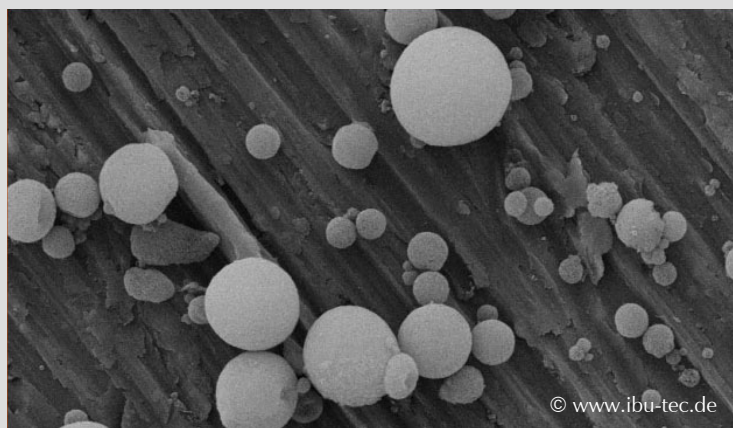


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Synthetic Nanoparticles

Stakeholder survey results



iku GmbH, Dortmund

ON BEHALF OF
THE FEDERAL ENVIRONMENTAL AGENCY

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Results of the interviews

In the run up to the “Dialogue on the evaluation of synthetic nanoparticles in work and environmental areas” event on the 11 and 12 October 2005, iku GmbH conducted 39 interviews with stakeholders. By stakeholders we mean the following players in the field of synthetic nanoparticles:

- public administration,
- science and research,
- industry
- relevant groups in society (environmental, consumer and social welfare associations, trade unions).

Most of the aforementioned players were very willing to devote time to the interviews.

The purpose of the interviews is to prepare the dialogue event thoroughly. The interests and positions of the interview partners are used to prepare the workshops on the second day (12 October 2005). We use them to develop central topics for the discussion. The expectations of the stakeholders with regard to the dialogue will influence subsequent steps in a stakeholder dialogue on future developments in the field of nanoparticles.

We would like to thank all those who participated in the interviews for their cooperation.

What are the main findings from the interviews?

Dialogue is welcomed

Discuss opportunities and risks in good time

In principle, all participants regarded a dialogue about nanoparticles positively. They felt it made good sense to focus on the topic “Opportunities and risks of synthetic nanoparticles” and that it was the right time for the invited players to have a professional discussion¹. The interview partners welcome the discussion

¹ At the moment we are not talking about a dialogue with the general public, but in the first instance a dialogue between stakeholders as roughly characterised above.

of open questions and risks of the technology at an early stage compared to other technologies.

Strong motivation for an objective and fair dialogue

All interview partners would like to avoid problems that arose with other key technologies in the past². Therefore, they aim to hold an objective and transparent dialogue, in which they can present their points of view for discussion. The players are aware that the dialogue is proactive at the moment and aims to steer clear of undifferentiated positions and guard against conflict escalation. The participants still have too few facts available to analyse the risks.

Great demand for knowledge

In our discussions, we found the knowledge of opportunities and threats of synthetic nanoparticles to be very heterogeneous. There is a need for the players to exchange information and opinions. More knowledge would need to be generated to close gaps in knowledge. The open questions relating to synthetic nanoparticles seen by the players are much the same. However they attach different importance to the open questions.

Big opportunities - clarification of the risks necessary

All agree on the great economic importance of the use of synthetic nanoparticles. The stakeholders are also of one mind that any risks posed by synthetic nanoparticles must be clarified before their use in products. The research on risks of synthetic nanoparticles should be intensified. The potential opportunities are assessed as being greater than the risks.

Occupational safety as a priority – Need for regulation controversial

In view of the potential risks involved many players attach high priority to occupational safety. There are different opinions as to the extent and type of regulation required. These opinions range from “existing regulations are sufficient” to a demand for approval procedures for nanoparticles with changed characteristics.

What do the interview partners agree on?

Not a topic in the public domain

The interview partners are of the view that after a wave of coverage in 2003 and 2004, there is currently almost no discussion about the risks of synthetic nanoparticles in the public domain. At most, the opportunities of nanotech-

² This is a reference, in particular, to the early determination of standpoints that prevents a discussion on particular interests. For example, nuclear energy, genetic engineering etc.

<i>Professionals discuss risks</i>	<p>nological applications were made the subject of discussion. The participants stressed that the risks and open questions were increasingly discussed amongst professionals and that there had been contact early on between industry and toxicologists.</p>
<i>Dialogue should go hand-in-hand with R&D</i>	<p>The dialogue should be conducted proactively, meaning that the different players should be involved early on in the research and development phase. Persons who bridge the gap between the different players should accompany the common dialogue in a supportive role, fostering the dialogue, generating understanding between participants and ensuring transparency. The interview partners desire transparency and provision of information in the dialogue, especially from industry and science. Everybody sees and accepts safeguarding the competitiveness of companies as the limit of transparency. Other players, full of hope, rate the current approach of industry in the sphere of nanotechnology as dialogue oriented. They notice a change in attitude compared to earlier experiences.</p>
<i>Information from science and industry desirable</i>	<p>The interview makes it clear that the players formulate the need for research and for action from their particular perspective. Only few interview partners are aware of and reflect the interests of the other players.</p>
<i>Interests of others little known</i>	<p>Need for action is seen in the following areas in particular:</p>
<i>Need for action</i>	
<i>- Standardisation</i>	<ul style="list-style-type: none"> • standardisation and nomenclature including the provision of reference material, which guarantees the comparability and repeatability of (eco-) toxicological studies, is considered urgent,
<i>- Research hazard potential</i>	<ul style="list-style-type: none"> • more research must urgently be carried out into the hazard potential of synthetic nanoparticles,
<i>- Clarify exposures</i>	<ul style="list-style-type: none"> • possible exposures and exposure paths in the life cycle of products must be clarified and
<i>- Develop measuring technique further</i>	<ul style="list-style-type: none"> • the existing measuring technique options must be developed further.
<i>Risk assessment not yet possible / product-related assessment suggested</i>	<p>As neither exposures nor hazard potential have been sufficiently researched, the players do not consider a risk assessment possible at this point in time. Possible risks are seen both for the environment and for people, and here in particular for workers and consumers. Many players support a product-specific risk/benefit assessment.</p>

manifold opportunities

The interview participants see manifold opportunities: potential for the reduction of pollution and environmental benefit, product optimisation and innovation but also luxury benefit³. The medical benefit is especially emphasized. Some regard that as the legitimization⁴ for nanotechnology.

Where do the views of the interview partners differ?

The interview partners differ in their views as to whether there is a need for regulation and, if so, what that regulation should be.

What special tasks and topics do the players pursue?

Industry:

- *Investment security*
- *Adequate regulation mechanisms*

Industry sees its task in the development of new, future-compliant products and services using nanotechnological processes and/or materials. They want security for their investments in the development of such products. Here the safety of the products (low risk of liability) plays an important role, especially for small and medium-sized enterprises (SMEs). Manufacturing companies consider standardisation to be necessary. They see the protection of their know-how as the limit of transparency. They consider existing regulation mechanisms to be adequate.

Administrative authorities:

- *Develop strategy*
- *Promote nanotechnology*

The administrative authorities are clarifying their tasks and responsibilities in relation to synthetic nanoparticles in this context and starting to develop strategies. Whilst ensuring fulfilment of their own tasks, they intend to promote nanotechnology and strengthen the position of the Federal Republic of Germany in nanotechnology.

³ Luxury benefit refers, in particular, to product optimizations that appeal to part of the public but are by no means essential, such as improved qualities in golf clubs or tennis racquets.

⁴ Statements: those who wish to forbid or restrict nanotechnology are obstructing the possible healing of cancer patients, for example.

<p><i>Environmental, consumer protection and social welfare associations:</i></p> <ul style="list-style-type: none">- <i>Avoid or reduce risks</i>- <i>Create transparency</i> <p><i>Scientist and researchers see themselves as service providers</i></p>	<p>Environmental, consumer protection and social welfare associations see their responsibility as avoiding or reducing risks to the environment, consumers and employees. They want to keep an eye on developments and are in favour of intensified research to determine and evaluate risks. Environmental and consumer organisations wish to increase transparency for consumers, and consider a product declaration, for example, to be appropriate.</p> <p>Scientists and researchers see themselves as service providers whose roles is to clarify open questions. They wish to promote nanotechnology through research and development. They hope for more funding for their research.</p>
<p><i>Trade unions and occupational safety bodies:</i></p> <p><i>Clarify need for regulation, adapt safety system</i></p>	<p>Trade unions, company and official occupational safety bodies wish to check whether the existing safety system has to be adapted. They see a need for regulation in this area.</p>

What topics should be dealt with in a future dialogue?

All parties agree that a dialogue is needed and are willing to enter into such dialogue. Thus, for the event on 12 October and for subsequent steps, it will be a matter of defining topics in a reasonable way, of obtaining committed people for the dialogue and of selecting the framework (target level, time frame etc.) so that the stakeholders feel that efficiency and fairness have been achieved.

In summary, on the basis of the interviews, we propose the following topics and their associated aims for a dialogue:

Dialogue topic	Aims and products
Drawing up of basic principles for risk/benefit assessment	Develop a common scheme for assessing benefits and risks of nanotechnological products.
Exchange of information and transparency	Agreement on organisational and technical solutions for the exchange of information and the creation of transparency. Agree on the limits of information and transparency.
Main areas of research	Set priorities for future topics and main areas of research jointly. Close gaps in knowledge. Clarify possible hazards.
Check the need for regulation	Check existing regulations for effectiveness in respect of nanotechnological processes and products. If need be, make amendments.
Exposure	Develop scenarios for exposure to nanoparticles.
Communication with the public	Develop a common strategy for raising public awareness with regard to the opportunities and risks of nanotechnological products.

The conference will produce further contributions on how this proposal should be modified. The following are some of the points still open:

- How will these topics be tackled – approach, groupings?
- Who can act as the promoter for this process?
- At which points do the threads merge, and are interfaces identified?

One of the tasks of the panel discussion at the end of the event will be to deal with these questions.

Appendix

Questions for the workshops

Questions Workshop Environment Protection

Exposure and monitoring

- How can synthetic nanoparticles get into the environment?
- At what points in the life cycle of products with nanoparticles is a release into the environment possible/highly probable?
- What data do we require to protect soil, water, air, animals, human beings and future generations from any adverse effects?
- Which methods of providing proof do we need for which purpose?
- How might be the nature of monitoring in the environmental sphere?
- How can we arrive at standardised methods of determining exposure and basic assumptions for the probability of exposure?
- What measures could be employed to limit risks to a certain area?

Effects

- How can we investigate the interaction effects of synthetic nanoparticles in air, water and soil?
- How can we investigate the persistence, deposition, metabolisation and solubility of synthetic nanoparticles?

Questions Workshop Risk Assessment and Risk Communication

Risk assessment

- How can a risk-benefit assessment of products be carried out? What criteria are required for this? Who should carry out the assessment?

- To what extent are the standard criteria suitable for a risk assessment⁵ of synthetic nanoparticles?
- Under what conditions are we prepared to accept open questions or risks of synthetic nanoparticles? What should the risk-benefit ratio be?

Risk communication

- How should information be presented so that it can be understood by the public?
- What do we want to tell the general public and what not?
- What is of interest to the general public and what is not?
- What risk comparisons help communication with the general public?
- What form could a common communication strategy of all players take? What messages should it convey?
- How can industry, public authorities, science and research be encouraged to be more active in informing the public about the opportunities and risks of synthetic nanoparticles?

Questions Workshop Occupational Safety and Occupational Medicine

- What toxicological risks from nanoparticles are there for employees? What gaps in knowledge must be closed urgently?
- What physico-chemical hazards (e.g. explosion hazard) arise from the new characteristics of synthetic nanoparticles?
- How can adverse affects on health, regardless of the risk assessment, be avoided or reduced even now?
- Are the filters currently used also fine enough to screen out synthetic nanoparticles? What "new" effects do the particles have on the filter materials?

⁵ Criteria: probability of risk and reliability of the assessment of the probability of risk; extent of the consequences of the damage and reliability of the assessment of the extent of the damage; ubiquity; persistence; irreversibility; delayed effect

- Is the personal protective equipment (PPE) adequate?
- What personal measuring devices are required?
- How do we define threshold values for airborne nanoparticles in the workplace?
- What is already being done now to minimise the risks for employees?
- How do we arrive at standardised investigation methods for exposure and probability of exposure?

Questions Workshop Measurement techniques

- What improvements are needed in measurement techniques with respect to measurements of nanoparticles in the workplace and in the environment?
- How can we measure particles by size, surface, weight, morphology and chemical composition?
- How should screening methods be designed for workplaces?
- What can we contribute to biomonitoring?
- How can we arrive at standardised investigation methods in measurement techniques?
- How do we get suitable reference material to collect usable data?

Questions Workshop Potentials for relief of environmental burden through nanotechnology

- What specific areas of application are there already to restore the environment or to relieve the burden on it? Which areas of application are under development?
- What criteria are used to measure the (potential) benefit of a product containing nanoparticles? How can these criteria be assessed?
- When does it make sense to draw up an ecological balance for products containing nanoparticles? What data would be required to do this?

- How should such a balancing procedure be structured? Who would perform this task with the required credibility?

Questions Workshop Environmental Medicine

Effects and translocation

- How can we determine more accurately the absorption routes (inhalation, persorption, injection, dermal, neuronal) and systemic translocation of synthetic nanoparticles?
- What cellular mechanisms are triggered by synthetic nanoparticles?
- What is the agglomeration/deagglomeration behaviour of the particles?
- How can we investigate the persistence, deposition, metabolism and solubility of synthetic nanoparticles?
- What are the critical parameters for the toxicology (size, surface, distribution, weight, morphology, chemical composition)?
- How do the synthetic nanoparticles affect the human protective barriers (e.g. placenta, blood-brain barrier)?

Methods

- How can we determine the risk potential of selected nanoparticles using simple tests?
- Under what conditions is it possible to carry out an extrapolation of individual results?
- Which investigation methods (in-vivo, in-vitro, epidemiology) are especially suitable for which questions?
- How do we arrive at standardised (new) investigation methods in toxicology?

Classification

- How can we formulate the previously shown behaviour in physico-chemical rules which describe the characteristics of new nanoparticles?
- How do we arrive at the classifications of hazard classes for synthetic nanoparticles?

Information transfer

- How can we sum up the existing knowledge, e.g. in a database, and make it available to professional circles?
- How can the existing knowledge of the aerosol manufacturers on safety in production processes be made available?

Other open questions

Standardisation and regulation

- How can we achieve standardisation in the nomenclature of synthetic nanoparticles?
- Are the current regulations in legislation concerning the environment, chemicals, foodstuffs and drugs sufficient? What additional regulations are needed?
- At what point do synthetic nanoparticles qualify as new chemicals under chemicals law? What does this mean for the publication of data, registration and licensing?
- How helpful would a Code of Conduct for synthetic nanoparticles be?
- Which framework conditions must be checked so that nanoparticles can be used in products?
- When must the products rather than the materials used be investigated for their safety and vice versa?
- How can an internationally uniform procedure be achieved on the subject of standardisation and regulation?

Questions relating to civil society, questions on sustainable development

- What regulations do we want for the use of nanotechnological processes and materials in the military field?
- How do the production and products affect the socio-economic distribution processes e.g. from a North-South hemisphere point of view?

- How can non-governmental organisations (NGOs) (environmental, consumer and social welfare associations) be supported so they can act on an equal footing?

Guide for the stakeholder interviews on nanoparticle dialogue

Start

1. In what (professional) context are you involved with the issue of nanoparticles?
2. How do you personally keep informed about the opportunities and risks of synthetic nanoparticles?
3. Who is currently talking about the opportunities and risks of synthetic nanoparticles? (professional circles; general public)
How do you perceive the public discussion about synthetic nanoparticles?
When do you think there will be a similar debate amongst the public at large in Germany?
4. How well informed do you think the public administration, government agencies and NGOs in Germany are about nanoparticles?
What basic knowledge should these have?

Topics and future development

5. What are the opportunities and risks of synthetic nanoparticles that you see?
6. From your point of view, what short, medium and long-term need for action is there?
7. What topic will in future dominate the public discussion on the topic of nanoparticles? Why do you think this will be so?
8. What information would you wish to have on the risks of nanoparticles?
Who should provide this information?
9. What information would you wish to have on the opportunities of nanoparticles? Who should provide this information?
10. What, in your opinion, would have to happen for the nanoparticle sector or individual companies to get bad press on the front page of tabloids like the German 'Bild'?
11. What would need to happen for nanoparticles to receive a good press in the same newspaper?

Dialogue

12. What advantages and disadvantages do you see in a dialogue on the opportunities and risks of nanoparticles?
13. What topics should definitely be dealt with in the dialogue? Which topic would you rather advise against? Reason
14. On what topics do you expect conflicts? Reason
15. What, in your opinion, would be an optimal outcome of the dialogue?
16. How do you rate the interest and willingness of the other stakeholders in respect of the further dialogue on opportunities and risks of nanoparticles?

Conclusion

17. What information on the subject (websites, specialist articles, grey literature) can you recommend on the topic?
18. Who else should we talk to?
19. Is there anything else you would like to say?

List of the interview partners

Organisation	Contact	Interview date and time
Allianz - Zentrum für Technik GmbH	Dr. Christoph Lauterwasser	19/08/05 at 2 pm
BASF AG, Hazardous Substance Management	Prof. Dr. Herbert Bender	05/09/05 at 1.30 pm
BASF AG, Toxicological Department	Dr. Edgar Leibold	01/09/05 at 11 am
Trade Association of the Chemical Industry BG Chemie	Dr. Maren Beth-Hübner Dr. Thomas Brock	written reply
Institute for Occupational Safety and Health BGIA	Carsten Möhlmann	30/08/05 at 10 am
Friends of the Earth Germany (BUND)	Patricia Cameron	12/09/05 at 3 pm
Federal/Länder Working Party for Chemical Safety BLAC	Dr. Eckard Klein	01/09/05 at 1 pm
Federal Office of Consumer Protection and Food Safety BVL	Dr. Christian Grugel	14/09/05 at 2.30 pm
Federal Office for Occupational Safety and Health	Dr. Reiner Arndt	29/08/05 at 2 pm
Federal Institute for Risk Assessment BfR	Dr. Burkhard Viell	02/09/05 at 9 am
Federal Ministry for the Environment, Nature Conservation and Nuclear Safety IG II 6	Arnulf Müller-Helmbrecht	12/09/05 at 9 am
Federal Ministry of Consumer Protection, Food and Agriculture	Rainer Gießübel	31/08/05 at 10.30 am
Federation of German Industries BDI	Dr. Thomas Holtmann	02/09/05 at 4 pm
Daimler Chrysler AG	Dr. Hartmut Presting	14/09/05 at 2 pm
Degussa Advanced Nanomaterials	Dr. Markus Pridöhl	09/09/05 at 3 pm
Degussa AG, Corporate Division Environment, Safety, Health and Quality	Dr. Hans-Jürgen Wiegand	12/09/05 at 10.30 am
FoodFirst Information and Action Network FIAN international	Michael Windfuhr	14/09/05 at noon
Forschungszentrum Karlsruhe GmbH - Institute of Toxicology and Genetics	Prof. Dr. Harald Krug	13/09/05 at 9 am –10.30 am
Forschungszentrum Karlsruhe GmbH Institute for Technology Assessment and Systems Analysis ITAS	Prof. Dr. Armin Grunwald	29/08/05 at 5 pm
Greenpeace Germany	Wolfgang Lohbeck	05/09/05 at 10 am
Henkel KGaA – Produktbetreuung VTS	Dr. Julia Scheel	31/08/05 at 9.30 am

Organisation	Contact	Interview date and time
Mining, Chemicals and Energy Industrial Union IG BCE	Stefan Weis	30/08/05 at 9 am
Infineon Technologies AG	Dr. Wolfgang Hönlein	29/08/05 at 12.30 pm
Institute of Energy and Environmental Technology IUTA	Dr. Thomas Kuhlbusch	07/09/05 at 9 am
Institute for Hazardous Material Research- IGF of the Mining Trade Association	Dr. Dirk Dahmann	06/09/05 at 3 pm
Institute for Tropospheric Research	Prof. Dr. Alfred Wiedensohler	24/08/2005 9.00 am
Environmental Health Research Institute IUF at Heinrich Heine University Düsseldorf	Dr. Roel Schins	09/09/05 at 3 pm
Interdisziplinäre Gesellschaft für Umweltmedizin IGUMED e.V.	Dr. Barbara Dohmen	02/09/05 at 3 pm
Länder Committee for Occupational Safety and Safety Technology LASI	Dr. Helmut Deden	02/09/05 at 2 pm
Nanogate Coating Systems	Dr. Rüdiger Naß	14/09/05 at 10.30 am
Schering AG	Dr. Sascha General	14/09/05 at 1.30 pm
Federal Environmental Agency	Dr. Wolfgang Dubbert	05/09/05 at 1 pm
University of Stuttgart – Department of Technology and Environmental Sociology	Prof. Dr. Ortwin Renn	07/09/05 at 5 pm
University of Darmstadt - Department of Philosophy	Prof. Dr. Alfred Nordmann	25/08/05 at 10 am
University of Leipzig – Nuclear Solid-state Physics	Dr. Tilo Reinert	12/09/05 at 1.30 pm
German Chemical Industry Association VCI	Dr. Hans-Jürgen Klockner	30/08/05 at 9 am
Consumer Protection Organisation North Rhine-Westphalia	Dr. Rolf Buschmann	09/09/05 at 11 am
WWF Germany	Detlev Drenckhahn	08/09/05 at 4 pm
Future Technologies Consulting of VDI TZ GmbH	Dr. Wolfgang Luther	30/08/05 11 am

Unfortunately, the planned interviews with the Federal Ministry of Education and Research and the Center of Competence in Nano-Scale Analysis in Munich did not take place. The Federal Ministry of Economics and Labour felt it was represented by the Federal Office for Occupational Safety and Health.

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