ÖAW ITA
Institute of Technology Assessment of the Austrian Academy of Sciences

nano trust dossiers
No. 017en • November 2010

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Nano Regulation in the European Union

Summary

Since 2004, the European Union has intensified its efforts with regard to regulatory aspects of nanotechnology. New legislation is based on existing regulations. At the beginning the assumption still prevailed that current legislation would suffice to cover nanotechnology. However, some fields have started to adapt; in particular with regard to chemicals, cosmetics and food. This dossier describes the changing EU regulatory strategy. It further gives an overview of legal fields important to nanotechnology. These fields range from workplace safety, chemicals and product safety to industrial and environmental law.

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Introduction

Products of nanotechnology, nano particles, and nano production processes are in general subject to existing law, especially concerning workplace safety, chemical substance licensing procedures, product safety, operational plant concessions and environmental law. However, the regulation of nanotechnology raises the question whether existing regulations are adequate or whether regulatory gaps have emerged through the characteristics of this new technology? In particular, whether regulations which mainly correlate to substance, rather than size, are suitable for nanomaterials.

International discussion about nano-regulation has been conducted with increasing intensity since the 1990s.[1] This dossier concentrates on discourses within the European Union. It starts with a chronological account of the EU regulation strategy, followed by an overview of the most important regulatory fields in this regard (workplace safety, chemicals and various products, as well as industrial law and environmental protection).

Chronology of the EU Regulation Strategy

2004 European Strategy Communication: In 2004, the (European) Commission[2] adopted a Strategy Paper. It was supported by the Council[3] and the European Economic and Social Committee.[4] The paper defined for the first time the goals of the European policy on nanotechnology. By the establishment of integrated and coherent measures it was intended to create an environment which would be conducive to innovation as well as guarantee the safe and responsible development of nanotechnology. The strategy paper stressed the importance of appropriate and timely regulation. The following regulatory and protective goals were emphasized: risk reduction, public health, safety, environmental protection, consumer protection, and the adherence to ethical principles. Regulatory measures should be based on, and established within the framework of, existing provisions. As a preparatory measure, the Commission recommended a review of existing regulations, to examine *inter alia* the appropriateness of existing limit values (e.g. production volumes, mass).

2005 Action Plan: In the following year, the Commission issued a communication on nanosciences and nanotechnologies: an "Action Plan for Europe 2005-2009".[5] In relation to the European Strategy Paper, the Action Plan specified the goals. In addition to public health, safety, consumer protection and environmental issues, employees are added to the list of subject to be of concern with regard to possible regulatory efforts; These efforts were intended to be oriented towards products already on the market (such as certain consumer goods, cosmetics, pesticides, foodstuffs or medical devices). Furthermore, it was recommended that when reviewing the relevant regulations, especially limit values, labelling requirements, risk assessment, and various threshold values should be addressed. In addition, the Commission called upon their Member States to examine their own regulations and to make amendments where necessary.

2007 First Implementation Report: The first implementation report[6] was presented by the Commission two years after the Action Plan. The Commission identified public health, safety, environmental and consumer protection as the main regulatory goals. The lack of data on health and environmental risks was acknowledged as a crucial problem. The Commission's first preliminary finding was that the existing legislative framework was, in principle, suitable and adequate. However, weaknesses were identified in implementation measures, and with regard to the implementation process of existing regulatory mechanisms, room for improvement was seen (e.g. especially with regard to thresholds, substance au-

thorisation, classification of hazardous waste, conformity assessment procedures and market restrictions). In addition, the report stressed the importance of appropriate instruments for market surveillance (for example safeguard clauses or warning systems).

2008 Communication on Regulatory Aspects of Nanomaterials: The Commission next issued a communication on regulatory aspects of nanomaterials[7] which substantiated its policies and declarations of intent issued relevant with regard to the examination of the applicable legislative framework. Like the First Implementation Report, this communication was principally concerned with nanomaterials in production and/or already on the market. A balance between opportunities and risks was identified as one of the main challenges in regulating nanotechnologies on the Community level. As within the previous documents, the central issues were the protection of health, safety, and the environment, while at the same time maintaining openness to innovation. The communication discussed legislation in the fields of workplace safety, chemicals, product safety, and environmental protection. The Commission furthermore stated that it found the existing legislation in this field to be sufficient. This account subsequently led to a heated debate, especially with the European Parliament.

2008 Code of Conduct: Another measure worthy of mention is the "Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research".[8] It contains a set of guidelines for integrated, safe, and responsible research. Its general basic principles and guidelines are designed to support the member states in their efforts to ensure safe, ethically acceptable and sustainable research and encourage dialogue. The Code supplements the pertinent regulatory measures of the Commission in the field and is thus addressed to the member states, national and regional authorities, potential employers, bodies funding research, and researchers, as well as to citizens and civil society organisations. The member states are called upon to evaluate their own measures every year, and the code of conduct is supposed to be revised every two years; this is currently in progress.

2009 European Parliament Resolution: In April 2009, the European Parliament formulated its response to the Commission's communication on regulatory aspects of nanomaterials.[9] This resolution can be characterised as a turning point in the European debate on nano regulation. It contests the Commission's view that existing legal provisions are, in principle, suitable and adequate. The Parliament calls on the Commission to deal with a number of measures, including the drafting of new regulations (especially in the fields of REACH, waste, air, and water, as well as workplace safety). In addition thereto, it advocates for the general implementation of the basic principle of "no data, no market".

2009 Second Implementation Report: In autumn 2009, the Commission issued its second report on the action plan.[10] In the section on regulation, it is pointed out that in some areas legislation has been adopted or will need to be adapted. This primarily concerns chemicals, novel food, food additives, and cosmetics. In addition, and presumably in response to the Parliament's resolution and to the report of the Economic and Social Committee,[11] the Commission announces further measures for 2011: first, an updated version of the Commission's report on regulatory aspects of nanomaterials, focusing on adaptations of the instruments of implementation; second, new legislation efforts as well as a greater consideration of international developments; finally, the Commission also plans to issue "information on types and uses of nanomaterials, including safety aspects".

The state of EU law on nanotechnology

Since regulatory activities by the EU in the field of nanotechnology are steadily intensifying, the present account of relevant EU legislation can only be an initial snapshot. More detailed accounts and analyses of nano-specific law shall remain for further dossiers.

Workplace safety

The main EU provision is the Workplace Health and Safety Directive.[12] It requires employers to take measures to ensure the health and safety of their employees. Employers are obliged to carry out risk assessments and to take measures to eliminate identified risks. The directive applies to all employees and covers all stages of the production process. Its application does not depend on the substances in use or the employees' activities.

According to the European Commission, risks arising from nanomaterials are fully covered by this directive. In addition, more specific separate directives can be issued on the basis of the Workplace Health and Safety Directive. Since EU health and safety provisions only set out basic requirements, member states can enact stricter legislation at any time.[13]

EU Regulation Chronology

2004	European strategy paper on nanotechnology
2005	Action plan for nanosciences and nanotechnologies
2007	First implementation report of the Commission on the implementation of the action plan Commission proposal for a new regulation on novel foods Entry into force of the regulation on the registration, evaluation, authorisation, and restriction of chemicals, REACH
2008	Code of conduct for responsible nanosciences and nanotechnologies research Communication from the Commission on regulatory aspects of nanomaterials
2009	Resolution of the European Parliament on regulatory aspects of nanomaterials Second implementation report of the Commission on the implementation of the action plan Entry into force of the regulation on food additives Entry into force of the CLP regulation
2010	Entry into force of the new cosmetics regulation Revision of the code of conduct for responsible research Revision of the Seveso II directive
2011	Updated report on regulatory aspects of nanomaterials Register of nanomaterials on the market and their uses Entry into force of the revised novel food regulation?
2012	Revision of the REACH regulation, possibly taking into consideration nano-relevant criteria?
2013	Entry into force of quintessential provisions of the cosmetics regulation
2018	Expiry of the registration deadline for phase-in substances in accordance with REACH

Legal scholars have issued doubts whether the legal instruments foreseen within the existing framework provide adequate protection against the hazards of nanomaterials? For one, the risks flowing from nanomaterials are not yet fully known. Moreover, the existing health and safety legislation acknowledges gaps in employers' knowledge of these risks. Thus, it has been demanded that the existing health and safety regulations are amended and accordingly, that they should be oriented towards the risk exposure of employees.[14]

Employees also have the right to access relevant data in relation to the substances with which they work, or to which they are exposed to (Art. 35 REACH, see below).

Given the inadequate state of knowledge, the European Parliament has demanded that "nanomaterials should only be used in closed systems or in other ways that exclude exposure of workers". In addition, legal liabilities should be introduced for producers and employers for damages arising in connection with nanomaterials.[15]

Chemicals, biocidal products and plant protection products

Four provisions that should be mentioned here are the REACH regulation (registration, evaluation, authorisation and restriction of chemicals), the main regulation on chemicals, the CLP regulation (classification, labelling and packaging of chemical substances), and the biocidal products and plant protection products directives.

REACH

Since 2007, chemicals in Europe have been subject to the REACH regulation,[16] a regulation which is directly applicable in the EU member states. This framework regulation covers, among other things, the manufacture, marketing and use of substances, substances in preparations, and substances in articles. In accordance with the precautionary principle, manufacturers, importers, and downstream users have to prevent adverse health and environmental effects. Risks involved have to be identified and managed by manufacturers and importers alike. In addition, the industry is obliged to make safety information available to product users (via classification and labelling systems as well as safety data sheets).[17]

All substances as such or in preparations, must be registered if they are manufactured or imported in quantities of more than one tonne per year. There is a transition period for the registration of certain substances (existing substances listed in EINECS, the European Inventory of Existing Commercial Chemical Substances, which are treated as phase-in substances under the terms of Art. 3 (20) REACH). These phase-in substances have to be registered by 2018. All other substances (known as non-phase-in substances) for which no exceptions have been laid down have been subject to the special registration regime since 2008.

Registration with the European Chemicals Agency (ECHA) serves the creation and collection of information about risks. The relevant factor for registration is the substance, not its form or size. Thus, substances in their nano forms are, in principle, also covered by REACH,[18] and consequently, with regard to their registration requirements are to be taken into consideration; however, while a large number of substances (e.g. nanosilver) do not have to be registered individually, a substance which has been registered in its macroscopic (bulk) form and which is going to be manufactured in nano form, must be updated regarding its relevant information.[19] The question of whether a nanomaterial is a new substance or one that already exists is to be answered on the basis of the substance itself rather than its form or size.[19]

Registration obligations exist, as mentioned above, only if one tonne per year of a certain substance is produced (Art. 6). Only if more than 10 tonnes per year are produced, a chemical safety report must be added to the technical dossier. The chemical safety report must then include toxicological and physical-chemical data relating to any properties that endanger health or the environment (Art. 10-14). Consequently, this basically means that nanomaterials are covered but for one not properly examined, or (for the time being) not covered as the quantities involved are not large enough – or, in the latter case, registered without an individual chemical safety report. Substances, including nanomaterials, used for research and development are exempted from registration for a maximum of five years (Art. 9), as long as certain obligations to provide information are met; the ECHA has the power to impose conditions here.

In the case of certain substances, an evaluation of the registration dossier can follow. The evaluation determines whether the dossier meets the requirements of the regulation. In addition to this dossier evaluation, a substance evaluation is also possible (Art. 44ff). Substance evaluation is performed in order to see whether the substance needs to be regulated to access the market or poses any health and environmental risks. Authorisation is required for substances of very high concern (Art. 55ff). Finally, REACH also provides for the possibility to impose restrictions. In the circumstance that a certain substance can pose an unacceptable health and environmental risk, such can be placed under restrictions (Art. 67ff). This also applies to nanomaterials.[19]

While in 2008 the Commission regarded REACH as adequate to handle nanomaterials, it has now come to the conclusion, similar to the European Parliament and legal scholars,[20] that measures of adaption in REACH are necessary to adequately incorporate nanomaterials (this is mainly because properties depend on size and form; shortcomings in thresholds; problems with the scope of various exceptions). Annex IV of REACH originally providing for registration exemptions for Graphite C and carbon dioxide, has therefore been amended, and the exemption has been removed due to the properties of these substances in nano form.[21] It seems likely that further regulatory adjustments will be introduced during the revision process in 2012. We can expect to see special implementation regulations for nanomaterials, for example in the registration and safety assessment of titanium dioxide, nano tubes and fullerenes.[22]

The demands put forward by the European Parliament would lead to changes in quantity thresholds and in the treatment of nanomaterials as distinct substances.

The CLP regulation

The CLP regulation[23] regulates the classification, labelling, and packaging of substances and mixtures. This regulation will replace the existing system[24] and supplements REACH. The goal is to identify hazardous substances and mixtures while using a system of symbols and safety data sheets to provide users with sufficient information about potential hazards. The regulation is also designed to protect human health and the environment. There are no provisions explicitly relating to nanotechnology. From 1.12. 2010 onwards, hazardous substances have to be notified to a central inventory, a database set up and maintained by ECHA (EU Chemicals Agency). Any information that could alter substance classification and labelling has to be made public. A notified substance being produced in nanoform could be regarded as such new information which has to be made public. The Commission rec-

ommends a separate classification and labelling of nanomaterials. In addition, certain substances (e.g. acutely toxic substances, those that are toxic by the dermal route, and carcinogenic substances) must be specifically labelled.[25]

Plant protection products

The plant protection directive[26] regulates the assessment, authorisation, placing on the market and control of plant protection products as well as of the active substances they contain. Plant protection products must be authorised in the country in which they are first placed on the market. Only plant protection products whose active substances have been approved and which involve no risks to human beings, animals, or the environment may be authorised. Neither the currently applicable plant protection directive nor the new directive to enter into force in June 2011 contain any nano-specific provisions.[27] Moreover, there are no plans for any separate labelling of nanomaterials. Under the terms of the plant protection regulation, plant protection products must be specifically labelled in accordance with the provisions of the legislation on chemicals (Art. 65). The Commission will issue further special provisions regarding the labelling of pesticides by June 2011 (Art. 84).[28]

Biocidal products

Active substances and preparations used for the chemical or biological control of harmful organisms fall within the scope of the biocidal products directive[29] since 1998. This directive created a legal framework which is capable of assessing, restricting, and reducing the risks arising from biocidal products. New active substances fall under this directive. As soon as an active substance has received a positive EU assessment and has been included in Annex I/IA of the directive, the national product authorisation or registration procedure can begin. Aim of the national authorisation or registration procedure is to assess the risks of specific products containing already authorised substances.[30]

Although not explicitly mentioned, biocidal products containing nanomaterials are in principle covered by the directive. However, the established risk assessment does not properly provide for nano-specific hazards. Therefore, during the revision process, the need for nano-specific risk assessment involving special testing strategies and methods has been discussed.[31]

The Commission's proposal[32] does not provide for any nano-specific regulations, however, as biocidal products are explicitly included in the catalogue of demands contained in the European parliamentary resolution, some measures specific to nanomaterials may still be included in the proposed regulation. In any case, the Commission's view is that nanomaterials are covered by the term "active substances".[33]

Products

There are numerous provisions at the EU level dealing with product safety. As a rule, these focus on the protection of human health, workplace safety, and the safety of consumers and patients. However, the product safety legislation currently in force pays less attention to environmental protection.

In addition to the directive on general product safety, there are various individual directives and regulations for specific lines of production (for example for medical devices, cosmetics, foodstuffs, and feed additives); as a rule, these provide for differentiated risk assessment and risk management systems. In the course of these systems, risks that could arise from nanomaterials also need to be considered. Whether the applied risk assessment and risk management systems are appropriate is monitored, dependent on the applicable legal framework, either before products are placed on the market via control and notification procedures (for example for medical devices, novel foods, and plant protection products) or through market surveillance (e.g. for cosmetics or consumer goods subject to the directive on general product safety).[34]

Specific regulation efforts designed to explicitly incorporate nano-specific regulations exist in the spheres of cosmetics, medical devices, and foodstuffs.

General product safety

In addition to the vertical (product-specific) product safety legislation summarised below, the EU also has horizontal (hazard-specific) product safety legislation. The central instrument in this area is the directive on general product safety.[35] This covers hazardous products, and applies to all products which are not covered by any specific legal framework. Adaptations with regard to nanomaterials are currently not under negotiation.

Cosmetics

The new regulation on cosmetic products entered into force on 1 January 2010.[36] The innovations, largely not applicable until 2013, range from the simplification and revision of how a product may be placed on the market, the responsibility of manufacturers for product safety, to market surveillance conducted by each member state. Partly as a result of prolonged pressure from the European Parliament, the regulation contains comprehensive provisions in relation to nanotechnologies and nanomaterials.[37] First, nanomaterials may only be used if they are safe. Secondly, ingredients in nano-form must be indicated in the list of ingredients and followed by the word "nano" in brackets (Art. 19). Thirdly, manufacturers are also obliged to notify the Commission of cosmetics containing nanomaterials (Art. 16). Finally, the regulation contains for the first time a legal definition of nanomaterials. Art 2. para. 1, section k defines "nanomaterial" as "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." The Commission, in cooperation with a committee, may adapt this definition at any time to technical and scientific progress and international developments (Art. 3 para. 3).

Foodstuffs

In the area of foodstuffs, efforts to incorporate nanotechnology in legislation have largely been driven by the European Parliament. There are provisions relating to nanotechnology in the regulation on food additives,[38] and also in the new regulation on novel foods, which is still passing through the legislative process.[39]

The regulation on food additives is the first piece of binding EU legislation to incorporate nanotechnologies explicitly. Art. 12 states: "When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market."

The planned nano-specific innovations in the revised regulation on novel foods will go a good deal further. While the Commission's proposal said very little about such regula-

tions,[39] the European Parliament, at the first reading, advocated explicitly for a definition of nanotechnology, as well as an incorporation of nanotechnology in the area of application of the regulation, the safety of foodstuffs manufactured with the help of nanotechnology, and included a definition of nanomaterials[40] in its proposal.[41]

The current compromise between the Council and the Parliament includes a definition of engineered nanomaterials and a recommendation that foodstuffs made from or containing synthetic nanomaterials should be subject to a specific authorisation procedure. However, due to the entry into force of the Treaty of Lisbon, and its new institutional framework, the fate of this common position is uncertain. As a consequence, the entry into force of the revised novel food regulation, which was originally planned for 2010, is likely to be delayed until 2011.[42]

Medical devices and medicinal products

In the area of nanomedicine, concrete regulation efforts are not as far advanced. Medicinal products as such are subject to a special authorisation procedure. At present however, nanomaterials play no role in these authorisation procedures. The Commission is currently examining possible ways of setting up a system to examine hazardous nanomaterials. An additional regulatory aspect in the area of nanomedicine concerns products which cross the boundaries of different regulatory schemes so that doubts as to which regulatory regime applies occur (for example medicinal products, medical devices, and cosmetic products).[43]

Industrial law and environmental protection

EU law also contains industrial law and environmental law provisions which are of relevance to nanomaterials. In its communication on regulatory aspects of nanomaterials,[44] the Commission emphasises the importance of individual provisions such as the directive concerning integrated pollution prevention and control (IPPC),[45] the directive on the control of major-accident hazards involving dangerous substances (Seveso II),[46] the water framework directive,[47] and EU waste legislation.[48] Regardless of the fact that none of these pieces of legislation refer to nanomaterials explicitly, the Commission holds that existing law suffices to cover currently known risks or, in any event, can easily be adapted if necessary. The IPPC directive can thus be employed to control the environmental effects of nanomaterials produced or used in facilities that fall within the directive's area of application. If certain nanomaterials pose a risk of major accidents, appropriate quantitative thresholds could be introduced into the Seveso II directive. In the framework of the water framework directive, nanomaterials could, if necessary, be classified as priority substances, and if they turned out to be dangerous they could be classified as hazardous waste, in accordance with EU waste law.

In its resolution,[49] the European Parliament emphasised the need to adapt EU waste legislation. It said that nanomaterials needed to be included in the list of waste, criteria for accepting waste in landfills needed to be revised, and that emission limit values for waste incineration needed to be re-examined. The emission limit values as well as environmental quality standards also need to be re-examined in the areas of water and air, in the view of the European Parliament.

In addition, the accompanying document to the second implementation report on the nanotechnology action plan[50] notes that the Commission is planning a revision of the Seveso II directive.

Conclusions

While the EU Commission originally considered the legal framework for nanotechnologies to be suitable in principle, in the meantime, amendments for chemicals, cosmetics and foodstuffs have been enacted. The primary force behind these amendments has especially been the European Parliament, and further regulatory changes (e.g. workplace safety, biocidal products, medicinal products, medical devices and waste) can be expected. A new communication on regulatory aspects of nanomaterials as well as an overview of products on the market is scheduled for 2011. In addition, the Commission will focus on an improved implementation and application of the statutory provisions as well as on those products which are not subject to any relevant examination before being placed on the market. Protection clauses, health monitoring measures, market surveillance, formal objections to rules, preventive measures, follow-up and reporting procedures, and early warning systems will gain particular importance in this context. The discussion about the regulation of nanotechnology at the EU level will thus continue. Everyone should now be aware that certain adjustments of existing regulations are essential in order to adequately deal with the possible risks of nanotechnology, in particular in relation to nano particles.

Notes and References

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5 COM (2005) 243.

6 COM (2007) 505.

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8 C (2008) 424; on this point, see also Nano-Trust-Dossier 016, epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier016.pdf.

9 P6_TA (2009) 0328.

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11 Opinion of the European Economic and Social Committee, 25.2.2009, INT/456.

12 Directive 89/391/EEC

13 See COM (2008) 366, p. 5.

14 A. Scherzberg, Alte Instrumente für neue Wirkungen, in Scherzberg and Wendorff (eds), Nanotechnologie (2009), pp. 219-231.

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[26] Directive 91/414/EEC.

[27] Regulation EC 1107/2009.

[28] For more on the new plant protection regulation, see portal.wko.at/wk/startseite_th.wk?dstid=0&sbid=1243.

[29] Directive 98/8/EC.

[30] For more on this, see www.biozide.at/biozid-regelungen.

[31] UBA, Nanotechnik für Mensch und Umwelt (2009), p. 12.

[32] COM (2009) 267.

[33] See SEC (2009) 1468, p. 81.

[34] See COM (2008) 366, especially p. 5f.

[35] Directive 2001/95 EC.

[36] Directive EC 1223/2009.

[37] On this point, see COM (2008) 49 and the first reading in the European Parliament (23-26.3.2009).

[38] Regulation EC 1333/2008.

[39] COM (2007) 872.

[40] Art. 3. para. 2 point f (P6_TA(2009)0171) says that ""engineered nanomaterial" means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the 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 to the nanoscale" (P6_TA(2009)0171).

[41] Proposal for a regulation on novel foods, first reading in the European Parliament (23-26.3.2009).

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[44] COM (2008) 366.

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[46] Directive 96/82/EC.

[47] Directive 2000/60/EC; see also Directive 2006/118/EC.

[48] Directives 2006/12/EC and 2008/98/EC; Directive 91/689/EEC.

[49] P6_TA (2009) 0328.

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MASTHEAD:

Owner: Austrian Academy of Sciences; legal person under public law (BGBl 569/1921; BGBl I 130/2003); Dr. Ignaz Seipel-Platz 2, A-1010 Vienna

Editor: Institute of Technology Assessment (ITA); Strohgasse 45/5, A-1030 Vienna; www.oeaw.ac.at/ita

Mode of publication: The NanoTrust Dossiers are published irregularly and contain the research results of the Institute of Technology Assessment in the framework of its research project NanoTrust. The Dossiers are made available to the public exclusively via the Internet portal "epub.oeaw" : epub.oeaw.ac.at/ita/nanotrust-dossiers

NanoTrust-Dossier No. 017en, November 2010: epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier017en.pdf

ISSN: 1998-7293