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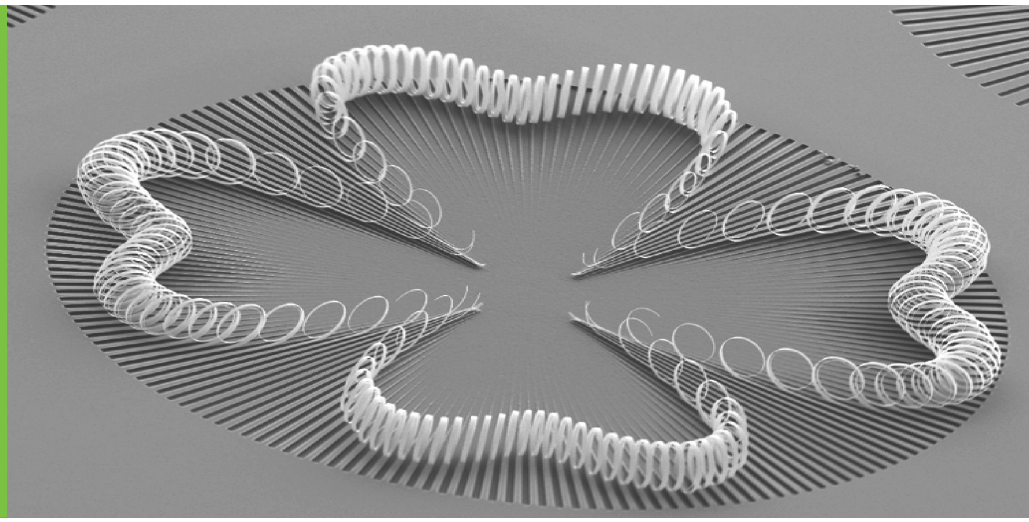
Nano-Regulation



A multi-stakeholder-dialogue-approach towards a sustainable regulatory framework for nanotechnolgies and nanosciences

Report

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About the author and the company

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The Innovation Society Ltd is a leading Swiss research and consulting company focusing on business applications and economic impact of nanotechnology. The company is based at the Technology Center of the Swiss Federal Institute for Materials Science & Technology (EMPA) in St.Gallen. The Innovation Society cooperates with leading international experts and provides *consulting, research and coaching* services in:

- *Technology and Innovation Management*
- *Safety- and Risk Management* / Regulatory issues
- *Technology Communication & Stakeholder dialogue*

In ***Technology and Innovationmanagement*** we support companies in making use of new scientific findings and in applying new technologies in order to develop new products or improve existing processes.

Our ***Safety- and Risk Management*** *services* aim to assess and evaluate risks and establish efficient and proactive risk management systems. The company has a broad expertise in safety, risk and regulatory issues of nanotechnology and therefore can provide unique strategic know-how to its customers.

We additionally combine our business and technology know-how with our experience in designing and managing ***Communication*** *and* ***stakeholder dialogue processes.*** *This generates supplementary added value to our customers and provides additional benefits in many ways.* Our clients range from international industry, retail companies and investors to governmental agencies and regulatory bodies, which are committed to successful and safe applications of emerging technologies.

The platform **"*Nano-Regulation*"** (*http://www.nanoregulation.ch)* is an example for a multi-stakeholder dialogue forum. It was launched in Switzerland in 2005 in cooperation with international companies, governmental bodies, scientists and NGO. It is focusing on safety, risk and regulation issues of nanotechnology. In the meantime it serves as an international stakeholder-network organisation, facilitating and supporting communication and dialogue processes on safety, risk and regulatory issues of nanotechnology, providing strategic relevant information and know-how in publications and reports and organising conferences and workshops.

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About the funding organisations

Nano-Cluster Bodensee *(St.Gallen, Switzerland)* is a project of the "Society Mikro- and Nanotechnology Euregio Bodensee". It interlinks businesses, research facilities, and institutes into a network. The goal of the cluster is to help industry to connect to research and to the increasing base of industrial related near-to-market nanotechnology. In the context of the network, companies initiate or expand their technology-related activities, enabling them to acquire a significant competitive edge and substantial market power through additional innovations.
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Nano-Europe is the leading European fair and conference for commercial applications and knowledge in the field of micro- and nanotechnology. Its goal is to transfer technology. The combination of fair and conference is its key to success. NanoEurope 2006 will focus on: Medical Devices, Plastics and Textiles and Nano-Regulation. The upcoming NanoEurope will be held in St.Gallen from September 12th – 14th 2006.
Web *www.nanoeurope.com*

Cover: *SEM-picture of silicon-chromium bilayer spiralling itself into helical nanobelts. (by courtsey of Li Zhang, Paul Scherrer Institute, Switzerland (PSI)*

1 Content

2 Executive Summary

Nanotechnology presents a bunch of new and exciting opportunities to improve materials and design new products with high benefit potentials. Coatings, computers, clothing, cosmetics, medical devices and sport equipments will be improved and our economies will be increasingly affected by nanotechnology as more products move from research and development to the markets. Nanotechnolgy has also the potential to improve the environment by either replacing hazardous substances through “green” chemicals or by making industrial processes cleaner and create environmentally friendly products.
On the other side there are unanswered questions about the unintended impacts of nanomaterials on health and environment. Due to the new properties of nanosized materials there are also new potential risks associated with these materials.
Risk is an important factor to be considered in the early stage of an emerging technology. If risks are considered in time, the ex-post costs of identifying important impacts on Health, Safety and Environment (HSE) and potential liability costs in case of damages can be minimised. Late identification and characterisation of HSE risks have hampered earlier emerging technologies substantially. Public debates on GM-food and Nuclear Power have proven that early preoccupation with potential risks is crucial for a sustainable and successful technology development. Transparent communication, open public dialogue, valid risk data and - if necessary - adapted regulations - are vital pre-requisites to build public trust and to create high-producing conditions for a successful development and application of nanotechnology.

This report describes the approach and some of the results of the stakeholder platform “Nano-Regulation” which addresses safety, risk and regulation issues of nanotechnology.

In spring 2005 the platform „Nano-Regulation”, an international multi-stakeholder-dialogue-forum was started in Switzerland. The platform was launched as a network of several industry, insurance, research, retail, government and NGO organisations. The goals of the platform are to

- establish an **international multi-stakeholder network** on regulatory issues
- characterise stakeholders **attitudes and expectations** towards safety and risk issues
- ***address safety, risk and regulation*** needs of nanotechnology from different perspectives
- facilitate **proactive solution oriented dialogue** processes on safety and risk issues
- ***identify and prioritise the fields of action***
- ***propose forthcoming activities***

During the first phase there were a series of expert interviews conducted, analyzed and finally reported in a DELPHI-study. Several meetings and a workshop were held and an international conference (Nano-Regulation) was organised. Furthermore an expert steering group was set up in order to prepare further steps.

Based on the key-results of the performed activities it can be stated that a **dialogue forum** about safety and risk-issues is broadly welcomed as a powerful and efficient instrument of **information, coordination and cooperation**[1]. A dialogue on **regulatory issues** was judged to be valuable in terms of an increased security of action for all stakeholders. The importance of early engagement of the public in order to prevent a sudden backlash in terms of lacking trust was stressed to be important by all parties.

Due to the fast technological development, the fast increase in products, containing nano-components and the rapid and broad application of nanoparticles and nanomaterials in manufacturing processes, there is an urgent need to clarify safety issues of nanotechnology and to identify gaps in either **occupational health safety, product and consumer safety** or **environmental** regulations.

There was also a common understanding that most countries of Western Europe (incl. Switzerland) should develop or adopt **internationally compatible** frameworks or standards. In order to overcome trading barriers an EU-wide or even global harmonisation of frameworks and standards would be appropriate. The question on which specific properties of nano substance (diameter, toxicity, surface characteristics, scope or exposition) the regulation should look at, remained open. However a thoughtful case-by-case risk-analysis is required with potentially hazardous nanomaterials and a proactive risk-management system has to be established.

The following points can be regarded as “guideline-milestones” for a structured and adjusted process towards a sustainable regulatory framework for nanotechnology. The points are the summarised outcome of the Delphi-Study, several workshops and the first international conference “Nano-Regulation” which had been held in St.Gallen in 2005.

1. **Terminology**: A clear and consistent definition of “nano” is still missing. Terminological definitions and standards are urgently needed in order to clarify the scientific and public debate and to avoid misleading or wrong wordings and definitions. In terms of definition BSI[2], ISO[3], CEN[4] and other organisations are currently working on a consistent terminology of nanomaterials, which should be applied in the near future.

2. **From risk-assessment to proactive risk management:** Risk data needs[5] have to be analysed and prioritised and important fields of research have to be identified. Appropriate measures (research policy, cooperation, etc.) have to be initiated systematically as soon as reasonable evidence for potential hazards is given. This ensures that the adaptation of existing regulation is

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1 The platform Nano-Regulation has its own website (www.nanoregulation.ch) providing additional updated information (e.g. a free database) containing relevant reports, news, events and further details.

2 British Standard Institution has published a Public Available Specification (PAS): “Vocabulary – Nanoparticles” (http://www.bsi-global.com/Manufacturing/Nano/index.xalter)

3 International Organization for Standardization (www.iso.org)

4 European Committee for Standardization (www.cenorm.be)

5 The report “A scoping study to identify hazard data needs for addressing the risks presented by nanoparticles and nanotubes” IOM (2005) gives an updated overview of current studies in the field of nanoparticles and nanotubes.

strongly evidence based and confirmed by research data. An undifferentiated regulatory "clear cutting-regime" would generally not increase present health or environmental security level. A moratorium or a "Nano-Law" does not seem appropriate from the present point of view. But doubtlessly there is a lot more of further in-depth-risk analysis needed in order to develop proactive risk management strategies.

3. **Review of existing legislations:** A review of existing (national and international) legislations (HSE) has to be made by experts in order to identify specific regulatory gaps, prioritise fields of action and suggest appropriate measures if needed. Cooperation between several regulatory bodies (health, environment, legal) is therefore indispensable and has to be established and coordinated on time. On the other hand, industry has to be integrated into this cooperation from the beginning. The following topics are of utmost importance:

   - occupational health safety (Laboratory use and large scale, manufacturing)
   - Product- and consumer safety (life-cycle-analysis (LCA), waste, emission)
   - Environmental safety (LCA, food-chain, waste, emissions)

   The highest priority should be given to the occupational health safety issue due to the already widespread applications of nanomaterials in research and manufacturing. Industry processes and applied research organisations formulated a clear need to get regulatory safety guidelines in order to prevent liability claims and to protect occupational health and consumer safety.

4. **Adaptation of existing legislation:** After a careful review process; prioritization is required to identify weaknesses in the existing regulatory framework and suggest proper measures. The following steps were suggested:

   Short term activities:
   - support precautionary measures in workplace safety, consumer- and product safety, environmental protection
   - support and strengthen stakeholders awareness (industry, research) for self-control measurements
   - strengthen and institutionalise the cooperation with international committees and organisations (EU, OECD, etc.)
   - strengthen public dialog and unpstream public engagement
   - development of national adapted Action plans nanotechnology (e.g. according to the EU Action plan 2006- 2009)

   Medium and Long term activities:
   - promotion of risk and safety research projects (universities, industry)
   - enhancement of risk evaluation and risk-assessment methodology in relevant sectors
   - promotion of harmonised methods for risk assessment of nanomaterials
   - support cooperation with international groups and governmental entities
   - adaptation of the existing regulations where necessary

5. **Accompanying measures**: In order to guarantee a high safety levels in manufacturing processes and laboratories and to strengthen acceptance of nanoproducts some of the following measures could be applied:

   - development of guidelines (best practices) for a safe and sustainable use and handling of nanomaterials (e.g. synthetic nanoparticles)

- development of a “Code of Conduct” for sustainable production, use and handling of nanoparticles
- evaluation of technical measures for the protection of health and environment (e.g. filters, low pressure fume hoods, etc.)
- voluntary labelling of potentially hazardous materials / consumer products
- inventories of potentially hazardous nanoparticles and nanoapplications
- inventories of expositions and quantities of nanosized particles
- review of threshold values for potentially hazardous nanoparticles / nanomaterials
- standards for declaration / self-declaration
- review of requirements for Material Safety Data Sheets (MSDS)
- LCA-studies of nanomaterials and nanoparticles must be conducted

6. **Self-control mechanisms**: Existing legislations in many European countries rely on a strong self-control principle, delegating responsibility for safety issues to the organisation which is producing or using chemical substances and materials. Producer and user of products are liable for the safety of their products. In this context stakeholder awareness of potential hazardous nanosized materials (especially synthetic particles) and adequate measures have to be strengthened.

7. **Cooperation:** Governmental bodies, industry organisations and scientists need to establish close collaboration. A financial investment by the industry sector for additional research projects related to further safety research of nanomaterials would be regarded as fair and highly welcomed by governmental organisations[6] and scientists. The role of mutual cooperation between different organisations and stakeholders seems crucial be it on the scientific, governmental or economic level and has to be strengthened on national and international level.

8. **Coordination:** Currently there are many national and supranational nanorelated projects and initiatives going on. In order to avoid duplication and make efficient use of time and money it is of great importance to coordinate stakeholders activities on a global level and establish organisational structures and tools to provide and enhance information and knowledge transfer. International organisations such as the OECD and the EU will play a crucial role as information brokers enabling processes on a global level.

9. **Communication and public dialogue**: Experiences from earlier risk oriented technology debates have shown that communication and stakeholder-dialogues are key factors to technology success. This is true for the communication among experts and the communication of experts with the public. Lessons from the GMO debate have clearly shown that information on technology, often disseminated by industry alone is seen as marketing driven and is often perceived as manipulative. Therefore interactive, bidirectional communication instead of one sided information is necessary. Suitable communication strategies involving specific structures and neutral communication platforms have to be established in order to ensure optimal preconditions to meet the needs of the involved stakeholders and the public.

[6] The german federal Ministry for Education and Research (BMBF) has recently started a 7.5 Mio Euro research project (NanoCare) which is funded by governmental and industry organisations (2:1)

10. **Upstream public engagement:** Communication about risks and benefits is crucial for the long-term success of nanotechnology. In order to detect signals of public distrust in an early stage and to gain high levels of acceptance;[7] an early "*public upstream engagement"* e.g. in Research & Development (R&D) is needed. This is a real challenge, since public understanding and knowledge about nanotechnology is very poor. A general public perception of nanotechnology is practically non-existent yet. However it's not tainted by negative experiences yet, but however accidents or unforeseen damages could easily dis-equilibrate the situation and influence regulatory processes in an unpredictable way.

In order to meet all these requirements we suggest to set up a global stakeholder dialogue platform, on safety, risk and regulatory issues. It should be supported by national, international and supranational stakeholders. The task of this platform is to coordinate the activities on a global level, enhance information and knowledge transfer, provide information to national authorities, and support proactive dialogue processes on this vital issue as soon as possible.

We therefore propose to extend our multi-stakeholder approach in cooperation with international organisations, industry, scientists, governmental authorities and NGO. The "***Swiss-dialogue -model***"[8] has proven to be very valuable to all involved parties in terms of coordination, cooperation and communication. It is applicable either on national level in particular countries or on international / global level to catalyse result oriented processes and provide constructive and practicable regulatory solutions. The main objective of the platform is to facilitate and support basic conditions for a ***successful, safe*** *and* ***sustainable*** development and use of nanotechnology**.**

7 See e.g. "The Ten Commandments of Nano-Communication" (Meili, 2005)

8 The concept and methodology of the platform can be adapted to specific national or supranational parameters and requirements.

3 Goals of this report

One of first goals of the stakeholder platform “Nano-Regulation” was to characterise the attitude of the different stakeholders towards regulatory issues of nanotechnology and to raise questions which were linked to this topic. Critical fields of action should be identified and necessary steps and actions should be discussed among the stakeholders. According to these goals, this report will therefore:

- outline the **structure** and the organisation of the platform and shortly describe the activities
- summarise the relevant **outcomes** in terms of relevant points and
- list **recommendations** and describe next steps.

As there are currently many international organisations (European Commission, OECD) discussing regulatory issues of nanotechnology this reports aims to describe a multi-stakeholder approach which can be used as a model to support complex multi-stakeholder-dialogue processes on contradictory issues involving stakeholders on an global level. The experiences which we have seen in the first stage[9] will be highly valuable when being integrated into a global dialogue process model. This report does therefore not reflect national or international legislation in detail[10] but is meant to rather envisage the “big picture” and moreover provide advice on the design of regulatory governance decision taking processes on an international level.

4 Introduction

Nanotechnology involving the production, manipulation and handling of materials in the nanoscale (1 – 100 nm) has become a field of major interest. The properties of nanosized materials often differ from the properties of microsized substances and materials. Due to smaller size and an altered volume, surface ratio, nanoparticles often show different physical and chemical properties, than their related bulk materials. For this reason nanosized materials bear the potential of many new applications in many fields and industries. As there is no commonly accepted definition of the term “nanotechnology”, in this report we adopt the definition of EPA (2005, 4).

> *“Nanotechnology is defined as research and technology development at the atomic, molecular or macromolecular level having a length scale of approximately 1-100 nanometer (10^{-9} m) in any dimension. The creation and use of structures and devices and systems that have novel properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale.”*

9 In the first phase of there were international industry and insurance companies and research organisations participating. The authorities were Swiss and therefore the regulatory focus was Swiss and European. The next phase will be focusing international regulations.

10 For an overview of existing regulatory frameworks, applying to nanosciences and nanotechnology see e.g. Davies (2006, p 10 ff) or Haum et al. (2004), p. 26 ff.)

4.1 Risk- and safety- issues of nanotechnology

Nanotechnology provides new opportunities in terms of better and improved materials and products. A survey (EmTech Research, 2005) has shown that over 600 nanobased raw and intermediate materials and over 80 costumer products already exist on the market (cosmetics, electronics, therapeutics, sports equipments, etc.). In the future our society will be increasingly affected by nanotechnology. Due to its broad impact nanotechnology is supposed to change many applications in almost every industrial sector. The economic potential of nanotechnology is predicted to reach over 1 trillion US$ market volume by 2015 (Lux Research Report, 2005).

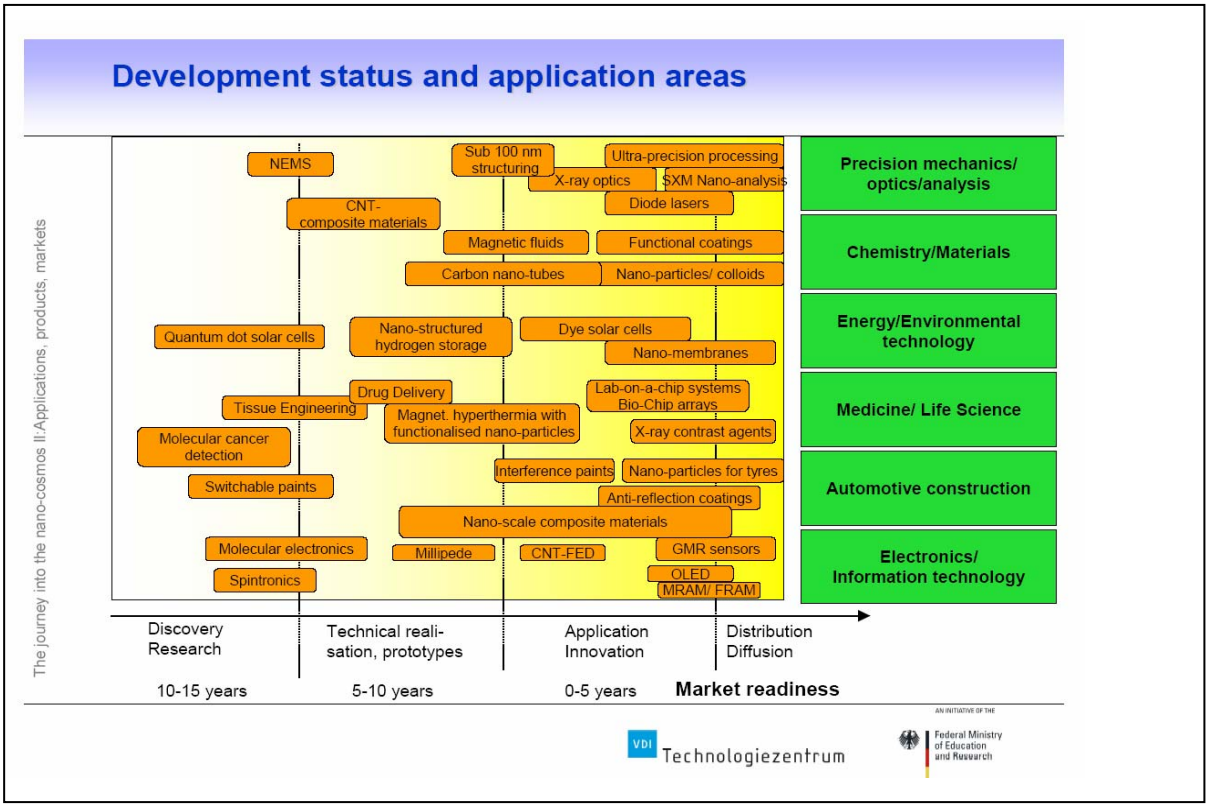

Figure 1: Development status and application areas of nanotechnology. (VDI, BMBF ; 2005) http://www.nanotruck.de/pdf/folien/pdf-print/engl/Teil2/Part2appl-products-markets2.pdf)

Obviously technological advancement in new technologies always relates to potential new hazards and risks. In terms of health and environmental implications of some nanomaterials, especially nanoparticles, there are many unanswered questions about potential hazards and unintended side effects of nanotechnology. Due to a lack of risk data, a non existing risk assessment methodology and a lack of long term observations the risk-database is presently very weak and the risk-assessment and evaluation methodologies are not validated yet. For this reason a public accessible database on *"Nano*

safety, risk and regulation" issues was launched by The Innovation Society[11] in December 2005. The database serves as a basic information broker offering relevant reports and relevant research data on the internet.

4.1.1 Risk focus on synthetic nanoparticles

Due to altered physical and chemical properties of nanomaterials, to the newness of certain nanospecies (e.g. synthetic nanoparticles) and the mobility of aerosol and unbound nanoparticles, free nanoparticles are prone to potential health and environmental side effects. Among the various nanoscaled particles there are several risk bearing materials, such as dust- and powder-formulated particles which could get into the body by inhalation and into cells by crossing the cell membranes without specific cellular mechanisms. In recent risk literature (e.g. Tran, et al, 2005) an amplified focus is therefore put on synthetic nanoparticles (e.g. carbon nanotubes). Nevertheless there are bigger quantities of e.g. combustion engineered nanoparticles (e.g. in diesel exhausts). It`s obvious that risk data from combustion engineered nanoparticles will serve as model data for synthetic nanoparticles.

4.2 Structure and development of the Platform Nano-Regulation

In 2003 the Canadian based ETC-Group (ETC-Group, 2003) called for a worldwide moratorium for manufactured, synthetic nanoparticles, pointing out that there was not enough risk data available for a sufficient protection for health and environment. This claim fuelled the discussion about necessary regulatory concepts among industry-, research- and governmental representatives. As there are already 500 - 700 nanorelated products on the market and many laboratories and production processes are already working with nanosized materials there is a common interest in safety and risk data as far as certain nanomaterials are concerned.
For this reason a multi-stakeholder-platform (forum) Nano-Regulation was initiated including international industry, insurance, retail organisations and representatives from NGO, academia and governmental bodies. The first stage of the project "Nano-Regulation" was initiated in spring 2005 addressing needs and requirements of the stakeholders in terms of regulatory questions of nanotechnology. It seemed very important to clarify the attitude of the stakeholders first and then address their requirements in a second step.
Looking back to earlier emerging technology debates as the GMO food debate it seemed obvious, that questions of safety, risk and regulation have to be tackled in a proactive way in order to prevent hazards and risks on time. Broad public legitimisation of technology and consumer acceptance has to be achieved. In this context the development of the platform started with an Expert-Delphi study in order to identify the stakeholders attitudes, questions, requirements etc. The Delphi was evaluated

[11] www.nanoregulation.ch

and discussed among the stakeholders and several points were clarified. The different perspectives were discussed during the Nano-Regulation conference in fall 2005 and the further steps were defined in collaboration with an expert group. The first steps of the development of the platform are presented in Table 1.

Development of the platform Nano-Regulation

Action	***Results***	***Time***
Delphi-Study on regulatory issues of nanotechnology	• clarifying stakeholder positions • summarising mutual expectations • listing relevant questions and identifying critical issues • Identifying regulatory needs	March – May 2005
Stakeholder-Workshop (June 05)	• discussion of the Delphi results • identifying critical issues • shaping the structure of the platform according to the requirements of the stakeholders • discussion of further activities and planning of next steps	30th June 2005, Berne
1st. International Nano-Regulation Conference (Sept. 05)	• presentation and discussion of different stakeholder perspectives (industry, government, insurance, NGO) • input about international regulation policy trends and actual projects • international contact and networking opportunity / community building • transdisciplinary contacts / exchange (regulators, practitioner, scientists, politicians)	14th Sept. 2005, St.Gallen
Workshops of the Expert group	• evaluation of the conference / workshops • initialising of further activities • Planning and conceptualising of upcoming events • establishment of cooperation with int. and supranational partners.	August 05 – January 06

Table 1: Development of the platform “Nano-Regulation” (Start: 2005) enlisting activities, results and timeframe.

4.3 Services of the platform Nano-regulation

The platform Nano-Regulation serves as a neutral dialogue platform for international stakeholders and provides information and expert-knowhow on safety, risk and regulation issues of nanotechnology. The services of the platform are generally accessible publicly and partly free (e.g. database). The annual, international conference “Nano-Regulation” in St.Gallen for instance, serves as a unique meeting opportunity for stakeholders from all over the world and is the international lynchpin of the platform. This event is organised as a meeting point of the global nanocommunity interested in safety, risk and regulation issues.

The platform is financed by public and private organisations and provides expert knowledge and information on strategic relevant issues and access to a multi-stakeholder network. In terms of information there are several services provided as e.g. periodical electronic reports and updates and on the latest safety and risk-related issues on global regulation policy trends in terms of HSE and product safety legislation. Stakeholder workshops and events are organised on specific issues and special topics. These and other services are offered to the members of the platform in order to provide business relevant information and establish a trans-disciplinary network.

The platform cooperates with leading experts and provides custom-specific services related to safety, risk and regulation issues of nanotechnology. Specific expert know-how will be made available in consultancy, research or coaching services. In the consulting projects valuable technology- and risk-management services are provided (e.g. risk assessment / risk evaluation / risk management of potentially hazardous nano-materials). In the research there are several services provided (e.g. occupational health guidelines, review of scientific papers, etc.), In this context there are also coaching services provided in the risk assessment / risk evaluation area of products and in product and process development. Table 2 gives a tabular overview over the services which are provided by the platform Nano-Regulation.

Services of the platform "Nano-Regulation"[12]

Content	Target audience	Access	costs
Database "Safety, risk & regulation of nanotechnology" *(www.nanoregulation.ch)* • Dissemination of HSE and ELSA relevant information on safety, risks and regulation issues to the public	*Investors, insurance companies, Industry, governmental bodies, international organisations, scientists, journalists, politicians, NGO, public*	public	free
2nd International Nano-Regulation Confernce *(13th- 14th Sept. 2006, St.Gallen)* • Safety & health aspects of synthetic nanoparticles (occup. Health) • Best practices in safe handling and use of synthetic nanoparticles • International Trends in Nano-Regulation • Nano-Communication	*Investors, insurance companies, Industry, governmental bodies, international organisations, scientists, journalists, politicians, NGO, public*	public	conference fee
Documentation and workshops *Publications* • *Constant, periodical information updates on recent developments in safety, risk and regulation issues* • *Srategic Trendreport* in safety, risk and regulatory issues of nanotechnology (*Events* • *Stakeholder-workshops* on specific topics relevant to safety, risk and regulatory issues • *Stakeholder focus groups*	*Investors, insurance, industry, governmental bodies, international organisations, scientists, politicians, NGO*	members of the platform Nano-Regulation	Platform membership fee
Research, coaching and consulting • *Research* on safety, risk and regulatory issues of nanotechnology • *Consultancy* (strategy / risk assessment / risk management / communication) • *Coaching* on strategy / risk assessment / risk management / regulation) safety and risk issues	*Investors, insurance, Industry, governmental bodies, international organisations, scientists, politicians, NGO,*	public	T & M basis

Table 2: Provided services of the platform "Nano-Regulation"

[12] For further information and details mail to: christoph.meili@innovationsgesellschaft.ch

5 Results

The following part summarises some of the hitherto existing results and describes the outcome of the activities in more depth. The presented results are meant to trigger further activities and actions of the platform in the future.

5.1 Results of the Expert-Delphi

Between March and May 2005 a Delphi-Study was conducted with several experts[13], which was based on oral interviews[14]. The outcome of the interviews are presented briefly hereafter. The statements are summarised to generalised stakeholder-statements, representing attitudes, expectations, questions particularly with regard to regulatory issues. The most important goal of the Delphi was to clarify the stakeholders attitudes and list arguments (pro and cons) in the regulatory discussion. There were representatives from the industry, insurance companies, retail organisations, governmental bodies, academia and media interviewed.

5.1.1 General findings in the interviews

All experts welcomed the opportunity to start a dialogue on safety, risk and regulation issues of nanotechnology. The starting point for a dialogue project was widely acknowledged as appropriate and timely. The experts stressed the importance of dialogue in order to omit problems which had been seen in earlier debates. Nuclear power technology and GMO food were mentioned in most interviews as bad examples. Therefore stakeholder dialogue activities were generally perceived as crucial. Especially dialogue with the public and potential pressure groups (e.g. health-, consumer-, environmental organisations) was mentioned of utmost priority. At the current state of knowledge a proactive dialogue is needed, experts said, because there are not enough risk data available yet. On the other hand, there is a need for a trans-disciplinary debate between nano-professionals, politicians and regulators in order to prevent unintended regulatory developments. Many experts agreed that the field of occupational health safety is most important. When only few risk data are available the precautionary principle should be applied.

5.1.2 Points of agreement

In many statements the poor public knowledge about nanotechnology was seen as a major challenge to further development of the debate. The dialogue should be led proactively and with all stakeholders which could be potentially affected. Transparency and the providing of relevant information should be in the focus of the process. The highest priorities in terms of actions are seen in:

[13] see Appendix 1

- Standardisation and terminology (*What are we talking about?)*
- Improvement of risk assessment methodologies and standards for measurements (characterisation)
- Support of further risk research (health / environment) (*How dangerous are these materials?)*
- Life cycle analysis (LCA) and paths of exposition (*immissions / emissions*)
- Education of the public / providing fact based information *(What is Nano?)*
- Training and sensibilisation of employees *(How to handle, use dispose nanosized materials)*

Due to a lack of data, concerning neither risk potential and probability a majority of the experts considered an overall risk-evaluation as not feasible today. The experts were voting for a clear and differentiated (productspecific) risk evaluation, considering potential exposition and hazards in regard to applications. In most interviews the importance of communication and education of the public was mentioned. People generally do not know much about nanotechnology and therefore are susceptible to biased information. As the public legitimisation of technology is needed it seems indispensable to integrate the public “into the communication and information-loop”. In this context medial play a crucial role and in the view of most experts, they could tend to characterise nanotechnology in a critical way.

5.1.3 Points of disagreement

Most contradictorily discussed was a general requirement for a nano-specific regulation. The “contra-regulation-arguments” were that nanosized materials are already regulated within the regulatory framework (e.g. chemicals) and therefore a nanospecific regulation is not needed. Furthermore it was stated that “overregulation” could hamper technological development and put jobs and technological innovation at risk. The affirmative regulation arguments stated that the new characteristics and properties of the nanomaterials and especially nanoparticles should be subject matter of regulation. Furthermore the regulation could build trust in terms of higher liability and better safety guidelines.

5.2 Stakeholder positions

In the following section the stakeholders positions are specified in more detail. The statements cannot be taken as the consolidated meaning of this stakeholder group, but they show the general concerns and the attitude of the group. The statements have been summarised and shortened to the very key contents.

5.2.1 Industry

For industry representatives nanotechnology of course has a high benefit potential and is mainly seen as an important tool to develop better materials and products. Nevertheless manufacturing processes always need investments and financial commitments. To guarantee a high return on investment there

[14] see Appendix 2

is a high safety standard in products and processes required. In order to prevent liability claims, clear regulatory guidelines, based on risk data, are crucial to industry. Product safety and high occupational health safety standards are therefore the most important issues related to nanomaterials in manufacturing process. In terms of regulation, industry representatives were calling for both: a clear regulatory framework (e.g. safety guidelines) in order to avoid liability claims and on the other hand a regulation as liberal as possible. In any case, any “overregulation” should be omitted in order not to kill the nanotechnology innovation boost. In terms of safety aspects industry representatives stated that they would be grateful for governmental support in terms of guidelines, risk assessment data for handling, processing and waste management for e.g. nanoparticles. Furthermore the classification of nanomaterials and substances should be made in hazard categories. Of high interest are synthetic nanoparticles which are airborne and can be inhaled or get in the environment. It was further stated that a legislation for nanoparticles would be indispensable - as in any other case of a chemical substance. The mere question is whether this would be in a specific regulation or under existing regulations. Therefore it has to be investigated whether nanomaterials and nanoparticles could be treated as ordinary chemical substances or not. Small and medium enterprises (SME) have a more intense wish for assistance and support than larger international companies which seem to be more familiar with regulatory procedures. For industry representatives it is very important, that regulation is internationally harmonised in order to prevent handicaps of trade and superficial bureaucracy.
In terms of communication, industry representatives stated that media are generally playing a crucial role by framing the public attitude towards emerging technologies. According to some experts the negative attitude of consumers towards GM-food was basically a product of media framing. In the case of nanotechnology, unbiased information and negative “imaging” could intimidate consumers. Generally, it was often stated, that the information in the media has to be more matter of fact based. One of the most feared risks of many industry representatives was the “nano-bashing” by the media. Therefore a balanced information strategy was often suggested and a cooperative collaboration with journalists and media was stressed.

5.2.2 Federal offices and governmental agencies

The governmental bodies in Switzerland have already started to discuss questions related to safety and risk issues of nanotechnology in health and environment protection context. The representatives of governmental entities commonly acknowledged the crucial role which nanotechnology is going to play for technological innovation processes. On the other hand, they are strongly aware of their task to protect public health and environment from unintended side effects. Officials saw their role in analysing the existing regulatory framework, analysing potential gaps and suggesting and implementing additional regulations as far as these will be needed. None of the representatives regulatory bodies expressed an urgent need for a specific “nano-regulation”. Based on the experiences which were gained until now, the new chemical legislation in Switzerland (PARCHEM), which is based on the Chemical Act and the Environmental Legislation seems to be a suitable legislation applicable to nanomaterials as well. One point to consider as critical is the lack of

harmonised testing procedures and risk assessment methodologies. In this context a valid and standardised methodology with toxicological and ecotoxicological endpoints should be developed. Presently there is no priority on which property (size, surface, toxicity, exposition) a particle should be assessed. In this process of risk assessment and evaluation it seems of utmost interest that industry is integrated into the process and can participate and provide safety and risk data in order to establish interdisciplinary expert bodies which can support proactive risk-manangement processes on a professional level. The existing legislation (e.g. Parchem), which is harmonised with international chemical regulation, will have to be reviewed. If necessary, the adaptions will also have to meet the requirements of an international harmonisation. In order to elucidate a call for action the Swiss Agency for Environment, Forests and Landscape (SAEFL) and the Swiss Office for Public Health will develop a Swiss action plan Nanotechnology (2006–2009). The action plan should be analogous to the action plan of the European Commission[15] which was presented in June 2005 and which suggested several activities to develop a sustainable and efficient regulatory regime for nanotechnology. Furthermore the Swiss Federal authorities are already cooperating with the OECD (e.g.) Nanotechnology group. .

5.2.3 Insurance industry

The business of insurance companies is risk. Insurance companies are selling insurance coverage for potential losses. Thus insurance industry enables other stakeholders (e.g. industry) to take certain risks by guaranteeing compensational payments in case of losses. Insurance premiums are calculated exactly and depend on severity and probability of potential losses. Important preconditions of insurability are therefore accountability in terms of probability, unpredictability and lack of manipulation. The basis for accountability are risk assessment and risk evaluation data. New technologies are always related with potential risks. If there is a fast technological development the risk-assessment data might not be available in an early stage of technology and an appropriate calculation of the premiums is therefore not possible. Insurance industry often has a shortage of essential risk data which are needed in the stage of emerging technologies. This is why new technologies are investigated by insurance industry very carefully. It is very important to acknowledge that insurance companies cannot be obliged – by governments or by any other regulatory body - to cover risks which cannot be calculated sufficiently on one side, and to see that insurance coverage does not guarantee security and a safer life at all. Insurance industry can facilitate risk taking by any stakeholder, but it cannot make technology safe. Within the spectrum of possible damages only a certain part of the losses imply liability. Within these losses the liability framework determines the extent of the insurability (see Figure 2). The risks which are posed by nanotechnology have to be treated the same as other risks posed by e.g. chemical substances. It seems most important to the insurance industry that risk assessment methodologies, hazard and exposition and life-cycle-analysis

[15] http://www.cordis.lu/nanotechnology/actionplan.htm

data can be provided in order to get a reasonable and robust data for risk evaluation and risk management measurements.

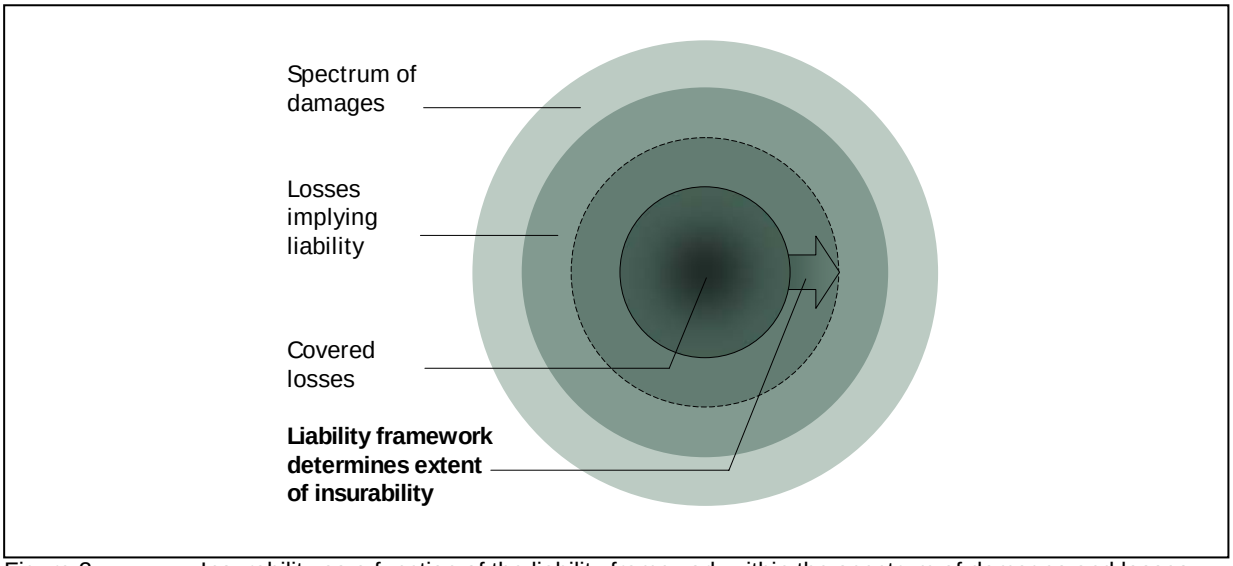

Figure 2 Insurability as a function of the liability framework within the spectrum of damages and losses implying liability (Dr. Th. Epprecht; personal communication)

In terms of insurability the greatest challenge for nanotechnology is therefore posed by its lack of risk data on one hand and the non-existing technology perception of the public on the other hand. The societal conditions and framework is crucial for the legal framework which is given by a society and is relevant for the technological development of nanotechnology.

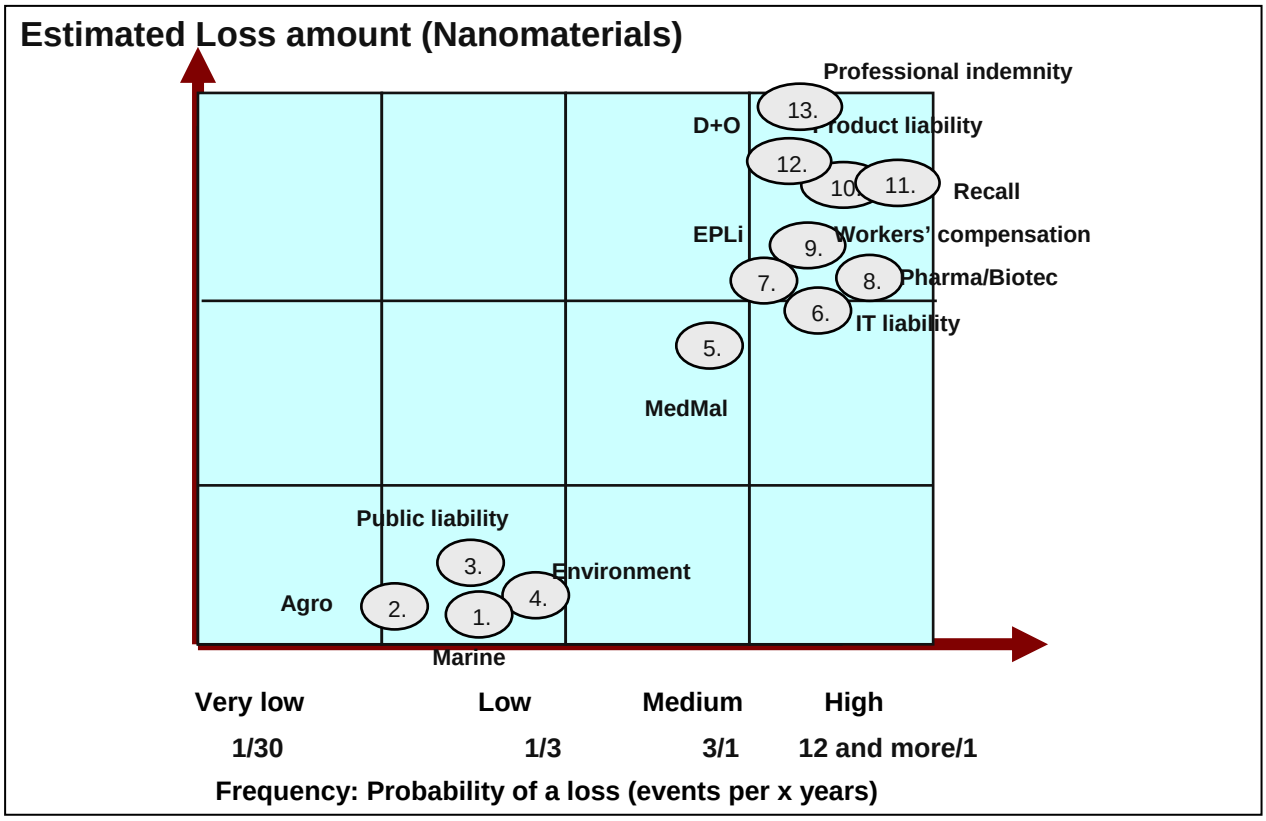

Figure 3: Estimated loss versus probability of a loss in several applications of nanotechnology (MunichRe, 2005)

Reports from insurance companies (SwissRe, 2004; MunichRe, 2005; Allianz, 2005) triggered and enhanced a debate about potential risks of nanotechnology. MunichRe has presented a preliminary assessment of nanorisks in terms of estimation and probability of losses in fall 2005 (Figure 3).

5.2.4 Retail organisations

The position of retail is to some extent similar to the industry position. By distributing and selling products, retail organisations are liable. In certain product groups especially food and near food products - they have to guarantee product safety by own risk assessments and quality control in the laboratory. In the non-food sector the product quality and safety must be guaranteed by the producer. In this field retail has to rely on industry. In this context it is very important for retail organisations that the products containing nanomaterials are safe to consumers and to the environment. This means that retail organisations often have to rely on external experts and knowledge especially on product safety information. On the other hand retail organisations depend on precise and clear basic conditions in terms of regulations. In this context the definition of the term “nano” and the labelling is highly critical, as “nano” is often used for marketing purposes. The lessons from earlier technology debates, especially GM-food have shown, that technology cannot be brought into market without accompanying measures, information activities and after all – consumer acceptance. Consumers are not generally critical towards technology but they are in some way “inquisitorial” in terms of information. This means that sufficient information has to be provided as a part of the product and sensitive products have to be labelled.

Figure 4: Members of T.H.O.N.G (Topless Humans Organized for Natural Genetics) a US NGO, were protesting in front of the Eddie Bauer flagshipstore in Chicago against non-labelled textiles containing nanofibers (May, 2005) (http://www.chicagothong.org/front.html)

A lack of information is a serious cause for distrust. Compared to GMO products, retail claims that in the late nineties when NGO and consumers were heavily protesting against GM-Food products, it had to bear the whole information burden. With nanotechnology this should not happen again.
That means that e.g. industry has an “information duty” and is expected to supply information both to their retail partners and to the consumers as well. Especially in products which are based on nanotechnology or contain nano-components, industry carries information responsibility. At present, the consumer attitude towards nanotechnology is not tainted like in the case of GM-food. But consumers do not know much about nanotechnology and this is seen as a severe risk for the reputation of nanoproducts.
Food and cosmetics were seen as the most important and critical product categories which bear the highest exposure to possible public concern and therefore, contain the highest “image-risk-potential”. Cosmetics on the other hand have a very high benefit potential in terms of improved product properties. Over all, the highest benefit potential for nano products is clearly seen in the non-food products, e.g. textiles, sports, material protection-chemicals and improved materials in general. It seems very important that the consumer benefits are communicated very clearly and unambiguously. The labelling of consumer sensitive products should therefore be an issue of high importance. A key issue for retail is insurability of nanotechnology, as consumers perceive technologies which are not fully insurable as potentially dangerous.

5.2.5 Academia

All of the scientific experts stressed, that in the laboratories scientists were quite aware of the safety issues especially related to free, airborne nanoparticles and to the potentially hazardous character of some of these particles. All scientists working with e.g. Carbon Nanotubes stated that there were measurements of precaution in order to protect their staff in the labs. Some of the research organisations have safety-guidelines for the use, handling and disposal of nanomaterials which are similar to those for hazardous chemicals. In terms of risk research all experts agreed that research on risks should be supported strongly in order to provide robust data for risk assessment procedures as fast as possible. This should be done in collaboration with industry and within a specific and coordinated research policy. On the other hand, applied research work should be done in order to provide new solutions and make valuable contributions to technology providing technological innovations. In R&D driven research units nanotechnology was seen as a mighty tool to solve problems, and to obtain new products, and improve processes. In the toxicological field the more risk-sided perspective is focussed on the understanding of potential hazards and identifying threats to health and environment. It was generally accepted that the risks should be evaluated very carefully as the beneficial potential has to be shown clearly.

5.2.6 Standardisation organisation

There are presently several standardisation organisations working on voluntary environmental safety and health standards. The American Society for Testing and Mateials (ASTN), the French Standards Agency (ANFOR) which have both established working groups on nanotechnology addressing the needs for standards and regulations. The ANFOR working group is participating with European Conformity scheme as part of the Working group 166 and with the International Standards Organization Technical Committee 229 “Nanotechnology” to support the conformity of global standards. In the US the American National Standards Institute (ANSI) coordinates the national efforts in terms of standardisation. In the PR China the National Technical Committee 279 within the Nanotechnology Standardization Administration has established several standards on testing of materials[16]. Some of these organisations are presently working on proposals for terminology and nomenclature. According to the experts, standardisation will be necessary to clarifiy and unitise terminology on the other hand it will be an important tool to supplement regulations and legal frameworks. The voluntary framework of standardisation could be a promising “para-legal” concept in terms of ensuring protection guidelines for health and environment standardisation principles. Furthermore standards do not have the same conflict potential as legislations and are therefore suited for better acceptance. Voluntary guidelines could provide at least a framework and could be subsidiary to governmental regulation policy and regulations as in other safety relevant fields as ISO standards are commonly used as complementary guidelines to regulations.

5.2.7 Media

Media play a crucial role towards influencing public attitude towards technology. Even though media coverage of nanotechnology is mainly positive, but it has been fairly poor in the past. A recent study on media coverage stated, that the most noteable fact about media coverage on nanotechnology was the absence of it (Woodrow Wilson, 2005). Compared to other emerging technologies there were not too many articles published in newspapers in the past. Biotechnology or IT are addressed much more in the media. People`s attitude towards nano is generally positive: more so in the US than in Europe (Macoubrie, 2005). The general knowledge of the public about nanotechnology is very poor (Gaskell, 2005). More than 50% of the public do not know anything about nanotechnology, and only 2% know very well about nanotechnology. In this context the role of media to frame nanotechnology is crucial. First in the sense of *information and education of the public* and second in *communication*.

5.3 Results from the Stakeholder Workshop and the Nano-Regulation Conference

After the Delphi-study was completed, two events were organised. First there was a stakeholder workshop held on 30th June 2005 in Berne and second the 1st Int. “Nano-Regulation” conference was

16 For further details see International Risk Governance Council (IRGC) (2005)

held on 14th September 2005 in St.Gallen. The two events are described and evaluated briefly in the following section in order to highlight the most important points and to summarise the results.

5.3.1 Stakeholder Workshop "Nano-Regulation" (30th June 2005; Berne)

The workshop was organised after the Delphi study was completed and evaluated. In this context all relevant information had been taken into account and was presented in the introduction of the workshop. The workshop was organised and coordinated by "The Innovation Society", St.Gallen". 25 persons were attending. The participants were representing the organisations, which had supported the project so far or served as experts for the Delphi-study. The goals of the workshop were:

- presentation and discussion of the Delphi-study
- presentation of different points of view (academia, government, industry) on the topic of regulatory issues of nanotechnology
- discussion on stakeholders positions and mutual expectations
- facilitation of contact and know-how transfer between stakeholders
- definition and priorisation of action requirements
- definition of further steps

5.3.1.1 Role, positions and requests of the stakeholders

The following general requests and concerns of the stakeholders were put up. These can be seen as background to clarify the positions and attitudes towards regulation.

Stakeholder	**What is the task of your organisation? (Self-perception)**	**Which is the attitude of your organisation towards regulatory issues of nanotechnology?**
Governmental authorities	Protection of Public Health and environment from detrimental effects	• No urgent need for specific "Nano-Law" identified yet (CH) • Specific topics need urgent attention (occup. health safety) • Existing regulatory framework should be adapted if there is a necessity shown by scientific results • Cooperation between governmental organisations and industry is crucial and should be intensified
Insurance industry	Facilitating risk related actions by risk transfer	• Need for risk related data to calculate risk potential and probability (data from further risk research is needed) • Lack of experience (as in every new technology) is a problem • Need for evaluated risk assessment methodology and LCA data
Industry	Applying Technology as important tool for innovation and improvement	• Product safety and occupational health are key • Claiming for a clear, but "non-restrictive" internationally harmonised framework
Retail	Selling products to consumers implies "stuck-in the-middle-situation" between industry and consumers	• Remains unclear where retail is affected by nanotechnology and regulatory issues • Communication and Information about technology is key • Information should be provided by industry as well
Science	High interest in nanotechnology as a research field	• Nanoparticles are health relevant. • There is a lot more research needed in the field of nanotoxicology

Table 3: Stakeholders self perception and attitudes towards regulatory issues.

5.3.1.2 Input of Swiss Agency for Environment, Forests and Landscape (SAEFL) and proposition for further actions

The risk assessment and risk evaluation processes in nanotechnology, especially as free nanoparticles or aerosolic nanomaterials are concerned, is characterised far more through ignorance than knowledge today. The European Commission has already suggested a proposal for an action plan 2005-2009 which will provide a guideline for the member states. On OECD level there are also several activities going on (nomenclature, hazard identification, etc.). For Switzerland therefore the following actions were suggested:

Short term activities:

- development of a Swiss Action plan nanotechnology (2006-2009) in collaboration with the Swiss Federal Office of Public Health and the State Secretariat for Economic Affairs (seco)
- support precautionary measures in workplace safety, consumer- and product safety, environmental protection
- support and strengthen stakeholders awareness for self-control principles
- cooperation with international committees / organisations to obtain harmonised solutions
- strengthen public dialog and unpstream public engagement

Medium term activities:

- promotion of risk and safety research projects (universities, industry)
- enhancement of risk evaluation and risk-assessment methodology in relevant sectors
- promotion of harmonised methods for risk assessments of nanomaterials
- support cooperation with international groups and governmental entities

Long term activities:

- Adaptation of the existing regulations in Switzerland (when necessary)

5.3.1.3 Key issues in the debate about regulatory issues of nanotechnology

In order to address important issues in the regulatory field there were three groups formed (industry, insurance; science organisations; governmental bodies, retail, NGO) to discuss the question:

What should be done to obtain a reasonable regulatory framework in nanotechnology ?

Industry / Insurance group	**Science / research group**	**Governemental bodies**
One should: • develop a consistent terminology and distinct definitions • develop possible regulations from existing regulations (instead of inventing sth. new) • identify and characterise additional risk fields and paths of exposition • develop a decision tree • focus on processes rather than products • promote cooperation among all stakeholders in order to obtain pragmatic solutions	One should: • differentiate between terms and definitions more precisely • investigate the interaction between nanoparticles and biological systems • characterise „Nanoeffects“ on biological and chemical level • characterise the „Key-Risk-Properties“ of particles (size, surface, etc.)	One should: • prioritise occupational health, environmental safety, consumer and productsafety in terms of nanomaterials and nanoparticles. • demand for personal and organisational responsability (self control) • involve the other stakeholders (industry, insurance, academia) into the regulatory processes and promote synergies by exchange of data and experiences.

Table 4: Summary of opinions on what should be done for a reasonable regulatory framework.

The point which was stressed the most, was unsurprisingly the lack of definition and the unclear terminology of the term “nano”. This problem has to be addressed very quickly in order to prevent misleading terminology.

5.3.1.3.1 Research funding

It was discussed to what extend risk research had to be financed by the public and to what extent industry funding could be integrated into research projects. Industry is liable for its products and their processes and should therefore contribute a major part to the identification of product related risks. As far as the research focus points are concerned health- and environmental toxicology of nanoparticles should be prioritised in the meaning of most stakeholders. In this field there are of course research points of utmost interest. Unbound nanoparticles seem to pose a much higher risk due to their high mobility properties than integrated or embedded particles. Risk research policy should make allowance of these facts.

5.3.1.3.2 Nanoproducts, benefits and declaration

Industry was therefore asked to develop and promote nanoproducts which offer a clear and tangible benefit to consumers. Especially in terms of potential higher risks of some of the nanomaterials industry should sustain from pushing nano-products into the market which have no clear advantage compared with “non-nano-products”. In this context a clear balancing between potential risks and perceived consumer benefits has to be made. Nevertheless it seems difficult to assess potential benefits. It was also stressed that the characterisation of potential product risks is not possible applying current risk data. Against the background of the unclear risk-data situation in terms of product approval an alternative assessment was suggested (like in the US) comparing several equal products and choosing the one with the best risk-benefit ratio.
As far as the possible declaration of Nano-materials in or on products is concerned, there was always the problem of a lacking definition of nanotechnology mentioned. If there are nanosized particles, which are mixed in products and these products agglomerate, the question whether these products are still nano and whether they should be declared as such or if these products are just ordinary chemicals remains unclear. Even if the definition and terminology problem has been already addressed by several institutions it was expressed, that one cannot wait with risk assessment and –evaluation studies until all terminology problems are solved.

5.3.1.3.3 Information, communication and public dialogue

The nano-information demand of the public is presently still low. Due to a lack of knowledge of most people, low interest in the issue and the particularly high complexity of the topic it seems difficult to bring information to the public. Recent studies proved, that most people do not even know the word “nanotechnology” or don`t know what is behind the technology (Gaskell, 2005; Macoubrie, 2005). Nevertheless Americans have generally a more positive attitude towards technology than Europeans. European consumers tend to be more sceptical and reluctant as far as new technologies are concerned (Scheufele, 2005). Ignorant and sceptic people are more susceptible to bad or manipulative news than well informed people. In this context communication with the public and public dialogue of all stakeholders are crucial. Furthermore

transparency, openness and clear communication as far as risks and benefits are concerned are most important. The experience with GMO food and the misleading information policy of industry in Europe in the late 90-ies was mentioned and should be omitted in nanotechnology at any costs.

5.3.2 Summary and recommendations

The need for further research activities was stressed by all stakeholders very distinctly. Despite an unclear terminology and a lacking nano-definitions, risk research must be continued, intensified and coordinated. In order to eliminate terminological disorientation a parallel approach should clarify the terminological obscurities on one hand and the risk research in HSE on the other hand. Risk-research projects should be supported by government and industry. Topics of utmost importance are:

- Occupational health safety (Laboratory and large scale, manufacturing)
- Product- and consumer safety (LCA, waste, imission)
- Environmental safety (LCA, food-chain, waste, emissions)

Due to the already widespread application of nanomaterials in manufacturing and laboratories the highest priority must be given to occupational health safety issues. It was therefore suggested that.

- guidelines for a safe and sustainable use and handling of nanomaterials should be developed
- technical measures for the protection of health and environment should be applied (e.g. filters, low pressure fume hoods, etc.)
- voluntary labelling of potentially hazardous materials should be performed
- inventories of potentially critical nanoparticles and nanoapplications should be made
- inventories of expositions and quantities of nanosized particles should be issued
- threshold values for potentially hazardous nanosized particles have to be set up
- rules for declaration / self-declaration should be established
- requirements for Material Safety Data Sheets (MSDS) should be reviewed
- LCA-studies of nanomaterials and nanoparticles must be conducted
- “Code of Conduct” regarding further product aspects

Research policy must be directed in regard to the needed data with highest priority. The political decisions in this context have to be made regarding and weighing up all relevant HSE issues. The political decision processes have to be supported by all stakeholders. An evidence based risk research policy is the key for rapid and efficient results.

5.3.3 The 1st International "Nano-Regulation"- Conference

The conference took part as a subsidiary conference of *NanoEurope Conference and Exhibition* 2005 on 13th Sept. 2005 in St.Gallen[17]. There were about 80 Participants attending. The participants were international representatives from industry, governmental organisations, academia or civil society The program of the conference is shown in Table 5.

Part	Topic	Presentations / Speakers
1	The governmental perspective (presentations)	• Nanotechnology - The regulatory challenge. Brian Fullam (HSE, UK) • Nanotechnology – Knowledge base for policy makers. Eva Hellsten (EU) • Is Nano-Regulation needed in Switzerland? Georg Karlaganis (SAEFL)
2	The industry / NGO / insurance perspective (presentations)	• The industry perspective on nano-regulation. Kai Schierholz (Nanoledge, SA) • The perspective of a Reinsurance Company. Gerhard Schmid (Munich Re) • Nanotechnology – Uncertain and unpredictable. Hope Shand (ETC-Group)
3	Workshop sessions	• Nano between liability and innovation. Gerhard Schmid / Kai Schierholz (Liability) • Ethical & Social implications. Armin Grunwald (ITAS)Contribution of Technology • Assessment to regulation. Sergio Bellucci (TA-Swiss)

Table 5: Program of the Nano-regulation conference 2005

5.3.3.1 The governmental perspective

5.3.3.1.1 Nanotechnology – the regulatory challenge

(Brian Fullam, HSE, UK)

The Health and Safety Executive (HSE) is the responsible organisation, regulating almost all the risks to health and safety arising from work activity in Great Britain since the last 170 years. The Royal Society report published in 2004, stated that nanotechnology poses no new risks but insufficient data are known about health, safety and environmental hazards arising mainly from free nanoparticles. The report triggered many activities in the UK and abroad in order to identify and characterise the potential impact of nanotechnologies on health, environment and society. It was stressed that the role of the stakeholder involvement into the regulatory process is crucial because it is up to the public to decide whether *"safe is safe enough".* The process of public involvement with e.g. focus groups, consensus conferences and further activities would make sense in situations where the regulators have a choice in terms of what has to be done. The stronger public "upstream-engagement" is therefore an important tool in the HSE decision finding process. The Office of Science and Technology is leading a process which is reviewing the existing UK legislation to identify potential gaps. The collaboration with supra- and international organisations like the EU and the OECD and the multilateral exchange of data are therefore very important, since there is no multilateral grouping of regulatory authorities seeking to lead and expedite the development of good regulation. This would be of high interest when it comes to avoiding unnecessary duplication of effort. In

[17] For further details see: www.nanoeurope.com

terms of the development of “evolutive” regulatory framework the regulators should not loose sight of the longer-term potential of technology and the challenges posed by second-generation active nanostructures and third generation nanosystems in order to establish a horizon-scanning system to spot the “runners” of nanotechnology on one side and to keep the flexibility to catch up with runners which were spotted later on.

5.3.3.1.2 Nanotechnology - knowledge base for policy making

(Eva Hellsten, European Commission)

In the EU, nanoscience and nanotechnology had been a priority on the research agenda for several years. With the recently adopted Communication Nanotechnology Action Plan[18] 2005-09 it would be clear that nanotechnology is also moving into a broader policy and regulatory debate. The main challenge for policy makers and legislators will be to strike the right balance between *creating a good climate and conditions for innovation* and development of applications, contributing to economic growth, welfare and sustainable development and *ensuring that potential risks* to environment and human health are spotted on time. Lessons from nuclear power and GMO debate have shown, that if potential risks are not analysed and managed from the outset and publicly communicated, technology development may be hampered at a later stage. A main activity for regulators would be to make inventories of different legislative frameworks to judge if and how they may apply. For the European Commission, this involves a broad range of legislative areas – worker protection, consumer safety, environment protection, liability etc, and is carried out in collaboration between the different Directorate General (DG). Parallel to this inventory, work is ongoing to identify scientific knowledge needed from a regulatory perspective. For example, knowledge about toxic or ecotoxic properties, exposures, measurement and analytical techniques would be needed to be developed in order to determine the applicability of several pieces of legislation in the areas of environment, public health and worker protection. It was announced that the Scientific Committee on Newly Identified and Emerging Health Risks was expected to come up with an opinion on the “appropriateness” of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies” by the end of September 2005. In the EU, the “Better regulation” package had been introduced. Regulations should be simplified, impact assessments should be carried out to ensure that benefits and costs of any proposed legislation are in balance, and broad stakeholder’s consultations should take place at early stages in the process.

5.3.3.1.3 Is nano-regulation needed in Switzerland?

(Georg Karlaganis, SAEFL)

Nanoparticles can be taken up by lung and enter the blood stream. Other uptake routes are known as well, such as olfactory nerves. The effects of nanoparticles when they have entered cells are largely unknown. Data gaps exist not only in toxicology and ecotoxicology but also in the field of definitions and exposure assessment. Which nanoparticles are expected to be released from which products during production, use and disposal? Testing methods which allow hazard identification of nanoparticles and methods for exposure

[18] http://ftp.cordis.lu/pub/nanotechnology/docs/nano_action_plan2005_en.pdf

and hazard assessment are urgently needed. The well known effects of ultrafine soot particles (diesel exhaust) on human health and the environment can be used as background knowledge. There are many questions which must be addressed in order to know whether and how to regulate nanoparticles, but there is also a lot of work underway. OECD has taken up the task to identify further needs for risk assessment within a regulatory context. EU has developed an action plan 2005–2009 “Nanosciences and nanotechnologies”. This action plan covers a broad range of issues from research and development to implementation strategies. Proactive risk assessment related to human health, the environment, consumers and workers as well as safety measures to minimise exposure are key points in this action plan. Based on these international activities an action plan for Switzerland in cooperation with the Swiss Federal Office of Public Health and the State secretary of Economic Affairs (seco) was proposed, developing a code of conduct to ensure workplace safety, promoting the development of measurement methods and the research on the potential impact of nanomaterials, reinforced cooperation with international organisations and establishing cooperation with industry on voluntary measures to minimise exposure of potentially hazardous nanomaterials. The goal of these activities is to propose, when appropriate, adaptations to the Swiss regulations to ensure a safe production, use and disposal of nanomaterials and nanomaterial based products.

5.3.3.2 The private economy- and the NGO-perspective

5.3.3.2.1 The Industry perspective on nano-regulation)

(Kai Schierholz, Nanoledge, SA)

Primarily a university lab spin-off company, Nanoledge SA has become one of the leading manufacturers of carbon nanotubes (CNTs) and a specialist in formulation of CNT composites in Europe. With the increasing production and expansion of the commercial activities, more and more emphasis was laid on identification of hazards and operability problems arising from use of nanotechnologies. In adapting and upgrading existing industrial regulations to this specific context, it was explained that Nanoledge had implemented appropriated security measurements that were applied to the production process and material shipping. The practical measures which were described are taken in the production of nanomaterials. Starting with isolation of equipment, remote controlled process management, technical tools and individual protection measures and appropriate safety data sheets. Further on, the safety measures in storage as the limitation of stored quantities in the facilities of the company and the shipping of CNT as slurries was explained in order to avoid the spilling of powders which could be inhaled or escape easily into the environment by accident.

5.3.3.2.2 The perspective of a Re-Insurance company

(Gerhard Schmid, MunichRe)

The crucial role of insurance companies in regard to the potential development of new technologies was outlined. On one side an insurance company will take over calculable risks demanding premiums as part of their business on the other hand the company will avoid risks which cannot be priced due to e.g. a lack of

data. In the field of nanotechnology, industry faces an enormous economic potential in many different applications and branches. On the other hand there are several unanswered questions concerning potential risks (e.g. uptake, effect, accumulation of NP, etc). The focuses of MunichRe in terms of potential nano-risks are occurrence probability, amount of loss and severity and quality assurance. Risk management measurements to prevent or avoid potential losses. In terms of nanorisk the loss-amount vs. probability–matrix approximation groups the nano-risks in two groups: A “low frequency – low loss”-group (comprising environment, Agro and public liability risks) and a “high frequency – high loss”- group (including product liability, professional indemnity, recall etc.) (see Figure 3).In this context there is a broad discussion needed about a specific regulatory framework of potentially hazardous products. The policy of MunichRe in terms of the risk-management with nanotechnology is the same as with other risks: Promoting awareness, identifying, assessing, reducing and controlling the risks.

5.3.3.2.3 Nano - Unknown and unpredictable - Reasons for a moratorium

(Hope Shand, ETC-Group)

The speaker warned that engineered nanoparticles could pose unique risks to human health and the environment. It was stressed that nanotech products had come to market in the absence of public awareness and regulatory oversight. Over 500 products containing unregulated and unlabeled nano-scale particles were commercially available yet – and thousands more are already “in the pipeline”. Engineered nanoparticles were already showing up in products applied to skin (cosmetics and sunscreens), sprayed on fields (pesticides), and applied in refrigerators (nano-scale food additives) – *“but no government has already developed a regulatory regime that addresses the nano-scale or the societal impacts of the invisibly small”* she said. In 2002, civil society organizations were calling for a moratorium on the release of manufactured nanoparticles until lab protocols were established to protect workers, and until regulations were in place to protect consumers and the environment. A report (SwissRe, 2004) on the potential risks of manufactured nanoparticles stated that, *“no reasonable expense should be spared in clarifying the current uncertainties associated with nanotechnological risks.”* While US and European governments were belatedly conceding that some type of regulation would be needed, it remained to be seen if nanotech regulations should be linked together using existing regulations for chemicals or if a new, precautionary approach would prevail. In May 2005 the US Environmental Protection Agency revealed that it was “considering a potential voluntary pilot program for nanoscale materials that are existing chemical substances.” The proposed voluntary initiative was slammed as “inadequate and inappropriate” by 17 environmental, health and civil society groups. *“Unfortunately, governments were acting as cheerleaders – not regulators”* the speaker said. Convinced that technological convergence at the nanoscale would be the “future,” leading nano nations – especially the US, Europe and Japan – were in an all out race to secure economic advantage: health and environmental considerations were secondary; socioeconomic impacts would have to wait; regulations, if they could not be avoided, must be voluntary so as not to hinder commercial development of nanotech R&D. With public confidence in both private and government science at an all-time low, full societal debate on nano-scale convergence would be critical.

5.3.3.3 Workshop sessions

To discuss the topics from different perspectives, the participants were split up in three groups discussing specific topics in three workshops. The topics were:

1. liability and innovation aspects of a regulation
2. ethical and social issues of nano-regulation
3. the contribution of Technology Assessment to nano-regulation

5.3.3.3.1 Workshop 1: Nano-regulation between liability and innovation

(Gerhard Schmid / Kai Schierholz)

There was a general agreement that a common terminology with common definitions and standards is needed, so that the calculations of the insurance companies are based on mandatory standards and definitions. It was stressed that, in terms of risk assessment and development of standards, there is a difference between big and small companies. Large companies have the infrastructure and ability to do this on their own, while SME`s have no possibility to do so, mainly because they often lack the appropriate staff. Risk assessment could also be difficult for companies because of the problem of upcoming knowledge and changing regulations: At the moment when a product is distributed in the market it is known to be safe, but suddenly the laws change, which means that the product is classified to be toxic for instance. To avoid these problems it was suggested to build up an early warning system and establish an “early warning expert- forum” (task-force) to detect and analyse changing societal and regulatory conditions. Focused on the question of liability, it was said that once a company has the knowledge about possible negative side effects, it is liable. Another fact about liability which has been discussed, was the general impact of regulation on liability. From the societal point of view, it was mentioned that governments and industry are sitting in the same boat. If hazard occurs, a loss of trust in the total industry is the consequence. However, in the opinion of the public, government is responsible for public health and in this case it can be difficult for the government to prove that it has done enough to protect health and environment. The question on which level (national, international) to start the necessary steps, was raised in the workshop again. Most of the participants agreed with the position that one had to overcome parallel organization in different nations, because doing the same again and again is very time consuming as well as ineffective. It was concluded that for economic reasons it should be done on an international level, because nobody has the capacity to cover all the these topics. At the end a so called risk map[19] was suggested, which compares types of NT with different kinds of exposure, so that a company like an insurance company knows where to prioritize. The idea was found interesting though the practical application could be difficult. For competitive reasons no company would publish such a map, because competitors could profit from it. Therefore the risk map would not be available for the public.

[19] The Innovation Society has developed a visualised risk-map tool (*Risk- and Opportunity Strategy Evaluation*) **ROSE**® which can be used for single companies and for groups. http://www.innovationsgesellschaft.ch/images/Ankuendigung20ROSE_Workshop1.pdf

5.3.3.3.2 Workshop 2: Ethical and social issues in Nano-regulation

(Armin Grunwald, ITAS)

The group focussed on the question “benefit versus risk”. The general impression was, that technology risks are generally assigned to the public while companies usually have the benefits. The general agreement was that there should be a balance and therefore, people should understand where the risks and benefits are allocated. Another agreement of the group was that the public should be involved in the process of setting up a regulatory system, the case that only governments decide should be avoided. To reach that goal, the public must be activated in order to put on a dialogue. If no neutral information is brought to the public, people could tend to see only the risks of the unknown technology. The group was not able to decide which steps were the best to be taken next. Nevertheless the participants agreed there should not only be transparent risk- but as well benefit – communication. A special wish was that studies and information should be easily available and comprehensible for the public. The public debate should be initiated as early as possible, and that this process should be managed, in a guided but non-manipulative way. There was no agreement how a public debate is defined exactly and who should be involved or not. In the stakeholder dialogue process two points should be discussed: first the public debate about the ethical and societal aspects of nanotechnology and second the question of differing debates between “experts” and “layman”. The two perspectives must be brought together in the following nano-regulation activities.

5.3.3.3.3 Workshop 3: The contribution of Technology-Assessment (TA) to the regulatory process

(Sergio Bellucci, TA-Swiss)

The first topic was the question which aspects of nanotechnology should be discussed in the public debate. The group came to the conclusion that before a real discussion could get started, the term “nano-technology” must be defined in order to differentiate between nano-tech and other technologies. Furthermore there should be a clear classification showing where and how people would get in touch with this technology and its possible hazards. An assumption for this classification is that science might expose to laboratory workers, scientists, consumers and the environment the effects of bioactive technology. The next topic to settle was the definition of TA. The group came to the conclusion that on one side, there is the interdisciplinary comparison of knowledge or the expert study and on the other side the public discussion about what issues are important to the public. One problem of open discussions is the general scepticism of the public against industry. Three goals of TA were named: (1.) gaining trust, (2.) translating complex information from a science-based language into a language comprehensible to the general public and (3.) collecting judgements from professionals and the general public in order to formulate recommendations for the regulators. Different TA-methodologies were discussed: In the UK for example an advisory committee of hazardous substances exists, that lets the general public take part in the discussion and has its reports publicly available on the web. TA-Swiss is responsible to advise politicians and the parliament from an independent position and open the discussion about potential hazards of new technologies (e.g. stem cells, GMO, Xenotransplantation). Discussing at which moment in the regulatory process TA should be initialized. The group came unanimously to the conclusion, that the initialisation should happen as early stage and prospective as possible. Furthermore, it was found that the timing is of high importance at this stage. The

next topics to be dealt with by TA-responsibles are to show the regulators and politicians that the word "nanotechnology" is not specific enough and should be exactly differentiated. At present, the expression "nanotechnology" is often used for marketing purposes. For a feasible regulation, science does not have an appropriate risk-assessment-methodology. Although regulations must be accepted by the general public, they also have to work. This implies interactive process of regulation, because it will be the only way to establish a generally accepted regulatory framework.

5.4 Expert-Group

An expert group was formed After the conference in order to review the results and to shape further steps. The group consisted of 12 experts representing governmental authorities[20] and research institutions[21] and industry. In several meetings there were different points of interest discussed. Swiss Agency for Environment, Forests and Landscape (SAEFL) and the Swiss Federal Office for Public Health have elaborated a cooperation to develop a Swiss Action Plan 2006 – 2009 for the "Risk-assessment and management of synthetic nanoparticles" should be made. Together with an national team of experts the governmental authorities will develop an schedule which assesses and analyses the current need for actions in different fields as legislation, communication, coordination and cooperation. If there are fields of further action identified, concrete actions should be proposed and measurements including a monitoring system should be implemented.

In terms of issues and topics the following topics will be addressed

- Workplace safety
- Occupational health safety (e.g. laboratories and manufacturing premises
- Consumer safety
- Product safety / liability
- Life cycle Analysis
- Environmental protection

5.4.1 The Swiss Action Plan Nanotechnology (2005-2009)

In a first step a Swiss action plan nanotechnology should be developed under the regime of the Federal Office of Public Health and the Swiss Agency for environment, forest and landscape and the State Secretary of Economic Affairs. The development of the action plan should be coordinated by an external coordinator. The development of the action plan will be supported by a board of national experts and experienced scientists in order to analyse the existing legislation and ongoing activities on a national and international level and to suggest subsequent measurements which should be taken in the following phases of the project. The Swiss Action plan will cover similar topics as the Action plan of the European Commission

[20] Representatives from: Federal Office for Public Health, Swiss Agency for Environment, Forests and Landscape, Technology Assessment (TA-Swiss) and the State secretariat for economic affairs (seco),

[21] Representatives from: University of Berne, Swiss Federal Instiute for Materials and Testing (EMPA)

- Risk assessment for health and environment methodology
- Emission / Exposition during the whole life cycle of a product
- Terminology / definition topic
- Risk assessment standards
- Support of affordable measurements to reduce exposition to particles
- Voluntary measures
- Review of existing regulatory framework in proposals for adaption
- Information and communication issues

It is important that the Action plan is elaborated particularly in regard to international regulatory framework and to European activities. It was stated that a regulatory framework should be harmonised with international and supranational regulations and therefore a close collaboration would be useful. The Action Plan is due until fall 2006.

5.4.2 Implementation of measures

After the Action plan has been approved by the directorate of the Federal authorities the described measures should be implemented. The voluntary self-regulation principle which has been made an example of in other regulatory frameworks as e.g. the chemical substances regulation (PARCHEM) will be crucial in this framework. The cooperation with industry partners will therefore be most important. On the other hand, the implementation process has to be directed according to scientific knowledge and has to be adapted to the state of the art and scientific data.

6 Recommendations and Outlook

Based on the results of the activities of the platform we would suggest the following recommendations in four specific areas:

- Proactive risk management and standardisation
- Coordination and cooperation among stakeholders
- Communication, information and stakeholder engagement
- Governance and regulatory processes

6.1 Proactive risk management and standardisation

In risk research there are several topics which have to be addressed. First of all there has to be done a lot more research work on potential hazards, exposures and risks. Most probably first in the human-

and ecotoxicologial field of synthetic nanoparticles. According to our results a clear priority must be given to occupational health and safety issues and product safety. In order to achieve the highest possible degree of safety in industrial processes and in laboratories, a high priority must be given to the education and training of employees in handling, use and disposal and to provide adequate guidelines. The sensitivity for self-responsibility in industry and laboratories has to be strengthened through appropriate measures. Further, an internationally harmonised categorisation and standardisation of testing procedures and methodologies in risk assessment have to be developed and established. It is of utmost importance to obtain comparable results. Product safety aspects have to be investigated under the aspect of Life Cycle Analysis in order to get risk related data profiles of products and materials over the whole cycle of use. In order to get a first preliminary picture of potential risks and expositions inventories of potentially hazardous materials (sources, sinks, quantities, flows, applications, exposure profiles) should be developed and internationally standardised. It will be important to establish a case-by-case approach to risk and regulatory evaluation. Furthermore we suggest

- the development and standardisation of nanospecific risk assessment procedures
- strategies for short, middle and long term control on potential environmental impact of nanomaterials (especially nanoparticles)
- measures to reduce emission of nanoparticles at the source and protect workers from imission
- address questions of ethical and social risks
- organisation of stakeholder forums and conferences in order to have their specific needs and perspectives considered in forthcoming legislature

Most important in this context is a multidisciplinary approach which must be guided by the vision of a proactive risk-management philosophy.

6.2 Coordination and cooperation among stakeholders

Nanotechnologies and nanosciences encompass many different fields and therefore many industries are concerned. Having in mind that risk research has to address both Health, Safety and Environment (HSE) and Ethical, Legal and Societal aspects (ELSA) it becomes clear that there is an urgent need to support structures and initiatives which provide transdisciplinary information and knowledge about risk related issues efficiently. Industry and research organisations, which are already applying nanotechnology in products and processes or which are planning to apply have a legitimate interest in HSE relevant knowledge in order to identify sources of potential hazards in time and to establish efficient risk-management systems. ELSA relevant information is of high interest to industry in terms of potential consumer acceptance and evaluation of social frameworks. Efficient early warning systems and valid market research results are of highest importance in respect to develop proactive communication and information strategies. In this context even for competing companies it is of high

importance that potential risks (e.g. in certain products or processes) are spotted as early as possible and that appropriate measures can be taken, because risks which are threatening industry as a whole are clearly non-competitive issues which have to be tackeled by all parties. In industry processes where airborne nanoparticles are produced or handled the experience of industry is valulable for regulators. Therefore we are going to see much more HSE joint-ventures research projects between industry and governments of which NanoCare[22] is a good example. In this context the coordination and cooperation between government and industry has to be amplified. Therefore on the governmental side, the existing HSE and ELSA research programmes on national and supranational level (EU or the OECD) have to be supported and joint venture projects with industry should be motivated. Results should be made available to private or governmental use by suitable channels. In this context the dissemination of information and knowledge and the accessability is crucial. A security officer of an SME, planning to handle airborne nanoparticles should have an easy and fast access to relevant information. Therefore information exchange structures, knowledge platforms and databases become more important[23]. As nanotechnology will be covered more intensely and more often in the media, more questions of consumers will arise. Therefore consumers should have the opportunity to address questions and use FAQ portals to get qualified answers.

Since it is impossible to overview all the activities in the risk and regulatory field, global network structures have to be implemented and interlinked to disseminate and institutionalise information flows as efficiently as possible. In this context there is a strong need for structures and organisations enabling multi-stakeholder dialogue processes on a global level. It is certainly an important task of a global dialogue strategy to organise dialogue processes. Hopefully supranational organisations as the European Commission and the OECD will play a key role facilitating these processes by resources, know-how and networking capacities. On national level it seems most important for all stakeholders to be “kept in the loop” in order to profit from recent results and information of other governments and to develop nationally adapted solutions. To obtain the goal of the highest degree of harmonisation in regulatory frameworks and guarantee a maximum of autonomy on national level, there is certainly a global multinational dialogue needed. This dialogue has to be based on both national experiences and scientific risk data. In terms of cooperation this means, that different governmental bodies have to cooperate closely with industry and scientists be it on national or international level. Nanotechnology - especially in its convergence with biotechnology, information technology and cognitive science - is likely to produce revolutionary products and processes that challenge the current regulatory structures. In some cases products may cross the boundaries of regulatory agencies. In most cases there may not be an agency with the authority to review and regulate such a product or process. Since nanotechnology applications will create enormous demand on the knowledge-base, skills, and capabilities of the regulatory agencies and their worker, multi-disciplinary cooperation will be vital. In some countries these cooperations between environmental and health bodies are already

22 NanoCare is a joint venture research project of industry and German Ministry for education and research on synthetic nanoparticles.

23 There are a few searchable databases on risk and safety issues which could serve as important source for practioneers (e.g. NIOSH: http://www.cdc.gov/niosh/updates/upd-02-23-06.html)

institutionalised. In most cases they will have to be strengthened and improved. It seems of utmost importance that industry is also involved into this process at an early stage. Be it on one side as a partner in the risk assessment and evaluation process and on the other hand providing funding and delivering risk data.

The platform "Nano-Regulation" is designed as a *"neutral ground platform"* which provides access for involved stakeholders allowing them to bring their request on an equal footing. In this context it could serve as an "integrating structure" bridging institutional boundaries.

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6.3 Communication, information and stakeholder engagement

In past technology debates, communication and stakeholder engagement have been found to be crucial for latter consumer acceptance and political legitimisation. In order to achieve true dialogue and efficient communication structures, various preconditions have to be met. First of all there should be a balanced information policy addressing benefits and risks. Second the information has to fit to the knowledge level of the recipients. And third, the information should be easily accessible for the different stakeholders especially to the public. This means that the dissemination channels for information should be adapted to content and recipient. Specific attention must be given to providing information to key players and opinion leaders (politicians, journalists, etc.). In terms of information channels there are several examples which demonstrate successful information tools for the public. In Germany the "Nanotruck"[24], a nano-exhibition truck was set up. There are nanoexhibitions for the public as e.g. NanoPubli[25] or several web-portals[26] providing information to the public. But most effective is direct, personal, transparent and credible information and communication by scientists, regulators or industry representatives in public arenas. A high credibility of the stakeholders is crucial in this context. We therefore propose:

- Regular stakeholder events (conferences, focus groups, publiforum, etc.)
- Involvement of researchers and practitioners of social sciences (psychologist, ethicist, etc.)
- Cross-disciplinary dialogue projects between governmental advisory boards (bio- and medicine ethical, legal social (ELSA-) committees and industry
- Establishing of communication / and information monitoring systems
- Institutionalised periodical reviews of the action and correction measurements.

[24] http://www.nanotruck.net/

[25] http://www.olma-messen.ch/wDeutsch/messen/nanoeurope/01_besucher/NanoPubli/HomeW3DnavanchorW262410354.php

[26] www.nano-world.org

The Swiss Nano-Regulation platform provides a unique opportunity for business, NGO, representatives, regulators, opinion leaders and journalists to meet and to address important issues. Additionally the annual conference “Nano-Regulation” offers a chance for networking, presentation and mutual exchange.

6.4 Governance and regulation

Regulating an emerging technology is tricky. It is all about striking the right balance between precaution and venture. On one side the protection of HSE aspects has to be guaranteed and potential risks must be reduced. At the same time, the future social value of nanotechnology should be maximized by all means. This dilemma is an area of potential conflict and can only be tackeld by a cooperative dialogue approach. Existing national and supranational legislations will have to be reviewed by experts. If necessary they will have to be adapted and internationally harmonised. To facilitate this process governmental bodies will need expertise from scientists and industry in order to assess potential risks and to gather data. On the other hand the psychological resistance has to be overcome, as regulation is often seen as limitation for economic activities it must instead be seen as a pre-requisite for the successful development of business and research activities. Having in mind that all research and industry activities need public approval and acceptance and that economic activities paticularly need a safety backup in terms of technical and financial coverage, this means that a certain regulatory framework is needed to ensure the achievement of specific research and business objective targets. In order to avoid overregulation on one side and to guarantee maximum possible safety standards it is suggested that:

- development of definitions, standards, best practises in production, handling and use and in regulatory concepts are coordinated on national, international and supranational level
- a coordinated review process of existing legislation is made on national, international and supranational level adaptions are made if necessary
- cooperation of governmental bodies with national and international expert bodies from industry and research organisations are institutionalised and supported
- self-regulation processes in industry and research areas are motivated and supported (e.g. by hotlines, safety portals, guidelines, etc.)
- reviewes of labelling / classification / registration guidelines of consumer sensitive products is undertaken and probably are set voluntarily.
- Institutionalisation of cooperation platforms with NGO, politicians, media, opinion leaders
- monitoring and early warning systems of safety and risk issues are supported which are addressing the sufficiency of existing regulation.

The last point proves to be of utmost importance, since a recent survey (IRGC, 2005) on nanotechnology governance has shown that “*many respondents among international organisations*

and governmental organisations recognised that nanotechnology may need new regulatory approaches due to specific implications. (…) For several of the countries the first step towards researching the need of adapting existing regulation is a focus on developing appropriate monitoring and warning systems when current legislation proves insufficient." (S. 13)

6.5 Outlook

Nanotechnology presents an exciting variety of new opportunities to create better materials and design new beneficial products. It has the potential to improve the environment by either replacing hazardous substances through "green" chemicals or by making industrial processes cleaner and create environmentally friendly products. The unanswered questions about the impacts of nanomaterials on health and environment must be tackled by all involved stakeholders. Due to the heterogeneous character of nanotechnology and the many involved parties, a multi-stakeholder-dialogue appreciating the potential benefits and addressing the risks at the same time is needed. Industry, governmental bodies, scientists and civil society have to negotiate passable solutions. None of the involved stakeholders can afford to assert their interests at the expenses of others. In case of conflicts instead of cooperative solutions, industry and scientists will suffer the most, because they depend directly on the quality and the sustainability of products and processes on one side and on the technology reputation on the other side. In order to avoid being at cross-purposes appropriate dialogue platforms are needed, facilitating structured processes and enabling stakeholders to bring in their interests on an equal footing. Since the benefits and risks of new products are not limited on single countries, such an approach has to be global.

To meet these requirements we will develop our multi-stakeholder-dialogue platform. In cooperation with international and supranational partners aiming to make a valuable contribution to the basic conditions necessary to realize the big potential of nanotechnology in a sustainable and successful way.

7 Appendices

7.1 Appendix 1: List of experts

Name	Function	Organisation	Participation[27]
Bellucci, Sergio, Dr	Managing director	Center for Technology-Assessment, TA-Swiss	2, 3
Binz, Thomas Dr.	Head of section biosafety	Swiss Federal Office of public health	1, 2, 3
Durrer, Stefan, Dr.	Project manager	State Secretariat of Econonic Affaris	2, 3
Edelmann, Xaver, Dr.	President / Member of the board of EMPA	Swiss norming organisation	1
Emmenegger, Michael	Project Manager	Center for Technology-Assessment, TA-Swiss	2
Epprecht, Thomas, Dr.	Risk expert	SwissRe	1
Frei Isabelle	Research / Documentation	Juvena International AG	1,3
Fullam, Brian, PhD	Head Corporate Science & Knowledge unit	British Health and Safety Executive	3
Gantner, Urs, Dr.	Head Research (staff position)	Swiss Federal Office for agriculture	1
Gehr, Peter Prof. Dr.	Aerosol scientist, Head institute of anatomy	University of Berne	1, 2, 3
Gohla, Sven, Dr.	Head Product Development	Juvena International AG	3
Göldi Jakob	President	Nano-Cluster Bodenseee	2, 3
Grunwald, Armin, Dr.	Head Technology Assessment	ITAS Karlsruhe	3
Hellsten, Eva	Scientific Advisor	European Commission	3
Hett, Annabelle, Dr.	Risk expert	SwissRe	1
Hewel, Manfred, Dr.	Head product development	EMS-Grivory, Domat-Ems	1, 3
Hofer Brigit	Consumer politics / economy	COOP Switzerland	1, 3
Jung, Thomas, Dr.	Scientist	Paul Scherrer Institute	1, 3
Karlaganis, Georg, Prof. Dr.	Head department soil, substances, biotechnology	Swiss Agency for Environment, Forest and Landscape (SAEFL)	1, 2, 3
Kastenholz, Hans Dr.	Senior scientist	Federal Institute of Materials, Research and Testing (EMPA)	1, 2, 3
Koch Walter	Technical director	NanoSys GmbH, Wolfhalden	1, 3
Muster Walter	Head of Dept. Advanced Material Sciences	Swiss Federal Institute of Materials, Research and Testing (EMPA)	1, 2, 3

[27] 1: DELPHI-Study expert
2. Steering group expert
3: Expert at Workshop / Nano-Regulation Conference

Näf, Hans	Head Nanotechnology group	Bühler AG, Uzwil	1, 3
Sajkowski, Franz, Dr.	Governmental & product affairs	Bayer AG	3
Schierholz, Kai, Dr.	Head Product Development	Nanoledge SA	3
Schmid Gerhard, Dr.	Head Risk Management	MunichRe	3
Shand, Hope	Research director	ETC Group N-Carolina	3
Siegmann, Stephan	Head of Group	Swiss Federal Institute of Materials, Research and Testing (EMPA)	2
Som, Claudia	Project Manager	Federal Institute of Materials, Research and Testing (EMPA)	2
Stöppelmann, Georg, Dr.	Head Product development	EMS-Grivory	1, 3
Studer, Christoph, Dr.	Senior scientist	Swiss Agency for Environment, Forest and landscape	1, 2, 3
Tabellion, Frank, Dr.	Senior Project Manager	Bühler AG, Uzwil	3
Tonascia, Nils	Project Manager	Swiss Norming Organisation	3
Wengert, Steffen Dr.	Head chemical substances	Swiss Federal Office of Public Health	1, 2, 3
Wick, Peter, Dr	Toxicologist	Federal Institute of Materials, Research and Testing (EMPA)	3
Ziltener, David	Managing Dirkector	NanoEurope	3

7.2 Appendix 2: Questionnaire for Delphi study

Interviewleitfragen zu Nanotechnologie und Regulation

Hintergrund:

Im Rahmen der Interviews sollen die verschiedenen Perspektiven der Akteure zum Thema "Nano-Regulation" beleuchtet werden. Uns geht es in erster Linie einmal darum herauszufinden, welche *Positionen* vertreten werden, welches die offenen *Fragen* und *Erwartungen* von Seiten der betroffenen Akteure sind und wo *Handlungsbedarf* besteht. Die Interviews dienen als Grundlage für einen ersten Experten-Bericht (Delphi-Studie), welcher Anhaltspunkte für die Diskussion im Rahmen der Plattform "Nano-Regulation" und für das weitere Vorgehen liefern soll. Die nachfolgenden Fragen sind als Orientierungsrahmen zu verstehen.

Themenbereiche des Interviews:

1. Fragen zur Interviewperson:

Funktion, Tätigkeitsbereich, Hintergrund, allg. Bezug zu Nano-Thematik

2. Unternehmen: Allg. Angaben zur Organisation (Grösse, Tätigkeitsbereiche, Dienstleistungen, Bezug zu NT

3. Betroffenheit / Haltung des Unternehmens im Bezug zu NT:

- Bisherige Betroffenheit vom Thema NT? (allg./ speziell)
- Wie sehen Sie die Perspektiven der NT? (CH, Europa, global)
- Welche NT-Themen sind für Ihr Unternehmen von Bedeutung? (allg. / Regulation)
- In welchen Bereichen liegt das grösste Interesse Ihrer Organisation? (NT allg./ -Regulation)
- Wie beurteilen Sie das Chancen- und Risikoprofil der NT? (allg. / Regulation)

4. Regulation der NT:

- Welche gesetzlichen Richtlinien sind für Ihre Organisation heute bei Chemikalien massgebend?
- Braucht es aus Ihrer Sicht eine Regulation der NT? (Begründung)
- Was wären die wichtigsten Eckpunkte für eine NT-Regulation?
- Wer sollte den Lead übernehmen in Fragen einer möglichen Regulierung? (CH, Europa, global)
- Was muss in Bezug auf eine mögliche Regulierung dringend getan bzw. vermieden werden?

5. Anliegen Ihrer Organisation:

- Welches sind im Bezug auf die NT Ihre wichtigsten Anliegen? (allg. / Regulation)
- Was sind Ihre wichtigsten Fragestellungen, Wünsche und Erwartungen in Bezug auf NT Regulation? (an Behörden, Industrie, Retailer, Versicherer, NGO`s, etc.)

6. Plattform Nanotechnologie und Regulation:

- Wer sollte in einer NT-Plattform (CH, Europa) vertreten sein?
- Was erwarten Sie grundsätzlich von einer interdisziplinären Plattform NT- Regulation?
- Welche Themen und Fragen müssen diskutiert werden? (Schwerpunkte)

7. Blick zurück aus der Zukunft:

Sie schauen zurück aus dem Jahr 2015: Wie hat sich die NT und die NT-Regulation seit dem Jahr 2005 entwickelt?

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Juvena International AG / Beiersdorf AG
Nano-Cluster Bodensee, (St.Gallen)
NanoEurope – Fair & exhibition
Nanosys GmbH, Wolfhalden
Nestlé Research Center
Paul Scherrer Institute (PSI)
Swiss Agency for the Environment, Forests and Landscape
Swiss Federal Office for Agriculture
Swiss Federal Office of Public Health
SwissRe
TA-Swiss, Centre for technology assessment
University Berne: Institute of Anatomy