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Ulrich Fiedeler*, Michael Nentwich, Sabine Greßler, André Gazsó, Myrtill Simkó

Voluntary approaches by industry in the field of nanomaterials

Summary

The current voluntary approaches to the regulation of nanotechnology are characterized by a broad variety and major differences. At present, there are registers, codes of conducts, certification schemes and risk management systems. In addition, even within the same type noticeable differences can be observed. For instance the BASF code of conduct is restricted to enterprises while that of the IG-DHS is restricted to a certain region and to a specific sector (food). In contrast, the EU code of conduct not only applies to the whole of the EU, but encompasses also many sectors and even social sub-systems such as the economy, research and politics. However, it is restricted to research activities and their organization. Apart from the certifications for textiles and the IG-DHS code of conduct, all voluntary measures are characterized by an openness concerning the fields of application of nanotechnology. With respect to the registration of industrially produced nanoparticles, a trend towards the establishment of a mandatory system (register) can be observed.

Introduction

Currently there is a controversial discussion ongoing whether the existing regulations with regard to product safety and environmental liability are also sufficient for the manufacturing and marketing of nanomaterials. This discussion not only takes place at the European level, but also at the national level. 1 Moreover, there are already some initiatives which aim at regulating the field of nanomaterials on the basis of voluntary conduct. This dossier gives an overview of the existing voluntary measures for the regulation of nanomaterial handlings.² These measures can be divided into four categories: (1) nano-registers; (2) codes of conduct; (3) certification schemes; (4) risk management schemes.

1. Nano-register

A first step towards achieving regulation consists in collecting data on manufactured nanomaterials and their fields of application. This follows from the fact that in order to assess the risk not only do their potential (eco-) toxicological properties play an important role, but also their exposure. However, currently there is no institution within Europe which can provide information which synthetic nanomaterials are being used commercially or which are being produced in larger quantities and used for research purposes. Against this background, not only environmental and consumer advocacy organizations, but also political institutions such as the EU Parliament,3 or national establishments such as the administrative authorities, propose a mandatory registration, one of the like as currently does not exist within or outside of the EU.4 Notwithstanding the lack of such efforts on a collective basis, a few states have undertaken, on voluntary basis and with different approaches, to determine those corporations which trade, import or use synthetic nanomaterials and moreover, to identify which nanomaterials are concerned in this process.

Voluntary Reporting Scheme (United Kingdom)

The Voluntary Reporting Scheme (VRS) was developed by the British Department for Environment, Food and Rural Affairs (DEFRA). It is aimed at collecting data concerning free engineered nanomaterials from manufacturers, commercial users, research and the waste industry. For the purposes of the collection, the VRS uses a very narrow definition with the following criteria⁵: the material is engineered deliberately (i.e. not material which is created naturally or unintentionally as a by-product of other processes); the material shows in two or more dimensions an extension of up to 200 nm, or is in two or more dimensions roughly within the nanoscale; the material "is free within any environmental media at any stage of a products life cycle"⁶.

Apart from the restriction that merely "free" materials are covered, the VRS is characterized by its high expectations towards corporations that they extensively deliver information on the materials. The following data is inter alia requested?: information as to the composition, properties and identity of the engineered nanomaterial, information as to its manufacturing process, source and use, as well as data concerning exposure, toxicology, ecotoxicology, and finally, information regarding the corporations' risk management practices.

With regard to most of these points, further detailed information is requested as well. During the period of data collection (September 2006 - September 2008) only twelve completed responses were submitted. To provoke more submissions and also to discover the reason why only so few responses were handed it, a telephone survey was conducted⁸. Despite this effort, only one further response was submitted and thus, this scheme must be deemed as little successful⁹. The Royal Commission on Environmental Pollution has therefore made the recommendation to DEFRA to make the reporting mandatory¹⁰. The program is not completed yet, and currently it seems that

^{*} Corresponding author



within DEFRA the opinion has managed to prevail which believes that in the future a revised version of REACH will be sufficient to gather the necessary information⁸.

Swiss Nano-Inventory (Switzerland)

Between 2005 and 2007 the Institute Universitaire Romand de Santé au Travail (IST) conducted a survey with the aim of estimating the extent of usage and significance of nanomaterials in the Swiss industry¹¹. In addition, to also capture measures relating to health, safety, the environment as well as the number of exposed workers. The study was divided into two phases: a pilot study and the actual survey.

During the pilot study, a series of telephone surveys was conducted with 198 corporations of which it could be assumed that they use or manufacture nanoparticles¹² to determine whether Swiss corporations would be willing and capable to provide information concerning their manufacturing or utilization of nanoparticles. Differently than usual, the study included particles up to 1000 nm as constituting nanoparticles. 13 Moreover, regarding the attribution of powders to nanomaterials a further difficulty arises from the circumstance that powder generally does not consist of nanoparticles of the same size (monodispers) but it always contains a particle size distribution, especially with regard to powder which has been produced through a grinding procedure. 14 This means that the decision whether one terms a powder as "consisting of nanoparticles" must be made arbitrarily. It is thus imaginable that a powder might, it its entirety, to more than 90 weight percentage consist of particles which are far larger than 1000 nm, however, the number of particles in the powder which are smaller than 100 nm could still be larger than the large particles. So far published literature does not reveal which criteria are used in the Swiss study to determine powders as "consisting of nanoparticles". During the main survey, particles were viewed as nanoparticles even in situations in which the particle size distribution or condition of agglomeration were unknown. In addition, all surface treatment was added which does not solely rely on polymerization or the formation of particles and droplets during its application is not precisely known.

Of the questioned 198 corporation, nearly a fourth confirmed the manufacturing of nanoparticles, approximately a fifth the usage. Almost all safety administrators were willing to answer questions. The amount of manu-

factured or used nanoparticles varied from a few grams up to thousands of tons, which however, especially with regard to the working definition used (see above), is only of limited use. The nanoparticles used mainly consisted of Ag, AlO₃, Fe-Ox, SiO₂, TiO₂ and ZnO. The fields of application were identified in coating, cosmetics, foods/feeds/food packages, metal, optics, colors, powder-production, research and surface treatment.

The pilot study served the preparation of the questionnaire for the main study, which was envisioned as a nation-wide survey. While the pilot study supplied qualitative data, the survey functioned as a quantitative assessment of the number of corporations in Switzerland as well as the number of employees who may work with nanomaterials. Equally, protective measures for human beings as well as the environment were compiled. The survey was conducted among the approximately 1600 corporations of various industrial sectors, which were statistically chosen from the clientele of the SUVA (Swiss accident insurance institution). From the collected data, it was possible to project that merely 0,63 % of the Swiss industrial corporations used or manufactured nanoparticles, these mainly concerning the area of the chemical industry. Corporations which only marketed nanoparticles were excluded from the survey. Regarding the compilation of protective measures concerning employees and environment, this decision is not fully comprehensible. The study has been completed and the results have been published in the final report.15

Nanoscale Materials Stewardship Program (USA)

In January 2008, the Office of Prevention, Pesticides and Toxic Substances of the US Environmental Protection Agency instigated the "Nanoscale Materials Stewardship Program" (NMSP): US corporations, which manufacture, import and process nanomaterials, are requested to give voluntary information on these materials. The concept paper 16 defines what is intended to fall under nanomaterials: materials where at least one dimension is the size range between the atomic/molecular state and the bulk/macro state (therefore below 100 nm and above 1 nm). On the other side, the US Toxic Substances Control Act (TSCA) proposes a definition which aims at determining "new" chemical substances, as only those must be reported on before they may enter the market. 17 According to this definition, all nanomaterials which in their "nano-version" show the same molecular construction as in their macro-version will not be understood as "new" chemical substances, even if they demonstrably possess other physical or chemical properties. Typical, and according to the TSCA "new", nanomaterials are fullerenes, such as carbon nanotubes or the so-called bucky-balls. This binary division of the problem of risk assessment regarding new materials clearly proves that in the area of nanotechnology the existing categories of substance, respectively molecular structure, find their limitations.

Until the end of 2008, 29 corporations have provided information concerning more than 123 nanomaterials, consisting of more than 58 different chemical substances. A majority of the materials is used in the area of research and development. According to the definition of the TSCA, 18 "new" substances could be identified. The collected data was compared to other data bases, and it then showed that the reported data only constituted a small part of known nanomaterials. ¹⁸

The EPA published a list of the corporations which took part in the programme and, if they so agreed, provided detailed information to the nanomaterials. In August 2009, the EPA announced to be working on the further development of the TSCA, to incorporate within its framework information on the manufacture, use and exposure of existing nanomaterials.¹⁹ This programme was continued until January 2010.

In the meantime, efforts to institute an obligation of registration of nanomaterials seems to be gaining momentum. For example, since spring 2009 a Californian authority (Department for Toxic Substance Control, DTSC) has been requesting chemical corporations incorporated in the State of California to deliver extensive information with regard to carbon- and other nanomaterials.²⁰ The register can be accessed over the internet.²¹

While the French government was called upon by a law in August 2009 to introduce a mandatory register for nanomaterials within two years, 22 the British government appears to keep relying on voluntary measures. 23 The EU Parliament requested the Commission in April 2009 "to compile before June 2011 an inventory of the different types and uses of nanomaterial on the European market [...] and to make this inventory publicly available."



2. Codes of Conduct

To date, there are five different codes of conduct which directly or indirectly refer to nanotechnology. They largely differentiate themselves through their sectorial area of application as well as their target group.

Responsible NanoCode (United Kingdom)

In 2006, the Royal Society, Insight Invest and the Nanotechnology Industries Association (NIA) formed a working group for the development of a code of conduct concerning nanotechnology in the industry. Later, the Nanotechnology Knowledge Transfer Network (Nano KTN) joined in as well. The voluntary code of conduct, with the target group industry, consists of a list of examples of good practices and seven principles²⁴, summarized as follows:

- 1. Board Accountability
- 2. Stakeholder Involvement
- High Standards of Worker Health & Safety
- 4. Risk Assessment of Minimizations of Potential Public Health, Safety or Environmental Risks
- 5. Wider Social, Environmental, Health and Ethical Implications and Impacts
- 6. Engaging with Business Partners for the Dissemination of the Code
- Transparency and Regular and Clear Disclosure.

The focus lies with the responsible manufacturing of nanomaterials- and products. The Code of Conduct was published in the Fall of 2007 for international consultations. In an update in 2008, the examples for good practices were finalized.²⁵ According to the NIA,²⁶ respectively forumnano²⁷, the Code of Conduct was already published in a final version in 2008. A few corporations have either incorporated the original Code or the Code in a modified form within their corporate structures (e.g. the Confederation of the Food and Drink Industries of the EU (CIAA)²⁸, and forumnano). As however no monitoring is conducted, it is unknown how many corporations have incorporated the Code of Conduct as well as how they have implemented it.29

Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (EU)

The EU Commission published the Code in February 2008 in a Recommendation.³⁰ The Code, the recommendations and the measures of implementation shall be examined every two years. The Code is addressed to the Member States, industry, academia, research centers and researchers; the main addressee is science. Similar to other codes, it is also not mandatory. The Code is characterized by seven comprehensive, not nanospecific, principles, summarized as follows:

- Comprehensibility to the public, respect of fundamental human rights, well-being of individuals and society
- 2. Ethical tenability, contribution to sustainable development, no harm to people, animals, plants or the environment
- 3. Precautionary principle, at the same time encouragement of progress
- 4. Openness to all stakeholders, transparency, access to information
- 5. Excellence, good laboratory practices
- 6. Encouragement of innovation and growth
- 7. Accountability of research.

The Code has far-reaching consequences. Hence, the seventh principle proposes that researchers shall be accountable for possible negative results of their findings. The Code does not contain any suggestions, guidelines, checklists, indicators or further ideas concerning its operationalization or implementation. In addition, the principles are formulated in an open manner, leaving large discretion for interpretation. The EU Commission envisions applying the Code itself as a guideline for its research policies in the area of nanotechnology. Moreover, it calls upon the Member States to adopt the Code of Conduct as well as implement it. Currently it is however unclear how a coordinated operationalization of the Code by the Member States would present itself in order to avoid a wide variation of interpretations. In Winter 2009/2010, the Commission conducted another public survey regarding the Code.31

IG-DHS Code of Conduct Nanotechnology (Switzerland)

The interest group retail trade Switzerland (IG-DHS) is an association of the six largest retailers in Switzerland: Migros, Coop, Denner, Manor, Charles Vögele and Valora. Together they dominate the Swiss retail market, and in 2008 they developed a Code for the handlings with nanomaterials in the food

sector, containing five principles³², summarized as follows:

- 1. Self-responsibility, state of scientific and technical knowledge
- Active information procurement with regard to legal regulations and new scientific discoveries
- 3. Openly available information for consumers
- 4. Requirements for producers and suppliers: risk management, work safety
- Disclosure of relevant product data (added value by use of nanotechnology, nano-specific effects, potential of danger).

The Code is characterized by the circumstance that it requests precise information concerning the use of nanomaterials from corporations located at the beginning of the supply chain (producers, suppliers). In addition, the advantages gained through the use of nanomaterials compared to normal materials shall be elaborated on, as well as the effect of the nanomaterial, the technical specifications and possible risks associated with their use. Moreover, the producers and suppliers are called upon to disclose their risk management measures as well as their work safety strategy. Due to the association's market power, the code of conduct can be viewed as a strong measure. Both the association and the Code still exist throughout 2010 unchanged.

BASF-Code of Conduct Nanotechnology (Germany)

The BASF Code of Conduct was developed in 2004 as a company-internal instrument by the German chemical corporation BASF.³³ The Code is aimed at, on the one hand, ensuring a responsible and safe production of nanomaterials, on the other hand, it is part of a communication-strategy, based on openness and transparency. The most relevant assertions are:

- 1. Protection of human life and the environment as a fundamental principle
- 2. Measures of risk identification and minimization
- 3. Involvement in activities and debates concerning risk assessments
- 4. Constructive participation in the regulation
- Marketing only of safe and harmless products
- 6. Information for customers and partners about the handling and disposal
- 7. Transparency and constructive, open and public debates
- 8. Immediate disclosure of new information.



The Code is connected with the Corporate Identity of the corporation as well as the Responsible Care Initiative (see below). Based on it, the "Guide to safe manufacture and for activities involving nanoparticles at workplaces in BASF AG" was drawn up.³⁴ BASF still adheres to the Code.

Responsible Care (International)

Despite the "Responsible Care Charter" not mentioning nanomaterials explicitly, according to its initiators they are considered adequately. Responsible Care was developed by the International Council of Chemical Association (ICCA) and is a comprehensive approach of the chemical industry to develop and document responsible behavior (corporate social responsibility, CSR) of corporations.35 The origins of the concept go back to 1985, and since then it has continuously been developing. In October 2004, the "Responsible Care Global Charter" was passed and introduced to the public in February 2006. Responsible Care is based on six fundamental principles which are marked by a similar wide discretionary space for interpretation as the EU Code of conduct. The initiative confirms the development of specific Codes, inter alia a Code for nanomaterials. The ICCA provides instructions, indicators for evaluation and checklists which support corporations in their commitments to the Code. The ICCA also determines measures to verify that corporations, which have adhered to the Code, abide by the Responsible Care principles. Corporations must reaffirm the application of the principles every two years. Currently, the Charta has been accepted by corporations in more than 50 countries and by two-thirds of the 110 largest chemical corporations.

3. Certification

A further voluntary measure with regard to the regulation of nanotechnology can be seen in certifications, of which currently there are three examples:³⁶

CENARIOS (Germany)

Since 2006, "Die Innovationsgesellschaft", together with TÜV-SÜD, has been developing a risk-management and monitoring system³⁷, which was officially introduced in June 2008.³⁸ With regard to the efforts in relation to implementation, it can be compared with the ISO 9000 certification, thus a complicated and tedious process. Following a suc-

cessful evaluation, the corporation receives a certificate, which however must be refreshed time and again. The advantages for a corporation with such a certificate are: it helps guaranteeing work place safety and product safety; it documents responsible conduct in the sense of Corporate Social Responsibility (CSR); and, in the instance of legal actions, the corporation can prove that its production process is in coherence with the state of technical knowledge. Certifications are conducted at TÜV-SÜD. So far, only one corporation has begun with the certification process.

Hohenstein Quality Label for Nanotechnology (Germany)

The Hohenstein Institute, together with Nanomat – a network of various research facilities and leading suppliers of nanomaterials –, have developed the "Hohenstein Quality Label for Nanotechnology" for the textile industry.³⁹ The main aim of the Ho-

henstein Quality Label is to stop the massive, but not always justified use of nanotechnology in advertising. It is being used since April 2005, and so far four products have been labeled.

Quality Seal Nano Inside (Germany)

Stemming from a similar motivation, the industrial alliance "forumnano" introduced a quality seal for nanotechnology in January 2008. ²⁷ However, the quality seal "nano-inside" is not limited to specific nanotechnological applications. Hence, criteria for the awarding of the seal are: that the product "contains nano", that the corporation has obliged itself to adhere to the "Responsible Nanocode" (see above), and that certain product characteristics actually are based on nanotechnology. According to the information on the website of forumnano, the seal has so far been obtained for one product.

Table 1: Overview over the different voluntary measures and their national scope of application

Measure	State	Туре	Object	Aim/Addressee
Voluntary Reporting Scheme	UK	Register	Nanomaterials	Regulatory efforts
Swiss Nano-Inventory	СН	Register	Nanomaterials	Regulatory efforts
Nanoscale Materials Stewardship Program	USA	Register	Nanomaterials	Regulatory efforts
Responsible NanoCode	UK, Int.	Code of Conduct	Products, manufacturing process	Consumers, employees
EU-Code of Conduct for Nano-Research	EU	Code of Conduct	Research	Society
IG-DHS-Code of Conduct	СН	Code of Conduct	Food sector, manufacturing process	Consumers
BASF-Code of Conduct	Ger.	Code of Conduct	Products, nanomaterials, manufacturing process	Consumers, employees
Responsible Care	Int.	Code of Conduct, Risk Management System	Products, manufacturing process	Consumers, employees
CENARIOS	Ger.	Certification, Risk Management System	Products, nanomaterials, manufacturing process	Consumers, employees
Hohenstein Quality Label	Ger.	Certification	Products	Consumers, fair competition
Quality Seal "Nano inside"	Ger.	Certification	Products	Consumers, fair competition
Nano Risk Framework	USA	Risk Management System	Products, manufacturing process	Consumers, employees

Key: UK = United Kingdom, CH = Switzerland, Ger. = Germany, Int. = International



4. Mixed Form: Risk-Management System

One initiative in the area of voluntary selfcommitments cannot be matched to either category as it contains elements of a code of conduct as well as of certification.

Nano Risk Framework (USA)

The Nano Risk Framework was developed by the chemical corporations DuPont and the Environmental Defense Fund (EDF), a US non-governmental organization (NGO), in 2007.40 Unlike codes of conduct, the framework contains detailed descriptions concerning a corporation's risk-management when engaging in the manufacturing or use of nanomaterials. However, in comparison to CENARIOS, the implementation is not documented by a certificate. The framework is conceptualized in a process-oriented manner and consists of six steps: description of material and its application (1), profile lifecycles (nanomaterial's properties, inherent hazards, exposures) (2), evaluation of risk (3), assess risk management (4), decide, document, and act (5), review and adapt. The framework offers instructions for the implementation and documentation of decisions as well as for the evaluation of the risk-governance-process and contains specific recommendations concerning the characterization of risks, the testing with regard to toxicity and ecotoxicity and the development of lifecycle assessments (eco balance). According to the International Risk Governance Council (IRGC), it is "probably the most detailed and, at the same time, practical code available"41. DuPont tested the framework on three projects concerning its consistency as well as its operationality 42 .

Discussion

The definition of nanomaterials is essential for the introduction of nano-registers, especially as it must combine the contradictory elements of being detailed but at the same time also manageable. A further factor of success is the degree of detail contained in the necessary information. Concerning the limited success of the British approach, the following reasons were identified⁴³: Too many objectives were set out to be achieved with one register; data collection is often too expensive for small and middle-sized corporations; the producers are not certain whether they should apply the scheme in

their corporation; there is uncertainty as to what the data will be used for (who has access to the data?)⁴⁴; and the benefit for a corporation to conduct the reporting-scheme is questionable. It can be assumed, that other nano-registers are confronted with similar difficulties. Introducing mandatory registration is currently being discussed in the US, France and England (see above). Europe could also follow the route of explicitly recognizing nanomaterials in the REACH-process.

The five Codes of Conduct can be differentiated both with regard to their focus and their subjects. Nevertheless, this variety could lead to mutual obstruction. For example, some corporations are of the opinion that the more comprehensive approach taken in "Responsible Care" is sufficient to also cover nanomaterials. However, it is also often criticized that the Codes of Conduct leave too much discretion with regard to interpretation and thus, do not offer any concrete instructions. Consequently, their steering function would also be perceived as limited. A possible solution to this problem could be to develop specific agreements for individual areas. The example of the Code of Conduct by the IG-DHS must be viewed differently. In this case it is apparent that the framework-conditions (as market power) necessarily influence the effectiveness of a governance-approach.

There are several reasons for the industry to submit themselves to a Code of Conduct. One of the most important is to ensure the trust of the consumers, especially as in the past this trust has been severely strained by serious accidents in the chemical industry.

Conclusions

With respect to nanomaterials at present, there is considerable debate whether the existing legal framework sufficiently regulates their responsible use. This discussion over the last few years has been accompanied by the launch of several initiatives aimed at regulating this field on a voluntary basis. In essence, the aim of these initiatives is to reduce the health risks in production and ensure safe consumer products. Some of them also aim at quality assurance, e.g. certifications for textiles. Hitherto, it has remained an open question whether these initiatives will guarantee a sufficient level of commitment despite their voluntary character in order to achieve their goals. Beyond doubt, these initiatives represent an important contribution towards the coordination of stakeholder activities concerning the responsible use of nanomaterials.

Further reasons are ratings by the financial market, based on adherence to CSR-criteria. However, NGOs have so far doubted the power of assertion of such reasons. Thus, against this background, it could be deliberated whether an official, respectively independent, system of certification or assessment would not be more effective.

Despite the fact that certifications often only occur on a voluntary basis, the number of corporations which follow this process could exert pressure on those corporations which not yet adhere to the system. The Swiss retail industry shows that corporations which are at the end of the supply chain, and accordingly possess considerate market power, can substantially contribute to the introduction of a certification system.

Notes and References

- ¹ See NanoTrust-Dossier 017en for the EU respectively 018 and 019 for Austria.
- ² The standardization efforts are not subject of this dossier. Standardization is an important condition for regulation, but these activities do no aim at implementation processes or measures, which shall be dealt with here.
- ³ www.europarl.europa.eu/sides/ getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2009-0328+0+DOC+XML+V0//DE.
- ⁴ Even if Canada formally has instituted mandatory registration (compare www.ec.gc.ca/substances/nsb/eng/a200706_e.shtml), this limits itself to very specific nanomaterials. For example, titandioxid, even if prevailing in nano-particular form, would not fall within the obligation of registration. Apparently only those materials which are also deemed by the US Chemicals Act as "new chemicals", such as carbon nanotubes, and are also subject to their registration, or even admission procedures, are covered by the Canadian act.
- DEFRA (Department for Environment Food and Rural Affairs), 2008, UK Voluntary Reporting Scheme for engineered nanoscale materials, www.defra.gov.uk/environment/quality/ nanotech/documents/vrs-nanoscale.pdf.
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- For more details see Schmidt (endnote 11), p. 2256.
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- ¹⁴ Compare NanoTrust-Dossiers 002.
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- According to the TSCA, the EPA is obliged to record possible risks and develop appropriate measures to protect human beings and the environment
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- ¹⁹ EPA, 2009, Federal Register, Vol. 74, No. 148, 4.8.2009, Notices, p. 38878, edocket.access.gpo.gov/2009/pdf/ E9-18469.pdf.
- www.dtsc.ca.gov/PressRoom/upload/ News Release T-25-09.pdf.
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- ²² See Article 42, www.legifrance.gouv.fr/ affichTexte.do?cidTexte=JORFTEXT0000 20949548&dateTexte=.
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- ⁴³ Morgan, Steve, 2008, The British Way the Voluntary Reporting Scheme of the DEFRA, NanoRegulation 2008, 16./17.9.2008, St. Gallen, Swiss. See also literature in endnote 8.
- This concerns highly sensitive data relating to the composition, quality of material, optical properties of the material etc. The data could enable a competing corporation to gain detailed information concerning the knowledge and processes of the concerned corporation, which could be used to its advantage.

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