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the innovation society

„No Data, no Market?“

Challenges to Nano-Information and Nano-Communication along the Value Chain

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Conference Report

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Content

Introduction

The "Nano Information Pyramid" Could Help to Solve the "No Data – no Market" - Problem of Nanotechnologies.

Dr. Christoph Meili, The Innovation Society Ltd., Switzerland

Consumers want to know what they buy, retailers have to know what they sell and processors and recyclers need to know what they handle. This applies to ordinary materials but also to products which contain engineered nanomaterials. However, the relevant nanospecific information does often not reach these recipients because there are no clear rules for a transfer of nanospecific information along the value chain. Nanomaterials could therefore easily become "black boxes" in terms of safety data and information flow or - even worse - "unguided missiles" as related to consumer acceptance and potential risks to health and the environment. There is an urgent need along the value chain for downstream users and even so for authorities to be informed about the structure and the characteristics of materials and products containing engineered nanomaterials. Tools to adequately handle information transfer about manufactured nanomaterials like the Material Safety Data Sheet (MSDS) are available but have to be further adapted in regard to nanomaterials.

The "Nano Information Pyramid" provides user-specific nano data

Consumer organisations have been calling for mandatory labelling and declaration of engineered nanomaterials since the beginning of the nano-debate. In 2005 an activist group called T.H.O.N.G (Topless Humans for Natural Genetics) protested in front of an Eddie Bauer store in Chicago against undeclared nano-textiles. In the meantime, the declaration and labelling issues of nanoproducts have made it to European legislation with the new European cosmetics legislation requiring industry to declare engineered nanoparticles in cosmetics in the form of X(nano) from 2012 on. Cosmetics are therefore the first mandatorily "nano-branded" product category in Europe. Similarly, in the updating of the Novel Foods Regulation (Regulation (EC) No 258/97), the declaration of engineered nanomaterials in foods as well as safety data requirements were clearly addressed. It is likely that this process will go on and especially consumer-near goods containing nanomaterials will have to be labelled sooner or later due to growing pressure. However, it remains controversially discussed whether any nano-label on consumer goods would actually enable consumers to make an informed choice. There are concerns that nano-labelling as such could be misunderstood as an indication of hazard, thereby raising new and potentially unnecessary fears among consumers. Therefore the purpose of a nano-labelling or declaration system should be

determined in advance (e.g. pure informational purpose, instructions on the use or precautionary guidelines).

Along the value chain, on the other hand, it seems clear that the information and data needs of downstream users have to be satisfied by appropriate means, and that the information and data requirements have to be communicated towards upstream players.

This implies several challenges:

1. Finding **appropriate and trustworthy tools** to transfer data and information along the value chain and which also serve to satisfy consumer needs.
2. Ensuring that the information flow (up and downstream) is **not interrupted**.
3. Allocating **costs** and **responsibilities** to the accountable stakeholders.

We hereby suggest a **"Nano Information Pyramid"** (Fig. 1) which provides an information exchange framework used to illustrate and satisfy the needs of the different stakeholders along the value chain. The Pyramid combines different recipient-specific tools in a constitutive system which takes into account the calls for more information on nanomaterials along the value chain on the one hand, but also hazard profiles of the substances (if necessary) on the other hand.

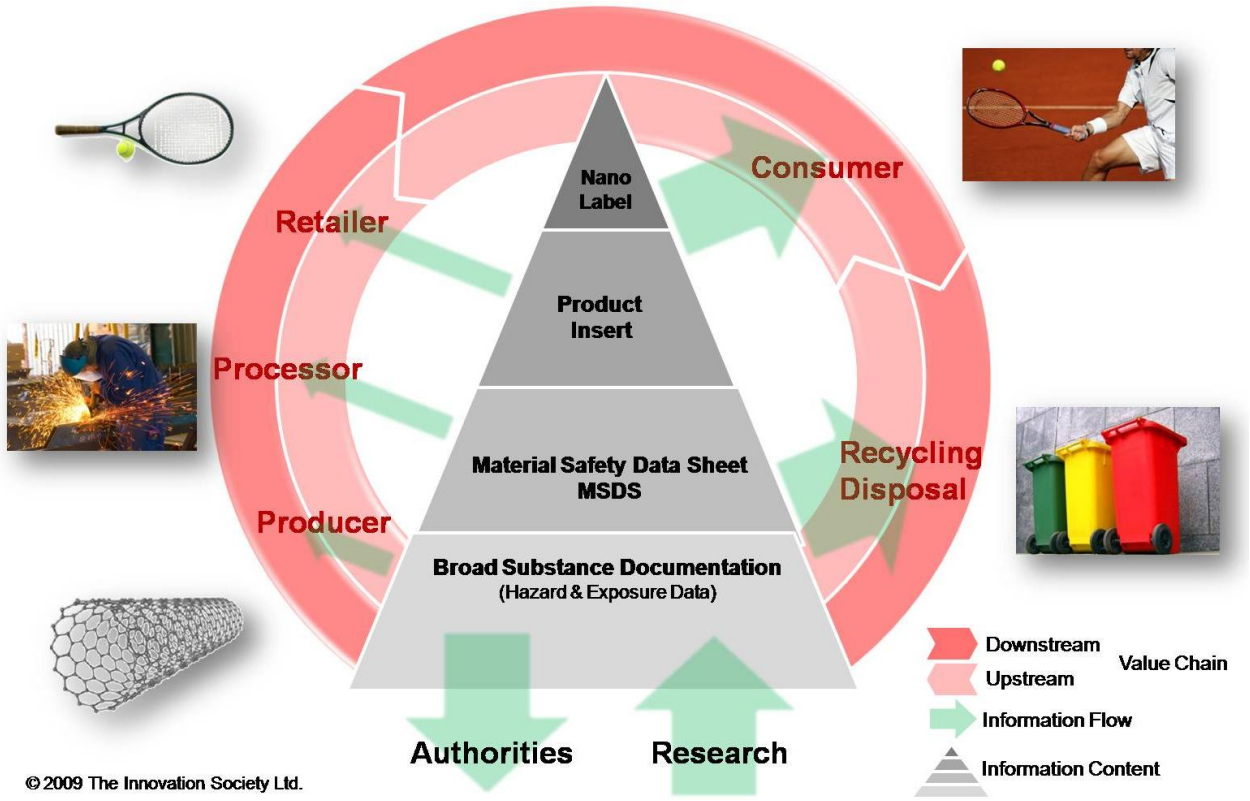

Figure 1: The **Nano Information Pyramid** provides user-specific data within the value chain at the example of a carbon nanotube reinforced composite tennis racket (Source: The Innovation Society Ltd., 2010).

At the bottom of the Pyramid there is the safety data which is provided to authorities and regulators by the industry in a ***Broad Substance Documentation*** (REACH and beyond). The Substance Documentation serves as a database to regulators and authorities for registration or documentation purposes, considering intellectual property and confidentiality issues. Lower Mass and volume thresholds of nanomaterials have to be taken into account subject to hazard and exposure potential of the substances (adaptation of REACH).

On the second level, the **Material Safety Data Sheet (MSDS)** should contain user-specific information on nanospecific properties of the substances which are provided. As the established system of MSDS contains expert information and addresses experts, it turns out to be the tool of choice to transfer information along the value chain from producers to processors, and possibly even further to recyclers. However, as widely recognised, the MSDS need to be adapted to cover the specific properties of engineered nanomaterials.

Figure 2 gives an overview on the interactions between the different steps of the value chain, the tools proposed to be applied at each step and the open issues concerning the information exchange between the individual elements.

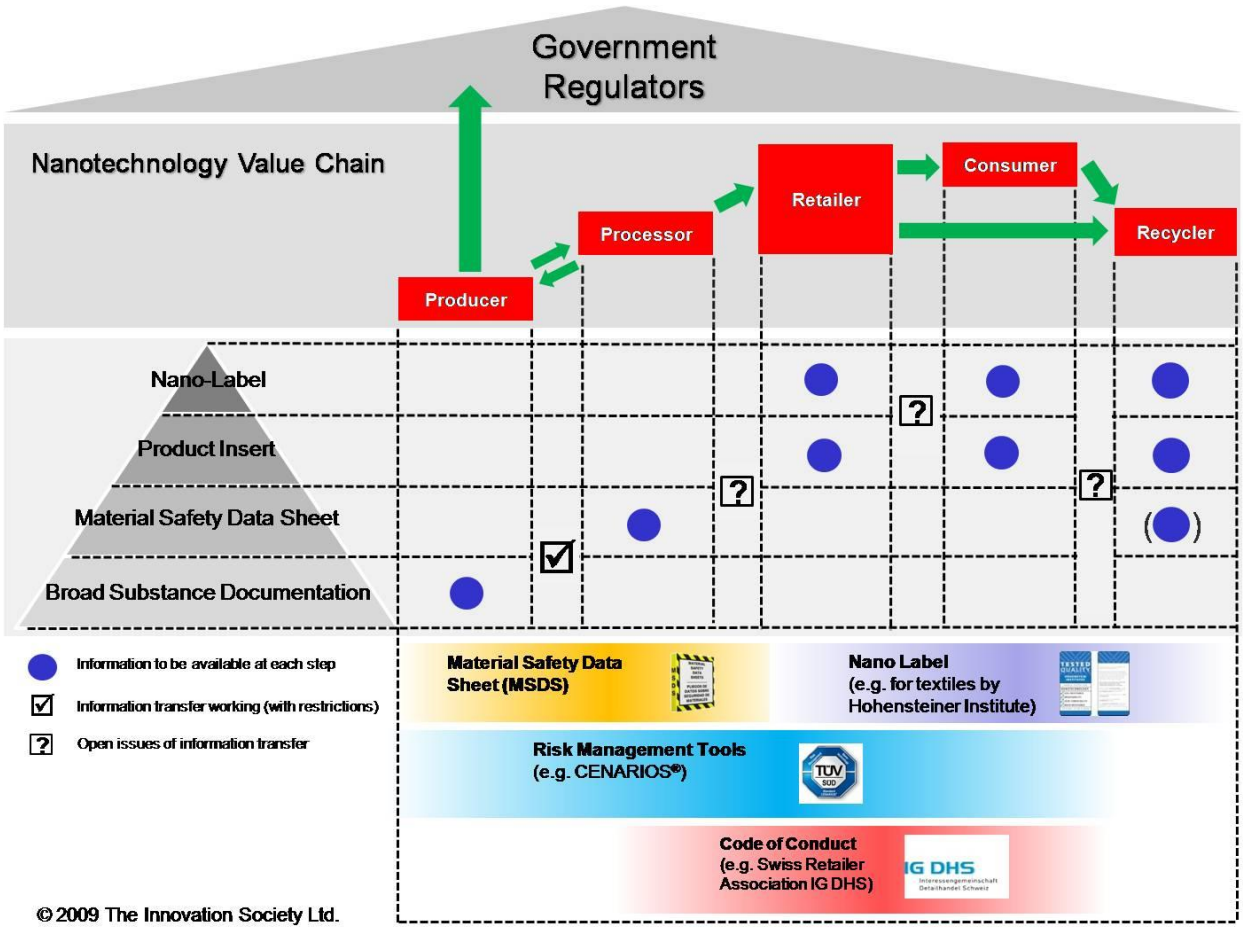

Figure 2: Tools, gaps and existing approaches for information exchange along the value chain (Source: The Innovation Society Ltd., 2010).

On the third level we recommend **"Product Inserts"** which are to provide user-specific information on the properties of the materials and products (properties, benefits, risks, recommendations concerning waste treatment, recycling, etc.) and address potential questions of users. Such Product Inserts could be both useful for ***consumer products*** (textiles, sports goods, etc.) as well as for ***industrial products*** (plastics, paints, surface coatings, etc.) containing engineered nanomaterials. Products Inserts should address the general public as they are used in consumer products.

On the fourth level **"Nano-Labels"** could be applied. Such a label would refer to both product or process properties. Product labelling seems to be particularly useful to indicate in a very concentrated manner certain quality features or environmental, health and safety properties of a product containing engineered nanomaterials.

Safety Labels referring to the safe production of a product containing engineered nanomaterials and to indicate a responsible risk management behind the product are important tools to create trust along the value chain. **CENARIOS©** is currently the only comprehensive standard for a nanospecific safety label which is approved by an accredited third party certification organisation (TÜV SÜD) and which can be communicated along the value chain. As the CENARIOS© certificate asserts that the risk management system of the corresponding company is based on the state of the scientific and technical knowledge regarding the risks of engineered nanomaterials, the relevant data can also be used to transfer to downstream users.

An overview over the key issues of the conference

The European Commission has recently made the point that the existing chemicals legislation REACH in principle also covers nanomaterials. REACH clearly shifts the responsibility to ensure the safety of products from the authorities to manufacturers and those who put them on the market. The European Parliament clearly disagreed with this opinion in summer 2009. The Parliament unmistakably stated in its report on regulatory aspects of nanomaterials that also for nanomaterials the REACH principle of "no data, no market" should be applied. The Members of the European Parliament wanted manufactured nanomaterials to be treated as new substances, requiring more extensive safety testing and mandatory labelling. In this context, the European Parliament called the European Commission to review all relevant legislation during the next two years.

The program of the 2009 NanoRegulation Conference therefore provides an overview over different aspects of the current regulatory discussion in the field of nanotechnologies, and a platform to discuss them. Some of the main points of view, which will be elaborated in more detail in the following sections, are hereby summarised in brief:

- **European Commission**: From the point of view of the European Commission, REACH in principle covers engineered nanomaterials. The existing legislation should therefore, possibly after minor adaptations and provided appropriate implementation, be adequate to handle nanomaterials. However, there are key issues which have to be discussed at an early stage, e.g. concerning the mass based thresholds and the deadlines for registration which have to be evaluated in terms of their adequacy regarding nanomaterials. Another point are the open definitions of nanomaterials and, probably most important, the request for industry to share data with the authorities.

- **European Parliament**: The European Parliament did not agree with the Commission and it is calling for a regulatory framework that explicitly addresses nanomaterials. The Parliament has called the Commission to review all relevant existing legislations within the next two years. It is likely that the second round of the political debate between the Commission and the Parliament will then be launched.
- **OECD**: The OECD covers several activities in the field of nanotechnologies. Most important are the development of test guidelines for several nanomaterials. As a summary of the ongoing activities it seems that the established test guidelines are also suitable for most of the investigated nanomaterials. A second point which seems interesting for the cooperation and coordination on global level is the OECD database on research projects.
- **Authorities**: Prof. Dr. Rolf Hertel from the German Federal Institute for Risk Assessment (BfR) reported that the BfR has conducted several studies and surveys and has also organised a Consumer Conference on public perception of nanotechnology. One of the key findings was that risk perception of the public is often underestimated when compared to risk management and risk assessment. In general there is a lack of information concerning exposure to nanomaterials, and there is also a knowledge gap concerning reliable market data. In Switzerland, the Swiss Federal Office for the Environment (FOEN) has commissioned a guideline document about "Treatment of Nano-Waste" which will be available early in 2010. The Swiss State Secretariat for Economic Affairs (SECO) will also provide a guidance document about the integration of nanospecific information in the MSDS.
- **Consumer advocates**: In order to provide best transparency and allow consumers to make an informed choice, consumer organisations are calling for a mandatory labelling of products which contain engineered nanomaterials. Such a label should be mandatory for all products unless they have been tested in a premarket safety testing.
- **Industry**: Along the value chain, the MSDS seems to be the tool of choice for information transfer. However, the MSDS needs to be adapted for the characteristics of "nano". Processors in the middle of the value chain need to be able rely on a bidirectional information flow; in order to guarantee an optimal feedback loop of information, it is crucial that there is information transferred not only downstream, but also upstream the value chain.

Part 1 Setting the Scene: Political and Regulatory Background

The Existing Regulatory Framework: Does It Apply to Nanotechnology?

Gustaaf Borchardt, European Commission, EU

Thank you for the opportunity to set the scene for this conference from the point of view of the European Commission. I am pleased to speak to you about the existing rules in the EU for nanotechnology and how applicable these rules are to this new technology. I am also taking the opportunity to appeal to your readiness to work together, in a partnership. You know that REACH was established very much in partnership with industry. The question we should examine together is in how far REACH is the adequate answer to the new phenomenon of nanomaterials as at the time of negotiating REACH, nanomaterials were not talked about.

I want to appeal to industry today not to hold back, but to be generous in sharing all its knowledge about substances in nano-form and their risks – the same as for ordinary chemicals. We as legislators are aware of regulatory burdens and red tape. It is not our intention to add to that if the systems already exist. The main thing is, that any law that is applicable to nanomaterials, should deliver high levels of protection for health and environment while stimulating innovation and competitiveness. To create trust in nanotechnology is key for consumers as well as for industry: long term investment planning.

About the nano-risks: The European Commission's view:

Note that I quoted that the researchers "hope to pressure companies to reveal….." Indeed in the EU with the implementation of REACH, companies are required by law to reveal "all uses of substances". **No data, no market**.

This is the basic principle of REACH and applies to nanomaterials just like to any other substance manufactured or put on the market in the EU.

This said, nanotechnology and nanomaterials are a good example of how new innovative technologies can challenge an existing regulatory framework. REACH of course is quite new itself. It is also considered by far the most advanced chemicals legislation in the world. REACH is there to ensure the safe use of all chemicals, including nanomaterials.

Under REACH, manufacturers, importers and downstream users must ensure that substances do not adversely affect human health or the environment.

Nanomaterials are in principle covered by REACH under the definition of a chemical substance. The general obligations in REACH therefore apply as for any other substance, even if in REACH there are no provisions referring explicitly to nanomaterials.

REACH sets the volume threshold for registrations of chemicals at 1 tonne per year. Under REACH, a Chemicals Safety Assessment is required for substances starting at 10 tonnes per year.

The tonnage trigger applies to the total volume of the substance, in all its forms. The information that must be given under registration is: information on the bulk form, information on the intrinsic properties where the nanoform may differ from the bulk, all the identified uses of the nanoform.

Note that if the classification of the nanoform is different from that of the bulk substance, this must be indicated; it may have a different Chemicals Safety Assessment, which must be provided. If there are relevant exposure scenarios specific for the nanoform they must be provided as well.

All relevant available information on the nanomaterial must be given to demonstrate that risks are controlled.

So, we may conclude that, with REACH, nanomaterials seem under control.

But, there are important question to be answered, for nanomaterials: Is what falls below the threshold a risk to health and the environment?

For standard chemicals the tonnage threshold is generally considered appropriate. Is this equally true for nanomaterials? Or for novel materials that will likely first enter the market in small quantities?

The tonnage threshold is one concern. The other concern is time/calendar. The lower tonnages are only registered by 2018, 9 years from now. This is an eternity in terms of nanotechnology, which was not widely known only 5 years ago. Can we afford to sit back and wait until the REACH registration deadlines have expired to find out what nanoforms are on the market?

We would like to know the risks now and whether they are controlled. Which nanomaterials are dangerous and which are not? These questions are very important. It is not only a scientific problem, but also a problem for society, for the legislators and for the confidence in these new products. Who produces nanomaterials? Where do they end up? And: Who comes in contact with them? Companies that produce nanomaterials can answer some of these questions, but unfortunately nobody has a good overview at this time of development.

REACH does have the potential to provide a good overview, but possibly too late and possibly only partially.

One further major concern regarding REACH is that nanomaterials are not specifically mentioned in the Regulation. Therefore, companies may tend to provide only information for the bulk form and may not sufficiently clearly distinguish the nanoform with its specific properties, uses and risks.
In this state of affairs, some EU Member States are of the opinion that the EU mills grind too slow, and they have proposed legislation of their own.

In France, legislation has been proposed that stipulates that any person that manufactures, imports or places on the market nanoparticle substances must declare their identity, quantity and uses to the authorities. They must submit available information on the hazards of the nanoparticle substances when

requested by the authorities. This proposal received overwhelming support in the National Assembly and Senate and is expected to be adopted shortly.

In the UK a revision of the reporting scheme for nanomaterials is underway. It is heading towards less but more targeted information than the current (not very productive) voluntary scheme. A voluntary scheme is seen by DEFRA as a complement to REACH. However, the Royal Commission Environmental Pollution recommends a mandatory scheme. The government has committed to re-assess a mandatory scheme if the revised voluntary scheme still fails to produce the desired industry response.

In Germany the Government's 'Nanokommission' is now considering the need for regulatory action. The need for more market transparency was identified as an early outcome of the debate. The importance of transparency is seen as a step towards acceptance of nanotechnologies. The government was asked to examine the possibility of labelling and the Bundesumweltministerium is considering a feasibility study for a country-wide product register, but many, including industry, feel that if these measures were to be considered it should be at European scale.

The principles governing chemicals management as set out in REACH are suitable for nanomaterials. These principles may need to be adapted, so that REACH closes the knowledge gap and provides for risk management of nanomaterials, in the same way as it is expected to do for ordinary chemicals.

When three Member States have gone ahead exploring new national legislation, we have to look at the effects for the internal market and whether action at EU level is not opportune.

Where are we at European level?

There are a number of similarities between the European Commission's outlook and that of these Member States:

- there is a clear recognition of the potential benefits of nanomaterials
- there is a need to ensure the safety of nanomaterials and that safety is seen as a prerequisite for the sustainable development of the technology
- any regulatory action should thus foster the further development of the technology by providing a predictable legal framework
- the predictable legal framework will ensure safety and will create room for long-term investment decisions

The three Member States further find that

The *European Parliament* has invited the Commission to consider whether regulatory change is necessary to address risks in relation to nanomaterials in an appropriate way. It considers it particularly important to address nanomaterials explicitly within the scope of legislation on chemicals, food, waste, air and water and worker protection.

In response, the Commission has committed to review all relevant legislation by 2011 to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle.

Conclusion

To conclude, the debate on the applicability of current rules for this new technology continues. REACH certainly provides the framework, but it may need to be fine tuned to make sure it provides the same protection for nanomaterials as it does for ordinary chemicals. Technology and research move fast. So fast that some Member States felt the need to think of introducing their own, supplementary national rules to be sure that nanomaterials are properly managed. This would not be opportune from the point of view of the internal market.

The European Commission will complete a review of all relevant legislation within two years, including of REACH. For the time being, REACH applies, as it stands today. Manufacturers and importers are required and strongly encouraged to register their chemical substances including the nanoforms by the designated deadlines. It is in their own interest to be as transparent as possible and provide the maximum amounts of information, to demonstrate that nano-substances can be handled safely.

„No Data, no Market": European Regulatory Requirements for Manufactured Nanomaterials

Axel Singhofen, Greens/European Free Alliance in the European Parliament, EU

1. Products on the market are rapidly increasing

"*While not comprehensive, this inventory gives the public the best available look at the 800+ manufacturer-identified nanotechnology-based consumer products currently on the market*." Woodrow Wilson Institute, January 2009 (1) (Note: At the launch of the inventory in March 2006, it contained 212 products)

2. The largest number of products available are those with highest exposure to humans or the environment

"In the existing product inventories, the product category personal care and cosmetics generally contains the largest number of products, followed by household and home improvement products, textile and shoes and miscellaneous." Study by European Parliament, 2007 (2)

"Potentially high exposures are expected from consumer products containing free nanoparticles with direct exposure to humans or environmental organisms (e.g. cleaning and personal care products, and cosmetics)." Study by European Parliament, 2007 (2)

3. There is concern about impacts on human health and the environment

"Taking into account that smaller particles have a greater (re)active surface area per unit mass than larger particles, toxicity and potential health effects may also increase. There is therefore concern about the potential impact of nanoparticles on human health and the environment." European Commission, 2005 (3)

"Our extensive enquiries produced no evidence of actual harm. However, having analysed the potential health and environmental impacts which flow from the properties of nanomaterials, we concluded that there is a plausible case for concern about some (but not all) classes of nanomaterials. Examples of potentially harmful nanomaterials include nanosilver, carbon nanotubes and Buckminsterfullerenes (C60)."

UK Royal Commission on Environmental Pollution, 2008 (4)

4. Science is lagging behind

"Currently it is extremely difficult to evaluate how safe or how dangerous some nanomaterials are because of our complete ignorance about so many aspects of their fate and toxicology." UK Royal Commission on Environmental Pollution, 2008 (4)

"The Committee points to major gaps in the knowledge necessary for risk assessment. These include nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate,

and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles." SCENIHR, 2006 (5)

"Current uncertainties for risk assessment of nanotechnologies and its possible applications in the food and feed area arise due to presently limited information in several areas. Specific uncertainties apply to the difficulty to characterize, detect and measure ENM in food/feed and biological matrices and the limited information available in relation to aspects of toxicokinetics and toxicology" EFSA, 2008 (6)

5. There are regulatory gaps

"*Analysis of individual legal areas has clearly shown that there are gaps at many points in sectoral environmental law regarding the specific properties of nanomaterials*." UBA, 2007 (7)

6. The large majority of the industry does not voluntarily notify applications, let alone EHS data

"*It appears that approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported under the Basic Program."* US EPA, 2009 (8)

"The low rate of engagement in the In-Depth Program suggests that most companies are not inclined to voluntarily test their nanoscale materials."[4 companies agreed to participate by Dec 2008] US EPA, 2009 (8)

7. Regulatory action is being called for ...

"Appropriate and timely regulation in the area of public health, consumer protection and the environment, is essential, also to ensure confidence from consumers, workers and investors." European Commission, 2004 (9)

"The UK Government should press the European Commission to proceed with urgency, in consultation with Member States, the European Chemicals Agency and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), to review REACH and the product- or sector-specific regulations. The object of this review should be to amend the regulations to facilitate their effective application to nanomaterials and the provision of adequate testing arrangements." UK Royal Commission on Environmental Pollution, 2008 (4)

"Although current legislation covers nanomaterials, regulations need to be made clearer as nanomaterials imply particular problems both in risk assessment and risk management. Moreover, nanomaterials in articles will in many cases not be covered by the chemical safety assessment carried out within the scope of REACH. The rapid development of the area in combination with the great lack of knowledge about health and environmental risks call for precautionary measures. This is likely to involve complementing the EU regulatory framework with rules for nanomaterials, including rules about the way in and extent to which companies must test nanomaterials' health and environmental hazards." KEMI, 2007 (10)

8. ... even partial moratoria ...

"As long as risk assessment studies on long-term safety is [sic] not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided." European Commission recommendation, 2008 (11)

"While any kind of blanket moratorium does not seem appropriate, there may well be specific cases where it is necessary to slow or even hold up the development while concerns are investigated." UK Royal Commission on Environmental Pollution, 2008 (4)

9. ... but in June 2008, the Commission only wanted to improve implementation.

"*Current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation. The Commission and EU Agencies will therefore in the first place review current documents that support implementation, such as implementing legislation, standards and technical guidance with regard to their applicability and appropriateness to nanomaterials.*" European Commission, 2008 (12)

10. Resolution of the European Parliament in reaction to the Commission communication

"*3. Does not agree, before an appropriate evaluation of current Community legislation, and in the absence of any nano-specific provisions therein, with the Commission's conclusions that a) current legislation covers in principle the relevant risks relating to nanomaterials, and b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks;*

4. Considers that the concept of the "safe, responsible and integrated approach" to nanotechnologies advocated by the European Union is jeopardised by the lack of information on the use and on the safety of nanomaterials that are already on the market, particularly in sensitive applications with direct exposure of consumers;

5. ¨Calls on the Commission to review all relevant legislation within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle, and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed;

6. Stresses that such review is not only necessary to adequately protect human health and the environment, but also to provide certainty and predictability to economic operators as well as public confidence;" European Parliament, 2009 (13)

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(5) The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), March 2006

(6) Draft Opinion of the Scientific Committee on the Potential Risks Arising 3 from Nanoscience and Nanotechnologies on Food and Feed Safety, European Food Safety Authority, October 2008

(7) Legal Appraisal of Nanotechnologies, Umweltbundesamt, Germany, March 2007

(8) Nanoscale Materials Stewardship Program, Interim Report, Environmental Protection Agency, U.S.A., January 2009

(9) Towards a European Strategy for Nanotechnology, European Commission, May 2004

(10) Nanotechnology - large risks with tiny particles? Swedish Chemicals Agency, November 2007

(11) Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research, European Commission, February 2008

(12) Regulatory Aspects of Nanomaterials, European Commission, June 2008

(13) European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials

Resolution by European Parliament (EP) on Commission communication

Resolution adopted on 24 April 2009
(submitted jointly by the five main groups in Parliament)

362 votes in favour
4 votes against
5 abstentions

= virtually unanimous support

The Greens | European Free Alliance in the European Parliament

EP base line: Need for clear and specific regulatory framework

- *"Is convinced that the use of nanomaterials should respond to the **real needs** of citizens,"*
- *"that their benefits should be realised in a safe and responsible manner within a **clear regulatory and policy framework** (legislative and other provisions)*
- *that **explicitly** addresses existing and expected applications of nanomaterials as well as the very nature of potential health, environmental and safety problems"* **(paragraph 1)**

The Greens | European Free Alliance in the European Parliament

EP position: Deplores, and disagrees with, the Commission approach

- *"Deplores the **absence of a proper evaluation of the de facto application** of the general provisions of Community law in the light of the actual nature of nanomaterials"* (paragraph 2)
- *"Does **not agree** ... with the Commission's conclusions that*
  a) current legislation covers in principle the relevant risks relating to nanomaterials, and
  b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation,
  *when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is **effectively unable** to address their risks;" (paragraph 3)*

The Greens | European Free Alliance in the European Parliament

Summary of key issues

- **Current approach neither safe, nor responsible, nor integrated!**
  - Products are on the market, particularly in most sensitive application
  - No EHS data upfront
  - Cion policy to deepen R&D to bring products to the market to boost competitiveness
  - No Cion regulatory initiative to ensure safety
- **Enact paradigm shift towards sustainable nanotechnology!**
  - Provide information to the public (inventory, labelling, EHS data)
  - Review legislation to make it nano-fit (in a prospective and adaptive manner)
  - Implement "no data, no market"

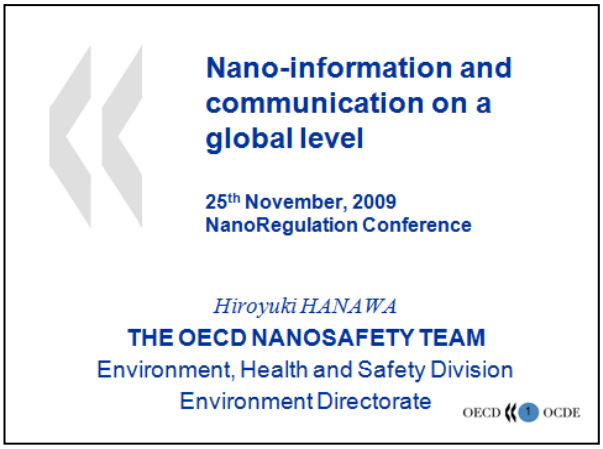
The Greens | European Free Alliance in the European Parliament

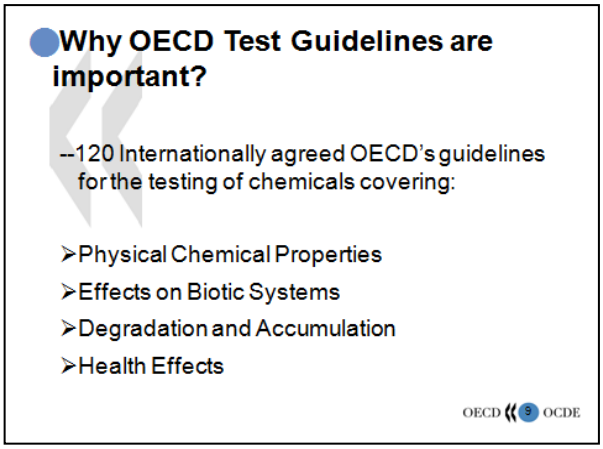
OECD: Nano-Information and Communication on a Global Level

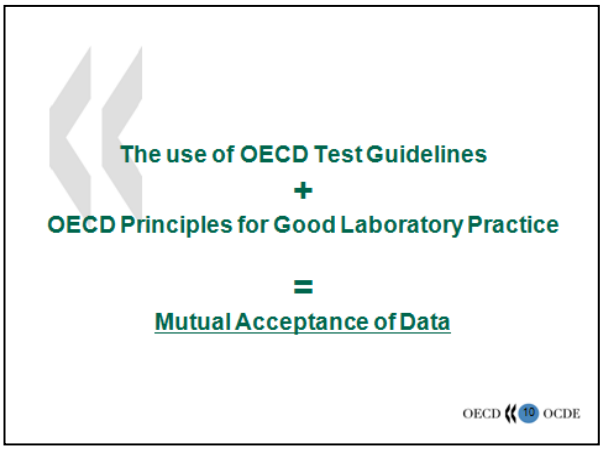
Hiroyuki Hanawa, OECD Environment Directorate, OECD

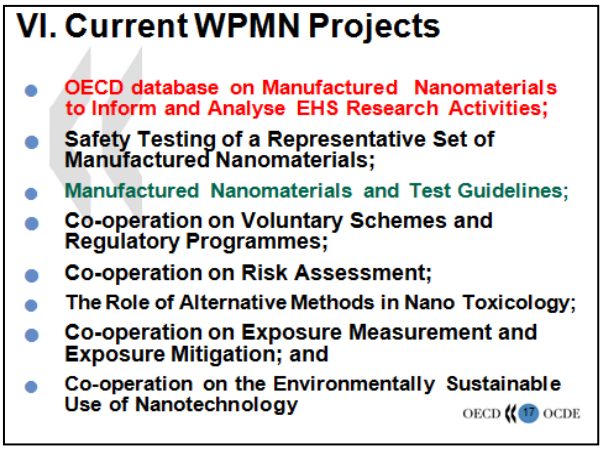
The term "manufactured nanomaterials" covers a diverse range of materials that are being developed to exploit the changes in behaviour and properties of materials that occur at the nanoscale. The number of products and the diversity of nanomaterials are predicted to increase rapidly in the coming decade as a result of the high levels of investment that is driving innovation in nanotechnology across many sectors. The main objective of OECD's work on the safety of manufactured nanomaterials is to assist countries in developing tools to allow them to better address the human health and environmental safety implications.

This presentation will mainly describe an OECD's tool for information sharing in the research area. It will introduce an OECD database which was recently launched, and this database contains information on research projects which address human health and environmental safety issues on nanomaterials. It will also introduce an overview of the projects of the Working Party on Manufactured Nanomaterials which was established in 2006 with aim of to promote international co-operation on nano-safety area.









VII. OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities

- **Objective**
  - To develop a global resource (Database), which details research projects and identifies research needs
  - To provide opportunities to identify the similar fields, and lead to create new collaboration and networks

OECD 18 OCDE

- **What sort of information is included?**

Research into the human health and environmental safety of MNs

Life-cycle assessment of MNs | Relevance to safety of MNs | Project title, status, funding source, URL, summary ...

Research themes | Material Name

OECD 21 OCDE

www.oecd.org/env/nanosafety/database

OECD Database on Research into the Safety of Manufactured Nanomaterials

Human Health and Environmental Safety Research

- **Status**
  - Database was publicly launched (April 2009);
  - And includes more than 730 records of research projects (Oct 2009)

OECD 22 OCDE

VIII. Summary

- **Nanotechnology presents many opportunities across a wide-range of economic sectors;**
- **At the same time, there are a number of challenges related to safety;**
- **The limitation of information on the safety of Nanomaterials may cause some concerns about risk; and**
- **Collecting information is based on the need for a science-based approach to regulatory considerations.**

OECD 23 OCDE

Website of the OECD database: www.oecd.org/env/nanosafety/database

Panel Discussion and Synthesis Part 1

At the European level it turned out that the situation did not change so much since the European Parliament's resolution on regulatory aspects of nanomaterials. The European Commission seems to be more or less happy with the current situation. However, Mr. Borchardt encouraged industry not to hold back important safety information and to support authorities in elaborating the necessary database to base adequate regulations on. Unlike the European Parliament, the Commission does not see the need for a separate regulatory framework for nanomaterials. To the question about a concrete deadline for developing a clear definition for nanomaterials on the European level, no specific answer could be given.

On the other hand, Mr. Singhofen, representing the Greens/European Free Alliance (EFA) in the European Parliament, clearly stated that the European Parliament is calling for a regulatory framework explicitly addressing nanomaterials, which, however, due to the lack of knowledge about manufactured nanomaterials' risks seems to be a difficult task. Mr. Singhofen emphasized again that the Parliament in its April resolution did not agree the Commission's regulatory measures regarding nanomaterials. As indicated in the presentation of Mr. Borchardt, the current status quo in Europe has led single Member States to develop their own (explicit) regulatory approaches on manufactured nanomaterials; examples are France, UK and Germany. While on the European level nanomaterials are still subject to a debate on whether and how to explicitly consider them in the regulatory framework, in other areas of the globe, for example in Canada, regulatory tools like a mandatory reporting scheme are already in use.

Further, the industry in Switzerland sees the need for certain communication and information platforms to get more transparency.

Part 2 Stakeholders' Needs and Expectations

Product Registration and Public Communication: What Authorities Need to Know and What They Can Tell the Public

Prof. Dr. Rolf F. Hertel, Federal Institute for Risk Assessment BfR, Germany

In August 2009, the Woodrow Wilson International Center for Scholars informed that nanotech consumer products have now crossed the millennial threshold.

Available representative surveys of public perception of nanotechnology from US, UK, Australia and Germany suggest that only few people have any understanding whatsoever of nanotechnology. It is interesting that no major risks are expected from nanotechnology: There is a broad acceptance for consumer products in the area of surface sealing, but the more nano-products come into contact with the own body, the more the acceptance falls. The BfR report "Public Perception about Nanotechnology" (01/2009) shows that only a minority group of consumers would buy foods with engineered nanoparticles. Thus the BfR Consumer Conference Nanotechnology (03/2009) came to a vote that the use of nanotechnologies in food is a very delicate area, and the report of "BUND" and "Friends of the Earth" are postulating a moratorium concerning engineered nanoparticles in foods.

For all consumers, labelling of nanotechnologies and reliable product registration are very important aspects.

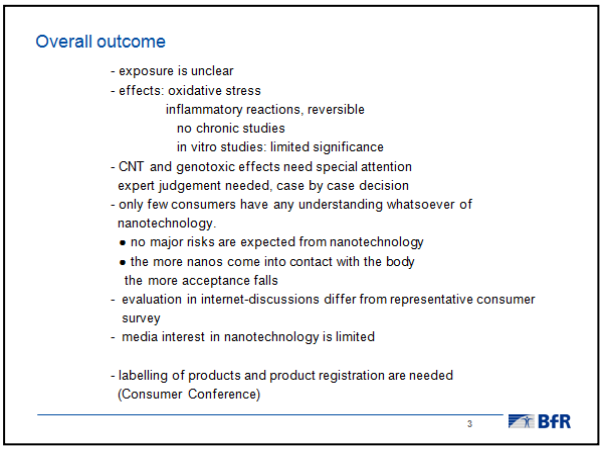
The European Parliament passed in 2009 the new cosmetic products regulation. In that regulation it is stated for the first time that all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients being printed on the container of packaging of a cosmetic product. The name of such ingredients shall be followed by the word "nano" in brackets. The information will be presented from the year 2012 on. Furthermore, all nanomaterials being present in the product have to be fully identified and tested to be able to perform a risk assessment. That information must be provided by the distributor.

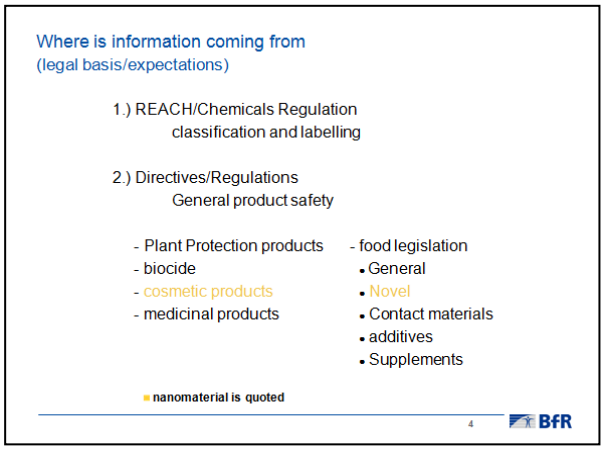
According to the EU directive on general product safety consumers expect that producers are obliged to place only safe products on the market. Thus, producers have to perform safety assessments. Responsible for the safety of the products are the producers.

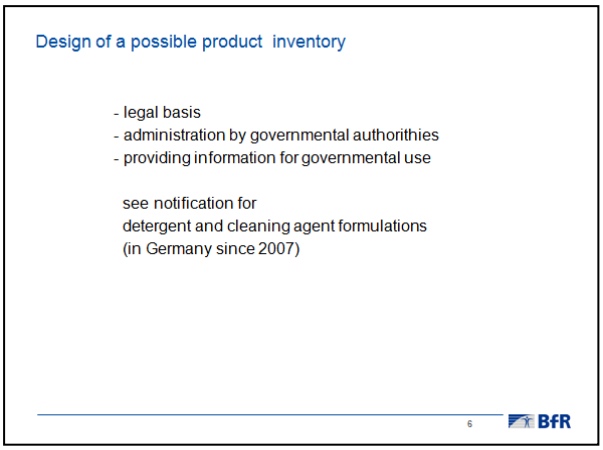
Labelling of a product is part of public communication. The label should provide consumers with all relevant information to enable them to assess possible risks inherent to the product.

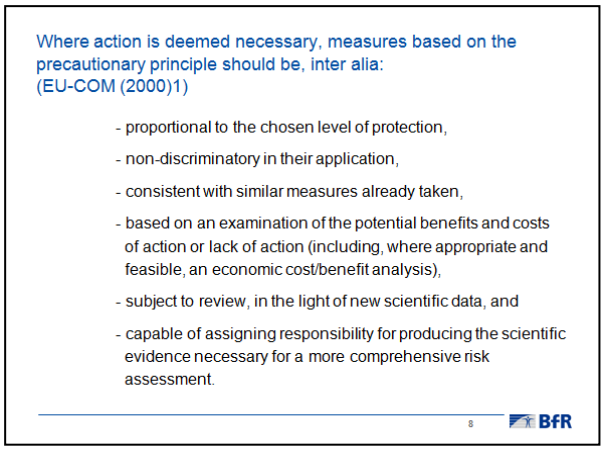
Research is needed to document the perception of that information by the public.

The simple statement "that there are nanoparticles in the product" is not really helpful: There are lots of well established products (e.g. ink, car tires, smoked foods) consumers came in contact with since years without negative impacts. Labelling of such products could lead to a general feeling of unsafety with undesirable effects. To assess whether nanoparticles added to a product can be a risk to the user/consumer at present is a case by case assessment needing expert judgement. A possible strategy would be the establishment of a product inventory on a legal basis which is administered by governmental authorities, providing information on the characteristics of the substance under discussion, relevant safety testes results, level of exposure and a description of uncertainties for a final assessment.









Consumers' Needs: What Consumers Want to Know about Nanotechnology

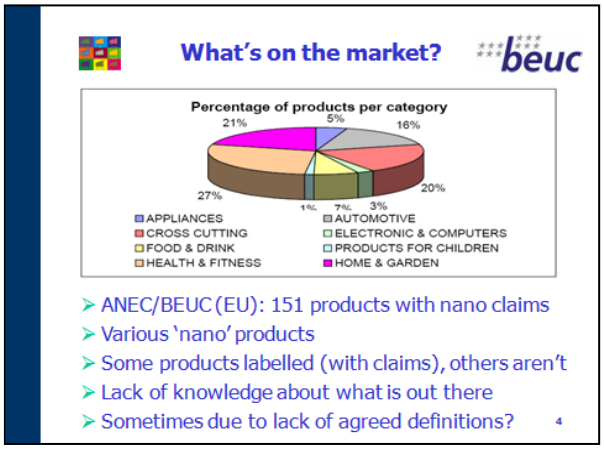
Laura Degallaix, European Consumers' Organization BEUC, Belgium

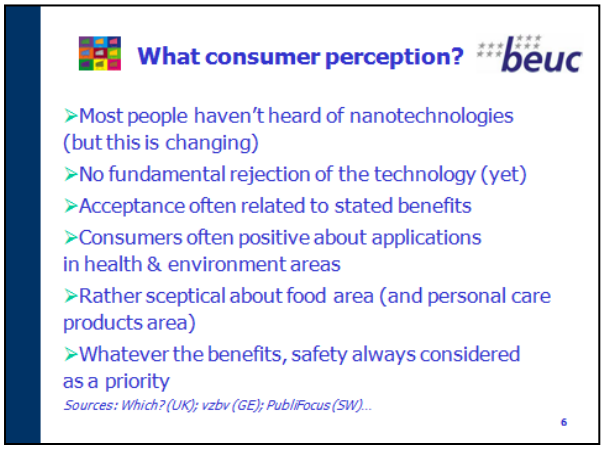
BEUC acknowledge that nanotechnologies have a potential to offer benefits in particular to consumers and the environment. They could be used to improve the resource and energy efficiency of appliances, the storage capacity and loading time of batteries, lead to new medical treatment opportunities or products of better performance. However, these technologies and materials may also present new risks which have never been properly evaluated. We are therefore concerned about the increasing number of consumer products containing nano-materials which are already (or will soon be) sold on the EU market without having been subject to a proper safety assessment.

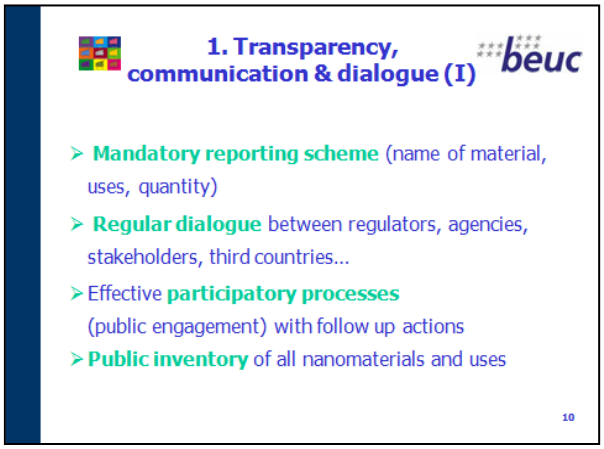
In the context of the development of the future action plan on nano-materials and nanotechnologies, BEUC, together with its sister organi-sation ANEC call for the European Commission to:

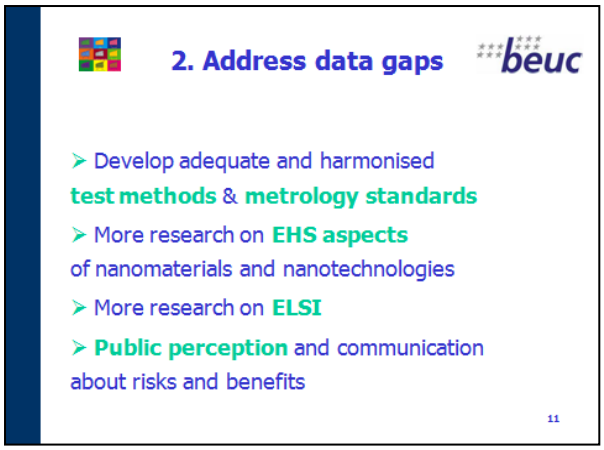
- Develop clear and enforceable **legal definitions** of nanomaterials and nanotechnologies;
- Ensure that the **precautionary principle** is applied in the field of nanotechnologies;
- Apply the "**no data - no market principle**" by requiring a pre-market safety assessment of nanomaterials in particular for nanomaterials that are intended to be used in consumer prod-ucts with which consumers come in direct, close or regular contact (e.g. food products) or in products leading to discharges to the environment;
- Promote the development of **adequate methodologies** for the safety and risk assessment of nanomaterials;
- **Adapt existing European legislation** (or develop new legislation) relevant to nanotechnologies and nanomaterials.
- **Adapt or establish specific legal safety requirements** (e.g. limit values for certain nanomaterials in products) and only reserve standardisation to technical specifications;
- Set up a **mandatory reporting scheme** through which industry would have to notify the use of nanomaterials, the quantity they produce and the products in which the nanomaterials are con-tained;
- Develop a **public inventory** of all nanomaterials that are used in products;
- Require the **labelling** of (some) consumer products containing nanomaterials in particular prod-ucts with which consumers come in direct, close or regular contact (e.g. food products);
- Encourage and support **effective participatory processes** to allow citizens to fully engage into decisions which will have an impact on their everyday life;

- Promote and prioritise **research funding on health, safety and environmental impacts** of nanomaterials and on ethical, legal and social implications.









Supporting Stakeholders' Needs and Expectations through Standardization

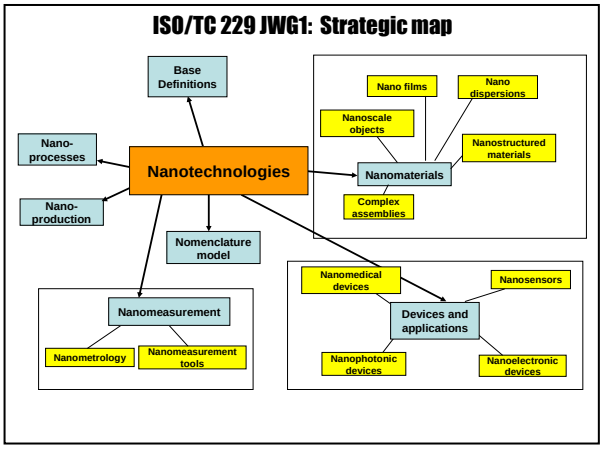
Dr. Peter Hatto, IonBond Ltd. / ISO TC229, United Kingdom

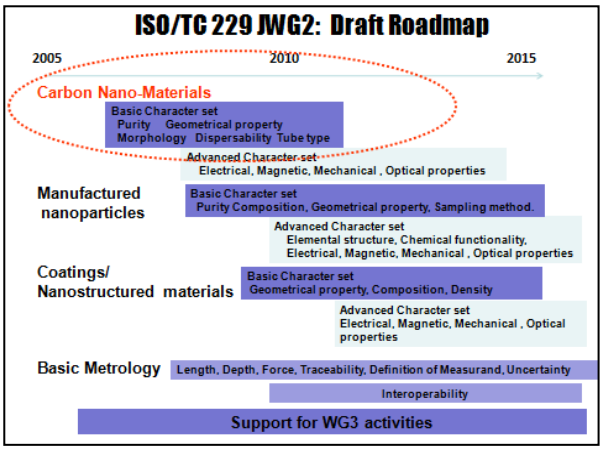
International standards are widely recognized as an important enabler of industrial activity through the provision of robust documents for naming, describing and specifying things, measuring and testing things, managing and reporting things, and ensuring health and environmental safety. Such standards derive their legitimacy from the voluntary, consensus based approach used in both their development and implementation – if someone uses such a standard it is because it provides utility, not because they are forced to use it.

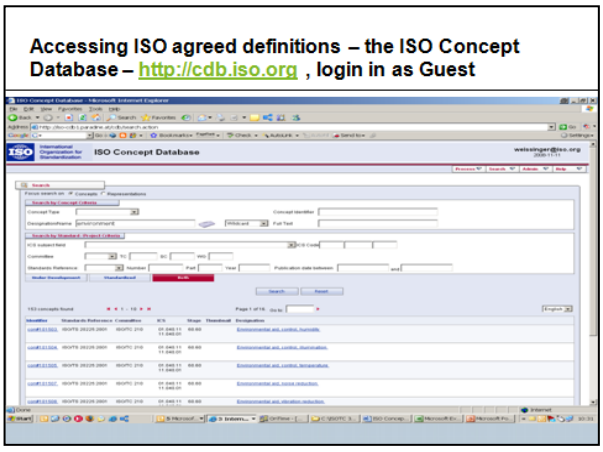
Whereas most standards are developed in relatively mature fields of endeavour, the emergence of nanotechnologies has provided standardization with what is essentially a "blank sheet of paper". Thus there are virtually no universally agreed definitions in what is an extensive and growing terminology, almost no validated measurement and characterization methods have been developed for use in the nanoscale, there are few certified reference materials for instrument calibration, and, so, far there are no agreed protocols to ensure human health and environmental safety. Given the high level of uncertainty over possible impacts associated with exposure to manufactured, and incidental, nanoparticles, this dearth of standards and protocols presents regulators with a dilemma – how can something be regulated if it cannot be reliably named, measured or characterized, and there is no clear understanding of its effects on health and safety?

For standards development in a new area of technology, such as nano, it is essential first to provide foundational or infrastructural standards to form a framework for the development of product standards in different sectors. Without agreement on 'horizontal' standards for terminology and nomenclature, measurement and characterization, health and environmental safety, and materials specifications, 'vertical', sector specific standards cannot be satisfactorily defined.

The challenge for standardization for nanotechnologies is to help ensure that this new field of endeavour, which promise so much for industry, for society and for the consumer, develops in an open, safe and responsible manner through the provision of agreed standards that support unambiguous communication, accurate and robust measurement, relevant and reliable means for identifying, characterizing and mitigating risks and hazards, and robust specifications for the materials associated with this new and fundamentally different area of science and technology. Unlike many other standardization activities, this work requires cooperation with and coordination across a diverse range of stakeholders and agencies to ensure the development of optimized and harmonized solutions relevant to the needs of the different interest groups and of society in general.







Panel Discussion and Synthesis Part 2

Prof. Dr. Hertel mentioned that the results of a BfR survey in Germany led to the conclusion that the risk perception and concerns among the public are often neglected compared to risk management and risk assessment. According to Ms. Laura Degallaix from BEUC a similar survey in the UK is supporting the results of the German study. Thus, independent of what kind of information handling approach will be used in the future these studies show that it is important to be aware of the consequences that such measures might have regarding the perception of nanotechnology overall among the broad public.

While the consumer advocates are calling for a general nano-label to create more transparency and free choice for consumers and to overcome the time that is necessary to develop standardized and broadly accepted pre market safety test methods, authorities and the industry have expressed doubts about the functionality of such a label. There are concerns that such a label could lead to a feeling of unsafety among consumers rather than being of informative character. And since nanotechnologies are applied in a wide variety of branches and sectors, such a nano-label was considered unfavourable by the industry. A sector and application specific approach was rated more sensible.

Some participants raised concerns whether the indication of particle size on the label is a proper means of characterising the material on the label. It might also be considered to include information about the novel properties of a product containing nanoparticles. On the other hand, however, it was mentioned that for such general nano-label so far not enough useful information about the properties and risks of the nanomaterials would be available.

Dr. Peter Hatto, chairman of ISO Technical Committee 229 illustrated the challenges of standardization in the field of nanotechnology. The fact that there is a big diversity of disciplines impacted by different nanotechnologies represents a huge challenge for the standardization process. From the consumer's point of view it was criticized that the composition of the expert pools responsible for the development of the ISO standards would not be enough heterogeneously. It would for example also be important to include consumer advocates. The lack of consumer experts within these expert pools might have the consequence that some specific exposure routes and consumer risks are underestimated.

Part 3 Nano-Information along the Value Chain

Nanomaterials and the Material Safety Data Sheet – The View of Swiss Authorities

Dr. Christoph Rüegg, Swiss State Secretariat for Economic Affairs, Switzerland

The Swiss Federal Council in April 2008 adopted the Action Plan "Synthetic Nanomaterials". The Action Plan is intended to create the basis for the safe use of synthetic nanomaterials and nanotechnology. It proposes different measures from enhancing communication and public dialogue to a National Research Program "Opportunities and Risks of Nanomaterials".

Within the framework of this Action Plan, the Swiss State Secretariat for Economic Affairs (SECO) is preparing – in close collaboration with other competent authorities – guidelines for the companies placing on the market chemicals which are synthetic nanomaterials or contain such materials on the necessary information in the safety data sheet (SDS) of these chemical products. Products undergo different changes during their lifecycle. The SDS must contain all the information necessary to handle the product and also possible downstream products during their whole lifecycle in a safe way.

The different chapters of the Safety Data Sheet are discussed in the guidelines and the information required to address the specific aspects of nanomaterials. Examples shall be given in the guidelines on how to give that information in a practical way that helps the companies using the product to decide about the necessary measures to protect their employees. Chapters 2 (Hazards Identification), 3 (Composition), 7 (Handling and Storage), 8 (Exposure controls/personal protection, 9 (Physico-chemical properties and 10 (Stability and reactivity) are regarded as the most important ones which require nanomaterial specific information.

Federal Department of Economic Affairs FDEA
State Secretariat for Economic Affairs SECO
Chemicals and Occupational Health

Nanomaterials and the Safety Data Sheet – the view of the Swiss authorities

5th NanoRegulation Conference: No Data, no market?
Rapperswil, Hochschule für Technik, 25/26. November 2009
(Best practices in nano safety information and public communication)
Christoph Rüegg / SECO / Labour Directorate

Swiss action plan „Synthetic Nanomaterials"

enacted by the Federal Council of Switzerland on 9 April 2008

basic information report (2007):
state of knowledge regarding the risks resulting from synthetic nanomaterials

- Current applications
- Health and environmental risks
- Physical chemical hazards
- Safety at work
- Analysis of areas to be regulated
- Technology assessment and communication
- Need for research

"..... strategy to control the risks of synthetic nanomaterials **on base of existing legislation** despite existing scientific knowledge gaps ....."

NanoRegulation 2009: Specific information in the SDS
FOEA/SECO/ABCH – Christoph Rüegg 3

Action-plan: Regulatory framework for the responsible handling of synthetic nanomaterials

- **Measures:**
  - Precautionary matrix for products and applications with synthetic nanomaterials
  - Self-supervision and measures of occupational health protection (Guidance)
  - **Providing safety information to the processing industry (guidance)**
  - Informing consumers about synthetic nanomaterials in products
  - Regulation for the disposal of products containing synthetic nanomaterials

NanoRegulation 2009: Specific information in the SDS
FOEA/SECO/ABCH – Christoph Rüegg 9

„Guidance document on integration of nanospecific information in the safety data sheet (SDS)"

1 Introduction and goals
2 Definitions and properties of nanomaterials
3 Possible risks of nano-objects
4 Example of a nano-product: Life-cycle of a surface-spray
5 Explanations regarding further chapters of the SDS
6 ADDENDUM SDB example: nano-specific information

NanoRegulation 2009: Specific information in the SDS
FOEA/SECO/ABCH – Christoph Rüegg 10

Principal chapters requiring specific information about the nanomaterial in the product

In the following chapters of the SDB at least minimal information on the nano-objects of a product has to be provided.

2	Composition/information on ingredients
3	Hazards identification
9	Physical and chemical properties

NanoRegulation 2009: Specific information in the SDS
FOEA/SECO/ABCH – Christoph Rüegg 12

Some Examples

Chapter 2 SDS (Composition/information on ingredients)
- if working with the product leads to the generation of dust, nanoparticles may be released
- spraying of the product may lead to the formation of aerosols containing nanoparticles.

Chapter 3 SDS (Hazards identification)
- contains NO nanoparticles
- contains dispersed nanoscale components of silver

Chapter 9 (Physical and chemical properties)
- contains uncoated nanoparticles in the range of 50-200nm.
- nanoparticles occur as agglomerates (200nm); they deagglomerate at physiological conditions.

NanoRegulation2009: Specific information in the SDS
FOEA/SECO/ABCH – Christoph Rüegg 13

Further chapters requiring specific information about the nanomaterial in the product

This information is necessary to decide on the required measures regarding safety at work as well as health and environmental protection.

1	Identification of the substance / preparation and the company	8	Exposure controls/ Personal protection
5	Fire-fighting measures	10	Stability and reactivity
7	Handling and storage	13	Disposal considerations

NanoRegulation 2009: Specific information in the SDS
FOEA/SECO/ABCH – Christoph Rüegg 14

Manufacturing Nanomaterials: What Safety Data and Product Information Are Provided by a Manufacturer?

Dr. Barbara-Christine Richter, Bayer MaterialScience, Germany

Bayer is an inventor company which operates globally with core competencies in the fields of health care, crop science and high-tech materials. We see nanotechnology as a key technology of 21st century. For Bayer it is an enabling science, which, through interdisciplinary research, can help us provide new and better product solutions in each of our business areas. In particular polymers and adhesives additives, nano-composite thermoplastics and nano-modified coating systems can benefit much from nanotechnology. A central project for Bayer is the responsible development of Carbon Nanotubes (CNT) under the trade name Baytubes®.

Bayer is committed to being a leader in product stewardship and sustainable development practices. Our goal is to ensure that Bayer products are handled both safely and with concern for the environment at every stage of the products' life cycles under the core principles and commitments of the chemical industry's Responsible Care® Global Charter.

The Product Stewardship program for Baytubes® focuses on characterization, the potential for exposure as well as on examination of the intrinsic toxicological and ecotoxicological profile of Baytubes®. Standard guideline studies have been performed with Baytubes® following Good Laboratory Practice (GLP), investigating oral, dermal and inhalative toxicity.

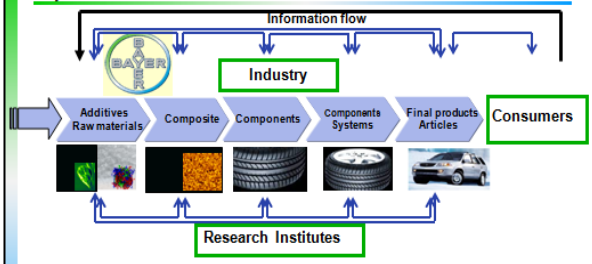
The success of nanotechnology is directly influenced with the level of responsible care taken by all partners along the value chain and all industrial stakeholders have to ensure that the production, handling, transport and use of products of nanotechnology are safe. As defined in REACH, Bayer sees the Material Safety Data Sheet as the key tool to communicate product stewardship information to their customers. This is accompanied e.g. by participation in cross industry activities to develop safe handling guidelines and in stakeholder dialogues projects like the *Nanodialog* of the German Government (lead by the Ministry of Environment). Furthermore Bayer is contributing to nanomaterial safety research projects like *InnoCNT* funded by the German Ministry of Education and Research (BMBF) which involves partners along the value chain.

Bayer MaterialScience

Manufacturing nanomaterials: What safety data and product information are provided by a manufacturer?

Dr. Barbara-Christine Richter
Bayer MaterialScience AG, Global Product Stewardship
5th NanoRegulation Conference, Rapperswil 2009-11-26

Bayer MaterialScience: Position in the Value Chain



- Bayer MaterialScience supplier of raw materials for the industrial/ professional use. Limited shipping of samples for research/development
- Nanomaterials are chemicals. Information needs to be appropriate to the related step in the products life cycle. There are well established and well proven tools available

2009-11-26 Dr. Richter - 5 -

Bayer MaterialScience

Tools for Value Chain Information

Trade press | Web based information | Customer talks

Trade fairs | Technical Data Sheet | Safety Data Sheet

2009-11-26 Dr. Richter - 6 -

Bayer MaterialScience

Material Safety Data Sheet: the relevant Tool for Information of Customers

- **SDS has key advantages:**
  - Legal instrument (REACH Article 31 and Annex II)
  - Safe handling and use covered
  - Long experience in the value-chain
  - Automated dispatch (at Bayer)
  - Duty to continuously update SDS when new information is available

REACH Article 31 / 6
1. Identification of the substance/ preparation and of the company undertaking
2. Hazard identification
3. Composition/information on ingredients
4. First aid Measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure control/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

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Bayer MaterialScience

Web based Information

Product Stewardship at BMS for Nanomaterials

BayCare Webpage www.baycareonline.com (Free registration, see "What's new" section)
Baytubes Webpage www.baytubes.com

2009-11-26 Dr. Richter - 11 -

Bayer MaterialScience

Summary

- Nanotechnology as such and Baytubes® offer great opportunities, emerging concerns need to be addressed
- Product Stewardship Program Baytubes® in place:
  - Extensive (eco)-tox testing
  - Work place exposure: methods and measurements
- Safe use of Baytubes® over its whole life-cycle
  - Communication along the value-chain implemented
  - Safety measures are available and communicated
  - Established instruments such as SDS are appropriate instruments to inform customers on the safe handling of the product
  - In addition, tools such as internet, fairs, technical data sheets are used to provide information
- Stakeholders dialogue platforms essential for general information exchange and to built a climate of trust

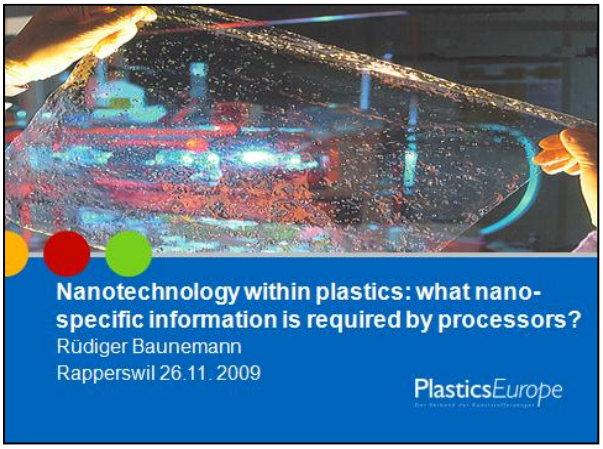
2009-11-26 Dr. Richter - 15 -

Bayer MaterialScience

Nanotechnology within Plastics: What Nano-Specific Information Is Required by Processors?

Dr. Rüdiger Baunemann, PlasticsEurope, Germany

- Plastics are well-established problem solvers in many fields of application - ranging from electrical engineering and electronics to construction, packaging, transport (automobile, rail, aircraft), sports, leisure, and medical technology.
- Some 70 percent of all technical innovations involve materials – directly or indirectly. Especially in this respect, huge potentials for resource efficiency and energy efficiency are being realized.
- Nanotechnology is seen as one of the key technologies of the future – with impacts on many areas of life. Innovative developments and potentials are forecasted for numerous applications of polymer materials.
- Nanotechnology, nanomaterials and nanoparticles – these collective terms describe structures which are not clearly defined as yet. This lack of definitions still remains an obstacle to discussion and evaluation.
- Together with the chemical industry, the plastics industry is actively participating in the gathering of information and in the development of risk assessments for free nanoparticles – with special consideration of occupational health and safety.
- The question whether nanoparticles enclosed in the plastic matrix require special attention and assessment within the evaluation of products throughout their entire life cycles (including recycling and disposal) is currently being discussed. The plastics industry is making constructive contributions to ongoing relevant activities.
- Before starting a debate about new regulatory measures, existing pieces of legislation (e.g. REACH) should be implemented and - if necessary - adapted. Such activities are possible only in an intensive dialog between all stakeholders.



Plastics and Nanotechnology

PlasticsEurope

- Nanotechnology, nanomaterials or nanoparticels – these collective terms describe structures which are not clearly defined as yet. This lack of definitions still remains an obstacle to discussions and evaluations
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Title of presentation / date of presentation 10

REACH and Plastics

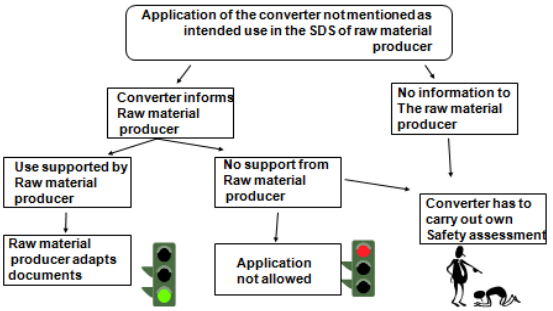
PlasticsEurope

- REACH will be/is relevant for the whole plastics value chain
- Huge uncertainty on how to deal with REACH
- Need for help and support
- Currently there is a periode of learning and identification of possible improvements steps
- Chance, to improve the communication within the different partners
- Need for coordination (industry associations)

Title of presentation / date of presentation 12

Communication scenarios under REACh

PlasticsEurope



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Challenges?

PlasticsEurope

- Up to now the focus is on the assessment of free nanoparticles
- Competition in the field of innovations makes cooperation more difficult
- Gaps in the assessment of product applications (food packaging, building products, medical devices,…)
- First results and discussions in particular questions (long term behaviour, migration, recycling, disposal)
- Versatility of products and applications makes it more difficult to find easy solutions

Title of presentation / date of presentation 16

Recommendation

PlasticsEurope

- **Acceptance that Nano is a chance for innovations**
- **Need for information gathering/ fact finding/ learning**
- **Cooperation within the value chain/ networking**
- **Participation in implementation processes**
- **Cooperation with all stakeholders is a must**

Title of presentation / date of presentation 18

How to Treat Nano-Waste: Challenges and Information Needs along the Value Chain

Dr. Mathias Tellenbach, Terra Consult Bern / FOEN, Switzerland

On April 9, 2008, the Swiss Government decided on the Action Plan "Synthetic Nanomaterials". The plan intends to create the basis for the safe use of such materials. It explicitly mentions the waste-treatment of nanomaterials as one of the items to be regulated: *"**Regulations for the disposal of products containing synthetic nanomaterials:** When disposing of products that contain synthetic nanomaterials, hazardous nanoparticles may enter the environment, or affect the recycling of composite materials and plastics. It has to be elaborated how a safe disposal of synthetic nanomaterials can be assured".* The Action Plan may be accessed online at http://www.nanotechnologie.admin.ch.

The responsible Federal Office for the Environment (FOEN) decided to develop Guidelines for the waste management of synthetic nanomaterials. A working group was constituted, with representatives of the relevant industries and responsible Federal and Cantonal agencies. It will shortly publish the preliminary version of the Guidelines, which should be "tested" by the concerned companies and authorities in order to gain experience with its practical application, before it will be finalized by the working group and the FOEN.

There exists virtually no nano-specific legal regulation for the management of nano-waste. This is mainly due to a lack of knowledge. The properties and risks of synthetic nanomaterials are often not known, the measurement of concentrations of free nanoparticles in the atmosphere or in water-effluents is difficult, and there are not yet any established technical standards and best practices for the environmentally sound recycling or elimination of nanomaterials.

The management of waste of synthetic nanomaterials in view of its correct and environmentally sound treatment therefore poses specific challenges to the different companies along the value chain up to the waste treatment plant, as well as to the authorities who have to draft and implement nano-specific regulations (e.g. issue the required permits).

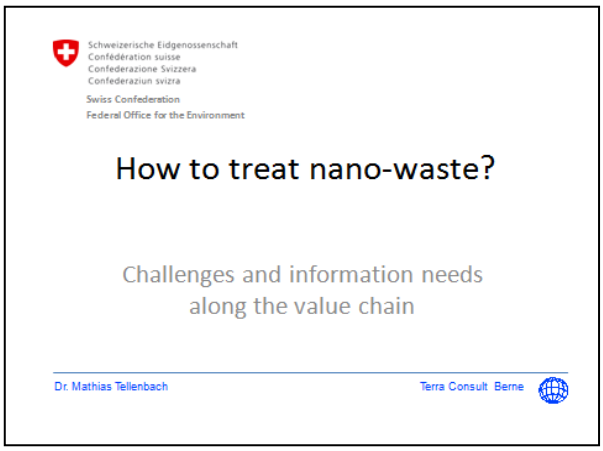
There exists a considerable risk potential if nanoparticles are set free into the workplace-atmosphere or into the environmental compartments air, soil or water. Any waste management therefore must follow the goals:

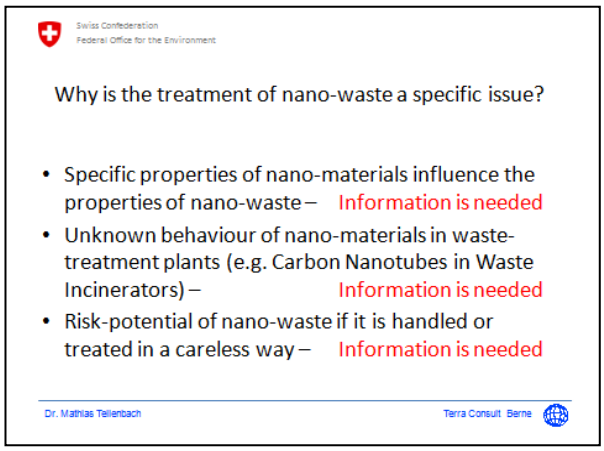
- To minimize the emissions of free hazardous nanoparticles.
- To minimize the risk of health and environmental impacts by free nanoparticles.
- To treat nano-waste in such a way that it can either be recycled as a secondary resource in the production process or that its nano-character is destroyed or put into a safe containment by the waste treatment process.

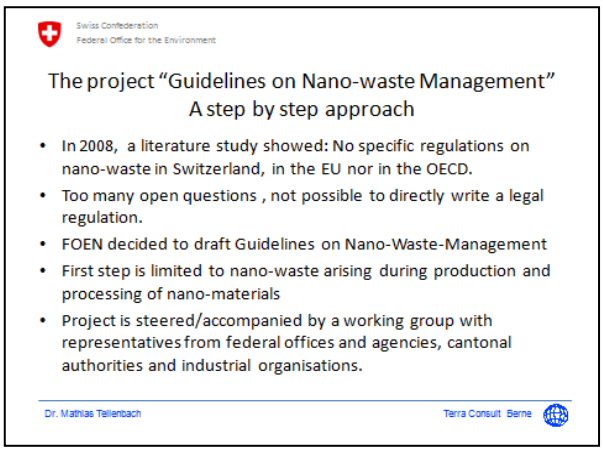
The Swiss guidelines will give recommendations for the management of nano-waste in order to attain these goals. They will cover the following fields:

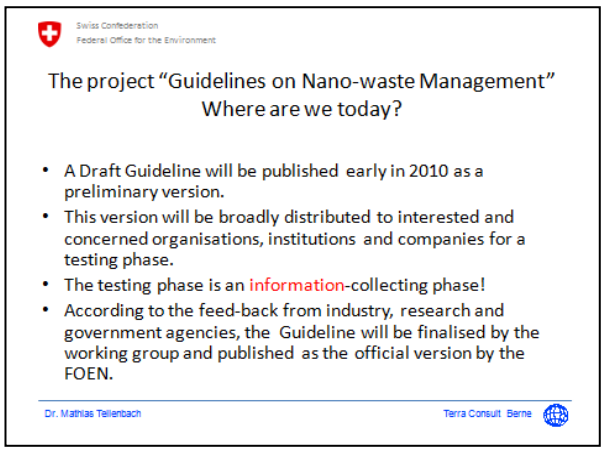
- Definitions for nano-waste being considered as hazardous waste
- Risk potential of nano-waste in the different waste management processes
- Waste management during production and processing of nanomaterials
- Requirements for waste treatment plants in order to deal with nano-waste
- Conditioning and elimination of nano-waste with free nanoparticles

The guidelines will refer to the protection measures at the working place (as recommended e.g. by the Swiss SUVA) and to the so called "Precautionary Matrix" *(Vorsorgeraster)* which has been developed to help trade and industry to identify possible sources of risk in the production, use and disposal of synthetic nanomaterials.









Swiss Confederation
Federal Office for the Environment

Treating what nano-waste?
The scope of the draft Guideline

- Not every waste with a nano-structure is a nano-waste
- The draft guideline addresses companies that *produce or process nano-materials* or that *treat nano-waste*
- The scope of the guideline are wastes arising during *production and processing of nanomaterials*
- The guideline deals with *wastes of nano-materials* or with *off-specification products containing nano-materials*
- Eventual proposals for treatment of end-of-life products containing nano-materials will be made in a later phase

Dr. Mathias Tellenbach Terra Consult Berne

Swiss Confederation
Federal Office for the Environment

Nano-waste is waste containing nano-material
The waste-management concept

Questions the waste-management-concept must consider:

- Does the production or processing cycle, including cleaning operations, generate waste that contains nanoparticles or -rods NPR?
- Who will handle these wastes? Does he or she know about them?
- The risk potential of the nano- waste at the working place
- What are the safety measures and the correct procedures when handling nano-waste?
- What is the appropriate Personal Protective Equipment when handling waste that contains NPR
- Information to pass on to the waste-treatment facility

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Consequences if a nanowaste is a hazardous waste

Hazardous waste (special waste, "*Sonderabfall*" in Switzerland") is ruled by a specific regulation, the Ordinance on the Movement of Waste (*"Verordnung über den Verkehr mit Abfällen VeVA")*

- Accompanying document with specific information about the waste with the appropriate waste codes
- Treatment facility needs a permit by the Canton
- Special waste may not be exported without a permit by the Federal Authorities

Dr. Mathias Tellenbach Terra Consult Berne

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Federal Office for the Environment

Treatment of nano-waste

- There are not yet any established best practices for waste-treatment of nanoparticles and -rods NPR
- Recommendations in the Draft Guideline are as yet limited to general principles, e.g.
  - acid dissolution of metals
  - high-temperature incineration of organic nanomaterials
  - sintering of ceramics or oxides
- Research, practical experience and information is needed!

Dr. Mathias Tellenbach Terra Consult Berne



Nanoparticles in Consumer Products: TA Swiss Study on Nanotechnology in the Food Sector

Andreas Hermann LL.M., Institute for Applied Ecology Darmstadt, Germany

Engineered nanomaterials have been used for many years as additives in food and in food packaging available in Switzerland and on the international market. Whereas nano-sized particles which occur naturally in food (like casein in milk) are not alarming, there are more reservations about specifically added engineered nanomaterials giving food new properties. These new properties might possibly also be linked with unexpected side effects. Against this background the Öko-Institut e.V. was commissioned by TA-SWISS, the Swiss Centre for Technology Assessment, to research the availability of these materials on the Swiss and international market and to evaluate the opportunities and risks attached to the use of engineered nanomaterials in food and food packaging.

In the range of different food products available in Switzerland, only a few are supplemented with engineered nanomaterials, and these have already been used in Switzerland for many years and undergone toxicity testing, inter alia the anti-caking agent E 551, carotenoids as a colorant agent or antioxidant and micelles as nano-capsules. In the packaging industry, the use of engineered nanomaterial is at a more advanced stage than it is in food production, e.g. nanomaterials are used in PET bottles to improve the gas exchange blocking properties of bottles against oxygen in particular or to improve the strength or rigidity of PET. In other European countries – not in Switzerland - packaging enhanced with antibacterial substances, e.g. nano-layers made of silver are used to sterilize fresh food.

At present, the contribution of nanotechnologies to sustainable nutrition, which is environmentally friendly, constitutional and ethically responsible is estimated to be rather low. In perspective, however, applications such as the enrichment of food with engineered nanomaterials (e.g. iron) could generate a constitutional advantage in developing countries to reduce malnutrition problems. Moreover, food packaging with engineered nanomaterials already offers several benefits for the consumers and holds a lot of potential for the future. Nanotechnology-derived food packaging can also reduce the environmental impacts. However, the technology needs to fulfil certain requirements such as the absence of migration of nanomaterials into the contained food, and that it is safe to the consumer's health and the environment.

Against this background, the main challenge is not only aiming at the short-term achievable benefits, but also towards a more sustainable nutrition with minimal possible health and eco-toxicological risks of the engineered nanomaterials in food. Thus, a risk governance framework for engineered nanomaterials in food and food packaging is required, which can facilitate and promote the implementation of sustainability potentials, but at the same time avoid possible risks to people and the environment. An approach

like this needs to be based on the precautionary principle as well as a life cycle perspective, and should also contain binding procedures in relation to stakeholder involvement for all players.

Basically, the Novel Foods Regulation (EC) No 258/97 could be regarded as a "nano food law" which principally covers the use of nanotechnology in foods or food ingredients. However, the Novel Foods Regulation is not applicable to food additives, flavourings or extraction solvents as well as food packaging. Therefore, the existing laws relevant for food additives and food packaging as well as statutory instruments associated to these laws need to be adapted to the requirements of nanomaterials. Therefore the development of nanomaterials in the food sector and the development of the legal framework should be guided by the precautionary principle which must be explicitly introduced in the Swiss food legislation. In addition to the abovementioned measures, a further risk management approach consists in the use of substances that are characterised through a particularly low toxicological risk potential. For food and food additives, corporate responsibility can be described in such a way that the toxicological safety of the used nanomaterials has to be guaranteed without doubt.

It is recommended to establish binding conditions for the risk management to be followed by the producers and importers, covering:

- a duty to notify food and food packaging containing engineered nanomaterials.
- a labelling of engineered nanomaterials used in the production process and in food packaging, especially with the purpose of tracing back food products, for monitoring the presence of nanotechnology-derived ingredients and additives, and for giving consumers the freedom of choice.
- a check if and how producers should adopt their obligation to comply with legal requirements of traceability - especially in respect to health protection – in order to trace and follow food and feed containing engineered nanomaterials through all stages of production, processing and distribution.

A "nano food law" seems to be of no help. In fact, the existing regulatory instruments on food and food packaging should be adapted to nano-specific requirements. Moreover a general moratorium for the use of any kind of engineered nanomaterials in food and food packaging is currently not being favoured. Nevertheless, a specific moratorium for the use of free engineered nanoparticles, or for certain application types (e.g. nano silver), could be the result of a societal dialogue.

In addition to establish the necessary regulatory frameworks, other major tasks are to intensify the human and eco-toxicological risk research as a primarily task for the producers and importers following the producer's responsibility, and to initiate a societal dialogue on common goals of the sustainable application of engineered nanomaterials in the food sector in order to avoid a debate like with GMO in food.

Panel Discussion and Synthesis Part 3

The most important tool for transferring information along the value chain is the MSDS, according to Dr. Richter from Bayer MaterialScience. It is important to include information about the nano-specific properties of the nanomaterials in the MSDS. Carbon Nanotubes (CNT), for example, possess different characteristics depending on their structure and therefore could also bear different potential risks. Bayer MaterialScience as a manufacturer tries to include every existing kind of information about their CNT into the MSDS. As soon as new toxicity data is available, the MSDS is updated.

Dr. Baunemann from PlasticsEurope, representing the processor's view within the value chain, called for simple and pragmatic concepts of risk assessment and information transfer for the many small and medium sized companies that represent the main part of processors that might be confronted with nanoparticles. He further emphasized that it is important that the information transfer is bidirectional, enabling converters and processors to fall back on the manufacturers about possible risks of certain nanoparticles related to their specific processing steps.

Regarding the handling of nano-wastes, it was criticised that the current focus is almost uniquely on the recyclers. It would be equally important also to account for the waste which is produced by households. Unfortunately, however, according to Dr. Tellenbach from Terra Consult, too many new products containing engineered nanoparticles are put on the market, and it seems therefore impossible to carry out meaningful safety tests for all of them.

The MSDS as a tool of information transfer is regarded favourably all along the value chain down to recyclers. However, in order to inform consumers about nano-specific risks as well as about accurate waste handling the MSDS cannot be the tool of choice.



Part 4 Better Safe than Sorry, but How? Workshop Session

Workshop I Consumer Products

Nano-labelling in Consumer Products

Moderated by: Andreas Hermann LL.M., Institute for Applied Ecology Darmstadt, Germany
Rapporteur: Marianne Dietiker, The Innovation Society Ltd., Switzerland

In this workshop, it was discussed what should be the objectives of a general nano-label and what might be its benefits for consumers. Further, the goal of the workshop was to identify the main concerns about such a label, to show its limitations and to point out possible alternatives.

Objectives of a nano-label

The overarching objective for a nano-label was identified to be to enable consumers to make an informed choice on whether to buy or not a certain product containing nanomaterials. Considering the lowest level of an "informed" choice, a nano-label would not need to contain detailed safety information, but the resulting choice would be a "question of faith" (nano or no nano). Further objectives of a nano-label were mentioned to be to

- provide information about the benefits resulting from the use of the nanomaterials in the product
- use the nano-label as starting point for further information
- use it as an interim solution to account for transparency until accurate and commonly accepted pre-market safety test methods are available
- provide information about direct or indirect exposure to nanoparticles
- provide different information (quality & quantity) depending on the target group (professional user or consumer)
- guarantee that the use of nanoparticles within a certain product really brings evident benefits for the properties of the product (this would require a legal basis to prevent the misuse of the term "nano" as a false advertise)

Main concerns about nano-labelling

The main concern of the industry is that a nano-label might raise a general feeling of insecurity and new (but possibly unfounded) concerns among consumers. Any simple nano-label was considered not being very informative and thereby easily misinterpreted as an universal "warning symbol". A more informative label, on the other hand, could probably lead to information overload, thereby also missing its target.

Limitations of nano-labels

- Is there really new information behind "nano"?
- Information content of a general nano-label is limited. There is not enough information behind the term "nano".
- Indicating only the particle size of a nanomaterial on the label is very limited concerning the information provided.
- Since the term „nano" is also used for purely marketing reasons, independent of whether a product really contains nanoparticles or not, a nano-label might lead to confusions among consumers. Thus, a nano-label would also request further explanations.

Alternatives to nano-labels

- Product register (at least for authorities, professional users and recyclers)
- Product insert (containing safety information, exposure data, waste handling instructions)
- No general "nano"-label, but specific solutions for different materials, particles, industry sectors etc.

Workshop II Industry and Nanomaterials

HSE Relevant Information Flow to Downstream Users and Authorities

Moderated by: Dr. Rüdiger Baunemann, PlasticsEurope, Germany
Rapporteur: Stephan Knébel, The Innovation Society Ltd., Switzerland

The goal of the workshop was to define what information is needed at what level along the value chain. Who should provide which information and what is the tool of choice to transfer information? Further it was discussed if there is need of a control body and if yes what should be the responsibilities of such a controlling instance.

What is the first impression of the different approaches?

- It is not clear why we are concerned about "nano" right now.
- Labelling is not the solution. Just from knowing whether a product contains nanoparticles it is not clear whether the product is safe or not.
- The most important point seems to be the coordination among the stakeholder.
- The communication of large companies is often more transparent compared to medium/small sized companies.

Which kind of information is needed / not needed by producers of raw materials?

- General statement: Since consumers do not have enough information about nanomaterials and nanoproducts they do not completely trust the producers.
- Agreeing on definitions (meaning: what is dangerous and what is not) is the starting point. The criterion must therefore be: Does the particle enter cells or cross the air-blood barrier? If not, the particle may not be considered dangerous.
- The most important question for the producer is to determine whether the testing setup is adequate to gain the necessary information.
- What would happen if the industry needed to repeat tests of substances just because they are used at the nano-scale? Not all old data is bad because testing results are not only depending on the characteristic of the particle size.

What kind of information is needed / not needed by the secondary industry?

- The secondary industry cannot test the raw material; they just examine the end product. However, what counts is a meaningful dialogue and efficient information/data-sharing between the supplier and the manufacturer.

What kind of information is needed on the product / consumer level?

- To which products consumers are most sensitive?
  - In general, the consumer considers the particles to be more dangerous when the application is close the human body (e.g. cosmetics, inks, food, toys)
- Where are no problems expected?
  - Products containing nanoparticles within a certain matrix (e.g. CNT in tennis rackets)
- What information do consumers need?
  - End of life cycle information
  - Waste handling instructions
  - Exposure information

Who should do the controlling? Do we need a referee?

- The workshop participants agreed that at present, no additional regulation is needed.



Workshop III Material Safety Data Sheet

Adapting the MSDS to the Requirements of the Nanoscale

Moderated by: Christoph Bosshard, SUVA, Switzerland
Rapporteur: Markus Widmer, The Innovation Society Ltd., Switzerland

In the beginning of this workshop session, the participants were asked to bring forward issues to be discussed under the topic of the adaptation of the material safety data sheet (MSDS) to the needs and peculiarities of manufactured nanomaterials. The participants mentioned the following five aspects, which were addressed in the subsequent discussion:

1. How to implement long-term and later life-cycle information in the MSDS?

The question was raised how it would be possible to better consider information in the MSDS which would be relevant in later product life-cycle stages. A case where a paint containing nanoparticles would be used on an oil rig served as a fictional example. The company in charge of disassembling the oil rig after its life span would most probably not know about the nanoparticle paint used nor would it get the necessary information on nanoparticle-related risks to be able to adopt adequate safety measures in the recycling and disposal.

- It was clarified that in principle any (known) information about risks needs to be mentioned in the MSDS, independent of the life-cycle stage it concerns. Nevertheless, this would require the manufacturer (which compiles the information in the MSDS) to be fully aware of all future uses of the concerning product – an assumption which seems unrealistic in many cases.
- In the light of these requirements, the further discussion also pointed to the need to balance the MSDS in terms of the amount of information presented and its usefulness depending on a simple and clear form.
- In practice, it was noted that the information chain is often broken somewhere in the manufacturing and processing chain, and that consequently, the end user of the final product and the recyclers / disposers are cut off from the information flow.

Furthermore it was questioned what role the MSDS could and should play in the addressing of long term risks of manufactured nanomaterials. It was criticized that, in its current form, such issues are not adequately addressed, and that not enough information on such risks is available yet.

2. Experiences with personal protective equipment (PPE)

Practical experience with airborne nanoparticles was reported to indicate that particles in the air usually adhere to each other and accumulate and do not remain airborne for a long time. This indicates that both time and spatial distance are in favour of workplace safety.

As compared to fine particles, current PPE were in general reported to be comparable or even more effective. Very small particles (nanoparticles) adhere to the filter material due to diffusive forces, and larger particles (above about 1000 nm) are caught in the filter mainly due to inertial impact and interception. Some uncertainties were mentioned regarding the efficacy of filters against particles of medium size (about 200 nm).

On the other hand, however, it was also pointed to the fact that the most important prerequisite would still be to use PPE in practice at all. One participant mentioned that the information indicating what exact PPE to use on the MSDS was often insufficient, e.g. only stating to "use appropriate respirator". This was considered against the law which determines that adequate PPE has to be specified (e.g. respirator P3).

Furthermore, one participant raised concerns that, despite the assumed efficacy of conventional PPE against nanoparticles, the necessary long term – low exposure studies to assess such risks are still missing – the question how to take up such information in the MSDS was among other things the subject of the discussions under point 1 above.

3. Nanospecific parameters to be included in the MSDS

In terms of the discussion of possible parameters of a given nanomaterial which need to be mentioned in the MSDS, the following related problems where brought forward by to the workshop participants:

- Often, the manufacturer of a nanomaterial (responsible to compile the MSDS) is not able to determine the nano-specific properties such as e.g. the particle size in the final product.
- One (negative) example was cited: Sometimes, carbon nanotubes are labelled as "graphite" (existing CAS number 7782-42-5) in the MSDS.
- The approach of the European Union was appreciated which requires one MSDS per identified use.

Instead of indicating the (mean) particle size alone, the indication of a particle size distribution was considered more useful. In addition, the shape of the particle was also rated important (particle, tube, plate, etc.). This opinion was further commented by stating that

- processors often do not consider the information in the MSDS, regardless of what information it contains. Although it was acknowledged that it is almost impossible to influence whether the information in the MSDS is actually used, it was pointed to the need to make people aware of and support them in interpreting the information in the MSDS (particularly SME).
- the MSDS must be kept simple.

Finally, Christoph Bosshard noted that in Switzerland there are currently taking place discussions about the introduction of reference values for certain nanomaterials in the list of threshold values by 2011.

4. Methods of compiling MSDS

The way how the information in the MSDS is created in practice was subject to discussions. The possibility to have an MSDS compiled automatically by software or externally for only 300 € was taken note of critically.

It was again argued that, even though the legal requirements for small and medium enterprises (SME) are the same as for large ones, SME might often be willing to take more risks. However, any "nano-incident" along the value chain, e.g. due to insufficient documentation of hazards in the MSDS, will affect all stakeholders, not only those responsible for the concerning deficient MSDS.

In order to minimise the effort to compile MSDS for nanomaterials, it would be important to have a commonly accepted, standardized methodology. There are already guidance documents available, e.g. the VCI Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets[1].

5. Who should be in charge of control?

Controlling the adequacy and completeness of the emitted MSDS through governments was reported to be difficult.

- On the one hand, government agencies lack the necessary resources to enforce and control full compliance with the requirements for MSDS.
- In Switzerland, the situation regarding control is clear: The government is in charge of control. However, Switzerland's approach of industry self-control implies that the manufacturers are responsible to ensure the safety of their products – similar as in the EU under REACH. To support the efforts of the industry, the authorities provide support by sensitizing users to possible risks of nanomaterials, and by providing suitable tools to assess and manage these risks.

[1] Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets, Status: 6 March 2008, available at http://www.vci.de, enter "guidance safety data sheet" in the search form.

- It was again mentioned that the risk appetite of small and medium enterprises might often significantly differ from the one of large (multinational) enterprises. Liability and litigation are seen as main drivers favouring a proper consideration of nanospecific aspects in MSDS. Companies were also reported to suffering from a lack of information which might prevent them from recognising upcoming issues such as those related to manufactured nanomaterials.

In conclusion, the workshop participants observed a lack of data and knowledge which hampers the adequate consideration of nanospecific aspects in the MSDS. The final discussion focused on the question whether and how the MSDS could be "made fit for nano": In general, it was concluded that the MSDS as a tool are regarded suitable also for nanomaterials, and that there is no need to start from scratch.

Speakers of the 5th Int. NanoRegulation Conference 2009

Speakers

Baunemann	Rüdiger	PlasticsEurope	Germany
Borchardt	Gustaaf	European Commission	EU
Degallaix	Laura	European Consumers' Organization BEUC	Belgium
Hanawa	Hiroyuki	OECD Environment Directorate	OECD
Hatto	Peter	IonBond Ltd., ISO TC229	United Kingdom
Hermann	Andreas	Institute for Applied Ecology Darmstadt	Germany
Hertel	Rolf	Federal Institute for Risk Assessment BfR	Germany
Meili	Christoph	The Innovation Society Ltd.	Switzerland
Richter	Barbara-Christine	Bayer MaterialScience	Germany
Rüegg	Christoph	Swiss State Secretariat for Economic Affairs SECO	Switzerland
Singhofen	Axel	Greens / EFA in the European Parliament	EU
Tellenbach	Mathias	Terra Consult Bern / FOEN	Switzerland

Conference Moderation

Meili	Christoph	The Innovation Society Ltd.	Switzerland
Henriques	Adrian	Middlesex University Business School	United Kingdom

Workshop Moderation

Workshop 1

Hermann	Andreas	Institute for Applied Ecology Darmstadt	Germany
Knébel	Stephan	The Innovation Society Ltd. (Rapporteur)	Switzerland

Workshop 2

Baunemann	Rüdiger	PlasticsEurope	Germany
Dietiker	Marianne	The Innovation Society Ltd. (Rapporteur)	Switzerland

Workshop 3

Bosshard	Christoph	SUVA	Switzerland
Widmer	Markus	The Innovation Society Ltd. (Rapporteur)	Switzerland

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