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ACTION PLAN

SYNTHETIC NANOMATERIALS

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Carbon nanotubes are firmer than steel. The SNSF nanosciences programme is investigating their application in molecular electronics. Photo: NCCR Nanoscale Science

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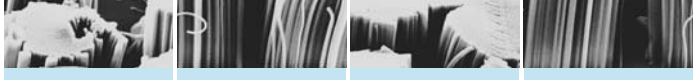


CONTENTS

SUMMARY

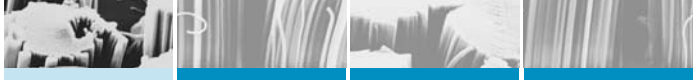
Nanotechnology is a rapidly growing field of research and development with increasing significance for business, research and society. It is therefore important to investigate thoroughly the potential risks as well as opportunities associated with it, and if necessary to take measures to protect humans and the environment. Investment in the wrong things, and the resulting costs to society and the economy, can thus be avoided. In the foreground of the discussion of risks are the synthetic nanomaterials used in nanotechnology. The Action Plan Synthetic Nanomaterials is intended to create the basis for the safe use of such materials and nanotechnology. The package of measures in the Action Plan pursues four objectives:

Communication and public dialogue are key prerequisites for the rational engagement with nanotechnology, and should therefore be encouraged. Including the public, industry and science in the debate about the opportunities and risks of nanotechnology must be an integral part of its development. Only in this way can technologies be developed which have sustainable economic and environmental benefits, and that find public acceptance.

Nanotechnology uses various kinds of synthetic nanomaterials. Possible risks for humans and the environment arising in the course of the manufacture, use and disposal of these nanomaterials cannot yet be conclusively evaluated, as the scientific basis is currently lacking. The knowledge needed can be worked out by the National Research Programme "Opportunities and Risks of Nanomaterials" that has been launched by the Federal Council on 28th November 2007 and through the strengthened commitment of Swiss researchers to the 7th EU Framework Programme.

The Action Plan will create regulatory framework conditions for the responsible handling of synthetic nanoparticles. In the first phase, high value will be placed on the personal responsibility of the industry. Self-supervision in the area of synthetic nanomaterials will be defined and voluntary measures by the industry will be supported. Only when the methodological foundations and well-grounded risk assessments of synthetic nanomaterials are available, can additional statutory framework conditions for the safe handling of synthetic nanomaterials be developed.

The potential of nanotechnology for efficient use of resources and health protection is of major social and economic relevance. The Federal communications strategy should include informing research and industry about existing Federal funding schemes (CTI, FOEN environmental technology promotion).



1 STARTING POINT

Nanotechnology[1] is a cross-application technology, which will influence the development of many fields, including biology, medicine, information and communications technologies, material and engineering sciences, through new methods of investigation, materials and applications. Synthetic nanomaterials[2] often display novel properties compared to conventional materials. They make possible a new generation of products with great economic potential in a diversity of fields.

Numerous products based on synthetic nanomaterials are already on the market. Cosmetics, extra-stable composite materials, or food packagings that give longer shelf-life, are only a few examples. Nanotechnological applications in research also promise to contribute to resource efficiency, e. g. in energy use and generation, and in the consumption of raw materials. In medicine, new diagnostic procedures and methods of drug delivery are being developed, which could lead to better forms of treatment. The combination of synthetic nanoparticles[3] (e. g. silicium dioxide, gold, magnetic iron etc.) with biological systems also opens up promising new possibilities in the development of vaccines, plant protection, and the fight against cancer.

Synthetic nanomaterials offer great opportunities in a diversity of applications. It is therefore all the more important to engage with the critical questions being posed today. Possible negative impacts on health, the environment and society must be recognised and anticipated as early as possible. Various studies have already shown that, because of their small size, unbound nanoparticles can be inhaled and enter the bloodstream via the lungs, disperse throughout the body and penetrate other organs. It has also been shown that, depending on their properties, some synthetic nanoparticles can be damaging to cells. Only a solid risk assessment can protect society and the economy from unnecessary life-cycle costs and false investments, and thus allow the whole potential of nanotechnology to be used.

With this as a background, the Federal Office of Public Health (FOPH) and the Federal Office for the Environment (FOEN), in collaboration with an interdepartmental working party, experts and affected stakeholders, have drawn up the current Action Plan.

The Federal Council approved the Action Plan Synthetic Nanomaterials on 9 April 2008 and authorised DETEC to publish it.

The Action Plan's objectives are:

- **Creating framework conditions for responsible handling of synthetic nanoparticles**
- **Creating scientific and methodological conditions to recognise and prevent possible harmful effects of synthetic nanomaterials on health and the environment**
- **Promoting public dialogue about the promise and risks of nanotechnology**
- **Better use of existing promotional instruments for the development and market launch of sustainable applications of nanotechnology**

[1] Nanotechnology: Nanotechnology concerns structures that are typically between 1 and 100 nm in size. It uses characteristic effects and phenomena that appear in the transitional area between atomic and mesoscopic size. Nanotechnology describes the targeted production and/or manipulation of individual nanostructures.

[2] Synthetic nanomaterials: Artificially produced materials with structural components (e. g. crystallites, fibres, particles) that have at least one internal or external dimension at the nanoscale level, typically between 1 nm and 100 nm. They have special properties or a special composition.

[3] Synthetic nanoparticles: Deliberately produced particles that (by design or fortuitously) are typically between 1 and 100 nm in at least two dimensions. The discussion of risk focuses on applications and products with (unbound) synthetic nanoparticles.

2 ANALYSIS OF THE SITUATION

The basic report on "Risk Assessment and Risk Management for Synthetic Nanomaterials"[4] summarises the current state of knowledge of the risks of synthetic nanomaterials. It gives an overview of various nanomaterials and their applications, as well as their effects on health and the environment, and sheds light on occupational health protection, the legislative process, technology assessment, and communication.

The level of knowledge presented in the basic report and the conclusions drawn are given below. Section 2.6 considers existing promotional instruments for the development of sustainable applications of nanotechnology.

2.1 Communication and promoting dialogue

The public's need for wide-ranging, balanced, independent, transparent and easily understandable information is proven. Communication is a key prerequisite for the public engagement with new technologies. This opinion-forming process may leave its mark on the development of technologies and their application. Communication should therefore extend further than the field of synthetic nanomaterials to encompass all of nanotechnology. It should reflect the current state of social, scientific and political knowledge and of public engagement. Account should be taken of both the promise of nanotechnology and the fears it generates.

The involvement of industry, authorities and the public in the debate on opportunities and risks must be an integral part of technological development. For an integrational approach, this debate should be as broad as possible and not restricted to individual levels or topics (scientific, psychological, sociological). Further details are given in Appendix 4.1.

Conclusion **Communication must illuminate both opportunities and risks, and permit the forming of opinions that integrate multiple aspects. Dialogue between affected parties must be promoted (see measures in Section 3.1).**

[4] Synthetische Nanomaterialien, Risikobeurteilung and Risikomanagement: Grundlagenbericht zum Aktionsplan. Umwelt-Wissen No. 0721. Federal Office of Public Health and Federal Office for the Environment, Bern. 284 pp.

[5] Agglomerate: An agglomerate is a group of particles held together by relatively weak forces (van der Waals, electrostatic forces and surface tension). In contrast to aggregates, agglomerates can be broken down into their primary particles relatively easily.

2.2 Effects on humans and the environment

At the moment, too little is known about the effects on humans and the environment of exposure to synthetic nanomaterials to give a well-founded risk evaluation.

The lung is the most critical organ for the uptake of unbound nanoparticles. It offers an enormous surface area of exposure, and through the extremely thin air-blood vessel barrier, inhaled and deposited nanoparticles can reach the blood. They spread throughout the body via the bloodstream and penetrate other organs.

Experiments using cell cultures have shown that nanoparticles can have harmful effects. In addition to the dose and the chemical composition of the nanoparticles, factors such as size, surface area, surface function, the tendency to aggregate, the form of particle, and the surface charge, can play a decisive role on their distribution in the body and their possible harmful effects.

After the lung, the skin is a further potential uptake organ. Currently, however, not a single study has provided evidence that nanoparticles can reach the bloodstream via intact skin. Increased uptake of nanoparticles through the gut wall has been observed in rats, but entry into the bloodstream has not been described. The excretion of nanoparticles in the gut seems to be efficient. The olfactory nerves in the roof of the nose are a further entry point. Extremely small nanoparticles can be transported out of the air breathed, via nerve fibres, directly into the brain.

There are few studies on the ecotoxicity and environmental behaviour of synthetic nanoparticles. To date, effects on aquatic organisms have been reported. Often, however, the studies were performed using high, environmentally irrelevant concentrations of particles, and insufficiently characterised test material. There are as yet no reliable estimates of the possible environmental immissions that could occur during the production, use or disposal of synthetic nanoparticles or products based on them. At present there are also hardly any data in the literature on bioaccumulation and the possibility of synthetic nanoparticles concentrating in the food chain. Studies have shown, however, that the uptake of nanoparticles by organisms in the environment is possible.

The specific physical and chemical properties that nanoparticles show in comparison with larger particles of the same material could also present unexpected safety risks. The most important physico-chemical hazards are the risk of fire or explosion, and unexpected or increased catalytic activity. The physical and chemical properties of many synthetic nanoparticles are however still unknown and the risk therefore impossible to evaluate.

Combining synthetic nanoparticles with biological systems could also produce new health and environmental risks. Criteria are required according to which the risks of such systems in terms of their production (in laboratories and production plants), their use in experiments on animals and humans, their use in release experiments, and their market approval, can be assessed (for further information see Appendix 4.2.1). .

Conclusion **The open questions about the possible effects of synthetic nanomaterials on health and the environment, on identifying the sources of pollution, and on possible safety risks, must be given high priority in the years to come (see measures in Section 3.2.). The Federal Council has launched the National Research Programme "Opportunities and Risks of Nanomaterials" on 28th November 2007. This programme will help to fill the existing knowledge gaps.**

2.3 Health protection at the workplace

Companies are required by law to ensure the health of their employees, and to take precautions accordingly to protect health throughout the facility, based on an evaluation of the specific risks.

According to current knowledge, occupational exposure to synthetic nanoparticles occurs primarily through processes that use unbound nanoparticles as starting materials, or that produce them as byproducts. The known principle of preventing exposure in the workplace also applies to synthetic nanoparticles: substances with unknown properties should be treated as potentially hazardous. The established protection strategy rests on hierarchically ordered measures: first substitution, technical measures, organisational measures, and finally, people oriented protective measures. There are still major uncertainties in terms of the efficiency of tech-

2 ANALYSIS OF THE SITUATION

nical protective systems and personal protective equipment, particularly for nanoparticles with a slight tendency to agglomerate[5]. In addition to direct health risks the specific physical and chemical properties of synthetic nanoparticles may also generate unexpected safety hazards such as the risk of fire and explosion or catalytic activity.

There is a clear need for action to develop and apply adapted protective measures. Recommendations on existing and recognised protective strategies – e. g. SUVA (Swiss National Accident Insurance Organisation) Recommendations for working with nanomaterials (available in German, French or Italian) – must be put into concrete terms and widely disseminated, so that the corresponding protective measures are applied in companies. In addition, the producers of protective measures should be supported in the research and development of these methods and products (e. g. via the Innovation Promotion Agency CTI). As yet there are no specific workplace limits for nanomaterials. With the increasing use of synthetic nanomaterials, however, an increase in high exposures in the workplace is to be expected. This may produce a demand in the medium to long term for workplace limits on particular synthetic nanoparticles. The scientific foundations for this must be elaborated now. Switzerland must cooperate in drawing up international recommendations for protective measures, safety data sheets and safety limits (details in Appendix 4.2.3).

Conclusion **The current recommendations for synthetic nanoparticles are based almost exclusively on analogies with particles at the micrometre scale. The effectiveness of these measures and methods must be investigated. Until there are relevant findings, the recognised protective strategies for substances of unknown hazard potential should be applied, and the potential exposure of employees should be kept as low as possible using technical, organisational and personal protective measures (see measures in Sections 3.2 and 3.4).**

2.4 Developing methods for measuring and testing: standardising terminology

One important condition for regulation is the presence of validated and standardised methods to measure exposure, and to test the properties of synthetic nanoparticles. The Organization for Economic Cooperation and Development (OECD) and the International Standardization Organization (ISO), in particular, are in charge of developing uniform terminology, nomenclature and standardised methods of measurement and testing in the areas of health, the environment and safety (further details in Appendix 4.2.2).

Conclusion **Standardisation must take place in an international context. Switzerland's participation in the OECD and ISO has high priority (see measures in Section 3.2).**

2.5 Risk assessment and regulation

Synthetic nanomaterials do not receive special treatment under current legislation (on pharmaceutical products, chemicals, epidemics, gene technology, food, environment, occupational safety etc.). Fundamentally, however, all regulatory authorities implicitly include synthetic nanomaterials or nanoparticles. There is thus no need at present for "nanospecific" legislation. At the level of implementation ordinances, however, both provisions relating to products and those with safety as a goal need to be re-examined (see Section 3.3.2). Existing gaps in the regulations could contribute to the industry's uncertainty about how to act or what investments to make.

Swiss regulations have various statutory instruments:

- Approval and notification procedures are coupled in each case with an obligation to test, adapted to the substance or chemical in question. The risk assessment methods take account of the specific demands on safety and efficacy.
- Self-supervision obliges the manufacturer to assess the safety of his/her products independently, using existing data and, if necessary, to take appropriate safety precautions and to inform his/her customers about them.
- Prohibitions or limitations on use, positive lists, threshold amounts and emission limits for pollutants in water or air. These are usually the result of risk assessments. Some emission limits have also been laid down as a precaution, according to the state of technology.

The foundations for a solid risk assessment of synthetic nanomaterials are still mostly lacking. Despite this, precautionary safety measures must be taken where necessary, taking into account the development of international legal measures, particularly in the European Union (e. g. REACH), further details in Appendix 4.3.

Conclusion **Both the definition of the term "nanomaterials" and the knowledge of associated potential risks to health and the environment are currently inadequate to draw up general requirements for the marketing and use of synthetic nanomaterials. Risk assessments based on simple criteria are necessary in order to set initial guidelines for the development, marketing and disposal of synthetic nanomaterials (see measures in Sections 3.2. and 3.3).**

2.6 Benefits of nanotechnology for consumers, employees and the environment

The way in which we use available natural resources has effects on our health and the environment. Natural resources are an important factor in the economy and an important element of our welfare. Technological innovations play a key role in the more efficient use of our resources. These innovations can also have positive effects on safety at work or health protection. At the moment, nanotechnology faces particular expectations. The Swiss universities have a broad knowledge in this area which can be used to develop applications of nanotechnology to market maturity, together with partners from the business world. Applications that contribute to sustainable development contribute to ensuring the long-term competitiveness of the Swiss economy.

In 2001 the Swiss National Centre of Competence in Research (NCCR) "Nanoscale Science" was launched with over 40 institutions of the ETH and universities participating. The aim is to promote interdisciplinary research in chemistry, physics, life sciences, engineering, information and communication technologies within the field of nanosciences. At the interface between research institutes and industry, the NCCR – if necessary, together with the Innovation Promotion Agency (CTI) – will contribute to the early recognition of promising applications and to fostering their development.

The Innovation Promotion Agency (CTI) helps to fund projects in applied research and development in nanotechnology. The condition for project funding is collaboration between universities and a business partner, who must carry at least 50 % of the development costs. The network of European Micro- and Nanotechnology MNT ERA-Net[6], which unites more than 20 promotion programmes in 17 European countries, gives researchers and industry a tool for coordinating such cooperative projects.

[6] MNT ERA: www.mnt-era.net

2 ANALYSIS OF THE SITUATION

The FOEN programme for funding innovative environmental technologies has been running since 1997. This supports pilot and demonstration projects, and measures to develop innovations for the international market. As at the CTI, cooperation between industry and research institutions, as well as financial participation of the business partner, are conditions for funding.

Conclusion **Switzerland disposes of several funding instruments to support applied research. These instruments are open as well for projects in the domain of nanotechnologies. In particular, for applications directed towards a more efficient use of resources or health protection, industry and research should collaborate more and submit joint projects (see measures in Section 3.4).**

3 MEASURES

The current measures show what should be done in the coming years to ensure the responsible development of synthetic nanomaterials. The measures are established through 4 priority actions.

3.1 Communication and promotion of public dialogue on the opportunities and risks of nanotechnology

Measures

Communication

The public, politics and the economy require clear access to information on current stipulations, regulations and recommendations. In addition, up-to-date scientific findings on the risks of synthetic nanomaterials must be available, taking similar initiatives at EU and global level into account. Based on a joint communication plan, the federal authorities responsible should collate specific and updated information for these groups.

Dialogue platforms

Efficient and broadly based approaches to the safe handling of synthetic nanoparticles must be created in dialogue with all those involved. Industry, the authorities and the general public must be included in the debate about the opportunities and risks of nanotechnology. This debate must be an integral part in the development of nanotechnology. Existing platforms (e.g. NanoConvention by Empa, Nanopublic by the University of Lausanne) should be supported and where necessary, new ones initiated.

Technology assessment

To identify the opinions, wishes and fears of the population, more participatory processes such as PubliForum, Publifocus and PubliTalk carried out by the Swiss Centre for Technology Assessment will be used, taking into account current developments in nanotechnology (see also Appendix 4.1.1).

3.2 Creating scientific and methodological conditions to recognise and prevent possible harmful impacts of synthetic nanoparticles on health and the environment

Measures

Increased support for independent risk research in nanotechnology

Independent risk research must be reinforced. There are several tools available for this: National Research Programmes, the normal support of the Swiss National Science Foundation (SNSF), the ETH, the universities and the Universities of Applied Sciences, and participation in the current 7th Framework Programme of the EU. Researchers should increasingly be made aware of the need for safety research to accompany innovation, and encouraged to use existing funding possibilities (see also Appendix 4.2.1).

Terminology, standards, methods of measuring and testing

Participation in current programmes, in particular those of ISO and the OECD, to develop a standardised terminology, standards for safety at work, and harmonised methods of measurement and testing guidelines for the risk assessment of synthetic nanomaterials, is being pursued and strengthened.

3 MEASURES

3.3 Creating regulatory framework conditions for the responsible handling of synthetic nanomaterials

Based on the scientific and methodological principles currently available, no conclusive requirements for the safety of synthetic nanomaterials can yet be formulated. Nevertheless, safety precautions must be taken. The measures must focus first on the reinforcement of the personal responsibility of industry and on better public information about possible risks of products using synthetic nanomaterials. When the methodological background and well-grounded risk assessments of synthetic nanomaterials are available, statutory framework conditions for the safe handling of synthetic nanomaterials may be created where necessary.

3.3.1 Phase 1 (short and medium term): Strengthening the industry's own responsibility

Measures

Safety matrix for products and application with synthetic nanomaterials

Because of the lack of scientific knowledge and the absence of methods of measurement and testing, the risks of synthetic nanomaterials basically cannot currently be evaluated. A safety matrix that builds on existing knowledge should help to estimate for which materials or applications possible risks should be considered. The matrix will be developed by collaboration between industry, science, authorities, consumer and environmental organisations, and international institutions, and be adapted to advances in knowledge (details in Appendix 4.3.2).

Self-supervision and measures of occupation health protection

Trade and industry are obliged to assess their products and applications as part of the existing provisions on self-supervision, if necessary to take measures to reduce risk, and to inform their customers of such measures. As employers they must take all the required measures to protect their employees. Corresponding instructions are being drawn up on the basis of the safety matrix.

Voluntary measures of industry in the manufacture, marketing and use of products and applications with synthetic nanomaterials

Industry associations could set guidelines for the sustainable handling of nanomaterials by drawing up self dependent agreements (Codes of Conduct). The industry associations could be supported in drawing up such Codes of Conduct (details in Appendix 4.3.3).

Provision of safety information to the processing industry

The Safety Data Sheet (SDS) is an important tool in chemicals legislation, informing the processing industry about possible hazards and necessary safety measures. Only if the SDS contain the necessary information for the safe handling of synthetic nanomaterials can the processing trade and industry take on the responsibility required to protect employees, consumers and the environment. The information necessary for the safe handling of synthetic nanomaterials must be contained in the SDS.

Informing consumers about synthetic nanomaterials in products

In collaboration with consumer associations and industry, measures to satisfy consumers' need for information should be examined. Product declarations should be considered as one possibility. International measures and initiatives should be taken into account.

Regulations for the disposal of products containing synthetic nanomaterials

When disposing of products that contain synthetic nanomaterials, hazardous nanoparticles may enter the environment, or affect the recycling of composite materials and plastics. It has to be elaborated how a safe disposal of synthetic nanomaterials can be assured.

3.3.2 Phase 2 (medium and long term): Creating statutory framework conditions for the safe handling of synthetic nanomaterials

The second phase will examine whether statutory measures that go beyond today's provisions are necessary. In drawing them up, the development of legal measures abroad, particularly in the EU (e. g. the further development of REACH), should be taken into account. Statutory measures that should be considered include:

- Introduction of a reporting obligation, or modifying the application or approvals procedure in the legislation on pharmaceutical products, chemicals, gene technology, food or the environment.
- Prohibitions or limits on the marketing and use of particular synthetic nanomaterials
- Establishing emission limits for air and water, as well as specific workplace limits for particular synthetic nanoparticles
- Establishing thresholds for synthetic nanomaterials in the Ordinance on Major Accidents.

3.4 Better use of existing promotional instruments

Measure

The potential of nanotechnology for resource efficiency and health protection are of great social and economic relevance, and must be used. A suitable communications strategy (see 3.1) should be used to promote the collaboration of research and industry, and to encourage submission of joint projects to the CTI or for FOEN's environmental technology promotion.

4 APPENDICES

4.1 Communication and the promotion of public dialogue about the opportunities and risks of nanotechnology

4.1.1 Technology Assessment (TA)

The mandate of the Centre for Technology Assessment (TA-SWISS) is to provide decision-makers in politics and business with the basic principles of new technologies, taking into account both opportunities and risks, with a eye on social, ecological, health, economic, social and ethical impacts. For interdisciplinary studies, TA-SWISS therefore involves technology assessment experts, and performs participatory processes (PubliForum, Publifocus, PubliTalk) with the public. These result in recommendations for politics, business, and the general public.

The latest TA-SWISS report focuses on "Nanotechnologies in the food sector" (due for publication in 2008). This not only concerns additives in foodstuffs that could be modified or enriched using nanotechnologies, but also the impact that nanotech packagings could have on the food they contain. The interdisciplinary study therefore aims to clarify in general the impact of synthetic nanomaterials in the particularly sensitive area of foodstuffs, taking into account legal and ethical aspects. It could provide the basis for going one step further towards declarations, which the participatory process has shown to be a clear public need. Both in Switzerland and internationally, we still lack the foundations on which to base the declaration of synthetic nanoparticles.

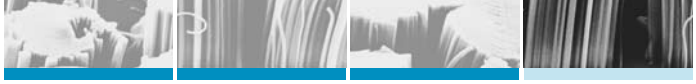
4.2 Creating the scientific and methodological prerequisites for recognising and preventing possible harmful impacts of synthetic nanoparticles on health and the environment

4.2.1 Research promotion

In line with other international research programmes, the basic report of the Swiss Action Plan "Synthetic nanomaterials" identifies a need for risk research in many areas. Research in these areas should be promoted. A particular need for research has been identified in the following areas:

- Health (toxicological in vitro and in vivo methods, toxicokinetics, clinical studies, particle translocation, metabolism, bioaccumulation and persistence, effects on organ systems, model systems)
- Environment (dispersal, accumulation and persistence of nanoparticles in the environment, transformation, long-term effect on environmental organisms, methods and models)
- Emissions (sources of pollution for consumers, sources of environmental pollution, emissions in manufacture, processing, consumption and disposal or recycling, substance flow analyses
- Metrology (instruments of measurement, surface properties of particles, standard materials)
- Health protection at work (measurement technologies, emissions, exposure models, protective measures in general and in production processes)
- Hazardous incident prevention (tests, toxicity, chemical/physical properties, particle behaviour, transport)
- Technology assessment (case studies on new developments in nanotechnology, risk perception)

As yet almost no systematic studies have been performed. The hazards and risks of nanomaterials that could burden humans or the environment during manufacturing, processing, use and disposal need to be identified, and measures to minimise the risks developed. Here, research projects that improve understanding of the fundamental processes in cells, organs, organisms and the environment are important. For most synthetic nanoparticles it is still unclear whether and how the body absorbs, distributes, translocates, accumulates or excretes them.



To determine the toxicity of synthetic nanoparticles in biological systems and their impact on health and the environment, it is extremely important to characterise the particles in terms of their size, shape, dispersibility, and most especially, their surface properties. Kinetic models could help to determine realistic particle doses for the potential target organs. This could clarify which exposure routes are relevant for which nanoparticles, and whether certain target organs can be deprioritised. It should also be determined whether nanoparticles disperse randomly or in a directed way in organisms and in organs, tissues and cells. This would permit conclusions to be drawn about their local effect in organisms and about the impact on health.

To cover the identified need for research for risk assessment and risk management, existing or new national and international programmes of research promotion should be used. An interdisciplinary approach that also encompasses ethical, legal, economic and social implications, would contribute to finding workable solutions to handling risks. It is intended to set up a shared, wide-ranging portal across various disciplines, into which data can flow from all the subprojects that contribute to clarifying open questions concerning the promise and risks of synthetic nanomaterials.

Coordination and collaboration with national and international research programmes is of great importance. Results of risk research should feed into the development of nanotechnological applications early on. The upcoming work can only be mastered together, and solutions found for a safe use of nanotechnology. It is vital to cooperate with the National Centre of Competence in Research (NCCR) "Nanoscale Science", the programmes of the EU 7th Framework Programme in general, and e. g. with the new DFG (Deutsche Forschungsgemeinschaft) Priority Programme SPP 1313, "Biological Responses to Nanoscale Particles (Bio-Nano-Responses)", in particular.

4.2.2 Standardisation of terminology, definitions, and methods for testing, measuring and evaluation

Harmonised terminology and clear definitions are important prerequisites for drawing up regulatory instruments. Standardised methods for testing and measuring, designed for the special properties of synthetic nanomaterials, are also needed. These include toxicological and ecotoxicological test methods, methods for determining environmental behaviour and physico-chemical properties, and methods of measurement to show the presence of nanomaterials in the air, soil and water and to determine the concentration in samples. Without such methods, the analysis of hazards and exposure and thus a risk assessment of synthetic nanomaterials are not possible. Furthermore, methods for the risk assessment of synthetic nanomaterials for consumers, employees and the environment must be drawn up. This work cannot be done nationally but only in an internationally coordinated way.
The OECD is one of the major international organisations concerned with developing standardised test guidelines and evaluation methods. The mandate of the OECD Working Party on Manufactured Nanomaterials (WPMN) was approved in 2006 and is valid for three years. It is assumed that the OECD Council will extend the mandate. The following eight projects are currently being developed:

- Project 1: Development of an OECD nanotechnologies research database
- Project 2: EHS research strategies on manufactured nanomaterials
- Project 3: Safety testing of a representative set of nanoparticles
- Project 4: Manufactured nanomaterials and test guidelines
- Project 5: Co-operation on voluntary schemes and regulatory programmes
- Project 6: Co-operation on risk assessments
- Project 7: The Role of Alternative Methods in Nanotoxicology
- Project 8: Exposure Measurement and Exposure Mitigation

Switzerland is a member of the OECD and will participate actively in the WPMN projects.

4 APPENDICES

The ISO currently has several working parties in nanotechnology concerned with the definitions, nomenclature and characterisation of synthetic nanoparticles. In addition, an ISO document "Occupational Safe Practices Regarding Nanotechnologies" is in preparation. Switzerland's active participation will ensure that the ISO standards are compatible with the needs of Swiss stakeholders. The Swiss Association for Standardization (SNV) will therefore follow and comment on the work of the ISO. The technical recommendations are directly relevant for safe working practices in all production facilities, and should influence the anticipated modifications of Safety Data Sheets.

One working party of the European Committee for Standardization (CEN/TC 352) is currently drawing up a series of standards for synthetic nanomaterials:
- Classification, terminology and nomenclature (Vienna agreement)
- Metrology, measurement and characterization (including procedures for calibration) (Vienna agreement)
- Health, safety and environmental issues (Vienna agreement)
- Nanotechnology products and processes

This work is coordinated with that of the OECD and ISO. The CEN work will also be followed and commented on.

4.2.3 Health protection at work

Companies are legally obliged to ensure the protection of the health of their employees. They are obliged to assess the risks that occur in their facilities and to take the necessary measures to control them. If particular hazards are present, they must involve specialists in occupational health or medicine, in accordance with Art. 11a VUV (SR 832.30). Little is yet known about the magnitude of the *risks* posed by synthetic nanomaterials, and there are no established procedures as yet for the assessment of possible occupational risks. Nevertheless, synthetic nanoparticles are already being handled in facilities. The following hierarchical classification of protective measures for work using substances of unknown risk (e. g. new chemicals or pharmaceutical agents) has been established:
1. Substitution of the substances
2. Technical protection measures (collective protection)
3. Organisational protective measures
4. Personal protective measures (individual protection/PPE)

This approach can also be adopted for synthetic nanoparticles.

Many of the currently available *recommendations on safety precautions* for synthetic nanoparticles at work are based on analogies with measures that have proved effective in handling larger particles. The efficacy of these processes for nanoscale materials has not yet been sufficiently researched and documented.

The safety precautions and strategies mentioned above for the handling of substances of unknown risk are often of a general nature (both SUVA and the German BAUA/VCI have already published such approaches [7]) and should be further developed by the agencies involved, together with the industry, into practical tools and educational materials. This could help companies (especially SMEs, laboratories etc.) to identify and apply correctly the measures that are suitable for them.

As part of their supervisory responsibilities, official agencies (e. g. SUVA; SECO, and cantonal health and safety executives) in Switzerland also have an important role in *advising companies and branches of industry* on their protection strategies. Research institutes at universities and universities of applied sciences are important partners here, when the issue is the research and development of novel, not yet generally recognised technological and operational ap-

proaches. It should be noted here that in German-speaking Switzerland, no such university institute exists.

In the case of many *technical solutions and Personal Protective Equipment,* it is unclear how effective they are in terms of nanoparticles. For methods that turn out not to be effective enough, new processes will need to be developed. A new market is opening up here for providers of innovative protection solutions. Such providers should be supported in developing suitable methods and products (e. g. via CTI).

There are as yet no specific *occupational exposure limits* for nanoparticles. With the increasing production and application of synthetic nanoparticles, rising occupational exposure is to be expected. As part of employee protection, medium- to long-term reliable occupational exposure limits, based on scientific findings, will need to be set. Measurement campaigns concerning workplace concentrations and the effectiveness of the protective measures employed should be performed both by the official agencies and as part of university research projects.

Recommendations on Safety Data Sheets are, if present at all, often aimed at large-scale production facilities and big companies with their own health specialists. Small companies are often less able to implement such recommendations, for personnel and financial reasons. The simple *identification of possible hazards* is a central hurdle in health protection, especially in small companies: it is recommendable either to make products inherently safe or to make the potential hazard identifiable directly on the product.

Switzerland's participation in formulating *international recommendations* for safety precautions and Safety Data Sheets is strongly recommended, so that the characteristics of Switzerland as a site of production are taken into account.

[7] SUVA: www.suva.ch/home/suvapro/branchenfachthemen/nanopartikel_an_arbeitsplaetzen.htm
BAUA/VCI: www.baua.de/nn_5834/nsc_true/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Aktivitaeten.html

4.3 Creating a regulatory framework for the responsible handling of synthetic nanomaterials

4.3.1 Synthetic nanomaterials under REACH

In the European Union, nanoscale chemicals (synthetic nanoparticles) fall implicitly within the scope of the REACH regulation, which came into force on 1 July 2007. According to its provisions, synthetic nanoparticles must be tested and assessed for their properties relevant to health and the environment as soon as annual production exceeds 1 tonne.

This requirement applies under current Swiss law only to synthetic nanoparticles that fall within the scope of so-called notified substances (new substances). In contrast to REACH, these become notifiable when annual production reaches 10 kg. The differences between EU law and Swiss law for existing substances (phase-in substances) will however only come into force after the transitional period for their registration has expired (i. e. from 2010)[8].

Nanospecific modification of the REACH regulations are currently under discussions including: the quantity thresholds for registration (> 1 t/a), the lack of suitable nanospecific methods for hazard and risk assessment, and the issue of whether synthetic nanoparticles in principle should be considered "non-phase-in" substances (new substances).

[8] Timetable for implementing REACH in the European Union
- June 2008: Registration for non-phase-in substances (previously "new substances") enters into force
- 1 June 2008 to 1 December 2008: Pre-registration of phase-in substances (previously "existing substances").
- 30 November 2010: Deadline for registering substances in quantities exceeding 1000 t/a, substances that are carcinogenic, mutagenic or toxic to reproduction (CMR categories 1 and 2) exceeding 1 t/a, and substances classified as "very toxic to aquatic organisms" (R50/53) above 100 t/a.
- 31 May 2013: Deadline for registering substances in quantities exceeding 100 t/a.
- 31 May 2018: Deadline for registering substances in quantities exceeding 1 t/a.

Registration dossiers will be accepted from 1 June 2008; voluntary registration is possible before the deadlines.

4 APPENDICES

4.3.2 "Safety matrix" for products and applications using synthetic nanomaterials

The safety matrix that will be drawn up should enable the hazards of synthetic nanoparticles and their applications to be assessed in a differentiated way, based on simple parameters. The probability and the extent of exposure of people and the environment will be included. Details of market volume, possible emissions of nanoparticles from applications such as coatings, persistence, and bioavailability, could be of great benefit here. Toxicological and safety-relevant properties such as the reactivity of the nanoparticles should also be considered.

It is important that the matrix remains applicable even with few data, and that new scientific findings can be incorporated. Attention should be given to different types of exposure in "employee protection" (areas of application, persons exposed etc.), "consumer protection "(which products are available), and "environmental protection" (product emissions over their whole life-cycle).

The safety matrix will help business and the authorities to identify applications with associated risk, and to take the necessary safety precautions. It provides a tool that should be applied in self-monitoring by the producers and importers of synthetic nanomaterials and the products based on them.

4.3.3 Voluntary measures by the industry: Codes of Conduct and risk management systems

A *Code of Conduct (CoC)* specific to the particular branch of industry could formulate guidelines that go beyond the requirements of self-supervision for the safe handling of nanomaterials. It may include safety monitoring or more advanced measures for reducing exposure (workplace, use, disposal/recycling), for transmitting information, and for voluntarily refraining from using particular synthetic nanoparticles or their applications. A CoC thus helps avoid the introduction of restrictive regulations. It also gives the industry the opportunity to contribute actively to designing the guidelines for future regulations.

Risk management systems (RMS) could help reduce the existing uncertainty about the manufacture and marketing of products based on nanotechnology, especially for consumer products. Potential liability and claims risks could be anticipated according to the state of science and technology. A (certified) risk management system promotes customer trust and demonstrates the industry's awareness of their responsibility.