This therefore includes instances where the likelihood of an event occurring and the potential for harm are known, but are so small that while harm is theoretically possible, it can effectively be ruled out. It also includes, however, instances where the potential harm and/or probability of harm actually occurring are completely unknown.

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[24] COM (2000) 1 final.

[25] Definitions of key concepts and terminology can be found in Annex I.

Risk identification: Risk identification involves gathering scientific data, describing potential risks using established scientific methods, taking into account gaps in knowledge and uncertainties, and estimating risk on the basis of the available facts. For this reason, the terms risk estimation or scientific risk assessment are sometimes used instead of risk identification.

Normative risk assessment: Normative risk assessment is where the results of the scientific risk assessment are used as the basis for evaluating the risk in a political light. A decision is then reached as to whether the potential risk is acceptable or not.

Risk management: Risk management involves weighing up strategic alternatives to decide on appropriate precautionary measures and the form these should take.

3.2 Conceptions of the precautionary principle

In situations where there is uncertainty and/or lack of knowledge regarding the consequences of new technologies, substances, products or production processes, the question arises whether the government can legitimately intervene to protect the environment and human health. As set out by the European Commission in its "Communication on the precautionary principle" (COM (2000) 1 final), the precautionary principle can serve as a guide in this regard. Using the Commission document as a basis, we will elucidate the precautionary principle below.

The precautionary principle is now firmly established as a component of the constitutional goal of environmental protection set out in Article 20a of the Basic Law for the Federal Republic of Germany (Grundgesetz, GG), of the corresponding aim of the European Union set out in Article 191 (2), 2nd sentence of the Treaty on the Functioning of the European Union (TFEU), and as a component of the principle of sustainable development in international law (c.f. Principle 15 of the Rio Declaration on Environment and Development). It is therefore reasonable to assume that it is recognised as a general principle of law (for more detail see: Calliess, *Rechtsstaat und Umweltstaat*, 2001, p. 179 ff.).

When discussing regulation on the basis of the precautionary principle, a distinction must be drawn between two levels of decision-making: that of the legislator on the one hand, and that of the public administration and the jurisdiction on the other. The task of regulating by enacting legislation falls to the legislator. If the legislator has established precautionary provisions as standard, then it falls to the relevant enforcement authorities to implement, for each individual case, the provisions specifying how the precautionary principle is to be applied in the given context. The discussion in the following sections focuses principally on issues that are critical in legislative terms.

3.2.1 The need for the precautionary principle to legitimise government action

In principle, government institutions must take preventive action by virtue of their duty of protection laid down in Article 2 (2) GG and Article 20a GG, in Article 191 (2), 2nd sentence of the TFEU and in Article 3 of the Charter of Fundamental Rights of the European Union, if a hazard (in the legal sense) to human health and life or to the environment is present. A hazard is deemed to be present if, on the basis of the available scientific knowledge, and taking into account forecasts and empirical knowledge, there is sufficient probability of harm occurring. The greater or more serious the potential harm, or the more important the protected asset under threat, the less knowledge is required concerning the degree of probability of harm occurring. The abstract possibility of harm occurring is not sufficient in itself, however, for assuming that a hazard is present.

The fact that a technology, substance or product is new does not in itself constitute grounds for initiating government measures to deal with uncertainty. In future too, trial and error may continue to be the method of choice in many cases when faced with uncertainty. This method is only suitable, however, for assessing small and largely reversible steps.

Trial and error is not acceptable as a means of exercising the protective function of the state if, on the other hand, an irreversible impact, or extensive or severe harm to protected assets may be expected to occur.

In situations – as is often the case with innovations – where there is a lack of experimental and scientific evidence establishing a connection (causality) between a technology, substance, product or production process and an adverse effect, it is not possible to assume that there is sufficient probability. To enable the state to take action in such situations, the complex task of risk prevention has been introduced alongside that of hazard control. In this context the precautionary principle plays a key role. Correspondingly, the concept of risk (in the legal sense) is the focus of attention here rather than that of hazard. This is understood to mean a situation in which harm is merely possible; in other words, where there are abstract grounds for concern that harm might occur. There must therefore be “indications through preliminary objective scientific evaluation that there are reasonable grounds for concern” (COM (2000)1 final).

Ultimately, then, this means that for the purposes of risk prevention it is legitimate for the state to take measures if there is merely an abstract possibility, rather than sufficient likelihood, of harm occurring. As a result, the point at which intervention becomes permissible is brought forward, enabling the government to take action before the hazard threshold is reached. The threshold for action in cases characterised by uncertainty, or the absence of conclusive evidence, under the law is reached when the possibility of a future adverse event occurring can be ruled out in practice, albeit not with absolute certainty. In circumstances such as this, one can assume – ultimately based on

a value judgement – that the residual risk is acceptable (for a more detailed discussion see: Calliess, *Rechtsstaat und Umweltstaat*, 2001, p. 153 ff.).

3.2.2 Scope and grounds for invoking the precautionary principle

According to Article 20a GG and Article 191 (2), 2nd sentence TFEU, the precautionary principle underpins both German and European Union environment policy. It has been implemented and transposed into specific contexts by numerous legislative acts in Germany and in the EU. The European Court of Justice even explicitly considers it to be a general principle of EU law. This view also underpins the Communication from the European Commission, according to which the precautionary principle basically has the effect of legitimising government measures in any situation where there is uncertainty – in other words, it is not restricted to environmental protection, but also extends to protection of human health and consumer protection. According to this view, the precautionary principle may be applied particularly in cases where the available scientific evidence is insufficient, inconclusive or unclear, but where there are indications through preliminary objective scientific risk assessment that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection prescribed within the EU (COM (2000) 1 final, p. 10. The precautionary principle thus makes it legitimate for the government to take action where a risk to the environment or to human health – in other words an abstract concern – is present. Alongside short and medium-term risks, long-term risks affecting the well-being of future generations are also taken into account in this context (COM (2000) 1 final, p. 8).

3.2.3 Conditions for recourse to the precautionary principle

In order to avoid unwarranted – and legally questionable – application of the precautionary principle, the grounds for invoking the precautionary principle must be established. To do this, a distinction needs to be drawn between two consecutive steps: risk identification (also referred to as risk estimation or scientific risk assessment) and normative risk assessment.

The purpose of risk identification is to gather all the relevant information as exhaustively as possible. Its aim is to establish and to explore the source and extent of the potential risk in a given context with a view to providing an objective and comprehensive scientific assessment allowing conclusions to be drawn regarding the existing objective evidence, the gaps in knowledge and the scientific uncertainties (COM (2000) 1 final, p. 16). This is followed by normative risk assessment to determine whether, on the basis of the results of the risk identification process, a risk (in the legal sense) is acceptable or not. Under the rule of law, assessment of risk is not solely a matter of scientific expertise. Rather, the final assessment must be made by the agencies of the state that carry the constitutional authority, and ultimately also the responsibility, for doing so. The role of scientific expertise, therefore, is to advise or make recommendations.

While risk identification can therefore be classified as the gathering of evidence by exhaustively researching all available sources, normative risk assessment involves the weighing and prioritising of the facts and mechanisms, of the gaps in knowledge and the uncertainties, and of the concerns of individuals versus those of society as a whole. Consequently, risk identification and normative risk assessment determine whether there are legitimate grounds for state intervention. An unclear outcome, in other words where uncertainty cannot be eliminated and it is not possible to identify clearly the grounds for recourse to the precautionary principle, raises the question: in such a situation – referred to as a *non liquet* – with whom does the burden of proof lie? To take due account of the preventive thrust of the precautionary principle, the burden of proof in this instance is reversed to enable the legislator to make provisions on the basis of the precautionary principle. Blanket reversal of the burden of proof, however, is not possible on epistemological grounds; nor is it desirable in terms of the prospects of new technologies, or permissible on the basis of considerations relating to the rule of law. In *non liquet* situations, then, under the rule of law the precautionary principle can only have the effect of a rebuttable presumption of hazardousness. Hence, neither the originator of the risk nor the legislator needs to provide positive proof of the possibility or impossibility of adverse effects occurring. Instead, it is sufficient if the established and reported facts provide sound indications that there are potential risks and potential hazards. If there are reasonable grounds for concern on this basis, responsibility for rebutting the presumption of hazardousness and disproving the grounds for concern falls to the originator of the risk. Here it suffices if facts concerning the potential adverse effect are established and presented which show that there is a reasonable likelihood that the adverse effect cannot arise (for more detail on the rebuttable presumption of hazardousness, see Calliess: *Rechtsstaat und Umweltstaat*, 2001, p. 223 ff.). The fact that recourse to the precautionary principle can also be triggered in the case of a *non liquet* provides no information as to what measures the legislator will choose and what form these will take.

3.3 Options for action – possible precautionary measures

Once decision-makers have concluded that there are grounds for recourse to the precautionary principle, they must then decide how to act. All interested parties should be involved as fully as possible in the decision-making process, and the procedure must be as transparent as possible (COM (2000) 1 final, p. 4). The potential consequences of not taking action must also be taken into consideration in the decision-making process. Accordingly, absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure cannot be used to justify delayed action. In deciding whether measures should be put in place, due account should also be taken of credible views of minority fractions of the scientific community. If a decision is made to wait for new scientific data, the reasons for this decision must be given (COM (2000) 1 final, p. 17 f.). In all

cases, as a precautionary measure new scientific information concerning the substances, products or technologies in question must be elicited or generated through monitoring.

If action is deemed appropriate, a wide range of options is available. While upholding the principle of economic freedom that ensures opportunities for innovation, the choice of action must be guided by the abstract level of concern, which in turn needs to take into account the potential extent of any harm. In this regard it can be helpful to work with formulae along the lines of “the more/less... the better/worse”, based on the criteria indicating concern or no cause for concern developed by the NanoKommission in its first dialogue phase.

Options that might be considered include not only legally binding measures, but also research funding, public information campaigns on the potential negative consequences of a product or process, or making recommendations (COM (2000) 1 final, esp. p. 4). Legally binding measures that might come into consideration range from information, reporting and labelling obligations to rules relating to liability (including liability regardless of fault) and mandatory prior authorisation requirements (prohibition of activities unless authorised). If a mandatory prior authorisation requirement is introduced, measures under the precautionary principle could include exposure limits. A provision could be included stipulating that the manufacturer or user must provide information relating to any uncertainties concerning hazards associated with a substance, product or process, and elicit or generate the scientific evidence demonstrating that a substance, product or process is non-hazardous (permitted under COM (2000) 1 final, p. 25). The “barrier” represented by the prior authorisation requirement is lifted only after such evidence has been produced, thereby permitting the product’s placement on the market. As was also the case in connection with justifying recourse to the precautionary principle in a *non liquet* case, systematic reversal of the burden of proof would not be appropriate. Instead, it would make more sense to assign the burden of proof in accordance with the considerations relating to rebuttable presumption of hazardousness. Hence, neither the applicant for authorisation, nor the administrative authorities would be required to provide positive proof. This would also give the state authorities the option of taking precautionary action in cases where uncertainty cannot be completely ruled out.

3.4 Requirements for precautionary measures

If the public decision-makers take action, any measures must be consistent with the fundamental principle of economic freedom, proportional to the chosen level of protection, non-discriminatory in their application, and consistent with similar measures already taken. In addition, the costs and benefits of action or inaction must also be taken into account in the decision-making process. Any measures taken must be reviewed as soon as new scientific data become available (COM (2000) 1 final, p. 4 f.). In this way the precautionary principle can be an effective instrument for balancing the opportunities and risks of innovation, thus enhancing acceptance.

3.5 Conclusions concerning the precautionary principle

Working Group 3 of the NanoKommission bases its understanding of the precautionary principle on the Communication from the European Commission on the precautionary principle (COM (2000) 1 final) and the definition by the European Court of Justice.

The precautionary principle plays an important role in the introduction and use of nanotechnologies, especially as knowledge is largely lacking with regard to any hazards they may pose. The precautionary principle allows the opportunities and risks posed by technologies to be systematically identified and assessed. Decisions concerning their regulation can thus be prepared in such a way as to ensure that the development of these technologies is supported and potential risks are limited at an early stage.

Applying the precautionary principle is both necessary and justified in the context of regulating nanomaterials, as there are scientific indications (grounds for concern) that the use of nanomaterials may have adverse effects on human life and on the environment. In this regard nanomaterials are no different from other chemicals. This gives grounds for an abstract concern with regard to nanomaterials, as for chemicals in general (see also section 5.1).

Working Group 3 of the NanoKommission believes that the Criteria indicating concern or no cause for concern developed by the NanoKommission in its first dialogue phase (Federal Environment Ministry, Report and Recommendations of the German Federal Government's NanoKommission for 2008, p. 42 ff.) are a good starting point for developing criteria to establish the rebuttable presumption of hazardousness.

4 Examples of existing legislative provisions

4.1 REACH

4.1.1 Scope

Regulation (EC) No 1907/2006 (REACH) governs the registration and evaluation of chemical substances on their own, in mixtures and in articles. “Substances of very high concern” are subject to an authorisation requirement under REACH and the Regulation also allows restrictions to be imposed on such substances.

The Regulation is based on the principle that persons “responsible for a substance”, in other words manufacturers, importers and downstream users (commercial users of substances and mixtures), must ensure that the substances they manufacture, place on the market or use have no adverse effects on human health or on the environment. The provisions of REACH are based on the precautionary principle (Article 1 (3) REACH).

The regulatory approach adopted in REACH is based on economic actors assuming responsibility for their own activities. They must gather the information necessary to identify and assess risks, and identify appropriate risk reduction measures. In addition, a manufacturer or importer manufacturing within the EU or importing into the EU more than one tonne of a substance annually (the “registrant”) must submit a registration dossier to the European Chemicals Agency (ECHA) in Helsinki. The dossier submitted by the registrant must cover the whole life cycle of the substance. For volumes of 10 tonnes or more per year, the information to be provided by the registrant as standard is more extensive, and a chemical safety report must also be submitted. For annual volumes in excess of 100 and 1000 tonnes per registrant, the standard information requirements increase again.

The deadline for submitting a registration dossier depends on whether the registrant can take advantage of transitional provisions. This applies in the case of “phase-in substances” as defined in Article 3 (20) REACH. For “non-phase-in substances” mandatory registration applies with immediate effect, while transitional deadlines for registration apply for phase-in substances. The final transitional deadline is set according to annual tonnage per registrant and particular categories of hazard, where these are known.

The uses of a substance, and hence also in principle the uses of a substance in the nanoscale form, must be described in the registration dossier and chemical safety report irrespective of quantity. Details must be given showing that any risks associated with the use of a substance are “adequately controlled”. The “fundamental obligation” of persons responsible for a substance referred to here applies both to registrants (Article 14 (6) REACH) and to “downstream users” (Article 37 (5) REACH). The latter must ensure that the risk management

measures set out in the registration dossier are applied in their sphere of responsibility. For any use of a substance outside the conditions described by the registrant, the downstream user must check whether he is required to produce his own chemical safety report in accordance with Annex XII (Article 37 (4) REACH) and inform the ECHA accordingly (Article 38 REACH). The same applies to any intended use the downstream user's supplier advises against.

To comply with the "no data, no market" principle (Article 5 REACH), a substance may only be manufactured or placed on the market if the registration dossier includes appropriate information on risks.

For the purpose of identifying risks, registrants have an obligation to gather **all** available relevant information (Annex VI[26]) and use it to assess whether any substance-related risks are "adequately controlled" throughout the whole life-cycle of the substance in accordance with the fundamental obligation laid down in the provisions on substances (Article 14 (6) REACH). In some cases it will be necessary to generate new data,[27] and this may include undertaking tests in addition to those required as standard in accordance with Annexes VII to X. Annexes VII to X do not at present set out nano-specific requirements. Responsibility for deciding which nano-specific data are necessary in order to comply with the requirements of REACH has hitherto rested with registrants.

All the information obtained is then used to make a hazard assessment in accordance with Annex I and must be documented in the registration dossier. Responsibility for ensuring the quality and completeness of the data gathered and assessment of the information lies with the registrant as the primary person responsible for the substance.

As a rule, the content of the registration dossier is not inspected by the authority. The provisions of REACH stipulate, however, that a minimum of 5% of the dossiers must be checked by the authorities for compliance ("Dossier evaluation"). Regardless of this, in the course of the substance evaluation the authorities may conclude that the information provided is insufficient and require the registrant to submit additional information. Such information may be supplementary to the information required under Annexes VII to X.

Irrespective of the registration procedure, REACH offers a means of subjecting substances of very high concern to an authorisation procedure or of imposing Community-wide restrictions (on a specific use or uses) of such substances.

Closely tied to REACH are the provisions on classification and labelling of hazardous substances under the "CLP Regulation" (Regulation (EC) No 1272/2008).

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[26] Step 1 (excerpt): The registrant should also collect all other available and relevant information on the substance regardless whether testing for a given endpoint is required or not at the specific tonnage level.

[27] Step 4 (excerpt): In some cases the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.

4.1.2 Regulation of nanomaterials under REACH

Nanomaterials are chemical substances and as such are covered in principle by the provisions of REACH. As for all other substances, a registration dossier must be prepared if volumes in excess of one tonne per year are to be manufactured or imported. In addition, for annual volumes exceeding 10 tonnes, a chemical safety report must be submitted. The uses described in the registration dossier, and therefore in principle also the uses of a substance in the nanoscale form, must be documented in the registration dossier and in the chemical safety report irrespective of the tonnage.

The obligation to prepare a safety data sheet for products classified as hazardous in accordance with Directive 67/548/EEC also applies regardless of tonnage, as do the classification and labelling obligations under the CLP Regulation and mandatory notification to the European classification and labelling inventory by the end of 2010.

The procedure for authorisation under REACH is discussed in Section 5.1.2.

To ensure that the provisions of the REACH Regulation are properly applied in the case of nanomaterials, the European Commission launched three REACH Implementation Projects on Nanomaterials (RIPoN) in June 2009. The three projects, which include stakeholders from industry, environmental organisations and trades unions, are aimed at drawing up recommendations on substance identification, information requirements, testing strategies and substance safety assessment for nanomaterials. These recommendations could result in amendments to the ECHA Guidance documents, but could also include proposals for amendments to the text of REACH or its Annexes. The RIPs on Nanomaterials are expected to conclude sometime between autumn 2010 and spring 2011. It is then up to ECHA to decide whether and when to recommend changes to the REACH guidance documents on the basis of the findings of the RIPs.

4.1.3 Current debate on the regulation of nanomaterials under REACH

Substance identity of nanomaterials

The key starting point for determining obligations under REACH is the definition of a substance set out in Article 3 (1) REACH. The definition here is as follows: “Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used...”

This definition of a substance also applies in principle for nanomaterials. When identifying a substance, it must be clarified whether a given nanomaterial is to be regarded

a. as a substance in its own right, or

b. as a specific physical form of a substance.

When deciding this, the registrant must take into account the provisions of Article 3 and Annex VI (2) of REACH, in conjunction with the ECHA Guidance documents. Neither REACH nor the ECHA Guidance documents, however, lay down binding requirements specifically for substances in the nanoform. The issue of how to distinguish between the bulk material and nanomaterial, and between the various nanoforms of a material, is currently being debated at EU level within RIPoN 1.

If, in the light of examination, a given nanomaterial is deemed to be a substance in its own right, it must be registered separately. If, on the other hand, the nanomaterial is deemed to be a specific physical form of a substance, the registrant must produce a dossier in which the risks are identified separately for the nanoscale and the non-nanoscale (bulk) form of the substance.

Evaluation of the data published so far by the ECHA on the substances (pre-) registered to date reveals that some nanomaterials have been classified by the registrant as substances in their own right and explicitly (pre-) registered as separate substances “in nanoform”. It is not yet clear whether nanomaterials are covered in the rest of the registration dossiers so far submitted. A whole range of substances which are also used in the nanoscale form have been pre-registered with the ECHA. They can therefore take advantage of the transitional registration deadlines.

Information requirements for nanomaterials

There are no provisions currently in place setting out nano-specific information requirements. As a result, uncertainty prevails both in the economic context for persons responsible for substances, and for the authorities evaluating them.

Taking advantage of transitional provisions

Depending on the substance identity assigned to a nanomaterial under REACH, different legal provisions apply. These have a direct effect on the registration deadline and thereby also on how any gaps in knowledge are to be filled.

If a given nanomaterial is identified as a substance in its own right, the registrant can only take advantage of the transitional provisions if the nanomaterial is a “phase-in substance”. This means that the nanomaterial must already be listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). If, on the other hand, a nanomaterial is not deemed to be a separate substance, but a specific physical form of another substance, it is sufficient for this substance to be a “phase-in substance” in order to benefit from the transitional regime.

In the case of some nanomaterials, separate registration dossiers have already been submitted to the ECHA, and other substances with nanoscale forms have been pre-registered, so they have been able to benefit from the transitional provisions for phase-in substances.

4.1.4 Deficiencies in the existing provisions

Based on the existing provisions on nanomaterials under REACH described above, and on the issues currently under debate as previously outlined, there is a need for clarification with regard to implementation of the precautionary principle. The Working Group has identified the following deficiencies:

- When registering a substance, there is currently no explicit requirement to carry out nano-specific tests or provide data on whether a substance is on the nanoscale. Indeed, the provisions appear inadequate in terms of ensuring consistent identification of nanoscale substances and their uses. To rectify this, the meaning of nanomaterials under REACH first of all needs to be defined.
- Test procedures need to be clarified in more detail at OECD level with a view to meeting the requirements on provision of information and complying with risk identification procedures.
- There is currently no evidence base for assessing whether or not the data on nanomaterials in registration dossiers already submitted are meaningful. It is also unclear how substances in the nanoscale are covered in the registration of the bulk form of materials and what nano-specific data are being submitted in this regard.
- If the nanoscale form of a substance is not deemed to be a different substance from its bulk counterpart, consideration needs to be given to how to deal with situations where a downstream user produces a nanoform of the material from the bulk material, but the manufacturer of the bulk material has not included the nanoform in his registration dossier. One possibility might be to amend the provisions limiting the obligations of downstream users compared to those of registrants set out in Article 37 ff. in conjunction with Annex XII of REACH for the case of nanomaterials.[28]
- Moreover, in the case of nanomaterials it is possible to take advantage of transitional registration deadlines for phase-in substances, despite the fact that in some instances these may be new forms of a substance about which,

[28] The obligation to produce a separate Safety Data Sheet (SDS), for example, does not apply if the volume of a substance used by a downstream user is less than 1 tonne per year, or if the registrant manufactures or imports less than 10 tonnes per year. The conditions set out in Article 39 REACH on the application of downstream user obligations in accordance with Articles 37 and 38 REACH also mean that in cases where the bulk material does not have to be classified as hazardous, but the nanomaterial might possess hazardous properties within the meaning of the CLP Regulation, these obligations do not apply. Even where downstream users have an obligation to produce an SDS, there is an additional deficiency in that there are no standard requirements regarding the data to be provided. As information on the bulk form of a substance is not necessarily transferable to the nanomaterial, the need to require separate data provision is all the greater. Overall, in cases where the downstream user produces a nanomaterial from the bulk material and is not considered the manufacturer, the information required under Articles 37 and 38 REACH is less extensive that required for registration. Amendment of these provisions may be called for.

in contrast to the bulk form, no empirical knowledge exists. This presents problems in terms of the precautionary principle.

- The tonnage bands under REACH should also be reviewed; these currently provide for a general registration obligation (for volumes of more than 1 tonne per registrant per year), but also set out specific requirements for data provision in each band.

Friends of the Earth Germany (BUND), the Federation of German Consumer Organisations (vzbv), the Institute for Applied Ecology (Öko-Institut) and Professors Calliess, Scherzberg and Führ also consider the following to be deficiencies in the current provisions:

- The limit of 0.1 percent by weight for "substances in articles" appears inappropriate as nanomaterials can exert specific effects at even smaller concentrations.
- As a matter of principle, Annexes IV and V (Exemptions from the obligation to register) should not include substances in the nanoform.[29]

4.1.5 Instruments to eliminate deficiencies in the existing provisions

It is necessary to amend the REACH Regulation and the ECHA Guidance documents to include nano-specific provisions and information requirements.

A key part of this will be amending the Regulation to include a definition of nanomaterials.

For substances on the nanoscale, the requirements relating to provision of information under REACH should be expanded to include nano-specific information.

Requirements concerning the data to be provided when registering substances under REACH are tied to the annual volume manufactured or imported by the registrant. In the case of nanomaterials even the use of minute amounts can give grounds for concern. For this reason, the volume (tonnage) threshold concept currently in use must be adapted if it is to be applied to nanomaterials. Nano-specific chemical safety assessment and production of a chemical safety report should therefore be compulsory at a lower volume threshold than 10 tonnes per year. Some participants in the Working Group call for the volume threshold to be set at less than one tonne per year.

The long transitional deadlines for registration of phase-in substances laid down in Article 23 of REACH should not apply to substances on the nanoscale. This would not be compatible with the precautionary principle. In order to ensure continuity of manufacturing, importation and marketing, however, a deadline should be set by which all substances in the nanoscale already on the market must be registered. A practical, albeit relatively long deadline would be 1 June 2013 (this is the current registration deadline for medium-tonnage phase-in

[29] In the case of carbon, graphite has already been removed from Annex IV because it can occur in nanoscale form.

substances). Some Working Group participants would like to see an earlier registration deadline put in place.

4.1.6 Conclusions and recommendations

In principle, the regulatory approach and instruments provided for under the REACH Regulation (registration, dossier evaluation, chemical safety assessment, risk assessment, risk reduction measures) are suitable for regulating substances on the nanoscale. To implement the precautionary principle, however, the text of the Regulation needs to be amended to include nano-specific provisions, with a view to providing guidance for registrants to fulfil their responsibilities in relation to substances and thereby also establishing criteria by which the authorities can monitor compliance.

When it comes up for revision in 2012, therefore, some of the provisions of REACH should be amended to include the specific requirements of nanomaterials. The REACH Annexes, however, should be brought up to date and amended as soon as possible in the light of new research findings concerning nanomaterials. Likewise, revision of the ECHA Guidance documents should be undertaken as soon as possible to include clarifications and instructions on implementing the provisions of REACH in the case of nanomaterials.

Priority is given to the following amendments:

- Introduction of a definition (this enables nanomaterials to be clearly identified and included in the definition of substance in the Regulation)
- Adjustment of requirements for provision of data on substances in the nanoscale
- Further review and, where appropriate, adjustment of the OECD testing methods and strategies to establish nano-specific toxic properties for human health and for the environment within the OECD context
- Provisions to incorporate nano-specific information into Safety Data Sheets
- Adjustment of transitional deadlines for the registration of substances in the nanoscale
- Lowering of the tonnage thresholds for a nano-specific assessment programme and chemical safety reports based on it.

Other, secondary amendments not listed here will also need to be made in the course of the Revision of REACH and its Guidance documents.

The provisions of the CLP Regulation will also need to be reviewed in a similar fashion to establish whether there is a need to make adjustments.

In the view of BUND, vzbv, the Öko-Institut and Professors Calliess, Scherzberg and Führ, the following additional points should also be considered:

- Treating nanomaterials as new substances (non-phase-in substances) as a matter of principle

- Lowering the 0.1% threshold for nanomaterials in the provisions on substances in articles
- Establishing criteria that enable differentiation of nanomaterials which have the same chemical composition but different properties and may need to be registered as separate substances
- Excluding the nanoforms of substances listed in Annex IV and V from the provisions on exemptions.

According to BUND, where a substance in the nanoscale is not deemed to be a separate substance from its bulk counterpart, the downstream user who produces a nanosubstance from the bulk form of a material must be considered to be the manufacturer within the meaning of REACH.

4.2 Health and safety in the workplace

4.2.1 Scope

Activities involving nanomaterials in the workplace are covered by the German Occupational Health and Safety Act (*Arbeitsschutzgesetz – ArbSchG*) and in particular by the German Hazardous Substances Ordinance (*Gefahrstoffverordnung – GefStoffV*) and the set of Technical Rules for Hazardous Substances governing its implementation in practice (*Technische Regeln für Gefahrstoffe – TRGS*). In the case of activities involving biological substances in the workplace, the provisions of the Biological Agents Ordinance (*Biostoffverordnung – BioStoffV*) also apply.

The German Hazardous Substances Ordinance and the rules set out in the Occupational Health and Safety Act are relatively abstract, drawing only broad distinctions between different types of substance or substance groups (e.g. carcinogenic, having adverse effects on fertility, etc.). Nanomaterials as such are not currently mentioned explicitly in the Technical Rules and no specific limits for nanomaterials have been established at government level.

It is a matter for the employer to plan and implement specific measures to protect the health and safety of affected employees in the workplace on the basis of a hazard assessment. The employer's responsibility covers not only the technical side but also organisational measures such as assigning responsibilities or instructing employees on the safe use of nanomaterials. The chosen measures depend heavily on whether or not substance-specific information or information on appropriate precautions is available.

Alongside the above provisions on occupational health and safety in the narrower sense, EU legislative provisions relating to the internal market (especially REACH and the CLP Regulation) also play a major role in terms of health and safety in the workplace. These provisions form the basis for obtaining safety-related information on a substance for transmission of this information along the supply chain. In the absence of this information,

employers are not in a position to undertake a proper hazard assessment in accordance with the occupational health and safety legislation.

4.2.2 Regulation of nanomaterials under occupational health and safety legislation

The German Hazardous Substances Ordinance also covers nanomaterials even though the term does not figure explicitly in the text of the ordinance. The term “hazardous substance” is defined in such a way as to encompass nanomaterials, if they possess hazardous properties or show adverse effects for employees depending on the activity or use to which they are put.

Furthermore, the Hazardous Substances Ordinance also contains an Annex on “Particulate hazardous substances”. This was introduced to take account of the special importance of dust, fumes and smoke for health and safety in the workplace. This Annex can also, in principle, be applied to nanomaterials (nanodust) and contains important preventive measures for health and safety protection.

The secondary Technical Rules for Hazardous Substances (TRGS) likewise cover activities involving nanomaterials although they do not at present contain any special rules on nanomaterials.

Complementing the Technical Rules are guidance documents produced in the course of drawing up a TRGS. In a joint initiative, the Federal Institute for Occupational Safety and Health (BAuA) and the German Chemical Industry Federation (VCI) have produced a guidance document of this sort on the use and handling of nanomaterials in the workplace.

The legislative provisions on occupational health and safety also take account of the precautionary principle. This is of particular relevance in the light of the present lack of knowledge of the risks posed by nanomaterials. TGRS No 400, for example, stipulates that, in the absence of relevant test data, employers must assume that hazardous properties are present for the purpose of their risk assessment. This also applies to nanomaterials. In addition, the principle of minimising exposure always applies as a basic requirement under the Hazardous Substances Ordinance. This basic requirement must be seen in conjunction with the provision in the Hazardous Substances Ordinance stating that an activity involving hazardous substances may only be commenced after a risk assessment has been conducted.

4.2.3 Deficiencies in the existing provisions

On the basis of current knowledge, some segments of the Working Group[30] do not see an immediate need to introduce specific provisions at the level of an Ordinance in addition to the provisions already in place. Some Working Group

[30] VCI and BLL, and Professor Scherzberg

members[31] nevertheless recommend conducting an open-ended review of whether the provisions of the existing legislation on occupational health and safety, including the Technical Rules, do in fact adequately cover all of the specific requirements relating to nanomaterials.

In the interests of health and safety in the workplace, one must also consider the need for surveillance bodies and occupational health and safety organisations to obtain information to identify companies working with unbound nanomaterials (i.e. not contained within a matrix).

Debate is currently under way in the German Government's Committee on Hazardous Substances (*Ausschuss für Gefahrstoffe – AGS*) and in the German Research Foundation's Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (*MAK-Kommission*) on setting a general, non-substance-specific limit for certain nanoparticulate dusts. Setting a limit of this sort would represent another regulatory instrument in the context of the Hazardous Substances Ordinance, akin to the general limits already in place for inhalable dust (10 mg/m³) and alveolar dust (3 mg/m³). Framework factors affecting scientific identification of a general assessment criterion would need to be tested and laid down on the basis of expert consensus within the relevant circles in the AGS.

In the longer term, it may potentially become necessary and feasible to set limits specifically for nanodusts.

Another important source of relevant information in this context are the legislative provisions relating to the EU internal market which concern occupational health and safety. In this regard there is a perceived need for adjustments to existing provisions. Efforts must be made to promote the generation of nano-specific test data. Inclusion of a clear and explicit clause in REACH stating that testing of a substance with a nanomaterial must be undertaken if the substance is placed on the market (or used) as a nanomaterial would be desirable here. This is particularly relevant for long-term studies on inhaled substances, which play a special role in occupational health and safety.

In addition, a provision should be introduced requiring Safety Data Sheets prepared in accordance with REACH to state explicitly if a nanomaterial is present. Employers need this information to enable them to decide whether to use the guidance documents on using and handling nanomaterials in the workplace.

4.2.4 Instruments to eliminate deficiencies in the existing provisions

As outlined above, from the point of view of occupational health and safety, priority must be given to generating nano-specific test data and other information on substances. Public funding for research could be channelled through the Federal Ministry of Education and Research (BMBF) research

[31] DGB, vzbv, BUND and Mr Adebahr

support system, but also through other government agencies' research programmes. In accordance with the "polluter pays" principle, however, the business sector carries the primary responsibility for promoting research in this field, as is laid down explicitly in the provisions on the EU internal market. Amendments to this legislation would also require actions at EU level.

As more information becomes available, the provisions in the narrower field of occupational health and safety legislation must be subject to continuous review in order to address potential adjustment requirements. Thanks to the structure of the Hazardous Substances Ordinance and Technical Rules, amendments can be put in place swiftly.

The topic of nanomaterials is currently under discussion in a working group of the Committee on Hazardous Substances. The Working Group has been mandated first of all to gather information and assess whether there is a need for a nano-specific Technical Rule relating to Hazardous Substances (a "Protective Measures TRGS").

As regards a general limit for nanodusts, the available scientific data must be reviewed with a view to establishing whether setting such a limit is feasible or advisable. In this context the Federal Institute for Occupational Safety and Health (BAuA) could undertake vital preliminary work for Sub-Committee III of the Committee on Hazardous Substances, the body to which the task of making an expert assessment and recommendations on such a limit would ultimately fall.

4.2.5 Conclusions and recommendations

Although nanomaterials are covered by current legislation on occupational health and safety, a review would be beneficial to determine whether the existing provisions are sufficient and reflect the current state of technology, and whether they provide adequate protection of employees in the workplace from a health and safety perspective. Particular attention needs to be paid in this context to processing and handling of products/articles. Even in applications that are widely used, the current state of technology will first of all need to be established and debated in many cases.

Risk assessment is the bedrock of occupational health and safety and the basis for planning protective measures. If insufficient information is available on the properties of a substance, under the provisions of the Hazardous Substances Ordinance the risk assessment must assume that certain properties are present.

The NanoKommission supports current efforts by the Committee on Hazardous Substances to initiate a Working Group review of any needs to be met in terms of Technical Rules, Occupational Health and Safety Guidance and, if appropriate, rules at the Ordinance level. The same goes for the MAK-Kommission's efforts to evaluate toxicological test data on nanomaterials. The NanoKommission also supports efforts to review the introduction of limits for nanodusts and establish what those limits should be.

It also seems appropriate on precautionary grounds to put in place transitional provisions for cases where no improvement is foreseeable in terms of the available information.

In the context of health and safety in the workplace, there are many difficulties due to the fact that specific exposure data are lacking or that procedures for testing nanomaterials are still in their infancy. In both of these regards there is a perceived need for action. Ultimately, the primary goal must be to establish a correlation between exposure levels and adverse health effects, as this is crucial for establishing substance-specific limits for nanodusts.

4.3 Cosmetics Regulation

4.3.1 Scope

"Cosmetic product" means any substance or mixture intended exclusively or mainly to be placed in contact with the external parts of the human body or the oral cavity with a view to cleaning them, protecting them, keeping them in good condition, perfuming them or changing their appearance (but excluding modifying the shape of any part of the body).

4.3.2 Regulation of nanomaterials in cosmetic products

Requirements concerning cosmetics are currently laid down at EU level in Directive 76/768/EEC on cosmetic products. The EU legislation is implemented in Germany by the Food and Feed Code (*Lebensmittel- und Futtermittelgesetzbuch – LFGB*) and the German Cosmetics Ordinance (*Kosmetik-Verordnung*). In accordance with these only products that are safe may be placed on the market. Prior to being placed on the market every cosmetic product must therefore undergo a safety assessment carried out by a suitably qualified person. These provisions also apply to cosmetics containing nanoparticulate ingredients.

In future the requirements concerning cosmetics will be governed by the Regulation (EC) No 1223/2009 on cosmetic products, which will repeal Directive 76/768/EEC. Under this Regulation, most provisions of which only come into effect from 2013,[32] safety assessment of such products will be more stringent and market surveillance more rigorous.

For the first time, this Regulation also contains provisions on nanomaterials in cosmetic products. Article 2 provides a definition of nanomaterials that is based on the definition of the EU's Scientific Committee on Consumer Products (SCCP). Article 16 of the Regulation sets out a notification procedure for certain nanomaterials in cosmetic products. According to this procedure, notification must be submitted to the European Commission 6 months prior to placing the

[32] The provisions of Article 15 (1) and (2) (substances that are carcinogenic, mutagenic or toxic for reproduction – CMR substances) come into effect from 1 December 2010.

product on the market, and must include a set of additional information. This information includes for example details of particle size, toxicological profile, and the quantity of the nanomaterial to be placed on the market. The Commission then assesses whether risk management measures are required. Nanomaterials intended for a use for which a positive list of permitted substances already exists (colourants, preservatives and UV-filters) are required to undergo a separate authorisation procedure and are therefore exempted from the notification requirements under Article 16.

Furthermore, all ingredients present in nanoparticulate form in cosmetics must be indicated clearly in the list of ingredients using the appropriate International Nomenclature of Cosmetic Ingredients (INCI) nomenclature, followed by the word “nano” in brackets.

The European Commission must also compile a catalogue of all nanomaterials used in cosmetic products.

4.3.3 Deficiencies in the existing provisions

The Cosmetics Directive that was in force until recently made no explicit provision for safety assessment or labelling of nanomaterials. More specific provisions were therefore included in the new Cosmetics Regulation (EC) No 1223/2009. It is too early as yet to be able discuss experience with the application of the new provisions.

Overall, Working Group 3 thought that the new Regulation on cosmetic products provides a good basis for regulating nanomaterials, although some Working Group members[33] would like to see tighter regulation in certain areas. They are particularly critical of:

- the relatively narrow definition of nanomaterials, which excludes soluble nanomaterials and materials with size-dependent properties which are larger than 100 nm, in contrast to the definition currently being debated for the Novel Food Regulation
- the fact that nanomaterials are not subject to an authorisation requirement unless they are intended for a use for which a positive list of permitted substances exists (UV-filters, colourants and preservatives)
- the fact that the Regulation does not come into effect until 2013.

On the other hand, the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW), the VCI, the BLL and Mr Adebahr consider it unreasonable and unnecessary to include soluble nanomaterials in the definition because this refers to oil/water emulsions that break down into their molecular constituents once in contact with the skin.

[33] BUND, vzbv, Professor Scherzberg and Professor Calliess

4.3.4 Instruments to eliminate deficiencies in the existing provisions

Regulation (EC) 1223/2009 provides for regular review of the provisions on nanomaterials and, if appropriate, for the Regulation to be amended to take into account scientific progress. The environmental and consumer organisations believe that this offers the possibility of eliminating the deficiencies they see in the current provisions.

4.3.5 Conclusions and recommendations

Cosmetic products are a ground-breaking case as this is the first product group to undergo Community-wide regulation of this sort. The safety assessment and notification procedure under the re-cast legislative framework provide industry representatives in the Working Group with an adequate basis for ensuring the safety of cosmetic products.

Meanwhile BUND, vzbv, and Professors Scherzberg and Calliess consider this to be an inadequate basis. Improvements that are needed in their view include a broader definition and making other applications subject to authorisation requirements.

4.4 Novel foods

4.4.1 Scope

According to a recent statement from the European Food Safety Authority (EFSA), deliberately engineered novel nanoscale substances are not used at present in foods within the European Union.[34] In the future, however, it may in principle become possible to give foods particular properties using novel ingredients in the nano size range. To foster responsible use of nanotechnologies and engineered nanomaterials and ensure protection of consumers' health, an appropriate legislative basis needs to be created.

4.4.2 Regulation of nanomaterials in novel foods

Foods containing nanoparticulate ingredients, like other foods, must comply with the general legislative provisions on foods, notably Regulation (EC) No 178/2002[35] and the German Food and Feed Code (LFGB).[36] In accordance with these provisions, only foods that are safe may be placed on the market.

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[34] EFSA SCIENTIFIC OPINION. The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety, 10 February 2009.

[35] Regulation (EC) No 178/2002 of the European Parliament and of 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 31 of 1.2.2002, p. 1-24).

[36] German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch – LFGB) in the version promulgated on 24 July 2009 (BGBl. I p. 2205).

If intentionally manufactured ingredients in the nanoscale are used in food for non-technological purposes, for example nutritional purposes, the provisions of Regulation (EC) No 258/97 on novel foods and novel food ingredients[37] may also apply in certain circumstances. This is the case where a food or food ingredient is modified by a new production process, for example nanotechnology, and that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances, and where that food was not used for human consumption to a significant degree within the Community prior to 15 May 1997 (date of entry into force of the Regulation).

In this context mention must also be made of foods and other food ingredients used in foods in the form of micelles. Use of micelles facilitates dispersal of fat-soluble components in water-based foods and vice-versa. This is not a new technology, but each case must be examined on its own merits to assess whether the use of this technology gives rise to a significant change in the food or food ingredient and whether it was used prior to 15 May 1997. This would fall within the scope of Regulation (EC) No 258/97.

Novel foods may only be placed on the market in the EU subject to approval on the basis of a safety assessment. Specific requirements may also be imposed, for example concerning conditions of use or labelling.

The EU provisions on novel foods are currently undergoing revision. Nanotechnology is a key issue in this process. In January 2008 the European Commission presented a proposal for a Regulation on novel foods. Aside from clarifying the application of the Regulation on a number of points, the Commission proposal envisaged maintaining the status quo as outlined above. Consultations in the relevant bodies within the Council and the European Parliament, however, revealed that opinion tends to favour more far-reaching and specific provisions.

The new draft is also expected to include, among other things, a definition of engineered nanomaterials and set out the scope of the forthcoming Regulation as it applies to foods containing or consisting of such materials.

4.4.3 Deficiencies in the existing provisions

The existing Regulation (EC) No 258/97 on novel foods (Novel Food Regulation) makes no explicit mention of nanotechnology and contains no details of specific methods for assessing foods modified using nanotechnology.[38] The stakeholders therefore agree unanimously that the revision process currently under way should ensure that the provisions of the Regulation are made more specific with regard to nanomaterials.

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[37] Regulation (EC) No 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43 of 14.2.1997, p. 1-6).

[38] The European Commission has, however, made recommendations for an application procedure under Regulation 258/97 which could also be used for nanomaterials.

In this context it should be pointed out that, according to EFSA, nano-specific testing procedures are currently in development, especially with regard to characterisation and analysis of nanomaterials in foods, optimisation of testing procedures for safety assessment and interpretation of the resulting data.[39] Although it is currently possible to carry out safety assessments on a case-by-case basis using the available methods, any individual assessment is subject to some degree of uncertainty.[40] For this reason, EFSA recommends actions to develop specific methods and include these in EFSA guidelines.

As regards the ongoing revision of the Novel Food Regulation, debate in the Working Group on the deficiencies of current food law was intense, highlighting the importance given to this issue.

The members of the Working Group would basically welcome tightening of the existing provisions with regard to the use of nanomaterials, but no agreement was reached with regard to the required scope of the relevant provisions. The controversial issues here mirror those arising between the European Parliament and the Council concerning mandatory labelling and prior development of nano-specific testing procedures as a prerequisite for approval.

4.4.4 Instruments to eliminate deficiencies in the existing provisions

BUND, vzbv and Professors Calliess and Scherzberg call for approval to be conditional upon a safety assessment carried out after prior development of nano-specific testing procedures, and for a general labelling requirement for nanomaterials in foods.

BLL and VCI believe that the envisaged case-by-case decision-making and evaluation of tests and testing procedures by scientific authorities is both appropriate and expedient; they consider it impractical to develop specific testing procedures in advance.

The positions of all stakeholders regarding product labelling are set out in a table in Section 0.

4.4.5 Conclusions and recommendations

As debate is still under way on the adaptation and revision of the legislative provisions of Regulation (EC) No 258/97 on novel foods, and because the opinions of the various stakeholders are so diverse, it has not been possible to provide a conclusive evaluation or consensus-based assessment here.

According to industry representatives in the Working Group, if the application of nanotechnology or engineered nanomaterials in food becomes relevant, existing food law and legislation in preparation provide an adequate basis for

[39] Request of the European Commission to the European Food Safety Authority (EFSA) for providing guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food, feed and pesticides.

[40] EFSA Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety, http://www.efsa.europa.eu/en/scdocs/doc/958.pdf, p.2

ensuring that the products concerned are safe. This segment of the Working Group is satisfied that the envisaged authorisation procedure based on a comprehensive safety assessment which, if need be, can trigger actions to develop the necessary specific testing procedures and, where appropriate, on a case-by-case basis, require that the presence of nanomaterials is indicated clearly, is adequate for ensuring the safety of nanomaterials in foods on the basis of the information available at the present time.

BUND, vzbv and Professors Calliess and Scherzberg, meanwhile, are of the opinion that approval should depend on prior development of testing procedures specifically for nanomaterials, and that mandatory labelling should be introduced.

4.5 Food additives

4.5.1 Scope

Applications of nanoscale ingredients for technological purposes are also conceivable, including for example as preservatives or colourings. Substances of this sort fall within the scope of Regulation (EC) No 1333/2008 on food additives[41] and Regulation (EC) No 1331/2008.[42]

According to a recent statement from the European Food Safety Authority (EFSA),[34] with the exception of nano-structured flow aids, deliberately engineered nanoscale food additives are not used at present in foods within the European Union. Future nanotechnology applications in this domain are nevertheless conceivable.

4.5.2 Regulation of nanomaterials as food additives

Food additives must not be placed on the market in the EU unless they have been authorised for a given technological purpose following a comprehensive safety assessment. This ensures that their use poses no hazard to human health.

In view of the potential use of nanoparticles in the food area, priority was given to the issue of nanotechnology when the EU provisions on food additives were revised. Regulation (EC) No 1333/2008 on food additives therefore makes provision for re-evaluation of safety and, where appropriate, re-authorisation of food additives used in a form that differs from the form previously used and assessed by the relevant authority, for example the nanoscale form.

If additives in the nanoscale intended for technological purposes are used in the form of micelles or similar, this too falls within the scope of the provisions on

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41 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354 of 31.12.2008, p. 16-33.

42 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L 354 of 31.12.2008, p. 1-6.

food additives. They must therefore meet the requirements of the authorisation procedure.

In principle the Regulation contains no provisions concerning specific testing procedures; the suitability and adequacy of tests undertaken is assessed in the context of the authorisation procedure and laid down by the relevant authorities, as are the conditions for use and, where necessary, specific requirements regarding indication of the presence of an additive in a foodstuff.

4.5.3 Deficiencies in the existing provisions

Overall, Working Group 3 believes Regulations (EC) No 1333/2008 and (EC) No 1331/2008 to be a good starting point for regulation of nanomaterials as food additives.

BUND, vzbv and Professor Scherzberg criticise the absence of a definition[43] of "nanoscale" and the absence of provisions on specific testing procedures for nanomaterials. They point out that, according to EFSA, nano-specific testing procedures are still in development (see Section 4.3.3), particularly as regards characterisation and analysis of nanomaterials in foods, optimisation of testing methods for safety assessments and interpretation of the resulting data. While it is possible at the present time to conduct safety assessments on a case-by-case basis, any individual assessment will be subject to a high degree of uncertainty.[44]

According to BUND, vzbv, the Öko-Institut and Professors Calliess and Scherzberg, authorisation should not be possible until standardised, nano-specific testing methods are available. They also criticise the fact that the Regulation on Food Additives makes no provision for specific labelling of nanomaterials. This is in contrast to the Cosmetics Regulation, which has introduced the requirement to append the word "nano" to product ingredient listings.

In the view of the BLL and the VCI, these needs are largely met by the case-by-case authorisation procedure and the possibility of imposing additional requirements for authorisation, notably concerning conditions of use and indication of the presence of nanomaterials.

4.5.4 Instruments to eliminate deficiencies in the existing provisions

Participants in Working Group 3 who outline deficiencies in the current provisions believe these might be eliminated by amending the Regulation to include a definition of nanoscale additives and specific testing methods. No

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[43] Professor Calliess sees a need for adapting testing procedures to take account of the distinctive features of nanomaterials before they are authorised as food additives. According to Professor Calliess, a definition of nanomaterials appears not to be essential, at least as regards authorisation, as any change in the particle size of a food additive would require a new authorisation, and so the absence of a definition does not give rise to any safety loophole.

[44] EFSA Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety, http://www.efsa.europa.eu/en/scdocs/doc/958.pdf, p.2

authorisation could be granted before such testing methods were in place. Another means of removing deficiencies in the legislation, they believe, would be to introduce mandatory listing of nanoscale additives in the list of food ingredients in a manner that makes it clear that an additive is on the nanoscale.

4.5.5 Conclusions and recommendations

Industry representatives on the Working Group believe that consumer safety is adequately guaranteed by the authorisation procedure which is a general prerequisite for food additives and includes safety assessment and compulsory re-evaluation and re-authorisation of substances previously authorised but now intended for use in a form, e.g. in nanoscale form, that differs from the form previously used and assessed by the authorities.

Other parties in the Working Group[45] advocate inclusion of a definition of nanoscale additives, prior development of nano-specific testing methods and identification of nanoscale ingredients in the list of ingredients on packaged foods.

Representatives of the industry bodies see no need for action in this regard, as specific testing methods are stipulated in the course of the case-by-case authorisation procedure, along with conditions for use and labelling requirements.

4.6 Food contact materials

4.6.1 Scope

In the case of food contact materials, a variety of products manufactured using nanotechnology is already on the market. These include packaging that acts as a barrier, or has coatings to block out moisture, oxygen or UV light, packaging materials with build-in antibacterial properties or packaging materials with an indicator function that can sense and provide an indication if a food is spoiled. Nanomaterials can also be used as process materials to modify the function of surfaces in food manufacture (e.g. on conveyer belts) to achieve a variety of effects: ease of cleaning (“lotus effect”), energy efficiency, adhesion properties, etc.

4.6.2 Regulation of nanomaterials in food contact materials

Food contact materials must comply with the general safety provisions of Regulation (EC) No 1935/2004 (referred to as the Framework Regulation on food contact materials). In accordance with this Regulation, materials intended to come into contact with food must not endanger human health or bring about an unacceptable change in the composition of food. The business operator has

[45] BUND, vzbv, Professor Calliess, Mr Hermann (Institute of Applied Ecology) and Professor Scherzberg

a responsibility to ensure this regardless of the particle size of the substance or type of material used.

Regulation (EC) No 1935/2004 also requires the business operator to inform the European Commission immediately of any new scientific or technical information that might affect the safety assessment of authorised substances in relation to human health. If necessary, the European Food Safety Authority (EFSA) may then review the original safety assessment of the substance. This also applies to the criterion “particle size”.

Substance-specific authorisation procedures (preventive ban with authorisation option) currently exist in EU law for certain components in food contact materials made from plastics (Directive 2002/72/EC) and from regenerated cellulose film (Directive 2007/42/EC). Authorisation of plastics includes as a matter of principle stipulating the conditions of use and, where necessary, setting migration limits for the substance. Both of these Directives are implemented in Germany by the Commodities Ordinance (*Bedarfsgegenständeverordnung*). Substances in so-called active and intelligent materials and articles will also require authorisation in future (Regulation (EC) No 450/2009).

Testing requirements are based on the EFSA Guidelines for the safety evaluation of substances in food contact materials. The legislative provisions also make reference to the EFSA Guidelines.

Testing methods are also set out in the EFSA Guidelines for the safety evaluation of substances in food contact materials. Under the EFSA Guidelines prior development of specific testing methods as a prerequisite for authorisation is not required in principle, and so neither is it required for nanomaterials (see also Section 4.3.3).

In order to implement EU legislation, the German Federal Government recently announced that it has authorised nanoparticulate titanium nitride (TiN) for use in food contact materials made from plastics. Authorisation is restricted to use in polyethylene terephthalate (PET) bottles, e.g. drinks bottles, in concentrations of up to 20 milligrammes per kilogramme. According to EFSA, no health risk is present under these specific conditions of use because migration into or onto food, and thereby consumer exposure, is not expected to occur.[46]

Under Regulation (EC) No 1935/2004 food contact materials must also be labelled with special instructions for their safe and appropriate use, where this is necessary in the light of their normal or reasonably foreseeable use.

[46] The Federal Ministry for Food, Agriculture and Consumer Protection (BMELV) also issued a statement early in 2010 clarifying that nano-silver and nano-clays are not authorised at present for use in food contact materials made from plastics, as neither clay nor silver are included in the list of permitted food contact materials made from plastics. Products manufactured in or imported into the EU before 1 January 2010 which contain either of these substances may continue to be sold. Products manufactured or imported after this date must not be placed on the market until such a time as an application to list silver or clay as permitted food contact materials has been approved.

4.6.3 Deficiencies in the existing provisions

Overall, Working Group 3 has concluded that the EU Regulations and Directives on food contact materials form a good basis for the regulation of nanomaterials.

BUND, vzbv and Professors Calliess and Scherzberg are in favour of going further on certain points. They are critical of the fact that the EFSA Guidelines on safety evaluation do not at present contain provisions for nano-specific testing procedures for the authorisation of nanomaterials for use in food contact materials. Professor Calliess and BUND also criticise the fact that so far no instruction or clarification has been issued to the effect that inclusion in the Community list requires nanomaterials to undergo authorisation in their own right. The Öko-Institut points out the lack of labelling, making it difficult to ensure traceability down the supply chain.

Industry federation representatives see no need to take action to require prior definition of specific testing procedures, as they believe appropriate and meaningful testing procedures are developed and applied in the process of case-by-case authorisation as necessary.

4.6.4 Instruments to eliminate deficiencies in the existing provisions

Regulation (EC) No 1935/2004 provides a legal basis for potential additional individual measures that could be applied to nanomaterials in fields where no specific regulations exist at present.

According to the stakeholders who highlighted deficiencies in the existing provisions, nano-specific testing procedures should be included in the EFSA Guidelines for the safety evaluation of substances for food contact materials as a prerequisite for authorisation of nanomaterials. In their opinion, potential future options for regulating types of material or classes of substances not specifically covered in existing legislation could include tools such as an authorisation procedure subject to restrictions (e.g. restrictions on use). The Öko-Institut believes there is a need to introduce labelling of food contact materials which contain nanomaterials to enable traceability across the supply chain.

Revision of the EU legislation on plastics intended for food contact materials is currently in preparation and a Commission Regulation on this is anticipated soon (late 2010). It is expected to address the regulation of nanomaterials specifically. The Regulation is intended to clarify that the nanoform of a substance is not covered by an authorisation applied for and granted in respect of the macroscale form of the same substance.

4.6.5 Conclusions and recommendations

As far as some of the stakeholders are concerned, the present legal framework is basically adequate to ensure that food contact materials manufactured using nanotechnology are safe. Whether there is a need for additional regulations

relating to nanotechnologies for food contact materials will depend on new scientific findings.

The environmental and consumer organisations advocate amending the legislative provisions and the EFSA Guidelines for the safety evaluation of substances for food contact materials to include the instruments mentioned in Section 4.6.4. The revision of the EU regulations on plastics for food contact currently under way could serve as an appropriate starting point for this.

4.7 Legislation on biocidal and plant protection products

4.7.1 Scope

The placing on the market of biocidal products is regulated by the EU Biocidal Products Directive (Directive 98/8/EC), while the placing on the market of plant protection products is governed by the Plant Protection Directive (Directive 91/414/EEC), set to be repealed on 14 June 2011 by the new European Regulation concerning the placing on the market of plant protection products (Regulation (EC) No 1107/2009 – Plant Protection Regulation). These provisions lay down that products must not be placed on the market unless they have successfully undergone a rigorous authorisation procedure. This is equivalent to a preventive ban with an authorisation option.

The reason for this strict control prior to placing on the market is that, regardless of their chemical properties, biocidal products and plant protection products are basically assumed to have potential harmful effects on human or animal health or an unacceptable impact on the natural balance. In the context of the authorisation procedure, applicants must submit research studies as evidence to prove that this is not the case.

In these areas of legislation, a two-tier process is implemented:

- assessment of active substances and inclusion in a positive list valid throughout the EU
- authorisation of substances or products at national level; as a minimum requirement for authorisation, a product must contain only substances included in the relevant positive list.

4.7.2 Implementation of the precautionary principle

There are elements of precaution in both legislative areas. As far as potential groundwater contamination is concerned, in the context of the authorisation procedure plant protection products and biocidal products are regulated primarily on the basis of the precautionary principle. The risk assessment “toolkit” for chemicals, biocidal products and plant protection products includes the option of making assumptions on precautionary grounds based on "realistic worst case" scenarios where exposure data are lacking, while lack of data on the impact side are compensated for using weighting factors. The aim of this procedure is to ensure that gaps in the existing knowledge do not lead to

underestimation of the risk. In addition, based on the limit for active pesticidal substances in drinking water, authorisation is granted only if the amount of the substance entering the groundwater is established to be < 0.1 µg/l (concentration), regardless of any other effects on the natural balance.

Under the current Biocidal Products Directive, other criteria must be also taken into account for precautionary reasons in addition to risk characterisation in order for a substance to be included in Annex I (in other words the Community list of permitted active substances).

The precautionary principle is referred to explicitly in the provisions on plant protection. Paragraph 4 of Article 1 (Subject Matter and Purpose) of the new Regulation on Plant Protection Products states "The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory."

Under the Regulation on Plant Protection Products, the precautionary principle is supplemented in a specific way by an additional legislative tool – exclusion criteria – in the interests of hazard prevention. This tool is retained in the Commission proposal on the revision of European law on biocidal products. In both cases the exclusion criteria relate to assessment of the active substances. Exclusion criteria means that where a substance is found to possess particular intrinsic properties which give cause for concern regardless of potential exposure or other risks, then that substance is automatically excluded from the Community list (Annex I); in other words it cannot be approved as a permitted substance. Substances meet the exclusion criteria if they are: carcinogenic, mutagenic, toxic to reproduction, endocrine-disrupting, or persistent, bioaccumulative and toxic (pbt).[47] The first step in the assessment of a substance by the authority is to establish whether such properties are present; if this is confirmed, the assessment process is terminated and a decision is issued that the substance cannot be authorised unless it fulfils one of the exemption criteria permitting inclusion of the substance in Annex I. It remains to be seen which exclusion criteria will be written into the new legislation on biocidal products, as numerous proposed amendments on this issue are currently being debated in the European Parliament.

Both the Biocidal Products Directive and the new Regulation on Plant Protection Products provide for "comparative assessment". This means that active substances or products having effects that are on the borderline between acceptable and unacceptable may be granted provisional authorisation with the

[47] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, Article 4 (1) in conjunction with Annex II No 3.7.2 includes a provision stipulating that an active substance can only be approved if it is not considered to be a PBT.

note that “concerns remain”, but must then undergo comparative assessment. The aim of this provision is to substitute them with active substances or products of less concern. Comparative assessment tied to requirements for candidates for substitution under the Biocidal Products Directive has rarely been applied in practice although the Directive has been in force since 1998.

4.7.3 Deficiencies in the existing provisions

Under current European law, there are no separate provisions concerning biocidal products and plant protection products which contain nanoscale substances.

The legislation should be reviewed to establish whether current guidelines on testing adequately take into account the specific properties of nanomaterials. If not, they should be amended. Preliminary work in this area is currently under way in the OECD. Established procedures for testing formulations and modifications to formulations must be adjusted where appropriate. A review of these must also take into account the very varied applications of these products.

The first reading of the new draft Biocidal Products Regulation in plenary session of the European Parliament was scheduled for September 2010, and the Council intends to deal with the provisions in December 2010.

4.7.4 Conclusions and recommendations

To ensure the greatest possible degree of harmonisation of the various provisions, many Working Group members advocate taking into account existing approaches (such as efforts to establish a uniform definition at the European level) in the context of the Biocidal Products Directive and the Regulation on Plant Protection Products – regardless of the particular substances and products concerned. The properties of a given substance should be identified in a manner akin to that prescribed under REACH, as this would enable nanomaterials to be dealt with, assessed and regulated in the same way. If existing test protocols such as the OECD test guidelines are expanded or modified to take account of testing of nanomaterials, these would be applicable under REACH, under Directive 91/414/EEC or Regulation (EC) No 1107/2009, and under the provisions on biocidal products. Due attention needs to be paid, however, to the specific uses of plant protection products and biocidal products to take into account any risks specifically associated with these over and above the general substance assessment.

No further conclusions or recommendations were made by the Working Group as the Biocidal Products Regulation is currently being debated at EU level, and because plant protection law is highly complex and does not at present contain specific provisions on nanomaterials.

5 Regulatory instruments

Here we discuss specific instruments offering a means of regulating nanomaterials. Ultimately, these instruments are aimed at implementing the regulatory approaches adopted. Attention must be paid to ensuring that they can be implemented in practice both by businesses and by the relevant authorities. First, a distinction needs to be drawn between various issues:

- Which instruments are appropriate?
- Which instruments are already contained in existing laws?
- How will the existing instruments need to be adapted, if necessary, to take account of the challenges presented by nanomaterials?

As a matter of principle, there must always be clarity with regard to the objectives the instruments are intended to achieve, the criteria for their application and whether they can be integrated into the regulatory approach.

5.1 Precautionary approach to authorisation procedures for substances and products involving the use of nanomaterials

5.1.1 Explanation and purpose

Compared to other regulatory instruments, introducing an authorisation requirement for placing a nanomaterial or a product containing nanomaterials on the market represents the strongest encroachment on the rights of manufacturers and users of nanomaterials in terms of its impact on their basic right to economic freedom. This is because they are then prohibited from manufacturing or using nanomaterials unless they hold an authorisation issued by the state authorities permitting them to do so. A distinction may be drawn between two types of authorisation:

- General authorisation: after undergoing a safety assessment, a nanomaterial is included in a positive list of permitted substances and can then be used by anyone for its authorised purpose. This ensures that only safety-tested nanomaterials may be used, but it does nothing to ensure transparency as regards which products actually contain that nanomaterial. This makes official monitoring of nanomaterials on the market difficult.
- Individual authorisation: a nanomaterial may be authorised generally for use by a particular manufacturer or user, or specifically for use in a particular product made by a particular manufacturer. This ensures case-by-case safety assessment by the authorities, and it creates transparency because the competent authority knows which nanomaterials are being used by which manufacturers or users in which products.

Authorisation may relate to a substance and its use(s), or to products. In some areas (e.g. consumer goods), there may be provisions requiring any substances/nanomaterials used to undergo prior official safety assessment as a

matter of principle, thus making them subject to authorisation. In addition, however, it is also possible to link an authorisation requirement to certain intrinsic properties of a substance/nanomaterial. In such cases the procedure needs to take account of how the burden of proof is assigned in accordance with the precautionary principle (see also Section 0). Introduction of an authorisation requirement would be justified in this regard if abstract grounds for concern are substantiated by scientific evidence, even if there are gaps in scientific knowledge regarding potential hazards to the protected assets health and the environment. It is sufficient for a hazard to be scientifically plausible on the basis of an initial suspicion. A substance/nanomaterial or nanoproduct is assumed to be hazardous if abstract grounds for concern regarding potential adverse effects on the protected assets health and the environment are justified, and especially in a situation where there is a legal impasse (*non liquet*) concerning evidence, where scientific opinions on the potential hazardousness to human health and the environment contradict one another. To break this assumption, it is for the manufacturer or user to set out the facts demonstrating the non-hazardous nature of a substance or product as a substantial probability. The requirements for authorisation must be designed in a manner that takes into account the basic rights of citizens (balancing economic freedom against the need to protect human health and the environment). In addition, introduction of an authorisation procedure based on the precautionary principle also requires that criteria be established for substantiating or disproving the abstract grounds for concern.

Establishing authorisation procedures not only helps to reinforce consumer confidence in the safety of nanomaterials and nanoproducts; it also means that responsibility for rebuttal of the presumption of hazardousness falls to businesses. In this way, the state too is assigned responsibility for product safety.

5.1.2 Areas of regulation in which this instrument already applies to nanomaterials

Provision already exists for authorisation of nanomaterials in some areas of regulation. No specific authorisation procedure has been established for nanomaterials in these cases, however. Instead, provision has been included in existing authorisation requirements. Within this, by explicit order, authorisations granted for the macroscale form of a substance are now no longer valid for the nanoscale form of the same substance. As a result, a separate authorisation must be obtained for the use of a nanomaterial. Under the provisions of the Cosmetics Regulation (EC) No 1223/2009, authorisation is required for substances intended for use as UV filters, colourants or preservatives. Toxicological assessment of these substances must also take particle size into account. Under the provisions of the Regulation on food additives (EC) No 1333/2008, a new authorisation must be obtained for food additives each time their particle size changes due to nanotechnology. Similar provisions are planned for novel foods as part of the revision of Regulation (EC) No 258/97,

which up to now imposed an authorisation requirement only in certain circumstances for foods or food ingredients produced using nanotechnologies.

In addition to the above, Regulation (EC) No 1907/2006 (REACH) provides the possibility of introducing an authorisation requirement for individual nanomaterials within its scope. This is based on hazard, however (rather than on the precautionary principle), as the nanomaterial in question must be deemed a “substance of very high concern” – the reason for this is that information on the hazardous properties of a substance and its different uses must be included in the registration dossier.

As regards implementation of the precautionary principle under REACH Professor Calliess points out that, due to the criteria aimed at hazard prevention set out in Article 57 of REACH, only substances of very high concern can currently be required to undergo an authorisation procedure. In the case of nanomaterials, meanwhile, a mandatory authorisation requirement cannot be imposed as long as there is insufficient knowledge about them, even if there are grounds for concern. This is incompatible both with the precautionary principle and with the concept of rebuttable presumption of hazardousness inherent to it.

From the VCI’s perspective, this line of argument is not conclusive since, following registration in accordance with REACH, information on hazardous properties of a substance and on its uses is available, thereby rebutting or confirming any presumption of hazardousness. For this reason, then, abstract potential grounds for concern no longer exist, although there may be concrete grounds for concern.

5.1.3 Conclusions

Depending on the risk, or rather, in concrete terms: depending on the degree of abstract potential grounds for concern with regard to possible adverse effects on the protected assets health and the environment, the introduction of a mandatory authorisation requirement is warranted on the basis of the precautionary principle. This may be general in nature (positive list). In addition, however, the precautionary principle also affords the possibility of making the manufacture or use of nanomaterials subject to authorisation on a case-by-case basis. Introducing an authorisation requirement of this sort is justified in the case of all nanomaterials where abstract grounds for concern are substantiated by initial scientific suspicions, even though there may be gaps in scientific knowledge with regard to specific properties that are hazardous to the protected assets health and the environment.

Authorisation by the public authorities, moreover, confers legal security on the manufacturer. He receives sovereign confirmation that his nanomaterial or nanoproduct is “safe” according to the current state of knowledge. Authorisation thus also has an intrinsic enabling function. It does not affect the primary responsibility of the holder of the authorisation, as demonstrated by the dynamic basic obligations that are a regular feature of authorisations, and the holder’s review and notification obligations that go along with them.

It would be useful to clarify in which areas an authorisation requirement will need to be introduced or extended specifically to cover nanomaterials in view of the particular challenges posed by nanomaterials (e.g. articles intended to come into contact with food, textiles, etc.). It would also be useful to elucidate whether and, if so, how the “Criteria indicating concern or no cause for concern” developed by the NanoKommission in its first dialogue phase might be used to help design an appropriate authorisation procedure. Another issue to be addressed in future is whether, based on the precautionary principle a specific authorisation procedure for nanomaterials should be included in the provisions of REACH.

5.2 Nanoproduct register

5.2.1 Explanation of the instrument

In the public debate on nanomaterials, their possibilities, uses and risks, the question frequently arises as to which products contain nanomaterials. The question is asked from a variety of perspectives (e.g. potential risks to the environment and to consumer and employee health, the need for regulation, consumer freedom of choice, availability of nanoproducts on the German market, etc.) and by a variety of stakeholders (consumers, businesses, environmental protection organisations, research institutions, government agencies, etc.). A range of diverse resources (such as the privately-owned, publicly accessible PEN database) show that there are numerous products on the German and international markets that are described as nanoproducts. And yet it is not possible to rely on the information contained in those sources. This is due in part to a lack of a binding definition, e.g. for nanomaterials or products containing nanomaterials, and also to the lack of an obligation to report the utilisation of nanomaterials.

A nanoproduct register could help to fill this gap. Product registers can serve a wide range of different purposes, and may therefore vary widely in many regards, such as responsibility for collecting and processing information, access for different parties, nature of information contained in them and the purpose for which they are intended. In the case under discussion here, a product register could be managed by a competent public authority. Persons manufacturing, importing or placing on the market a nanoproduct for the first time would have a mandatory reporting obligation requiring them to submit to the competent authority information on the identity of the manufacturer or importer, the identity of the product, and other information on the nanomaterial(s) contained in the product.

5.2.2 Possible purpose of a product register

Possible objectives that could be served by a nanoproduct register include:

- to create transparency with regard to which products contain which nanomaterials;
- to support authorities, manufacturers and distributors of nanoproducts in terms of appropriate risk management measures, and enabling such measures (such as traceability down the production chain, or product recall);
- to guarantee freedom of choice for consumers, in other words to give them the option of buying products with or without nanomaterials.

5.2.3 Possible scope of a product register

The term “nanoproducts” is often used very loosely. For the purposes of a nanoproduct register it will need to be clearly defined in order to establish legal clarity as regards which products are to be included in the register.

Nanomaterials themselves may be understood as nanoproducts. A fundamental question that then arises is which substances should be defined as nanomaterials within the meaning of Article 3 (1) of REACH. To date a number of very different definitions of nanomaterials have been proposed, based primarily on the nano size range (see Section 0). The only legally binding definition of nanomaterials currently in existence is that in the EU Cosmetics Regulation. Other legally binding definitions for specific sectors may follow, for example in the Novel Food Regulation.

Furthermore, mixtures within the meaning of Article 3 (2) of REACH, which contain nanomaterials, may also be understood as nanoproducts.

In the case of semi-finished and finished products which contain nanomaterials and would therefore be included in the product register, the definition of “article” in Article 3 (3) of REACH could be applied.

A nanoproduct register should, if possible, be introduced at the European level as this would help to ensure a high level of protection of human health and of the environment throughout the European Union and interfere less with the free movement of goods than regulation at national level. The initiative for this could, however, come from Germany as an EU Member State, and an announcement that a national regulation was under consideration would help to move matters forward.

Whether this is feasible and meaningful in legal terms will need to be ascertained on a sector-by-sector basis in the light of the existing legislative provisions.

Also requiring clarification are the issue of the scope and the relationship to other, individually regulated product sectors, and that of the registration and publication obligations arising as a result of authorisation requirements (see 5.2.6).

5.2.4 Possible information content of a product register

The register should contain at least the following information:

- Name and address of the manufacturer, importer or distributor of the nanoproduct,
- The product name and trade name of the nanoproduct
- The country of origin, in the case of an imported nanoproduct
- The nanomaterials used in the product (in the case of mixtures, semi-finished and finished products)
- Guidelines for safe use of the product.

As the aim of the product register is to cover as comprehensively as possible all nanomaterials that are produced or placed on the market in Germany, the information must enable the authority to identify clearly “manufacturers”, “importers” and “distributors” and their products.

If the information contained in the register is also intended to be used for traceability purposes concerning nanomaterials, the registration number of the nanomaterial in accordance with REACH and information on the specification of the nanomaterial could also be submitted to the register. A product register would also be able to collect information in the run-up to a revision of REACH, and it could also cover nanomaterials which are not subject to mandatory registration.

It would also be conceivable to include a) products which contain nanomaterials and must be labelled accordingly, and b) products which contain nanomaterials but are not subject to labelling requirements in existing or future product registers, in the event that these are established in all EU Member States in future.
This would be a cost-effective way, using accepted safety arrangements and existing legal frameworks, to achieve the functions of a nanoproduct register in practice.

Finally, information on the amount of nanoproducts on the market in Germany could also be important to enable the public authorities to estimate the potential effects of these products on human health and on the environment.

5.2.5 Possible rules concerning access to product register information

Another important issue which also depends on the purpose of the product register is that of who should have access to the information contained in the product register. This question arises inter alia in connection with the protection of trade secrets and confidential business information and also in connection with public risk perception.

Various gradations are conceivable for communicating information:

- a public register in which all the information provided is publicly accessible
- a public register in which only certain information is publicly accessible, or

- a register which is only accessible to the competent authority, but which produces a publicly accessible report on nanomaterials on their own, mixtures and articles on a regular basis (e.g. annually).

As a rule, irrespective of the form chosen for communicating information from the register, the publication of information conflicts with the protection of business interests in the following cases:[48]

- details of the complete composition of a nanoproduct or a mixture within the meaning of REACH
- the precise use, function or application of a nanomaterial or mixture containing nanomaterials
- the precise quantity in which the nanomaterial, the mixture containing nanomaterials, or the nanoproduct is manufactured or placed on the market.

In addition, publication of a product name carries the risk that a nanoproduct could become stigmatised as dangerous simply as a result of being listed in the register.

5.2.6 Areas of regulation where product registers and similar instruments are already in use for nanomaterials

Cosmetics Regulation

The requirements concerning the use of nanomaterials in cosmetics have changed as a result of the new EU **Cosmetics Regulation**.[49] To ensure a high level of consumer protection, manufacturers, importers and distributors are subject to certain information requirements under the new Cosmetics Regulation. Cosmetic products containing nanomaterials must be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market (Article 16 (3)), giving the following information:

- the identification of the nanomaterial, including its chemical name (IUPAC) and other descriptors as specified in Point 2 of the Preamble to Annexes II to VI of the Cosmetics Regulation
- the specification of the nanomaterial including size of particles, physical and chemical properties
- an estimate of the quantity of nanomaterials contained in cosmetic products intended to be placed on the market per year
- the toxicological profile of the nanomaterial
- the safety data of the nanomaterial relating to the category of cosmetic product in which it is used and
- the reasonably foreseeable exposure conditions.

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[48] Cf. also Article 118 (2) REACH.

[49] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, OJ L 342 of 22.12.2009, p. 59 – hereafter referred to as the "Cosmetics Regulation". See also: European Parliament legislative resolution of 24 March 2009 on the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast) (COM (2008)0049 – C6-0053/2008 – 2008/0035(COD)).

Novel foods

Current situation

When applying for authorisation, the applicant (the person responsible for placing the product on the market in the EU) must submit all the necessary information[50] to the competent authority in the relevant Member State[51] in which the food is to be placed on the market for the first time. The applicant must also include a proposal for the presentation and labelling of the food and a summary of the application dossier. Guidelines for preparing applications in accordance with Regulation (EC) No 258/97 are contained in Commission Recommendation 97/618/EC.

The application documents are available to the competent authorities via a Commission database, but they are not published (some of the information they contain is confidential). Practice varies among the Member States, however. Some, for example, make particular application documents (excluding confidential data) and initial assessment reports produced in that Member State available on the website of the competent authority.

Any opinion delivered by EFSA is published on its website.

Authorisation decisions as a rule are taken by the Commission and are published in the Official Journal of the European Union, thereby making them accessible to everyone. In addition, a list of applications submitted in accordance with Regulation (EC) No 258/97, together with the application status (e.g. authorised, Commission Decision No XX/XXXX) is available on the Commission website and on the website of the German Federal Office of Consumer Protection and Food Safety and the German Federal Institute for Risk Assessment (BfR).

Future outlook:

Under the new EU provisions on novel foods, the applicant will continue to be responsible for submitting the information necessary for carrying out the safety assessment. Applications may be submitted to the Commission by an EU Member State or by a natural or legal person (e.g. a business or association – "the applicant"). From there, the applications are made available to EFSA and the competent authorities in the Member States.

Under the provisions of the new Regulation currently under consideration, risk assessment will be carried out exclusively by EFSA in future.

Novel foods are included in a Community list of permitted novel foods by a Commission Regulation. This is published in the Official Journal of the European Union (including any specific conditions for their use, labelling

[50] This includes copies of any studies which have been carried out and any other material which is available to demonstrate that the food or food ingredient complies with the criteria laid down in Regulation (EC) No 258/97 (in other words to demonstrate, among other things, that it poses no risk to consumers).

[51] This information is also made available to the Commission and the competent authorities in the other Member States (by means of an official internal database). If additional assessment by the European Food Safety Authority (EFSA) is deemed necessary, then EFSA too receives a copy of the information.

requirements, etc.). Moreover, relevant information on novel foods will be published on a dedicated Commission web page.

As before, EFSA opinions will be publicly accessible via the Authority's website.

Food additives

When applying for authorisation, the applicant (the person responsible for placing the product on the market in the EU) must submit all the necessary information required for safety assessment of the food additive (starting with the specification of the substance and including any studies that have been carried out). Applications may be submitted to the Commission by an EU Member State or by a natural or legal person (e.g. a business or association – "the applicant"). From there, the applications are made available to EFSA and the competent authorities in the Member States.

Food additives are included in a Community list of permitted novel foods by a Commission Regulation, published in the Official Journal of the European Union. Authorisation includes rules concerning scope of use, along with the specification of the product and purity criteria. EFSA opinions are publicly accessible via the Authority's website.

Food contact materials

Substance-specific authorisation procedures currently exist in EU law for certain components in food contact materials made from plastics (Directive 2002/72/EC) and from regenerated cellulose film (Directive 2007/42/EC). Both of these Directives are implemented in Germany by the Commodities Ordinance (*Bedarfsgegenständeverordnung*). Substances in so-called active and intelligent materials and articles will also require authorisation in future (Regulation (EC) No 450/2009).

Details of information to be submitted with an application for authorisation are set out in the EFSA Guidelines for the safety evaluation of substances in food contact materials. The information must be submitted by the applicant in question, and are forwarded to EFSA via the competent authorities in the Member States (in Germany this is the Federal Office for Consumer Protection and Food Safety (BVL)). Substance data are entered into an EFSA database to which the national authorities and the Commission have read access. Evaluations carried out by EFSA are available to the general public via the Internet.

The Community lists of authorised substances (positive lists) are included in the Annexes to the legislative acts mentioned above. There are no separate lists for nanomaterials. In the positive list of the Regulation on materials used in plastics (currently in the process of revision) it is anticipated that in future details will need to be provided regarding whether a substance is used in nanoform. The legislative provisions are published officially and are publicly accessible. The lists of authorised substances include the following information:

- the identity of the substance(s)

- the function of the substance(s)
- the reference number
- if necessary, the conditions of use of the substance(s) or component
- if necessary, restrictions and/or specifications of use of the substance(s)
- if necessary, conditions of use of the material or article to which the substance or component is added or into which it is incorporated.

REACH and the ECHA classification and labelling inventory

The data contained in the REACH registration dossier are entered into databases of the European Chemicals Agency (ECHA). Whether or not a separate registration dossier is compiled for nanomaterials depends on, among other things, whether the nanomaterial in question has been identified as a substance in its own right or as a specific physical form of another substance (see Section 4.1).

Public access to the ECHA databases is regulated under Article 77 (2) e) and Articles 118 and 119 of REACH. In accordance with these provisions, the following information held by the Agency is made available to the public free of charge: the classification and labelling of a substance, the physico-chemical properties of a substance, data on pathways and environmental fate, the result of each toxicological and ecotoxicological study, any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC), and the guidance on safe use provided in accordance with Annex VI of REACH. Corresponding information on substances that have been evaluated by the authorities in the Member States or by the ECHA is also published in the database in accordance with Article 77 (2) f).

In accordance with Article 64 (6) and (9) REACH, in the context of the granting of authorisations, parts of Agency opinions and a summary of the Commission's authorisation decision are made publicly available together with the authorisation number, information on the substance (in accordance with Article 118 and Article 119) and, if appropriate, details of suitable alternative substances and reasons.

The restrictions in Annex XVII of REACH constitute an example of a register that not only contains information on substances, but also restricts the use of substances/products or permits their use only if they comply with certain conditions. Additional restrictions are imposed by laying down product-specific rules (e.g. for substances used in construction materials, electrical and electronic equipment or toys).

In accordance with Article 42 of the CLP Regulation, information in the ECHA classification and labelling inventory is also made publicly available.

Biocidal products and plant protection products

The registers/databases presented in this context do not currently contain any information as to whether or not nanomaterials are present in the products

listed. However, in the case of biocidal products for example it is anticipated that data reporting requirements under the authorisation procedure and, where necessary, the content of relevant databases, will be adapted to incorporate information on any nanomaterial content. The section below relates to the existing registers in the area of biocidal products and plant protection products.

Biocidal products

Applicants for authorisation of a biocidal product must submit to the competent authority a dossier or a letter of access for the biocidal product and a dossier or a letter of access for every active substance in the biocidal product, satisfying certain requirements according to the state of the art in science and technology. It is not envisaged under the Biocidal Products Directive (98/8/EC) that these data will be made publicly available.

Following the Commission Decision of 21 May 2010, a Community Register for Biocidal Products (R4BP) has been established at European level (see https://webgate.ec.europa.eu/env/r4bp/user.login.cfm). The Register is intended to facilitate compliance by the Member States with the requirement to submit the information concerning authorisation and registration of biocidal products set out in Article 18 (1) of Directive 98/8/EC and to ensure consistency of the data. The Register is not intended for public use.

In Germany, authorisations and registrations of biocidal products, the content of authorisations or registrations and their expiry date, and the withdrawal of any authorisations and registrations, are announced in the Federal Gazette by the German authorisation body (at the Federal Institute for Occupational Safety and Health (*BauA)*.

The German authorisation body has set up a page on its website providing access to background information on all biocidal products authorised or registered in Germany (https://www.biozid-meldeverordnung.de/offen/index.php). This includes information on the name of the biocidal product, its registration number, active substance, type of product, authorisation expiry date and use.

Transitional provisions have been put in place for biocidal products containing “existing active substances”, but to take advantage of the transitional regime the biocidal product must be notified to the authorisation body responsible for the national product register. The deadline for notification of biocidal products on the market prior to or in May 2005 was 28 July 2005; moreover, notification must take place before first placing on the market. Notification of biocidal products is free of charge and includes, inter alia, the trade name of the biocidal product and the name and CAS and EC numbers of the biocidal active substance. If a biocidal product is marketed under a variety of trade names, multiple notifications are required. This data is available to download from the authorisation body (see above). In accordance with the Regulation on the notification of biocidal products (ChemBiozidMeldeV), notified products are issued with a registration number that must accompany the product itself.

In addition, any manufacturer, importer or other market participant placing a biocidal product on the market under a different trade name must provide the Federal Institute for Risk Assessment (*BfR*) with information for documentation in the Poison Information Database (*Giftinformationsdatenbank*).[52] Mandatory notification in accordance with Article 16e of the German Chemicals Act (*ChemG*) encompasses information on the trade name, the composition of the product, labelling, use and recommended safety precautions, and emergency measures in the event of accidents. These data are intended "only" for the purpose of dealing with poisoning incidents and so have a very limited use. The data are treated confidentially by the BfR and cannot be made available to the public or to other authorities.

Plant protection products and plant strengtheners

Applicants for authorisation of a plant protection product submit to the competent authority a dossier on the plant protection product and any active substance(s) contained in it, and any necessary instructions for use in cases where the applicant is not the owner of the dossier. The requirements for the dossier are laid down in Annexes II and III of Directive 91/414/EEC as harmonised Community rules. It is also stipulated that the data must satisfy the requirements in the light of current scientific and technical knowledge. Publication of this data is not envisaged under the current Directive (91/414/EEC) on plant protection products or under the new Regulation (EC) No 1107/2009, and some of the data is also covered by data protection provisions.

At the present time, there is an EU database on pesticide residues (http://ec.europa.eu/sanco_pesticides/public/index.cfm), containing information on active substances assessed in the EU regardless of whether or not they have been listed in Annex I of Directive 91/414/EEC. Database entries for each active substance include, inter alia, relevant toxicological information and the maximum residue levels in or on food and feed. Information on active substances currently authorised at national level within Member States has been available since 2009. In the case of active substances that have undergone a Community assessment, EFSA publishes a comprehensive Peer Review Report containing a summary of the identity, toxicology, residue behaviour and ecotoxicology (see http://www.efsa.europa.eu/en/scdocs.htm).

In Germany, details of authorisations granted for plant protection products, the expiry date of authorisations, any transitional or grace periods, or withdrawal or suspension of authorisations are published in the Federal Gazette by the authorisation body, the Federal Office for Consumer Protection and Food Safety (BVL).

The BVL also provides an online database of authorised plant protection products with a variety of research options, giving access to background information on all plant protection products authorised in Germany. The

[52] Mandatory notification applies not only to biocidal products, but to **all** hazardous substances and mixtures intended for consumer use.

information in the database includes the name of the plant protection product, its authorisation number, active substances contained in it, applications, expiry date of its authorisation and any requirements or special conditions attached to its use. In addition, since July 2009 all authorisation and approval reports relating to authorisation and approval procedures for plant protection products are also published on the BVL website.

Products described as "plant strengtheners" are subject to a listing requirement under Article 31 of the German Plant Protection Act (PflSchG). These lists are published in the Federal Gazette. The competent authority (the BVL) updates the list monthly and makes it available, along with other information, on the internet (http://www.bvl.bund.de/cln_007/nn_492710/DE/04__Pflanzenschutzmittel/00__doks__downloads/PflStM__liste,templateId=raw,property=publicationFile.pdf/PflStM_liste.pdf). The list may include indications of constituents present in nanoform, as in the case of listing number 5925-00 (as of 7 June 2010).

Other registers and information instruments

Mention must be made here of the European system **RAPEX** (Rapid Alert System for non-food consumer products).[53] RAPEX enables market surveillance authorities to inform each other if risk management measures are to be put in place with regard to a consumer product that presents a serious risk to consumer health and safety. However, it only intervenes in the event of a specific threat to human health. Hazards in the workplace and environmental hazards are not covered. Moreover, the RAPEX system does not enable the competent authorities to obtain an overview of nanoproducts available on the market and reporting via RAPEX tells them nothing about whether the product in question contains nanomaterials.

A similar system is in place for the food and feed sector – RASFF (Rapid Alert System for Food and Feed).

5.2.7 Positions on a nanoproduct register

The following table presents the positions of the stakeholders and representatives of the public bodies in Working Group 3. Positions on a nanoproduct register can be closely tied to opinions on labelling requirements, especially relating to consumer products.

Stakeholders	What should the purpose of a nanoproduct register be?
German Federation for Food Law and Food Science (BLL)[54]	For the food sector, the provisions of the Novel Food Regulation provide for compulsory listing and publication (Official Journal of the EU, Commission website) of authorised products, including conditions of use and labelling requirements. The same applies to food additives and components of commodities for which authorisation is mandatory, such as food packaging materials and household items intended to come into contact with food;

[53] See EU website: http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm

[54] See section 5.2.5 of this paper and corresponding references to the legislative texts.

Stakeholders	What should the purpose of a nanoproduct register be?
	authorisation leads to listing in the Regulation, and thereby publication. In these areas, therefore, a nanoproduct register would be redundant and unjustified.
Friends of the Earth Germany – BUND[55]	Market transparency for authorities/decision-making bodies and civil society/consumers, so it should be publicly accessible.
Prof. Calliess, Hermann (Öko-Institut)	Transparency based on a precautionary approach for all market participants, stakeholders and authorities, and to facilitate product recall.
Confederation of German Trade Unions (DGB)[56]	Problem: For occupational safety and health there is no mandatory information instrument for **articles**, so a register would facilitate communication of the presence of nanomaterials (NM) in articles. This must be seen against the background that NM release during the processing of articles cannot be ruled out – thus giving rise to occupational exposure. As long as no mandatory communication instrument (akin to the Safety Data Sheets for substances and mixtures) exists for articles containing NM, product registers or notification requirements for articles containing NM could provide a basis for (i) creating transparency regarding the extent of the problem, (ii) enabling the supervisory authorities to make recommendations (Guidance documents, Technical Rules) for specific occupational safety arrangements, and (iii) enabling the supervisory authorities, in their hazard assessment, to provide specific instructions to affected sectors/businesses/users to take account of the presence of NM in articles during processing operations.
Prof. Führ, Prof. Scherzberg	Transparency for all market participants, stakeholders and authorities.
German Chemical Industry Federation (VCI)	As a matter of principle, a product register should only be established for substances with hazardous properties. As nanoproducts and nanomaterials do not in themselves possess hazardous properties, the VCI rejects the idea of a nanoproduct register. In general terms, product registers allow products requiring notification or authorisation to be grouped together in a consistent manner. Specific registers already exist in the relevant areas of regulation. In the case of hazardous products, a product register provides support for information centres dealing with poisons or emergencies.
Federation of German Consumer Organisations (vzbv)[57]	The creation of a product register would provide transparency with regard to which products containing nanomaterials are on the market. This would give consumers the chance to make informed decisions.

Authorities	What should the purpose of a nanoproduct register be?
Federal Office for Chemicals (BAuA Fb5)	• To close gaps in knowledge concerning nanomaterials on the market • To clarify whether measures are necessary to eliminate shortcomings in the existing regulatory system relating to nanomaterials (precautionary principle). A situation in which there are abstract grounds for concern constitutes a trigger for recourse to precautionary measures. In this context, it is sufficient for a hazard to be scientifically plausible. The purpose of a nanoproduct register, therefore is:

[55] Supplementary information and opinions can be found at www.bund.net

[56] From the DGB's point of view, the debate on a nanoproduct register should be combined with a debate on appropriate strategies for market surveillance with regard to "nanoproducts". In this debate the product register is merely the means to an end, and not an end in itself. Closer analysis of operating conditions for market surveillance, along with its objectives and resource base, including enforcement aspects, is strongly recommended. In recent times health and safety staff have been cut drastically (in some cases around 30%), and this trend is continuing. Preventing hazards from arising as a result of inadequately tested, rogue products placed on the market without proper reflection should surely also be in the interests of any industry that takes itself seriously.

[57] Supplementary information and opinions can be found www.vzbv.de

Authorities	What should the purpose of a nanoproduct register be?
	• To expand the knowledge base, • To improve enforcement of the legislative provisions, • To exploit existing information opportunities for users • To exploit existing market surveillance instruments and intervention mechanisms.
Federal Environment Agency (UBA)[58]	To provide public authorities with knowledge, an overview of the market and a basis for future action. Research into nanomaterials is on the increase, and if, for example, hazards for human health or the environment are revealed, the register would enable the public authorities to respond immediately because they would know which nanomaterials are present where.

Stakeholders	What would be the relationship between the product register and a labelling requirement?
German Federation for Food Law and Food Science (BLL)	(see above)
Friends of the Earth Germany (BUND)	They are complementary. A product register is more comprehensive, and can include products for which labelling poses problems. A link to the product register could enable interested consumers to obtain more detailed information to supplement label information.
Confederation of German Trade Unions (DGB)	Debate on the product register (or compulsory notification) should be separate from any discussion on labelling obligations, as they are intended to serve different purposes (Labelling: freedom of choice; product register: inter alia, a basis for hazard-related considerations (see above)).
Prof. Führ	Relationship not absolutely necessary. The transparency created by the nanoproduct register would, however, facilitate decision-making on where labelling requirements are most needed.
Prof. Calliess, Hermann (Öko-Institut)	They complement one another. It also depends on decisions regarding access to the register. Labelling enables immediate recognition of whether a product contains nanomaterials (useful primarily for consumers). The register provides an overview of the market (primarily useful for public authorities).
VCI, Prof. Scherzberg	Product register and labelling obligations are separate matters.
Federation of German Consumer Organisations (vzbv), Hermann (Öko-Institut)	Product register and labelling can complement one another. The issue of whether the product register is to be publicly accessible needs to be discussed, however. If the answer is yes, then a product register can provide more extensive information to supplement labelling.

Authorities	What would be the relationship between the product register and a labelling requirement?
Federal Environment Agency (UBA)	They complement one another. It also depends on decisions regarding access to the register. Labelling enables immediate recognition of whether a product contains nanomaterials (useful primarily for consumers). The register provides an overview of the market (primarily useful for public authorities).

Stakeholders	Which products should be included in the product register?
Hermann (Öko-Institut)	Reporting should be required for: • Manufacturing, importing or placing on the market nanomaterials on their own or in mixtures in the area of application of the Regulation • Producing or placing on the market semi-finished or finished products containing nanomaterials in the area of application of the Regulation, and for importing any of the aforementioned products into the area of application of

[58] For more detailed discussion see the Federal Environment Agency (UBA) Background Paper "Nanotechnology for Humans and the Environment", October 2009, http://www.umweltdaten.de/publikationen/fpdf-l/3906.pdf

Stakeholders	Which products should be included in the product register?
	the Regulation Where appropriate, existing nanomaterials should be excluded, especially those already covered under other sectoral legislation, e.g. • Products covered by the Cosmetics Regulation, the Novel Food Regulation or the Food Additives Regulation • Medicinal products as defined in Directive 2001/83/EC and veterinary medicines as defined in Directive 2001/82/EC • Medical products and devices as defined by Directive 90/385/EEC and Directive 93/42/EEC which are invasive or used in direct physical contact with the human body, or as defined by Directive 98/79/EC • Semi-finished products, mixtures and consumer products which do not contain deliberately engineered nanomaterials • R&D materials
German Federation for Food Law and Food Science (BLL)	(see above)
Friends of the Earth Germany (BUND)	All consumer products and applications that are open to the environment
Confederation of German Trade Unions (DGB)	From an occupational health and safety perspective: all articles that may be used in a professional context by businesses (including craft industries/trades, cleaning firms, etc.).
Prof. Führ, Prof. Scherzberg	Basically all substances, mixtures and articles (except intermediates)
Prof. Calliess, Hermann (Öko-Institut)	To afford a comprehensive overview of the market, the scope of the nanoproduct register should be broad, including nanomaterials on their own, mixtures containing nanomaterials, and articles (or components of articles) which contain nanomaterials. Certain products may be excluded, for example products for which other provisions already impose a mandatory reporting requirement in respect of nanomaterial content.
German Chemical Industry Federation (VCI)	As far as the VCI is concerned, the product registers described in Section 5.2.6 are adequate. They cover any "nanoproducts" falling within their scope.
Federation of German Consumer Organisations (vzbv)	Consumer products which fall within the scope of the German Food and Feed Code (LFBG) (textiles, cosmetics, foods, food contact materials, toys, and commodities broadly defined)

Authorities	Which products should be included in the product register?
Federal Office for Chemicals (BAuA Fb5)	Reporting should be required for: • Manufacturing, importing or placing on the market nanomaterials on their own or in mixtures within the area of application of the Regulation • Producing or placing on the market semi-finished or finished products containing nanomaterials within the area of application of the Regulation, and for importing any of the aforementioned products into the area of application of the Regulation. Where appropriate, existing nanomaterials should be excluded, especially those already covered in other sectoral legislation, e.g. • Products covered by the Cosmetics Regulation, the Novel Food Regulation or the Food Additives Regulation • Medicinal products as defined in Directive 2001/83/EC and veterinary medicines as defined in Directive 2001/82/EC • Medical products and devices as defined by Directive 90/385/EEC and Directive 93/42/EEC which are invasive or used in direct physical contact with the human body, or as defined by Directive 98/79/EC • Semi-finished products, mixtures and consumer products which do not contain deliberately engineered nanomaterials • R&D materials
Federal Environment Agency (UBA)	To afford a comprehensive overview of the market, the scope of the nanoproduct register should be broad, including nanomaterials on their own, mixtures

Authorities	Which products should be included in the product register?
	containing nanomaterials, and articles (or components of articles) which contain nanomaterials. Certain products may be excluded, for example products for which other provisions already impose a mandatory reporting requirement in respect of nanomaterial content.

Stakeholders	What information should be kept in the product register?
Hermann (Öko-Institut)	Mandatory reporting to the competent authority by manufacturers and importers first manufacturing or placing on the market nanomaterials within the meaning of the product register should include the following information: 1. the name and address of the manufacturer or importer 2. the product name and trade name of the nanomaterial 3. the country of origin, in the case of an imported nanomaterial 4. the specification of the nanomaterial, including particle size and particle size distribution, physical and chemical properties, external form and, where appropriate, any modification(s) made to its surface (coatings), 5. the registration number of the nanomaterial in accordance with REACH and 6. an estimate of the quantity of the nanomaterial to be placed on the German market per year. Mandatory reporting by manufacturers and importers first manufacturing or placing on the market mixtures or articles containing one or more nanomaterials should include the following information: 1. the name and address of the manufacturer or importer 2. the product name and trade name enabling clear identification of the specific article or mixture, and the product category 3. the country of origin, in the case of an imported article or mixture 4. the registration number for the nanomaterial(s) used in the article or mixture, in accordance with the product register 5. an estimate of the quantity of the nanomaterial(s) in the article or mixture to be placed on the market in Germany per year. In both cases it is also proposed that manufacturers appoint a person to be responsible for dealing with all matters concerning the authority; where a nanoproduct presents a risk to human health, the responsible person shall have an obligation to make available to the authority immediately any further information necessary.
German Federation for Food Law and Food Science (BLL)	(see above)
Friends of the Earth Germany (BUND)	Product name and trade name, manufacturer /seller, nanomaterials used in the product, instructions for safe use, link to corresponding substance in REACH internet database (if and when all the information has been included in it).
Confederation of German Trade Unions (DGB), Prof. Calliess	From an occupational health and safety perspective: information relevant for occupational health and safety akin to that under discussion concerning Safety Data Sheets for substances and mixtures in connection with NM (see also the recommendations of the VCI in relation to Safety Data Sheets)
Prof. Führ, Prof. Scherzberg	Basic data: substance identity, uses, risk information from Safety Data Sheet (if available)
German Chemical Industry Federation (VCI)	As far as the VCI is concerned, the information required by law for the product registers described in Section 5.2.6 is adequate. They include information on any “nanoproducts” falling within their scope.
Federation of German Consumer Organisations (vzbv)	This depends on whether the product register is public or only accessible to public authorities.

Authorities	What information should be kept in the product register?
Federal Office for Chemicals (BAuA Fb5)	Mandatory reporting to the competent authority by manufacturers and importers first manufacturing or placing on the market nanomaterials within the meaning of the product register should include the following information: 7. the name and address of the manufacturer or importer 8. the product name and trade name of the nanomaterial 9. the country of origin, in the case of an imported nanomaterial 10. the specification of the nanomaterial, including particle size and particle size distribution, physical and chemical properties, external form and, where appropriate, any modification(s) made to its surface (coatings), 11. the registration number of the nanomaterial in accordance with REACH and 12. an estimate of the quantity of the nanomaterial to placed on the market in Germany per year. Mandatory reporting by manufacturers and importers first manufacturing or placing on the market mixtures or articles containing one or more nanomaterials should include the following information: 6. the name and address of the manufacturer or importer 7. the product name and trade name enabling clear identification of the specific article or mixture, and the product category 8. the country of origin, in the case of an imported article or mixture 9. the registration number of the nanomaterial(s) used in the article or mixture, in accordance with the product register 10. an estimate of the quantity of the nanomaterial(s) in the article or mixture to be placed on the market in Germany per year. In both cases it is also proposed that manufacturers appoint a person to be responsible for dealing with all matters concerning the authority; where a nanoproduct presents a risk to human health, the responsible person shall have an obligation to make available to the authority immediately any further information necessary.
Federal Environment Agency (UBA)	Data on production, use, characterisation and functionality of any nanomaterials used, product name and trade name

Stakeholders	Who should have access to the information?
German Federation for Food Law and Food Science (BLL)	(see above)
Friends of the Earth Germany (BUND), Prof. Scherzberg, Hermann (Öko-Institut)	In accordance with REACH, different access arrangements could be put in place for public authorities /decision-making bodies and consumers.
Confederation of German Trade Unions (DGB)	Supervisory bodies. If access is to be made public, clarification is needed regarding different levels of information content for different user groups (public authorities, general public)
Prof. Führ	Access via the internet as set out in Article 119 of REACH
Prof. Calliess	Public authorities and the general public; if necessary, certain information could be excluded from the public register (to protect trade secrets and confidential business information).
German Chemical Industry Federation (VCI)	Depending on the product sector and the confidentiality of the information required for the product register, access could be restricted to public authorities and poisons and emergency information centres. Alternatively, certain information could be made publicly accessible. In any case, adequate protection of trade secrets and confidential business information must be ensured.
Federation of German Consumer Organisations (vzbv)	Two-tier access: in our view the product register should have two tiers: one providing extensive information on chemical composition for the public authorities, and the other with more concise information for consumers

Authorities	Who should have access to the information?
Federal Office for Chemicals (BAuA Fb5)	The following scenarios are conceivable: • a public register in which all the information provided is publicly accessible • a public register in which only certain information is publicly accessible, or • a register which is only accessible to the authority responsible for maintaining the register, but which produces a publicly accessible report on nanomaterials in consumer products on a regular basis (e.g. annually). Consideration must be given to whether publication of data could have an impact on business interests: • details of the complete composition of a nanoproduct or a mixture within the meaning of REACH • the precise use, function or application of a nanomaterial or mixture containing nanomaterials • the precise quantity in which the nanomaterial, the mixture containing nanomaterials, or the nanoproduct is manufactured or placed on the market • relationships between a manufacturer or importer of nanoproducts or nanomaterials and other actors in the manufacturing chain, such as manufacturers of semi-finished products or mixtures.
Federal Environment Agency (UBA)	Public authorities and the general public; if necessary, certain information could be excluded from the public register (to protect trade secrets and confidential business information).

5.3 Labelling of consumer products

In the discussion on labelling that follows, attention is focused primarily on those products in which nanomaterials are NOT bound in a stable matrix. These are mainly products that are used frequently and which come into especially close contact with the human body, or which are used in the open environment. Hence, for example, the discussion does not cover computer components or individual vehicle parts containing nanomaterials.

5.3.1 Explanation and purpose of the instrument

A general distinction needs to be made between

- voluntary labelling schemes, which include environmental labelling schemes and voluntary self-declaration by manufacturers, quantitative data sheets and results of comparative product testing, and
- compulsory labelling, which includes for example declarations of contents, as in the case of cosmetics and lists of ingredients in foods, but also includes instructions for use and waste disposal, labelling of products using hazard warning symbols, and declarations of conformity, for which CE marking can be used in the European Union.

The Federal Institute for Risk Assessment (BfR) has concluded from its study on this issue, that (voluntary) product labelling is an appropriate instrument for influencing purchasing decisions for or against products. The desired direction

of purchasing decisions can be influenced by means of label form and content.[59]

Labelling basically serves to provide transparency about products and the ingredients they contain, and enables consumers to alter their purchasing behaviour if products with alternative ingredients are on the market.

The discussion below focuses on compulsory labelling, as only this type of labelling can be influenced by regulation.

5.3.2 Areas of regulation in which labelling is already used or is under discussion for nanomaterials

At present, only the Cosmetics Regulation makes explicit provision for labelling of nanomaterials in products (ingredients must be followed by the word “nano”). The Cosmetics Regulation also contains its own definition setting out the scope of the special labelling requirement.

The proposal for a revised Novel Food Regulation currently under consideration, like its predecessor Regulation (EC) No 258/97, envisages that authorisation of a novel food may, where appropriate, be subject to specific labelling obligations. This also applies to novel foods containing manufactured nanoparticles. According to the position of the Council on the first reading of the draft, no labelling requirement for nanomaterials in general is envisaged. Instead, regulating on a case-by-case basis continues to be the preferred approach. The European Parliament, meanwhile, advocates specific labelling of all nanomaterials and has reaffirmed its position on this matter in the second reading. Adoption of the new Regulation is not anticipated before 2011. Whether or not specific labelling obligations will be included in the Novel Food Regulation remains to be decided in a conciliation procedure between the Council, the European Parliament and the Commission.

Biocidal products and plant protection products are subject to an authorisation procedure and are labelled in great detail (although the labelling requirements do not include indicating the presence of nanomaterials). Labelling in the case of these products includes warnings and instructions for safe use and waste disposal in accordance with the specific hazardous properties of a given product. Introduction of nano-specific labelling is under discussion in the revision of the Biocidal Products Directive.

[59] Epp, A., Kurzenhäuser, A., Hertel, R., Böl, G.F. (eds) Grenzen und Möglichkeiten der Verbraucherinformation durch Produktkennzeichnung. BfR-Wissenschaft 05/2010, Berlin 2010.

5.3.3 Positions on labelling

The positions of stakeholders and expert opinions of the higher federal authorities are set out in the following tables.

Stakeholders	Should general compulsory labelling be introduced?
German Federation for Food Law and Food Science (BLL)	No; provision of information on particular product characteristics is a matter for voluntary labelling / product description. General product safety provisions oblige distributors to guarantee that products are safe and to engage in market monitoring.
Friends of the Earth Germany (BUND)[60]	Labelling for all consumer products and applications that are open to the environment.
Prof. Führ	No, only where potential grounds for concern cannot be ruled out.
Prof. Scherzberg	In my opinion, labelling products with the word "nano" is not very meaningful as it gives no indication of the properties of the product. It would be more important to state clearly, where appropriate, any risks associated with the product.
Prof. Calliess	Compulsory labelling should be introduced primarily for consumer products and applications that are open to the environment.
German Chemical Industry Federation (VCI)	No. Labelling should only be required if a product has hazardous properties.
Federation of German Consumer Organisations (vzbv)[61]	Consumer products should be labelled.

Authorities	Should general compulsory labelling be introduced?
Federal Environment Agency (UBA)[62]	Compulsory labelling should be introduced primarily for consumer products and applications that are open to the environment.

Stakeholders	Should general compulsory labelling be introduced for consumer products?
German Federation for Food Law and Food Science (BLL)	No. There is no justification for compulsory labelling in this area, especially as specific regulations are in place (including, among others, the Novel Food Regulation) which provide for safety assessment and authorisation as a prerequisite for placing a product on the market. Authorisations stipulate the possible uses and properties of a product and lay down any labelling requirements. Authorisation implies that the consumer /product user is, or must be, able to rely on official decisions and the professional judgement of experts.
Friends of the Earth Germany (BUND)	Yes, because voluntary labelling would never achieve coverage of the whole European region. This would deny consumers true freedom of choice, and it would also mean that there was no level playing field in terms of competition.
Prof. Führ, Prof. Calliess	Yes.
Prof. Scherzberg	In the case of consumer products too, I believe a description of hazardous properties or gaps in scientific knowledge is more meaningful than abstract labelling with the word "nano".
German Chemical Industry Federation (VCI)	From the perspective of the VCI, the labelling requirements for cosmetics and the food sector are sufficient. In the case of cosmetics, for example, a system for correct listing of ingredients is provided through the INCI list, covering not only nanomaterials; in principle, this could also be used as a basis for listing

[60] See www.bund.net for position statements and various publications that touch on this issue

[61] For more detailed information www.vzbv.de

[62] Federal Environment Agency (UBA) Background Paper "Nanotechnology for Humans and the Environment", October 2009, http://www.umweltdaten.de/publikationen/fpdf-l/3906.pdf

Stakeholders	Should general compulsory labelling be introduced for consumer products?
	ingredients in products in the food sector.
Hermann (Öko-Institut)	Yes, for products intended for final consumers (e.g. textiles, cosmetics, foods, food packaging). Depending on the final consumer product in question, compulsory labelling should apply to the nanomaterial used rather than to the product in general.
Federation of German Consumer Organisations (vzbv)	Yes, for products intended for final consumers (e.g. textiles, cosmetics, foods, food packaging).

Authorities	Should general compulsory labelling be introduced for consumer products?
Federal Environment Agency (UBA)	Yes.

Stakeholder	Do you advocate voluntary labelling of consumer products?
German Federation for Food Law and Food Science (BLL)	Yes. Providing information on particular characteristics of a product to enable consumers to make informed decisions and to influence purchasing decisions is a voluntary instrument available to the provider.
Friends of the Earth Germany (BUND)	No – see above. Voluntary arrangements do not have a good track record.
Prof. Führ, Prof. Calliess	No, voluntary labelling would be inadequate as it denies the consumer certainty.
German Chemical Industry Federation (VCI), Prof. Scherzberg	Every business is free to provide information on the ingredients used in its products.
Federation of German Consumer Organisations (vzbv), Hermann (Öko-Institut)	No, this is not sufficient. Our experience with voluntary labelling schemes has shown that these can end up reducing market transparency further and confuse consumers. It is important to ensure standardised labelling.

Authorities	Do you advocate voluntary labelling of consumer products?
Federal Environment Agency (UBA)	No – see above.

Stakeholders	Should products that have already undergone an authorisation procedure (e.g. in accordance with REACH) be labelled?
German Federation for Food Law and Food Science (BLL)	No – see above.
Friends of the Earth Germany (BUND), Hermann (Öko-Institut)	Yes, because the issue here is to inform the consumer and ensure freedom of choice. Nanomaterials behave differently from other substances and the gaps in knowledge are likely to outweigh the available data regarding safety assessment of nanomaterials for several years at least. Labelling is also widely advocated for substances of very high concern under REACH.
Prof. Führ	Yes, because the issue here is to provide freedom of choice for consumers rather than warnings.
Prof. Scherzberg	Yes, risk-related labelling as outlined above.
Prof. Calliess	Yes, primarily for consumer products and applications that are open to the environment. To ensure freedom of choice for consumers, efforts should be geared towards creating an appropriate labelling system that informs without suggesting that a hazard is present.

Stakeholders	Should products that have already undergone an authorisation procedure (e.g. in accordance with REACH) be labelled?
German Chemical Industry Federation (VCI)	Substances that have undergone authorisation in accordance with REACH or other provisions must be labelled according to their hazardous properties. Merely indicating the presence of particular substances provides no added value.
Federation of German Consumer Organisations (vzbv)	Yes, because the issue here is to provide freedom of choice for consumers rather than warnings.

Authorities	Should products that have already undergone an authorisation procedure (e.g. in accordance with REACH) be labelled?
Federal Environment Agency (UBA)	Yes, primarily for consumer products and applications that are open to the environment. To ensure freedom of choice for consumers, efforts should be geared towards creating an appropriate labelling system that informs without suggesting that a hazard is present.

Stakeholders	What should be the relationship between labelling and a product register?
German Federation for Food Law and Food Science (BLL)	Listing and publication of authorised products should be mandatory (see BLL position on the product register).
Friends of the Earth Germany (BUND)	They should be complementary. See comments in connection with the product register and in the next box.
Prof. Führ	Labelling should include a reference to the registration number in the nanoproduct register.
Hermann (Öko-Institut), Prof. Calliess	They complement one another. It also depends on decisions regarding access to the register. Labelling enables immediate recognition of whether a product contains nanomaterials (useful primarily for consumers). The register provides an overview of the market (primarily useful for public authorities), e.g. by enabling identification of the total amount on the market.
German Chemical Industry Federation (VCI), Prof. Scherzberg	Product register and labelling obligations are separate matters.
Federation of German Consumer Organisations (vzbv)	See comments in the table on the product register

Authorities	What should be the relationship between labelling and a product register?
Federal Environment Agency (UBA)	They complement one another. It also depends on decisions regarding access to the register. Labelling enables immediate recognition of whether a product contains nanomaterials (useful primarily for consumers). The register provides an overview of the market (primarily useful for public authorities), e.g. by enabling identification of the total amount on the market.

Stakeholders	What information should labelling convey?
German Federation for Food Law and Food Science (BLL)	
Friends of the Earth Germany (BUND), Hermann (Öko-Institut)	At the moment the issue is only about the presence of nanoparticles. Interested consumers could obtain more detailed information via an internet link either to a product register or to a future REACH database.
Prof. Führ, Prof.	The information contained in the nanoproduct register.

Stakeholders	What information should labelling convey?
Calliess	
Prof. Scherzberg	Information on existing knowledge/lack of knowledge concerning hazardous properties of the product or substance. Merely to indicate that a product contains substances on the nanoscale is not, in my view, appropriate.
German Chemical Industry Federation (VCI)	Mandatory labelling provided for by law must always be informative and clear and must not lead the consumer in a particular direction. As far as the VCI is concerned, labelling should only be required if a product has hazardous properties.
Federation of German Consumer Organisations (vzbv)	This would depend on whether labelling operated in parallel to a product register that would enable the consumer to obtain more detailed information.

6 Concluding remarks

The Working Group discussed issues concerning regulation of nanomaterials and nanoproducts in the context of the precautionary principle, as set out in the Communication from the European Commission. Difficulties were identified especially with regard to the manner in which the precautionary principle is implemented in specific legislative provisions. These difficulties were due in part to the fact that key terms are given different meanings in different contexts.

Regulation of nanomaterials is taking place most extensively at the level of the European Union. All of the areas of regulation examined by the Working Group relate to EU Regulations or Directives. It is therefore essential for the Federal Government to convey German positions on these issues to the EU.

7 Abbreviations

TFEU: Treaty on the Functioning of the European Union

AGS: Ausschuss für Gefahrstoffe – Committee on Hazardous Substances (http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/AGS/AGS.html)

BAuA: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (www.baua.de) German Federal Institute for Occupational Safety and Health

BGBl: Bundesgesetzblatt – Federal Law Gazette

BLL: Bund für Lebensmittelrecht und Lebensmittelkunde e.V. (www.bll.de) – German Federation for Food Law and Food Science

BUND: Bund für Umwelt und Naturschutz Deutschland (www.bund.net) – Friends of the Earth Germany

BVL: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (http://www.bvl.bund.de) – Federal Office of Consumer Protection and Food Safety

CLP Regulation: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

COM: Commission of the European Union

DGB: Deutscher Gewerkschaftsbund (www.dgb.de) – Confederation of German Trade Unions

DIN: Deutsches Institut für Normung (www.din.de) – German Institute for Standardisation

DNEL: Derived no-effect level (Abgeleitete Expositionshöhe ohne Beeinträchtigung)

ECHA: European Chemicals Agency – Europäische Chemikalienagentur (http://echa.europa.eu)

EFSA: European Food Safety Authority – Europäischen Behörde für Lebensmittelsicherheit

EC: European Community

R&D: Research and development

GG: Grundgesetz (Basic Law for the Federal Republic of Germany)

ISO: International Organization for Standardization (www.iso.org)

IUPAC: International Union of Pure and Applied Chemistry

LFGB: Lebensmittel- und Futtermittelgesetzbuch – German Food and Feed Code

MAK-Kommission: Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe – Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (http://www.dfg.de/dfg_profil/gremien/senat/gesundheitsschaedliche_arbeitsstoffe/index.html)

Nm – nanometre

OECD: Organisation for Economic Cooperation and Development (www.oecd.org)

PBT: persistent, bioaccumulative, toxic

PNEC: Predicted no-effect concentration

REACH: Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals

SCCP: Scientific Committee on Consumer Products

SRU: Sachverständigenrat für Umweltfragen – German Advisory Council on the Environment

WG: Working Group

TRGS: Technische Regeln für Gefahrstoffe – German Technical regulations on hazardous substances

UBA: Umweltbundesamt (www.umweltbundesamt.de) – Federal Environment Agency

UV: ultraviolet

VCI: Verband der chemischen Industrie e.V. (www.vci.de) – German Chemical Industry Federation

I. Annex 1: Meanings of key terms in the context of precaution and various areas of regulation

Table 1: Comparison of meanings of the term "hazard"

Term **Context**	**Hazard**
Precautionary principle	A hazard is present when there is sufficient likelihood that, if an objectively expected event is allowed to take place unhindered, it will cause harm, in other words significant impairment of an asset that is protected by law. The concept of hazard here is relative. The greater the potential harm or consequences of harm, or the more important the protected asset under threat, the less knowledge is required regarding the degree of likelihood attached to the hazard.
Food law[63]	Hazard refers to a biological, chemical or physical agent in, or condition of, a food or feed, with the potential to cause an adverse health effect.
Epidemiology/ toxicology	Source of potential harm
Genetic engineering law	A situation that entails an identifiable, objective, and immediate possibility of damage occurring, in other words where, if an objectively expected event is allowed to take place unhindered, harm will result. If a hazard is identified, hazard control measures must be taken.[64] (These are not to be confused with risk prevention measures). **Harm**: Any significant impairment, or reduction in number, of real, normal legal assets or resources essential for life by external events. There must be a degree of probability of harm occurring but certainty is not necessary. The greater or more severe the potential harm, the lower the degree of probability of its occurrence needs to be.[64] **Suspected hazard** The potential for harm is suspected or is at least conceivable on the basis of actual evidence, although it may not be possible to provide evidence concerning the likelihood of its occurring. The potential for harm to occur cannot, however, be ruled out with probability bordering on certainty. Suspected hazard is based on a remediable absence of evidence or gap in knowledge, in other words to a temporary situation in which there is insufficient knowledge. [64]
Law on substances	In the legislation on substances, the terms "hazard" and "hazardous" ("Gefahr" and "gefährlich" in German) are used to describe intrinsic properties of substances and mixtures, in other words in the meaning of a danger that is intrinsic to the substance or mixture. A substance or mixture is deemed hazardous if it possesses particular hazardous properties, e.g. if it is carcinogenic, acutely toxic or caustic. This applies irrespective of the extent of any potential harm or of the probability of its occurrence in the course of an activity involving the substance or mixture.
Occupational health and safety law	

[63] Regulation (EC) No 178/2002 of the European Parliament and of 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, 01/02/2002 p. 1- 24.

[64] Koch & Ibelgaufts: GenTG-Kommentar, VCH 1992

Table 2: Comparison of meanings of the term "risk"

Term Context	Risk
Precautionary principle	A risk is described as being present where an adverse effect is possible or cannot be ruled out. While "hazard" assumes that there is sufficient likelihood of harm occurring, "risk" requires merely the possibility of an adverse effect. In contrast to hazard, then, "risk" also encompasses cases where there is uncertainty or subjective lack of knowledge regarding individual factors or cause-and-effect relationships.
Food law	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Epidemiology/ toxicology	A product of hazard plus exposure: the potential and extent of a hazard for the environment or a person for a given exposure.
Genetic engineering law	Occurrence of harm is possible, but is so unlikely that it is not regarded as presenting a hazard (hazard threshold). Precautionary measures may be taken to minimise risks. Based on the principles set out here [under German law], even high levels of risk remain below the hazard threshold. [Under German law] It is only possible to work with, release into the environment or place on the market any genetically modified organism subject to compliance with the hazard thresholds. See, for example, the safety precautions prescribed for genetic engineering facilities in category S1 – S4 areas, requirements relating to release into the environment or placing on the market of GMOs.[64]
Law on substances	In English-language legislation on substances, the word "risk" is usually used (most EC Directives and Regulations relating to substances were originally drafted in English). The term "risk" takes account of the level of potential adverse (environmental or health) effects and the probability of their occurrence. "Risk" can be translated into German as "Risiko", and in fact the concept of risk/Risiko plays a key role in actuarial mathematics, where it is defined as a product of the extent of damage and the probability of occurrence.
Occupational health and safety law	In occupational health and safety legislation (German Occupational Health and Safety Act, Hazardous Substances Ordinance, etc.) the term "risk" is translated as "Gefährdung". Its meaning is the same as that used in the legislation on substances.

Table 3: Comparison of meanings of the term "risk identification"

Term Context	Risk identification
Precautionary principle	For the purpose of risk identification (Risikoermittlung), scientific data are collected using established scientific methods to describe potential risks taking into account any gaps in knowledge and uncertainties, and risks are then estimated on the basis of the available facts. For this reason, the terms "risk estimation" or "scientific risk assessment" are sometimes used instead of "risk identification".
Food law	Risk assessment (Risikobewertung) is a process based on scientific principles. It comprises four steps: hazard identification, hazard characterisation, exposure estimation and risk characterisation.
Epidemiology/ toxicology	Quantification or estimation of risk on the basis of potential hazard quantification, dose-response assessment, and exposure assessment.
Genetic engineering law	Not used in the context of genetic engineering law.
Law on substances	
Occupational health and safety law	The English term "risk assessment" is not translated as "Risikobewertung" in German, but as "Gefährdungsbeurteilung". This is now established practice and terms such as "Risikoermittlung", "Risikobewertung", "Gefährdungsermittlung", or "Gefährdungsbewertung", which have similar meanings, are only seldom used in the occupational health and safety context.

Table 4: Comparison of meanings of the term “normative risk assessment”

Term **Context**	**Risk assessment (Risikobewertung)**
Precautionary principle	Normative risk assessment: the results of risk identification are used as the basis for political evaluation of the risk. A decision is made as to whether the potential risk is acceptable or not.
Food law	--
Epidemiology/ toxiciology	Characterisation and evaluation of the nature and extent of the risk on the basis of hazard estimation, dose-response assessment, exposure assessment, risk identification and evaluation of the associated uncertainties.
Genetic engineering law	Evaluation of the potential for harm to occur below the hazard threshold. [64]
Law on substances	
Occupational health and safety law	The English term “risk assessment” is not translated as “Risikobewertung” in German, but as “Gefährdungsbeurteilung”. This is now established practice and terms such as “Risikoermittlung“, “Risikobewertung”, “Gefährdungsermittlung”, or “Gefährdungsbewertung”, which have similar meanings, are only seldom used in the occupational health and safety context.

Table 5: Comparison of meanings of the term “risk management”

Term **Context**	**Risk management**
Precautionary principle	In the context of risk management, the various strategic alternatives are weighed up to decide what precautionary measures should be taken and what form these should take.
Food law	Risk management – a process distinct from that of risk assessment, and which involves consideration of the available strategic options in consultation with those affected, taking into account risk assessment and other factors that warrant consideration, and where necessary adopting appropriate prevention and control measures.
Epidemiology/ toxicology	Development and implementation of regulatory measures on the basis of scientific risk assessment and evaluation of the measures.
Genetic engineering law	A process distinct from that of risk assessment, entailing consideration of the available options for prevention or control of risks (Article 3 (6b) of the German Genetic Engineering Act (GenTG). This is used in the sense of “dealing with” (“Umgang mit”) risks.)
Law on substances	
Occupational health and safety law	In the occupational health and safety context, the term “risk management measures” is not translated into German as “Risikomanagementmaßnahmen” or “Risikominderungsmaßnahmen”, but as “Schutzmaßnahmen”.

II. Annex 2: List of relevant areas of regulation

Below is a list of areas of regulation and specific Regulations, Directives, legislative acts, etc., which the Working Group recommends reviewing to ascertain whether nanomaterials are adequately regulated. Provisions discussed in this paper are highlighted in bold.

A. Substances

- **REACH Regulation (EC) No 1907/2006 and Guidance**
- **CLP Regulation (EC) No 1272/2008 and Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of substances and mixtures**
- Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- German Chemicals Act (*Chemikaliengesetz*)
- German Chemicals Prohibition Ordinance (*Chemikalien-Verbotsverordnung*)
- **German Hazardous Substances Ordinance (*Gefahrstoffverordnung*) and Technical Rules (*Technisches Regelwerk – TRGS*)**

B. Food contact materials

- **Regulation (EC) No 1935/2004 (Framework Regulation) on materials and articles intended for food contact**
- **Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food**
- **Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs**
- **Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs**
- German Food and Feed Code (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*)
- German Commodities Ordinance (*Bedarfsgegenständeverordnung*)

C. Food

- **General Food Law Regulation (EC) No 178/2002 laying down the general principles and requirements of food law**
- **German Food and Feed Code (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*)**
- **Novel Food Regulation (EC) No 258/97 (currently under revision)**
- **Regulation (EC) No 1333/2008 on food additives**

D. Cosmetics

- **Cosmetics Regulation (EC) No 1223/2009**
- German Food and Feed Code (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*)

E. Biocidal products

- **Directive 98/8/EC concerning the placing of biocidal products on the market (currently under revision)**
- German Chemicals Act (*Chemikaliengesetz*)
- German Biocide Notification Ordinance (Biozid-Zulassungsverordnung)

F. Plant protection products

- **Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products**
- German Plant Protection Act (Plant strengtheners), Article 31

G. Commodities

- German Food and Feed Code (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*)
- German Commodities Ordinance (*Bedarfsgegenständeverordnung*)

H. Products

- Product Safety Directive 2001/95/EC
- German Equipment and Product Safety Act (*Geräte- und Produktsicherheitsgesetz*)
- Toy Safety Directive 2009/48/EC

In the textiles sector there are no provisions regulating nanomaterials. This area should be reviewed to assess whether there is a potential need for regulation here.

I. Waste

- Waste Framework Directive 2008/98/EC
- German Closed Substance Cycle and Waste Management Act (*Kreislaufwirtschafts- und Abfallgesetz*)
- German Ordinance on the European List of Waste (Verordnung über das Europäische Abfallverzeichnis)
- WEEE Directive 2002/95/EC (currently under revision)
- RoHS Directive 2002/96/EC (currently under revision)
- German Electrical and Electronic Equipment Act (*Elektro- und Elektronikgesetz*)
- Packaging Directive 1994/62/EC
- German Packaging Ordinance
- Directive 2000/76/EC on the incineration of waste

- German Ordinance on Waste Incineration and Co-incineration (*17. BImSchV über die Verbrennung und Mitverbrennung von Abfällen*)
- Sewage Sludge Directive 86/278/EEC (scheduled for revision)
- German Sewage Sludge Ordinance (*Klärschlammverordnung*)
- Directive 1999/31/EC on the landfill of waste
- German Landfill Ordinance (*Deponieverordnung*)
- German End-of-life Vehicles Ordinance (*Altfahrzeugverordnung*)

J. Air

- IPPC Directive 2008/1/EC (currently under revision)
- Air Quality Framework Directive 2008/50/EC + Daughter Directives
- Seveso II Directive 96/82/EC (currently under revision)
- German Federal Immission Control Act (*Bundesimmissionsschutzgesetz – BImSchG*) + Implementing Ordinances (esp. 4th, 12th, 22nd BImSchV)
- German Technical Instructions on Air Quality Control (*Technische Anleitung zur Reinhaltung der Luft – TA Luft*)

K. Water

- Water Framework Directive 2000/60/EC
- Groundwater Directive 2006/118/EC
- Regulation (EC) No 648/2004 on detergents
- German Federal Water Act (*Wasserhaushaltsgesetz*)
- German Waste Water Ordinance (*Abwasserverordnung*)
- German Groundwater Ordinance (*Grundwasserverordnung*)
- German Ordinance on Installations Handling Water-Polluting Substances and on Specialised Enterprises (*Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen und über Fachbetriebe*)
- German General Administrative Regulation implementing the Federal Water Act, concerning the Classification of Substances Hazardous to Waters into Hazard Categories (*Allgemeine Verwaltungsvorschrift zum Wasserhaushaltsgesetz über die Einstufung wassergefährdender Stoffe in Wassergefährdungsklassen*)
- German Detergents and Cleaning Products Act (*Wasch- und Reinigungsmittelgesetz*)

III. Annex 3: List of Working Group members

Name	Institution
Speaker of the Working Group Prof. Dr. Christian Calliess	Freie Universität Berlin, Rechtswissenschaften (Department of Law)
Walter Adebahr	Ministry of the Environment, Nature Conservation and Transport, Baden-Württemberg (for BLAC)[65]
Katharina Adler[66]	Federal Ministry of Food, Agriculture and Consumer Protection – BMELV[67]
Inga Beer[66]	Federal Environment Agency – UBA
Monika Büning	Federation of German Consumer Organisations (Verbraucherzentrale Bundesverband – vzbv)
St a.D. Wolf-Michael Catenhusen	Chair of the NanoKommission
Dagmar Friese[66]	Federal Ministry of Health – BMG
Prof. Dr. Martin Führ	University of Applied Sciences Darmstadt
Dr. Ilka Grötzinger[66]	Federal Ministry of Health – BMG
Andreas Hermann, LL.M.	Institute for Applied Ecology – Öko-Institut e.V.
Dr. Rolf Hertel[66]	Federal Institute for Risk Assessment – BfR
Liane Horst[66]	Federal Ministry of Education and Research – BMBF
Dr. Anke Jesse[66]	Federal Environment Ministry – BMU
Dr. Hans-Jürgen Klockner	German Chemical Industry Federation – VCI
Martina Kohlhuber	Bavarian State Office for Health and Food Safety – Division Environmental Medicine – LGL
Dr. Dietmar Kopp[66]	Federal Ministry of Economics and Technology – BMWi
Cornelia Leuschner[66]	Federal Environment Ministry – BMU
Dr. Hanns Pauli	Confederation of German Trade Unions – DGB
Walther Quasigroch[66]	Federal Ministry of Food, Agriculture and Consumer Protection – BMELV[67]
Dr. Marcus Schaper	Evangelische Akademie Loccum
Dr. Jutta Schaub[66]	Federal Ministry of Food, Agriculture and Consumer Protection – BMELV
Prof. Dr. Arno Scherzberg	University of Erfurt
Dr. Frauke Schröder[66]	Federal Institute for Occupational Safety and Health-BAuA
Dr. Agnes Schulte[66]	Federal Institute for Risk Assessment – BfR
Dr. Sieglinde Stähle	German Federation for Food Law and Food Science – BLL
Jurek Vengels	Friends of the Earth Germany – BUND
Dr. Heiner Wahl[66]	Federal Ministry of Labour and Social Affairs – BMAS
Dr. rer. nat. Rudolf Weinand	Evonik Degussa GmbH
Dr. Karin Wiench	BASF

[65] BLAC: Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit (Federa/Federal State Working Committee Chemical Safety).

[66] As the German Federal Government is the recipient of the NanoKommission's recommendations, representatives of the various government bodies have a different role to that of the stakeholders in the Working Group. Participants from the Federal ministries and institutions within the ministries' areas of operation were mandated to provide expertise and advice to support the work of the Working Group. Expert input provided by these individuals does not necessarily represent the official position of the ministry concerned.

[67] Ms Adler and Mr Quasigroch provided support in written form but did not attend the Working Group sessions.