

European Conference

Working and Living with Nanotechnologies

Trade Union and NGO positions



2 April 2009, Brussels, European Parliament

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Summary

The capacity building project NanoCap (2006-2009) organised a structured discussion between European Trade Unions, NGO's and academic experts on environmental and occupational health and safety risks of nanotechnologies. This paper summarizes the results of the final conference of the NanoCap project, organised with STOA/European Parliament, to present the positions and perspectives on nanotechnologies at the workplace and in the environment adopted by these civil society organisations. It reflects the dialogue that took place in two panel discussions between trade unions, environmental NGOs, consumer organisations, employers associations, industry, European parliamentarians, the European Commission and a broad audience.

The TUs and NGOs presented their respective collective European position statements. Their stance is quite positive towards the development of nanotechnologies, but characterised by an emphasis on a precautionary risk approach. Key issues are: transparency of the composition of „nanoproducts“, the need to get related risk information to be provided by the industry throughout the production chain, and responsible risk management. Initiatives like the Code of Conduct may be a helpful guide towards the responsible development of nanotechnologies. However, according to the opinion of the TUs and NGOs this type of voluntary code cannot replace binding legislation. The European Commission supports the precautionary approach and emphasizes the role of the industry in providing data and related communication on substances, as well on nanoparticles.

Employers' organisations and industry state that current legislation is sufficient to deal with nanomaterials, although it might need some modification. The European Parliamentarians, TUs and NGOs state that a good legal framework is needed to manage the possible risks associated with nanotechnology. Adaptations of existing legislation are necessary. The rapid nanotechnological developments, and the many products that are on the market, or about to reach it, legitimise the quick acceptance of precautionary measures, preferably stimulated by binding legislation. Labelling of nanoproducts and a public inventory of all products containing nanoparticles are important steps, but other steps are required such as the development of occupational exposure limits for nanoparticles. Notification of products containing nanoparticles and an obligation for employers to register workers working with these products with a possible exposure are important issues. Industry will have to play an important role in this respect.

It is stated that we already know a lot about the hazardous properties of different nanoparticles, about the nanoparticles itself and from the substances of which these nanoparticles are derived. Although we know very little about the actual exposures both in the workplace and in the product chain, we know enough to derive precautionary exposure limits: to regulate in analogy. References are being made to REACH to provide the framework for nano-legislation, but adaptations are needed. Loopholes in REACH will have to be closed in the next two years.

Nano - research and development should be driven by real societal needs and based on ecological, social and sustainable development considerations and not only on the 'marketability' of products.

'Non-sense' products, that is products without a real societal need and possibly polluting the environment or products with unverified claims should not be allowed on the market.

The message envisaged from the actual developments of nanotechnologies is that product development is not going to wait for scientific evidence of safety or harm (which may never become available). A good legal, preferably binding legal framework is needed to manage the possible risks associated with nanotechnology.

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Chair of the day: Pieter van Broekhuizen (IVAM UvA B.V. – Coordinator NanoCap)

1. Introduction

The results of the three-year NanoCap project were presented and discussed with a broad international audience at a conference in Brussels on 2nd April 2009. The conference was organised in cooperation with STOA (Science and Technology Options Assessment) an official organ of the European Parliament. This allowed presentations of the position statements of the European Trade Unions and environmental NGO's within the European political context. The respective positions were publicly discussed in two subsequent panel discussions. The first discussion was presented by the Trade Unions and was orientated towards the workplace, the second discussion presented by the environmental NGOs who considered nano and the environment. The opinions of the European Parliament on the future development, and the need for legislation for nanotechnologies were presented and related to European Commission activities.

There were approximately 200 participants representing the majority of the Member States of the European Union, as well as participants from Northern and Mid Africa, Asia and Canada. The professional background of the participants is presented in the following table:

Professional background of participants	%
Industry	26
Trade Union	17
Non Governmental Organisation	19
Consumers organisation	4
European Commission	4
European Parliament	3
Member States' Government	7
Research Institute	19
Other	1

2. Opening address

Malcolm Harbour- Member European Parliament

Harbour emphasized the difficulties of evidence based policy making in relation to nanotechnologies. He argued that a multidisciplinary approach was required to address, in depth, many nano-issues. He believed that the communication, such as that organised by NanoCap, was important to keep up the dialogue with the Parliament and with the different stakeholders.

3. Introduction to the NanoCap project

Pieter van Broekhuizen (IVAM-NanoCap)

An overview to the NanoCap project was given by its coordinator, van Broekhuizen. He explained how the project was set up and provided a short overview of the results and societal demands of the NGOs and trade unions involved.

NanoCap, he explained was a capacity building project for trade unions and environmental NGOs granted by the FP6 - Science & Society programme. It was conducted over the period September 2006 – September 2009 and involved 5 environmental NGOs, 5 Trade Unions and 5 Universities under the coordination of IVAM UvA (NL). The participating institutions were based in many European and (by membership of one of the partners) several non-European (North African) countries. NanoCap operated through focussed working conferences, position discussions and workplace visits. It covered the following topics: technical issues, environmental issues, occupational health and safety issues, ethical issues and benefits of nanotechnology.

The project has contributed to the public nanodialogue via discussions with members, authorities, industry and the public.

TUs and NGOs in the nano-discussion

The conclusions to be drawn from the project was that the capacity building of NanoCap was successful in supporting Trade Unions and NGOs in developing their position statements. The increase in knowledge gained by the partners did not result in an aversion to nanotechnologies. Trade Unions and NGOs were able to develop collective European position statements, sometimes complemented with national refinements. A key role in both statements was the precautionary approach to the use of nanomaterials.

Workers' interests in nanotechnologies

The goals for Trade Unions is their aim to ensure a safe workplace for all working with nanotechnologies and nanomaterials. Nanotechnologies and manufactured nanomaterials might have considerable potential for the development and application of new products, certainly technological improvements will emerge and new jobs will be created in this field. However, the trade unions' call for a transparent and independent risk assessment is essential. The precautionary approach should be applied in cases where data is lacking. According to their position, legislation for nanotechnologies should be realised and complied with.

NGOs interests in nanotechnologies

The responsible governance of nanotechnologies and nanomaterials, along with their various applications, is crucial for environmental NGOs. The backbone of such governance is the adoption of a strict regulatory framework which will ensure environmental and human health safety, while following the principle of sustainability. Furthermore, environmental NGOs demand that the precautionary principle should be employed in nanomaterials development and use until there is an adequate EU regulatory framework for nanomaterials oversight.

At present, according to the NGOs the highest priority should be given to consumer products already on the market or in near-market stage, which should with no delay be comprehensively assessed on their human health and environmental impacts. A key challenge is to ensure that the setting up of a long term action plan, engaging all stakeholders in an open discussion, at an early stage of development of this powerful, innovative, high-end technology so as to ensure that it moves towards the resolution of many of the world's current problems without posing environmental, social, economic and health hazards to humans and the environment.

Lessons from NanoCap

It is difficult to identify products manufactured with the use of nanotechnology. At the same time, due to a lack of knowledge, it is difficult to judge the benefits from nanotechnology. Policy instruments must be used to balance the two ends of the scale: *economic value* (claimed benefits, replacement of scarce raw materials, stakeholder interests, "nanotech index", new job creation) balanced against '*acceptable*' risks (hazard and exposure assessment, risk behaviour, uncertainties). A simple weighing of the pros and cons is not possible.

Taking the precautionary approach seriously is an essential but difficult task. To accept precautionary measures (possibly comparable to preventive measures), might be problematic for many companies. Initiatives like the voluntary Code of Conducts may be helpful guides but, the view of the TUs and NGOs, this that these types of voluntary systems cannot replace binding legislation.

Building blocks for a precautionary nano approach

A starting point for the trade Unions and the NGOs is to make the precautionary approach more practical for industrial practice, to accept the somewhat adapted REACH adagio: *no data* → *no exposure*. To achieve transparency on the composition of nanoproducts, a notification obligation for manufacturers as well as suppliers of nanoparticles / nanomaterials used in products is essential. This would enable the user of such products to make a reliable risk assessment (declaration of type and amount of NP in the product to an independent body and declaration of nano-content of product through the production chain). In this respect, the Material Safety Data Sheet can be used to create a transparent risk communication. The MSDS should supply information on known nano-risks, how to manage the risks, and info on the existing knowledge gaps. Additionally there is the call to provide a Chemical Safety Report (REACH) also for substances brought at the market in lower tonnages: >1 ton/year/company).

In the workplace, exposure registration should be obligatory. This could be based either on the registration for carcinogenic substances or for reprotoxic substances. Nano-OELs (occupational exposure limits) should be derived. For those nano-substances where hazard data is lacking a worst case approach could be applied by deriving nano reference values¹, using well considered safety factors as proposed by NIOSH (National Institute of Occupational Safety & Health). A hazards ranking system for nanoparticles could be established as proposed by the British Standards Institute. At the same time, workers who are potentially exposed to nanomaterials should be regularly monitored to identify any adverse affects as early as possible (development of an early warning system). The building blocks can be summarised as follows:

Building blocks for a precautionary nano approach

- No data → no exposure
- Notification nano product composition for manufacturers and suppliers
 1. Declaration of type and amount of NP in the product to an independent body
 2. Declaration of nano-content of product through the production chain
- Exposure registration for the workplace
 1. Analogue to carcinogenics registration for nano-fibres and CMRS–nanomaterials
 2. Analogue to reprotox registration for other non-soluble nanomaterials
- Transparent risk communication
 1. Information on MSDS on known nano-risks, management and knowledge gaps
 2. Demand a Chemical Safety Report (REACH) for substances >1 ton/year/company
- Derivation of nano-OELs, nano reference values for:
 1. fullerenes, SMCNT, MWCNT, Carbon Black, nano- polystyrene and dendrimers
 2. Ag, Fe, TiO₂, CeO₂, ZnO, (amorphous)SiO₂, alumina, nanoclay
- Development of an early warning system
- Measures to avoid marketing of “non-sense”products

Measures to avoid the marketing of ‘non-sense’ products

Although it is almost impossible to define clear and unambiguous criteria for what type of products should be classified as ‘non-sense product’, it is clear for all CSOs that products should not be brought on the market if they introduce new, or uncertain risks to health or the environment, while their claimed good or beneficial performance cannot be substantiated.

4. Governance and Ethics of Nanotechnologies under the Science in Society programme of the EU’s Framework Programme for Research

Peteris Zilgalvis (Head of Unit. Ethics and Science. European Commission)

Zilgalvis gave a brief explanation of the diversity of nanotechnologies, the evolvement of Ethics & Governance of Nanosciences and Nanotechnologies under the Science in Society Programme: ethical acceptability of technology, early identification of benefits and risks, European and international research cooperation and governance. He argued that the lessons that were learnt from the GMO debate should be taken seriously. While in the R&D stage there was public concern and involvement of all stakeholders, ethical issues have to be emphasized by the need to balance privacy and security. It is the challenge for governmental institutions, research and the industry to involve civil society actors in the discussion on nanotech research. He believes that the NanoCap project provides an example of this, creating tools to discuss the acceptability of technology. A reliable assessment and balance of product benefits against product safety is crucial. Also, mapping governance and ethics issues at EU and international levels is essential.

He emphasized the current risk issues: safety, ethics, research on risks; application of precautionary principle; implementing the Code of Conduct; at the same time he highlighted that the EC is committed to public debate.

The European Commission policies include: the adoption of a European strategy for nanotechnology (May 2004) and the Action Plan (June 2005) emphasizing the need for a “safe, integrated and responsible development of nanoscience and nanotechnology; announcement of the adoption of a

¹ As proposed by BSI (2007)

Code of Conduct at international level; Implementation of International Dialogue. Now the EC recommends Member States to adopt the Code of Conduct in national policies, to be used as an instrument to encourage dialogue at all governance levels among policy makers, researchers, industry, ethics committees, civil society organisations and society at large. The deadline to inform the EC about the Member States' activities, as stated in the EC Code of Conduct, is February 2010 (but so far, there has only one response been received); Cooperation with the EC to monitor and review the Code of Conduct biannually is foreseen.

NanoCap enabled Civil Society Organisations to elaborate on views on nanotechnologies and thus to contribute to an informed public debate; its results can feed into ongoing multi-stakeholder dialogues. It is an early example of a more deliberative approach of RTD (Research and Technology Development) policy. No debate-fatigue: today is an example!

5. Nanotechnologies – Assessment of Technological Potential and Policy Implications: a STOA Perspective

Mikos Györfi, STOA – European Parliament

In the presentation the mission STOA was explained. This is to provide parliamentary bodies with independent high-quality and scientifically impartial studies. This allows the identification for the best course of action which can then be carried out with the support the European Parliament (EP) in its role as legislator. STOA's work has long-term objectives and differs from the work of the EP Secretariat General's research departments.

STOA deals with a variety of issues of science and technology covering all areas relevant to the work of the European Parliament. Outstanding research subjects of STOA in the past legislature were those associated with nanotechnologies and nanomaterials. As such the technology assessment of the convergence of nano-, bio-, info- and cognosciences was analysed and it was established as crucial factor for the control of the process and who benefits of it. Another STOA project dealt with the possibility of substituting dangerous chemicals by nanotechnology. Results stated that currently nanotechnologies cannot replace hazardous substances, but nevertheless there is considerable potential for substitution. The need for a lifecycle approach in this respect was emphasized. STOA also participated in events discussing the potential of nanotechnologies.

6. Trade Union position, perspectives and discussion

Joel Decallion – Confederal Secretary of the European Trade Union Confederation (ETUC)

The European Trade Union Institute (ETUI) as partner in the NanoCap project prepared the trade unions' positioning which was agreed by the Members of the ETUC who came together in a Nano-working Group and prepared the European Trade Union position. This was adopted as the ETUC resolution on nanotechnologies and nanomaterials in 2008.

The ETUC is convinced that nanotechnologies and manufactured nanomaterials might have a positive potential in technological improvements and in the creation of new jobs, but there are concerns about potential risks to human health and to the environment; they call for an in-depth debate.

The ETUC Resolution addresses the following issues:

1. Marketing The REACH adagio "*No data → No market*" must be applied as a general frame for nanotechnological products that are intended to be introduced to the market. However, the registration procedure in REACH must be modified in order to cover all nanomaterials, including those produced or imported in quantities below 1 ton/year. At the same time, better communication and risk assessment in the workplace is needed.
2. Workers Protection: Workers and their representatives have to be involved in the organisation and performance of workplace risk assessments. As part of the precautionary approach, the Chemical Agents Directive 98/24/EC should be amended to require employers to implement risk reduction measures when the hazards of (nano)substances used are still unknown. Workers' information about nanomaterials that may be present in products to which they are exposed to has to be

improved. To do this, safety data sheets must state whether nanomaterials are present. Training and health surveillance for workers exposed to nanomaterials is necessary, as are measures for exposure control.

3. R&D The budget for health & environmental risk research must be increased. This means at least an allocation of 15% (currently 5%) of public research budgets for nanotechnological health and environmental risk research; this holds for both at national and European level. At the same time, an essential element for all NT research projects should be the inclusion of an health & safety assessment as a compulsory part of the reporting.
4. Terminology A standardised terminology for nanomaterials is urgently needed to prepare meaningful regulatory programmes. For that reason, the ETUC calls on the European Commission to adopt a definition of nanomaterials which is not restricted to objects below 100 nanometres in one or more dimensions.
5. Legislative framework in the EU The ETUC's examination of the current legislative framework has identified several loopholes. Some regulatory changes are needed:
 - Amend the Chemical Agents Directive as well as REACH for a better coverage of all potentially manufactured nanomaterials. A Chemical Safety Report has to be provided for materials on the market below 1 ton/year production volume.
 - Apply the precautionary approach 'No data → no exposure' in the sense that workers' exposure should be *avoided as much as possible*.
 - Voluntary initiatives and codes of practices may be useful if some conditions are met, but nanotechnologies *need proper legislation*.
 - In order to secure that the implementation of preventive measures is effective and is complied with, *penalties* would be a potential instrument if obligations are not complied with.
6. Consumers' protection The ETUC wants all consumer products be labeled if they contain manufactured nanoparticles which could be released under reasonable and foreseeable conditions of use or disposal. The ETUC calls on Member states authorities to set up a *national register* on the production, import and use of nanomaterials and nano-based products.
7. Application of the Precautionary Principle Preventive actions must be taken where uncertainty and lack of knowledge prevails. This is an essential prerequisite for the responsible development of nanotechnologies and for helping to ensure society's acceptance of nanomaterials. The registration process at REACH is a clear example of how precautionary is applied to register substances, as well as the implementation of risk assessment for all materials.

As a final remark: Undoubtedly, there are some benefits. However, to gain more credit for those benefits, the amount of knowledge (e.g. performance and wear, environmental fate, toxicity) about nanotechnology (nanoparticles) needs to be increased.

7. Nano at work debate: next steps, implementing safe work practices and a precautionary principle

Panel: Tony Musu (ETUI), Frank Barry (AMICIUS/UNITE Irish-British trade union), Willem-Henk Streekstra (Business Europe,) Jan Cremers (MEP), Antonis Angelidis (European Commission-DG Employment).

Chair: Ben Nemery (Medical Faculty - Catholic University Leuven)

The Chair opened the discussion and stated that there were two important principals for implementation:

1. that the precautionary principle is the most important principle that has to be implemented in the development of nanotechnologies and
2. that life cycle assessment (LCA) is the other important principle that would be necessary to assess the impact of nano related products.

SUMMARY OF THE DEBATE

For a better understanding of that debate, the major issues discussed are summarized below.

Health & Safety strategy: The majority of the panellists agreed that health & safety should become an integral part of all research projects. For instance, health & safety practices regarding nanomaterials and products should be adjusted to a precautionary approach if enough reliable data are lacking. However, some of them pointed out that gaps should be identified and a strategy should be developed to fill them. As a general approach, health & safety should always be addressed in one way or another in every research project.

Legislative issues: According to industry and the European Commission, both existing EU and national legislation handle the risks properly; to their opinion current legislation is sufficient to deal with nanotechnological risks. In contrast, it was stated from the trade unions' side, the MEP and the general audience that it is necessary to amend some current loopholes in legislation and to derive proper legislation for nanomaterials. Gaps, either in REACH or in the Chemicals Agents directive, have to be closed amended to protect workers involved in the use of nanomaterials.

Chemical Safety Report and Safety Data Sheets: As a general opinion, the panellists consented on the lack of sufficient knowledge about nanomaterials and protective measures. The differences of working between closed and opened systems, were highlighted, the industry stated that the application of the precautionary principle was precisely working in closed systems. The discussants agreed on the necessity of improving the content of the Safety Data Sheets and to extend the obligation to provide Chemical Safety Reports to the lower tonnage nano-substances as well.

Codes of Conduct: Here the debate separated into two positions. The representative of the Industry claimed that there was no need for any additional codes of conduct. On the other hand, the trade unions' representatives outlined the difficulties of enforcing them. They highlighted the lack of compulsory measures in the event of non compliances with such voluntary Codes in the industry.

Other issues such as labelling, standardisation, patents and hazards detection, were briefly touched. The panel agreed that there was the need for more research on the health and safety and environmental aspects of nanoparticles and called for an open dialogue between all stakeholders.

DEBATE

Cremers stated that, in dealing with health & safety practices regarding nanomaterials and products, the precautionary principle should lead. At present many workers are working under conditions of major uncertainty concerning health risks. The efficiency of the OHS management in place is uncertain.

Streekstra under the name; Business Europe represented the Dutch employers' organisation - VNO/NCW. He summarised the activities of the working group Risks of Nanotechnology, a Platform on Risk management of Nanotechnology, initiated by industry. Additionally, there is the Dutch SER (Social Economic Council) report Nanoparticles at the Workplace (2009). The Dutch deliberative platform between TU's, NGO's, industry and the government works as a good instrument (a reflection of the so-called "Polder-model"). In the first week of April 2009, the SER-advice on how to deal with nano at the workplace was presented to the Minister of Social Affairs. Streekstra stated that according to this document there is no need for an additional code of conduct, since the current EU and national legislation handles the risks properly: present legislation is sufficient to deal with nanotechnological risks.

Barry emphasized that the debate on the development of new technologies was ongoing for 10 years. The two main issues were that the Trade Unions did not want a second asbestos scandal. There was the absolute need for data in order that workers were informed of the risks of nanomaterials and their use in the workplace.

Musu stated that his opinion is in line with Cremers. It would be most important to tackle the legislative issues in the EU. At present there are many shortcomings and loopholes that should be resolved. He opined that health & safety should become an integral part of all research projects.

Streekstra reacted that this has been discussed in the Netherlands. At present the situation is that industry does invest in health & safety for all their projects. The question is, should this combination of technical and risk research be done in all cases, and if so, how or in what way? As there are many

different types of research, different materials and applications. From a company perspective it would not be reasonable to allocate a fixed percentage to the health & safety investments per project. On the contrary, this should be defined project-specific.

Angelidis reacted that he is very open to an internal and external dialogue on this subject. Currently, there is a gap in the scientific knowledge related to the behaviour and characteristics of nanomaterials and products. However, much is already known. Gaps should be identified and a strategy should be developed to fill them. However, in every research project, health & safety should always be addressed in one way or another.

Musu added to this by stating that the TU's position was that each research paper should contain a section which covers the identified health & safety issues related to the topic and the measures that have been taken to prevent possible risks.

Axel Singhofen, (Adviser for Health and Environment Policy, The Greens) reacted from the audience that there is a clear need to change legislation (ETUC statement), Cremers mentions similar needs. However, the Commission still states that the current legislation is sufficient. Question to Angelidis: is the Commission now going to revise its statement?

Angelidis: responded by stating that a health and safety strategy is essential. But he added that scientific evidence is needed for policy making. Until that is it the Chemical Agents Directive (CAD) that sets the frame – employers have the legal responsibility to deal with risks.

Streekstra: stated that we cannot wait for scientific evidence. According to him the precautionary principle is already applied in the form of the occupational hygiene strategy (in CAD). Possible exposure in the workplace is managed by working with nanomaterials in closed systems and by taking exposure measurements. Furthermore, there is a CoC in place on how to apply the precautionary principle. Main principle of companies is to do their best to eliminate risk. It was his opinion that the Dutch Code of Conduct works well.

Musu reacts that there is a loophole in the CAD (98/24/EC) (Chemical Agents Directive) that applies to all chemicals regardless of the quantity used. The primary obligation for employers is to perform a risk assessment in case a substance used at the workplace is identified to be hazardous. In the case where the hazard data are lacking, the substance will not be identified as a hazardous substance with the consequence that no risk assessment is performed and risk management measures are not put in place. An amendment of the CAD should be made to require employers to implement risk reduction measures when the hazards of (nano) substances used are still unknown. And as long as the hazard (and therefore the risk) is unknown, any exposure has to be avoided. This means, for example, to work with a closed system to minimize the risk. There are companies, though, that on a voluntary basis follow this precautionary behavior in a strict way.

Nemery put the following question to the panel: Is it OK to apply nanomaterials and not to know the hazards or not to know how to measure these hazards or how to detect them?

Angelidis responded to this question by stating that REACH can be interpreted differently. However, there is a focus on risks for workers. Very few substances are safe. There is a difference between the precautionary principle and the minimum occupational health & safety approach. Member States have the duty to take action to evaluate the significance of the measures taken to protect the workers against risks. It is important to recognize that on this topic there are big international differences.

Barry stated that there are a lot of difficulties with the enforcement of voluntary codes. In the case where a company fails to address the hazards of any substance because of their unknown effects and fails to apply the voluntary code of conduct in place, the results of such a position is at the very least vague. He stated that there was no penalty to be applied in such circumstances. It was his opinion that changes to legislation or amendments to existing legislation are necessary to protect workers.

Audience: The Canadian workers' representative speaking from the audience highlighted the uniqueness of the European approach. He stated that the ongoing debate in Canada and North America does not include a debate between industry on the one hand and NGOs and TUs on the other. He stated that he didn't believe that under the present circumstances, the arguments to develop

new legislation are not sufficient. The problem is known but as the extent of the problem is not clear, you cannot say that you do not need further legislation.

Streekstra reacted that regulation might help but would not be enough, and that it is more important to reach an agreement with NGO and TU to work on the future. Voluntary codes are therefore very important. Multinational companies use different standards, global standards are about to be reached. SMEs are fully aware of the issue, but have no knowledge; they need to be helped by providing information to them. It is not an asbestos era anymore, multinationals have different attitude these days. The expectation is, though, that not all industry will follow the CoC.

Cremers was sceptical; most of the time people are really sceptical about soft laws (i.e. voluntary code of conducts)

Audience: Ulrik Spannow (Danish Construction Workers Trade Union) stated that the EU approach is well appreciated: the current status is that workers do not know, employers do not know and enforcers do not know much about in which products nanomaterials might be contained, and what protection measures to take. So we need action now! How to urge the member states to draw up action plans in the field of nanotechnology at workplaces? Just to make sure that directives are given on the national level until we wait for the European solution.

Barry replied by stating that, at the average workplace, nano is unknown and that there should be a health & safety strategy for the workplace. It is a question of awareness. What is it? How to deal with it? It is important to have a position on it.

Angelidis replied that there is already some knowledge on nano, but it is still not enough. More research is needed to gather information. For this, an open dialogue with the stakeholders is necessary, in order to have a proper new action plan for 2010-2015.

Streekstra reacted that the logical place is to communicate nano in the Material Safety Data Sheets (especially concerning the size specification). It is difficult to discern the complete supply chain due to the global trade. That's why it is important not to have different systems between Member States, so we suggest that REACH, covering the whole European level, provides a good starting point

Audience: In order to apply the precautionary principle (PP), more knowledge would be needed, since how to know whether the application of the PP were necessary?

Angelidis stated that a focus on the minimum requirements is more efficient.

Musu explained that REACH is based on the precautionary principle. An example of how this principle should be applied in practice can be illustrated with dossier registration. Under REACH, producers have to register their substances prior to marketing to show that they can be used safely. When safety data are based on a test that is known to be inadequate for nanomaterials, this information should be considered as missing and the registration dossier incomplete. As a consequence, the producer should not be allowed to market its substance until the registration dossier is completed. This will also be an incentive for adequate nano-safety tests to be developed.

Audience suggested: only permitting the use of closed systems: would that be feasible?

Streekstra replied that production of nanomaterials "in general" takes place in closed systems; application of nanoproducts is normally not in closed systems. The risks appearing in the product chain have to be thoroughly studied, since implementing conditions comparable to a closed system along the whole production chain is impossible. Still each case is different. One should communicate to the workers that effective risk assessment and risk management are possible.

Musu confirmed that there are companies using closed systems. Safety data sheets need to be improved, and adapted to reflect the risks of nanoparticles, and additional training for employees is necessary.

Barry: The transfer of nanoparticles from the closed system to the open system is the key problem. Here expertise is needed. This might be done through the chemical safety report as set out in REACH.

Audience: How about the comparison of Nano to GMO?

Angelidis stated that nano and GMO are not well comparable. However, what they do have in common is that labelling is an issue, which could be an instrument useful for differentiation.

Audience: According to the adagio *no data → no market*, regulation is of no great use. France and the United Kingdom are currently developing regulation to allow production of CNT only in closed environments. Standardising is an interesting instrument.

Streekstra confirmed that there is a lot of discussion ongoing on standards for nano.

Angelidis emphasized that the determination and definition of nanoparticles and materials is needed first.

Audience: Obligation cannot be fulfilled. In the absence of a proper risk assessment method, legislation acts blindly. BUT workers have to be protected.

Audience (Health Ministry France): What is the commission's response on standardization of carbon nanotubes? Is a Code of Conduct a useful tool in this respect?

Angelidis: It is necessary to have a full agreement on definitions before taking action.

Nemery: Will this conference speed up the process?

Angelidis: Since it is a multidisciplinary question, this conference cannot be the only necessary input.

Streekstra: This conference helps in many ways to speed up the process!

Nemery: The departments of universities also need instil the health and safety issue. Researchers of the academy in terms of education have the duty to talk about these issues upstream. At the same time patents should not be accepted unless there is something that tells something about the safety of production and development of these new materials. Sometimes we do not need precautionary principle, just elementary prevention principle, since there are already some risks we already know already, and precautionary principle is necessary only for unknown risk. They made to be very reactive, to have different biological effect, but prevention is enough, no necessary need for precautionary principle.

8. Environmental NGOs position, perspectives and discussion

John Hontelez (Secretary General of the European Environmental Bureau)

Hontelez presented the common views and positions of five NGOs involved in the NanoCAP project, Baltic Environmental Forum, EEB, LEGAMBIENTE, MIO-ECSDE, and Natuur en Milieu. The main message of the NGOs is: There is an urgent need for sustainable and responsible governance of the development and use of nanotechnologies, covering both nanomaterials and nanoproducts, at national and EU level.

Nanotechnologies promise to bring improvement in many sectors: healthcare, environment, energy, electronics. However, as yet only limited societal benefits have been brought about by most of the commercially available products currently on the market. The optimistic expectations on the benefits of nanomaterials may in some cases prove to be true. Thus, a strict regulatory framework, based on the precautionary and producer responsibility principles, should be adopted in order to ensure that these nanomaterials are developed and used, and that they are not posing threats to the environment and human health through their entire lifecycle.

Policy and regulation issue NGO demand

1. Existing legislation needs to be amended, to address nanomaterials more explicitly and comprehensively, and it needs to be reinforced to ensure safety to human health and the environment as envisioned in existing laws.

2. Development of a regulatory and policy framework for existing and future nanomaterials.
3. Implement the “no data → no market” principle in the real world. No further market introduction should be allowed for products containing manufactured nanomaterials until appropriate impact and safety assessment tests have been developed.
4. A clear, harmonised and internationally accepted definition of nano-technologies and nanomaterials should be adopted to avoid inconsistencies in risk governance and enhance the applicability of existing and future legal frameworks.
5. Nanomaterials as a whole should be defined, treated and labelled as a new class of substances.
6. Develop a pre-market registration and approval framework.
7. Guarantee transparency, traceability and provision of information to consumers through information on products that contain nanomaterials.
8. *Full lifecycle analysis including environmental, health, and safety impacts must be performed prior to commercialisation.*
9. **Current voluntary codes** for the safe development and the responsible use of nanoscaled materials should **become mandatory**.

Research and Development NGO demand

1. Nano-research and development should be driven by real societal needs and based on ecological, social and sustainable development considerations, but not on the ‘marketability’ of products.
2. Clearly identify the limitations of existing safety assessment and management tools in relation to nanomaterials.
3. In particular, there is an urgent need for additional toxicological and ecotoxicological studies, tests and protocols in order to assess health and environmental impacts.
4. All new nano-related projects receiving EU funding should be required to include a sustainability assessment and appropriate decision making mechanisms, including public participation.
5. A research strategy identifying a roadmap towards the safer development and use of nanomaterials in their different applications should be developed and implemented.
6. Sustainability assessment of (new) technologies tools should be developed, for their more systematic use in both research and product development.

Public awareness, Public participation & Decision making NGO demand

1. Transparent and effective communication of the risks of nanotechnologies to society is needed.
2. Environmental NGOs urge the European Commission and the Member States to immediately undertake an EU-wide public debate on nanotechnologies and nanomaterials.

Developing countries & countries with emerging economies – NGO demand

1. There is a need to place nanotechnologies and nanomaterials use in the context of development and employ these to meet internationally agreed poverty reduction goals, such as the Millennium Development Goals.
2. *Assure that no new risks to environment and health are created in developing countries as a potential dumping ground for nano waste or as an “easy”, not strictly regulated market.*
3. Nanoproductions should not become expensive alternatives to existing effective local technologies, e.g. in water treatment.
4. Nanoproductions should not substitute the products traditionally produced by developing countries.
5. Attention should be paid to specific risks that might affect developing countries due to their particular environmental and social conditions.
6. Partnerships should be established in order to assist developing countries or countries with economies in transition to build scientific, technical, legal and regulatory policy expertise related to risks of manufactured nanomaterials.

Clearly, much more work is needed on EU policy level to improve environmental and human health protection and to build governance structures based on the premise of public participation in decision-making, the precautionary principle and cradle-to-cradle product sustainability when addressing nano- and new technologies.

9. Nano and the environment debate - Panel discussion

Panel : Dragomira Raeva (EEB), Laura Degallaix (BEUC), Lena Perenius (CEFIC), Carl Schlyter (MEP), Henrik Laursen (European Commission DG Environment), Lucas Reijnders (University of Amsterdam)

Chair: René von Schomberg (European Commission DG Research)

SUMMARY OF THE DEBATE

The panel discussion focused on the following issues with respect to nanomaterials: risks assessment and management, regulatory requirements, and transparency of the market.

Risk assessment and management

Discussing the different aspects of risk management and the application of the “no data, no market principle”, some panellists pointed out that there are extensive data for some nanoparticles already (i.e. TiO_2 and SiO_2) including on the impact of airborne exposure on human health. It would be relatively easy to derive limits for exposure based on currently available information and already regulate for some nanoparticles. The lack of risk assessment methods for nanoparticles is not seen as a limitation by policy makers. There is already an initiative at OECD level on investigating the applicability of existing risk assessment methods to nanoparticles. In principle the tools to assess the risks are available, the Commission stated, the challenge is to make these operational for nanomaterials. Risk acceptability was challenged by the environmental NGOs. They claimed that the precautionary principle should apply when data are insufficient before the discussion on risk acceptability. Acceptability should in any case be decided by public debate. This was done for GMOs, and can be repeated for nanomaterials. In any case, risk communication tools should be applied ensuring timely communication with the public and all concerned stakeholders.

Acceptability is also linked to a discussion on which products containing nanomaterials are “good products”. Consumer groups made it clear that a good product is on the first place safe for the environment and human health. At least for cosmetics and foods there cannot be acceptance of risks that can be easily avoided by using nano-free products. Industry representatives insisted that risks and benefits need to be reviewed jointly, especially when considering the application of nanomaterials in green/ clean technology, such as in water purification.

Regulatory aspects

During a discussion on the mandatory registration of products containing nanoparticles, a European Parliament representative confirmed that this is the way to go until REACH is fully adapted to cover the registration of nano materials. Consumer groups backed up this position by highlighting that mandatory registration by industry would help gather public data on safety and toxicity. Industry however, opposed this view, claiming nanoparticles can already be dealt with within REACH, ensuring that about 80% of nanoparticles currently on the market will go into the first phase of REACH, before 2010. CEFIC also agreed that REACH will not cover everything and that the assessment methodology is not yet fully in place, but nevertheless existing methods are applicable, with some modifications. The mandatory registration of products sounded unappealing to industry though, with no clear benefits it would generate in addition to REACH registration of materials.

DEBATE

Von Schomberg: The panel discussion will focus on the following issues: risks, regulatory requirements, and transparency of the market. The first issue will be risks: the statement ‘no data → no market’ is often cited regarding nanomaterials. What does that mean? Do we have data and are they adequate?

Reijnders: We already know a lot. There are extensive data for some nanoparticles, especially TiO_2 and SiO_2 . Also there are data regarding the impact of airborne exposure on health. It would be relatively easy to derive limits for exposure based on what we know from research into particulate matter. We could already regulate for titanium and siliceous nanoparticles. It is strange that we have not done that yet. We also know a lot about certain applications, such as sunscreens. The risks to human health are linked to the photo-catalytic effect of the particles. Complete coating of these particles should be made mandatory. We can also regulate by analogy. We know that bacteria develop a resistance to antibiotics if they are regularly exposed to them. We could apply this

knowledge to limit the use of nano-silver, so that it remains effective in treating infection in burns. There is also an analogy between nanotubes and asbestos.

Von Schomberg: There are no risk assessment methods for nanoparticles. What does that mean for legislation in Europe?

Laursen: We are not starting from scratch. The OECD is investigating the applicability of existing methods. Some apply to nanoparticles, some don't. We have tools to assess the risks of many nanoparticles. The challenge will be to bring all the information together and make it operational. More work is needed but we have a good base to start from.

Von Schomberg: Once we have assessed the risks, how do we decide whether these risks are acceptable or not?

Raeva: We should apply the precautionary principle when data are insufficient. This comes before a discussion on which risks are acceptable. Acceptability should be decided by public debate. This was done for GMOs, it could be repeated. And consequently: no data → no market.

Question from the audience: We are already in the nano-world. Is the precautionary principle still relevant, or has its moment passed? There are worries in North Africa about the risks. REACH should be adapted to deal with nanomaterials quickly.

Von Schomberg : Is REACH based on the precautionary principle?

Laursen: The precautionary principle is set in the EU Treaty. REACH refers to it. Currently, there are 2.7 million pre-registered substances. It is difficult to say how the precautionary principle will be applied without having a concrete case.

Von Schomberg : Should risk assessment be mandatory?

Laursen: There is a difference between risk assessment and risk management. In absence of data, decisions will have to be made using – among other things – the precautionary principle.

Von Schomberg: Should there be mandatory registration of products containing nanoparticles? What is the opinion of the European Parliament?

Schlyter: A recent vote in the Environment Committee called for a public inventory of all products containing nanoparticles. This is not the same as applying the precautionary principle. REACH is not yet suited to deal with nanoparticles. The Environment Committee also voted to close the loopholes in REACH in the next two years.

Von Schomberg : Would mandatory registration work for companies?

Perenius: REACH is one of the most comprehensive chemical regulations in the world. It can already deal with nanoparticles: they can be registered at the same time as the bulk version of the same substance. In that way, 80% of nanoparticles currently on the market will go into the first phase of REACH, before 2010. REACH will not cover everything and indeed the assessment methodology is not yet fully in place. But existing methods are applicable, with some modifications. The industry wants to listen and take account of the concerns of stakeholders. We have to come to a shared vision of sustainable development. As to mandatory registration: what would be its purpose? What benefits would it generate in addition to REACH?

Degallaix: It is disappointing that consumer organisations were not included in the NanoCap project. There is a lot of concern about the potential effects of nanoparticles. Transparency about the uses of nanoparticles is necessary to assess exposure of consumers/citizens and the environment. Therefore we need mandatory notification by industry. Also the data on safety and toxicity need to be made accessible to the public. The Commission needs to ensure transparency to also allow for market surveillance, risk assessment and the withdrawal of products.

Question from the audience: In France there is concern about carbon nanotubes and their similarities to asbestos. Should we wait until REACH is completed in 2018 or should we take measures before that? Also it is necessary to develop nomenclature to properly manage the risks of nanoparticles. We have to be able to distinguish between different forms of the same nanoparticle.

Laursen: The development of a thorough nomenclature takes time. In the interim we will have to work with the vocabulary at hand

Degallaix: In France an inventory of products containing nanoparticles is under preparation. This will be a very useful tool that will help us evaluate the level of exposure. Labelling requirements for consumer products containing nanoparticles with which consumers come in direct or regular contact (e.g. cosmetics, food products) need to be imposed while an EU-wide inventory of nanoparticles-containing products is being developed. Such requirements could be to indicate the word 'nano' next to the name of an ingredient in the ingredients' list on food products as it will soon be required on cosmetic products according to the new regulation.

Reijnders: We need to speed up the process of data-flow. It takes a lot of time before research data reach the people who actually work with the products.

Perenius: Transparency is the cornerstone of the CEFIC strategy for responsible nanotechnology. The chemical industry sells mainly to business. Safety data sheets are required there; in REACH extended data sheets will eventually be introduced. Some companies already invest in educating both their workers and their customers.

Schlyter: It is good that industry is now working for transparency. This was not the case when REACH was being developed. This change of mood is helpful. Parliamentarians have a responsibility for what is allowed onto the market: it should be safe. This guarantee cannot yet be given for nanoparticles.

Question from the audience: In their presentation, the NGOs did not address the benefits of nanotechnology. The discussion focuses on the risks. The environmental benefits of nanotechnology in general should be taken into account, not just the risks of nanoparticles.

Raeva: EEB has developed a brochure listing potential benefits of nanomaterials. The NGO movement is not blind to the opportunities, but also not blind to the risks.

Question from the audience: In Tunisia the discussion on nanotechnology and its possible risks is limited to a very small circle. However, it brings back memories of mad cow disease and asbestos. Is there a technology transfer programme in the EU? Is attention being given to the implications of nanotechnology for global sustainable development and the gap between developed and developing countries?

Von Schomberg: The EU favours research that is driven by society when it comes to the millennium goals.

Question from the audience: 'Responsible' appears to be the new sexy adjective. It hides power relationships and conflicting interests. How responsible is responsible, if different actors have different definitions?

Von Schomberg : The Code of Conduct outlines a programme to promote responsibility. It is not just a question of enforcing, but of enabling, inviting, and persuading. The basic question is which actors will take up responsibility. There is a positive response to the Code of Conduct from industry and NGOs. The Member States are hesitant. Perhaps the European Parliament can help there.

Schlyter: Responsibility expresses a feeling. The European Parliament gives it meaning in its report. It also gives directions how to translate responsibility into legislation.

Von Schomberg: The issue of benefits was raised. What is currently on the market is not very exciting. What would be a good nano-product?

Degallaix: First we need to know which nanoparticles are safe. There is as yet no proof of the benefits (nor of the safety) of nanoparticles in products. So it is impossible to say what a good nanoproduct would be. In medicine there definitely will need to be a weighing of benefits and risks, but cosmetics and foods should be safe. There should be no acceptance of risks in cosmetics and foods. A good nanoproduct is a product that is shown to be safe without any compromise on its safety.

Laursen: Benefits should not be a pretext to accept risks that can be easily avoided. Safety first, to make benefits possible.

Perenius: Risks and benefits need to be reviewed jointly. But clean technology is needed, for example cheap, safe water purification. That would be a good nanoproduct.

Question from the audience: The NanoForum in France wants to initiate a stakeholder dialogue but finds it difficult to get companies to take part. Maybe this situation is better in other countries?

Perenius: It can be difficult to get a dialogue going. CEFIC will give the right information to the right audience in the right way. Industry needs to be in dialogue with stakeholders and take seriously what is being learned in the process.

Question from the audience: There is need for the general public for easy understanding of information. Next to mandatory reporting, there should also be ordinary reporting.

Degallaix: The public needs to be engaged in decision making. Risk communication tools should be applied. Consumers need the facts, and need to know about uncertainties.

Question from the audience: Do environmental NGOs have a suggestion which percentage of the research budget should be spent on safety, health and environment?

Reijnders: Currently, only a relatively small amount of money goes to risk research, probably no more than 5%. The NanoCap project wants to have this raised.

Von Schomberg: currently risk research is 7-8% of the budget under the EU Framework Programme. In FP7 there is 3.5 billion euro for nanoresearch. There is the need to spend that money wisely, also when it is applied to risk research.

Raeva: The EEB wants to increase the budget for risk research. Public participation and involvement in setting research priorities is essential.

Laursen: The Commission is engaged in dialogue with industry, NGOs and trade partners outside the EU. REACH has changed the burden of proof: now the producer has to prove that his product is safe. This should not be reversed in the case of nanotechnology, putting the burden of proof for safety on public authorities.

10. Conference Conclusions

Alfred Nordmann (TU Darmstadt)

Background

- The nanotechnology ethics portfolio (as written during the course of the NanoCap project) is work in process that will continue within and grow beyond NanoCap.
- What is needed is not a list of ethical concerns that are presented by well-meaning and sensitive or aware individuals but a representation of vital interests in the face of a new way of doing things. Such new ways are needed, since traditional precautionary and regulatory attitudes unwittingly imply a moratorium, and that is definitely not considered to be the preferred state. The message of nano: It can't wait for scientific evidence of safety or harm (which may never become available). And if for precautionary reasons all possibly nanoparticles emitting applications would have to be contained in close systems, it won't flourish in the market.

The conference had two significant dimensions:

- Within the existing framework of “responsible development of nanotechnologies by all stakeholders” the trade unions and NGOs highlighted and specified their genuine points of contention and decision making (e.g. regarding REACH)
- Beyond this, their powerful social involvement raises the stakes for political, deliberative negotiations on nanotechnologies.

Learning process:

1. Adapt the realities of nano (for now especially: nanoparticles) to regulatory expectations, safety concerns, precautionary approaches.
2. Develop new strategies and criteria for “responsible development” which soften the regulatory demands and yet do not fail us in the end.

This is a learning process for European knowledge societies and within NanoCap.

Strategies at work today:

1. Responsible (sustainable) development: Including codes of conduct, observatories, public engagement, ELSI-research (Ethical, Legal and Social Issues).
 2. Precaution: to see how far we can go without producing a moratorium. If we do not know that a substance is hazardous, let's treat it as if it were; preference on closed systems
 3. Spirit of “collective experimentation” – anxiety and euphoria. Toxicologists advertises knowledge gaps, economists don't, and their optimism about nano feeds the hopes of everyone.
- All today's discussants engaged in the tentative and careful balancing of unknown risks and unknown benefits. E.g. everyone agrees to “*no data → no market*”, but it is difficult to tune differences of interpretation into clear-cut decision items.
 - Concerted vigilance proceeds in the mode of conversation and mutual learning from all stakeholders, but there were hints today of stronger political deliberative moments and possibilities.

Deliberation beyond conversation:

1. Social movements assembled at the conference: stakeholders defined as advocates rather than being reduced to concerned individuals.
2. Injecting hard principles into soft law – social movements have the power to unilaterally apply the missing sanctions to the voluntary codes.
4. (No-) nonsense products and projects: the ensured societal benefit of nano is still missing. (missing agenda and research priorities)

11. Closing remarks

Mrs Dorette Corbey, MEP

It was a very encouraging event. I picked up a number of political points:

- A good legal framework is needed to manage the possible risks associated with nanotechnology. A legally binding framework is better than a voluntary one. Voluntary approaches work well in some countries, but not in others. This framework should include risk assessment.
- Communication is important. Labelling of products is only a first step. Consumers need to know more. The role of technology needs to be assessed. Technology can cause alienation and this could also apply to nanotechnology: it could alienate people from the products they use, from their houses, from their environment. Communication could help here.
- Who is in control? Is it business, science, governments, NGOs? NGO's definitely should be empowered to share control. What about the general public? NGOs not always represent the ordinary citizens. Techniques need to be developed to involve the public in decision-making. The mistakes made during the GMO discussion need to be avoided.

Brussels/Amsterdam
28/7/09

ANNEX I: PowerPoint presentations



Introduction to the NanoCap project

NanoCap conference Working and Living with Nanotechnologies

Thursday 2 April 2009
European parliament, Brussels
Pieter van Broekhuizen
IVAM UvA BV Amsterdam



NanoCap

Nanotechnology Capacity Building NGO's

FP6 Project, Science & Society programme

Capacity building project for trade unions and environmental NGOs

Working conferences, positioning discussions, workplace visits

- Technical issues
- Environmental issues
- Occupational health and safety issues
- Ethical issues
- Critical assessment of benefits

Contribution to public nanodialogue

- Discussion with members, authorities, industry and the public

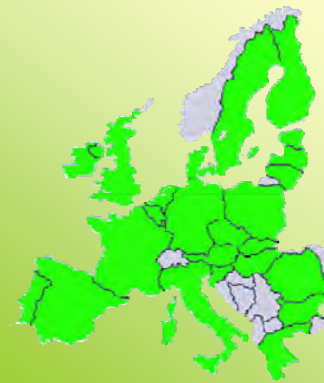
Period

- September 2006 – September 2009

NanoCap coordination



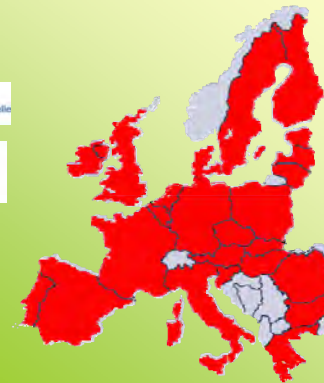
Environmental NGOs

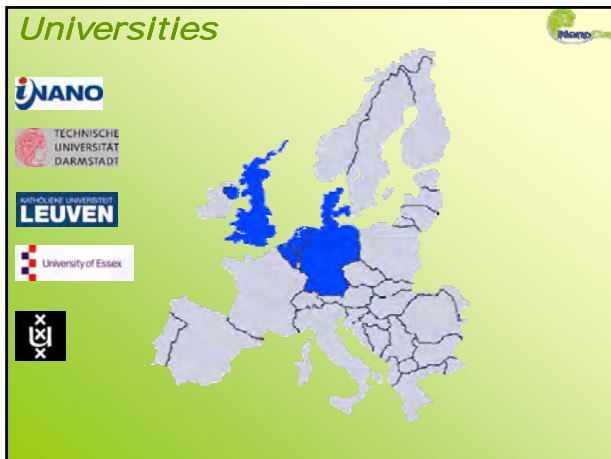


MIO - network countries



Trade Unions





TUs and NGOs in the nanodiscussion

- The capacity building of NanoCap was successful to support TUs and NGOs developing their nano-positioning
- The knowledge increase did not result in an increased aversion against nanotechnologies
- Both were able to develop collective European position statements, sometimes complemented with national refinements
- The TU and NGO positioning do not converge much
- The precautionary approach plays a key role in both positionings

Workers' interests in nanotechnologies

- Safe workplace
- Transparent and independent risk assessment
- Precautionary approach in case of lacking data
- Full compliance with legislation

NGOs interests in nanotechnologies

- Sustainable technologies and safe products
- Non-disperse use of nanoparticles
- Precautionary approach in case of lacking data
- Full compliance with legislation
- No nonsense products

What we learned in NanoCap many questions.....

- **Difficulties in recognizing nanoproducts**
 - Who are the nanoproduct manufacturers ?
 - Who are the professional users?
 - What is nano in the product ? *
 - Where are the nanoproducts ?
- **Difficulties in judging the benefits**
 - Are the benefits really benefits? (LCA)
 - Nonsense or no-nonsense products?



The nano-under pants....

With use of an innovative technological process originating from NANO-technologysofter optimal absorption....

Product packaging for HEMA RealCool Cotton underwear, featuring text in multiple languages and a barcode.

What we learned in NanoCap many questions.....

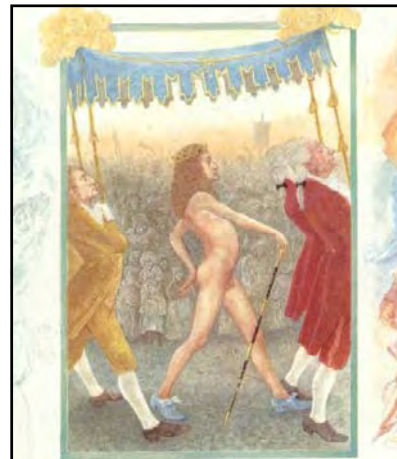
- **Difficulties in recognizing nanoproducts**
 - Who are the nanoproduct manufacturers ?
 - Who are the professional users?
 - What is nano in the product ? *
 - Where are the nanoproducts ?
- **Difficulties in judging the benefits**
 - Are the benefits really benefits (life cycle approach)
 - Nonsense or no-nonsense products?

Some examples of questionable benefits

- **Self cleaning roof tiles:**
What if a bird shits on the TiO_2 – UV catalysed coating.....?
selfcleaning or non-cleaning?
- **Car glass treatment:** water repellent and.....
helps save you money, too, by cutting down on windshield wiper replacements and the amount of washer fluid used.....?
durability after abrasion and a few rains.....?
and what about environmental pollution.....?

Some other examples Nonsense or no-nonsense ?

- **Anti-odor and anti-bacteria socks**
For healthy feet..... Wellbeing from pure silver
Other non-sterilizing anti-smelling options?
- **Bactericidal walls for surgery room**
Prevention of accidental infections.....?
- **Car exhaust NO_x converting road asphalts**
Efficiency in $\text{NO}_x \rightarrow \text{NO}_3$?
Environmental TiO_2 pollution.....?



Real benefits
or
the Emperor's
new (nano)
cloths
?

Balancing nano risks and claimed benefits



Economic value ? Health & Environmental risks



Taking the precautionary approach seriously

Essentials

- **Ignorance of precaution:**
 - Carrying out a social experiment, exposing society at large to NP and NT (quote Andrew Jamison)
- **Insight in nano properties**
 - Intended technical effect may (will) affect organisms in a similar way
- **Incorporate uncertainties in R&D, introduction and use of nanotechnologies**
 - in risk assessment and - management
 - in economical forecasts
 - in social and ethical aspects

Consequence of accepting a precautionary approach 1

- **Operationalising the precautionary approach**
 - Practical useable set of measures
 - Accept limited evidence as argument to take precautionary measures
 - Acceptance of the "risk" that with growing evidence initial preventive measures might have been chosen too strict
 - Inform about what you know *and* what you don't know
 - Comprehensible info for users of NP and NT
 - Transparent deliberations

Consequence of accepting a precautionary approach 2

- **Conditions for acceptance of Code of Conducts**
 - Organizing a more binding status
 - External monitoring of compliance
 - Call for a safety notice to be included with all journal publications (just reporting what precautionary measures did the researchers actually take)
 - Call for a uniform European CoC for industrial production (Prevent an unlimited proliferation of different CoCs)

Building blocks for a precautionary nano approach

- **No data → no exposure**
- **Notification nano product composition for manufacturers and suppliers**
 1. Declaration of type and amount of NP in the product to an independent body
 2. Declaration of nano-content of product through the production chain
- **Exposure registration for the workplace**
 1. Analogue to carcinogenics registration for nano-fibres and CMRS-nanomaterials
 2. Analogue to reprotox registration for other non-soluble nanomaterials
- **Transparent risk communication**
 1. Information on MSDS on known nano-risks, management *and* knowledge gaps
 2. Demand a Chemical Safety Report (REACH) for substances >1 ton/year/company
- **Derivation of nano-OELs, nano reference values***
 1. fullerenes, SMCNT, MWCNT, Carbon Black, nano- polystyrene and dendrimers
 2. Ag, Fe, TiO₂, CeO₂, ZnO, (amorphous)SiO₂, alumina, nanoclay
- **Development of an early warning system**
- **Measures to avoid marketing of "non-sense"products**

Proposed nano reference values (benchmark exposure levels*)

Cat	Description	Benchmark levels	Remarks
1	Fibrous, insoluble NM	0,01 fibre/ml	In analogy with asbestos
2	NM CMRS in its molecular or larger form	0,1 x OEL	NM potential increased dissolving rate Safety factor 0,1
3	Insoluble or poorly soluble NM (not covered under i or ii)	OEL / 15	In analogy with NIOSH (2005) Increased surface → increased reactivity SF = 1 / 15 (x 0,066)
4	Soluble nanomaterials (non i-iii)	0,5 x OEL	SF = 0,5

* As proposed by BSI (2007)




 **Governance and Ethics of Nanotechnologies under the Science in Society programme of the EU's Framework Programme for Research**


European Commission
Research DG

Head of Unit Governance and Ethics,
Péteris ZILGALVIS, J.D.



 **Overview of this Presentation**


1. Evolvement of Ethics & Governance of Nanosciences and Nanotechnologies under the Science in Society Programme: What is at Stake?
2. Prospective issues
3. European Commission policies and commitments




 **NANOTECHNOLOGY. WHAT IS AT STAKE?**


- Ethical acceptability of technology
- Early identification of benefits and risks
- European and international research cooperation and governance







 **LESSONS FROM THE GMO DEBATE**


- Early intervention of society in RTD Stage
- Early involvement of all stakeholders
- Creating regulatory oversight and certainty




 **NANOTECH IS DIVERSE**

Human Health		Nanomedicine
Detectors/surveillance		Security
Environment		Safety



 **(PROSPECTIVE/CURRENT) ETHICAL ISSUES**


- Human enhancement- ICT brain implants, augmentation of senses, retardation of ageing
- Predictive Nanomedicine: growing gap between diagnosis and possible therapy
- Surveillance and Detection: Balance between privacy and security






CHALLENGES

- Involving civil society actors in nanotech research: Project NANOCAP provides an example!
- Acceptability of Technology: product benefits and product safety are crucial
- Map governance and ethics issues at EU and international levels

(PROSPECTIVE) CURRENT RISK ISSUES

- Safety, Ethics, Research on Risks
- Application of Precautionary Principle
- Implementing the Code of Conduct
- EC is committed to Public Debate





European Commission policies

- Adoption of European Strategy for Nanotechnology (May 2004) and Action Plan (June 2005) emphasizing the need for a "safe, integrated and responsible development of N&N."
- Announcement of adoption of Code of Conduct at international level
- Implementation of International Dialogue, but failed to adopt a CoC





EC recommends Member States

- CoC to be used as an instrument to encourage dialogue at all governance levels among policy makers, researchers, industry, ethics committees, civil society organisations and society at large
- Inform the EC by February 2010
- Cooperate with EC to monitor and review Code biannually

NANOCAP

- NANOCAP enabled CSO's to elaborate views and thus contributes to informed public debate
- NANOCAP results can feed into ongoing multi-stakeholder dialogues
- Early example of a more deliberative approach of RTD research policy
- No debate-fatigue: today is an example: Congratulations



European Parliament, DG Internal Policies of the Union, Directorate A: Economic and Scientific Policy, Policy Department, STOA (Science & Technology Options Assessment)

Nanotechnologies - Assessment of Technological Potential and Policy Implications: a STOA Perspective

Paula Hernández, dr. Miklós Györffi,
Policy Department A: Economic and Scientific Policy
DG Internal Policies, European Parliament

Working and Living with Nanotechnologies, 2 April 2009, European Parliament Brussels

European Parliament, DG Internal Policies of the Union, Directorate A: Economic and Scientific Policy, Policy Department, STOA (Science & Technology Options Assessment)

STOA Rules - Mission

Article 1(2): "... STOA shall:

- provide Parliament's ... parliamentary bodies ... with independent, high-quality and scientifically impartial studies ... for the assessment of the impact of possibly introducing or promoting new technologies and shall identify ... the options for the best courses of action to take ..."

Article 1(3): "STOA shall carry out its work in such a way that the results are relevant to the European Parliament in its role as legislator."

Article 1(4): "STOA's work shall have long-term objectives and it shall differ from the work of the Secretariat's research departments, the task of which is to meet specific sectoral or short-term requirements".

Working and Living with Nanotechnologies, 2 April 2009, European Parliament Brussels

European Parliament, DG Internal Policies of the Union, Directorate A: Economic and Scientific Policy, Policy Department, STOA (Science & Technology Options Assessment)

STOA Rules - Studies of Technology Assessment (Article 6)

- Studies of technology assessment should provide an answer to medium- to long-term, complex and interdisciplinary problems relating to the impact of scientific and technological developments on society.
- The proposals submitted for that purpose are approved by the STOA Panel on the basis of the following criteria:
 - relevance of the subject to Parliament's work, scientific and technological nature of the proposal, and
 - availability of scientific evidence covering the subject.

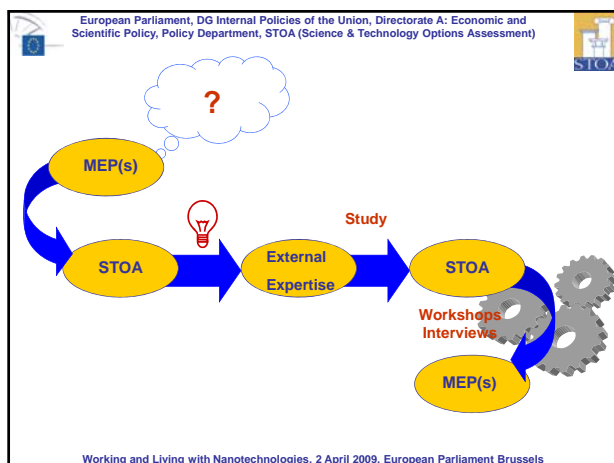
Working and Living with Nanotechnologies, 2 April 2009, European Parliament Brussels

European Parliament, DG Internal Policies of the Union, Directorate A: Economic and Scientific Policy, Policy Department, STOA (Science & Technology Options Assessment)

The STOA profile

- STOA work is focused on the scientific assessment of the impact of new technologies and identification of policy options relevant to Parliament's role as legislator.
- STOA projects address medium to long-term issues and are distinct from the projects financed from the expertise budgets of committees.
- STOA maintains contacts and cooperation with other parliamentary technology assessment bodies, in particular with members of the EPTA (European Parliamentary Technology Assessment) network.
- STOA establishes links with the scientific community, as well as with society at large, as the recipient of the consequences of science and technology policy.

Working and Living with Nanotechnologies, 2 April 2009, European Parliament Brussels



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Recent STOA activities linked to Nanotechnologies

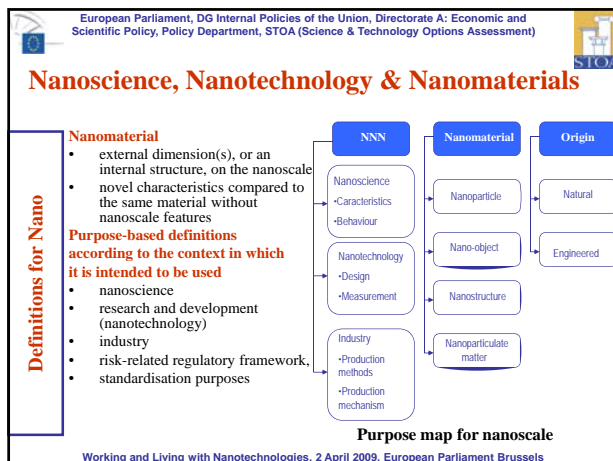
Projects:

- Technology Assessment (TA) on Converging Technologies (viWTA)
- The Role of Nanotechnology (NT) in Chemical Substitution (ITAS)
- Nanotechnology - Threat or Opportunity ? Workshop in the EP, 5 March 2008 (Karita Research)
- *Future: Nanosafety*

Links with the scientific community, as well as with society at large:

- Collaboration with the European Commission:
 - European Forum on Nanosciences - 19-20 October 2006, - Nanocafé - Will Nanosciences Shape Future Society and How Will Citizens Benefit from it ? - Nanologue Project
- Participation in external events:
 - Roundtable "The Ethical Aspects of Nanomedicine", 21 March 2006, Brussels
 - Conference "Nanotechnology – Products and Processes for Environmental Benefit", 16 – 17 May 2007, Royal Society, London

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Political questions

Workshop held in the EP in Brussels on June 27, 2006 based on the **literature study and vision assessment**

Dorette Corbey, MEP, member of the STOA Panel:

- Who is in control?
- What are the values of converging technologies and what is the impact on society? Who benefits?
- Where are converging technologies headed? Is countervailing power possible?
- Popular support: are Newbics applied in the service of humanity? How can we organize the debate arena?

TA on Converging Technologies

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Literature Study - Objective

TA on Converging Technologies

- Three perspectives on NBIC convergence:
 - Historical
 - Overview of the public debate risen in the past few years
 - Technological
- Provide an accessible and well-informed basis for the discussion on the social impact of nano, bio, info and cogno sciences (NBIC) convergence
- Informing policy makers and politicians about how the public and political debate on NBIC convergence is developing and what role they can play in this upcoming discussion

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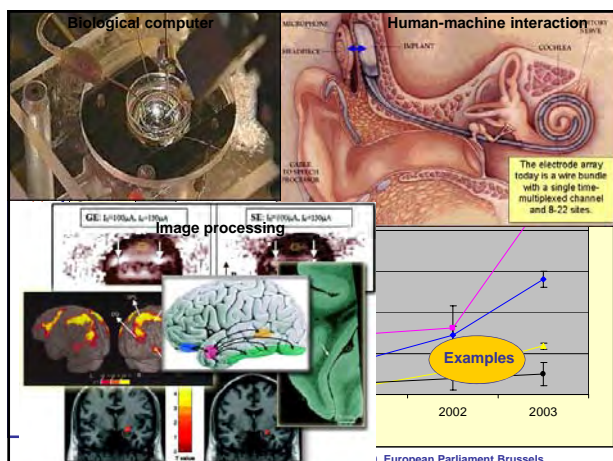
European Parliament, DG Internal Policies of the Union, Directorate A: Economic and Scientific Policy, Policy Department, STOA (Science & Technology Options Assessment)

Public Debate on NBIC convergence

Scenario	Heaven (US)	Hell (US)	Prevail (EU)
People & Parties	Eric Drexler (1986) Ray Kurzweil (1999) Gregory Stock (2002) Roco & Bainbridge (2002a) - NSF-report Converging Technologies for improving human performance	Bill Joy (2000) Francis Fukuyama (2002) Bill McKibben (2003) President's Council on Bioethics (2003) Susan Greenfield (2003) ETC Group (2003) Martin Rees (2003)	Antón et al. (2001) RAND Alfred Nordmann (2004) - Converging Technologies Shaping the future of European Societies
Outcome technological development	Progress	Disasters and catastrophes	Outcome co-evolution technology and society is principally uncertain
Development humankind	Human nature is 'under construction' Intelligent machines (Übermensch) win the evolutionary struggle with humans	Technology changes the principle characteristics of human nature. Humans as a species are threatened by technology	Belief in moral progress and growth of communication between people under the influence of technology
Ideology	Transhumanism	BioLuddism	Down-to-earth

TA on Converging Technologies

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Trends in the convergence of nanotechnology

TA on Converging Technologies

And biology

- Many processes of biology takes place at exactly length scale than nanotechnology
- The convergence is occurring in two directions
 - Nano to Bio → nanotools (microscopy and sensors)
 - Bio to Nano → biological fabrication routes and biological materials as building blocks

And new materials and ICT

- 10% of the publications in the overlap area ICT-new materials are the same as the publications in the ICT-nanotechnology
- Also similar convergence can be identified in:
 - Electronics and photonics in telecommunication
 - Simulation, modelling, image processing and pattern recognition, and neural networks

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Literature Study - Conclusions

TA on Converging Technologies

**Transhumanist and BioLuddist
Heaven and Hell**

Positive	Negative
<i>Grab the attention</i> of the media and policy makers and thus are effective in setting the agenda	<i>Assumption</i> of exponential development and radical change
<i>Expose the most sensitive issues</i> in the debate and clarify the normative deep core issues at stake	<i>Danger</i> that the political debate be dominated by extreme futuristic visions that are speculative
Focus currently on the most delicate issue: human enhancement on the one hand and technologies getting out of control and leading to huge societal catastrophes on the other	Emerging polarisation within the public debate <div style="text-align: right; color: blue;">Preventing it → Alternative images of future</div>

NBIC convergence is expected to push biopolitics central stage
=> Normative issue put forward

Down-to-earth

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NT in Chemical Substitution

NT in Chemical Substitution

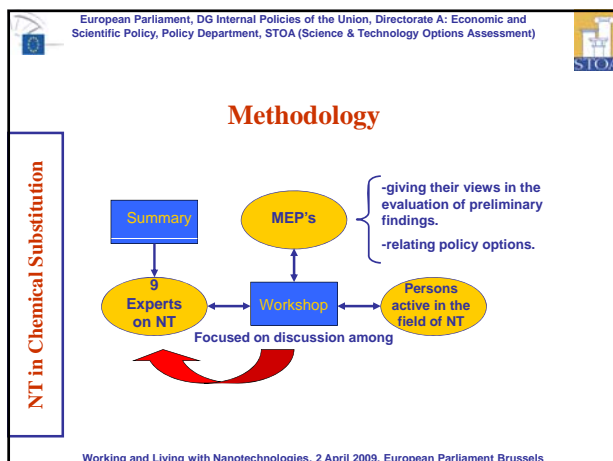
Objective

- Determining the potential of NT for the substitution of hazardous substances in chemistry
- Identifying new applications of NT which could help to reduce the risks related to hazardous substances and chemical processes

Questions addressed

- Which substances are considered as 'hazardous chemicals'?
- What is meant by the term NT and how can it be distinguished from biology and chemistry respectively?
- What is the meaning of 'chemical substitution' in relation to NT?

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Substances considered as 'hazardous chemicals'

NT in Chemical Substitution

Only substances which are already known as toxic and dangerous to human and the environment were considered:

- Heavy metals
- Dirty dozens (most of them insecticides)
- Brominated flame retardants
- Volatile organic solvents
- Toxic organic pollutants

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Substances considered as 'hazardous chemicals'

NT in Chemical Substitution

- Prioritisation of hazardous substances
 - Toxicity
 - Amount of material used
 - Variety and amount of products containing these substances
 - Distribution of the products
 - Release of the substance by the products
 - Contact with humans
 - Degree of existing regulations and agreements on the respective substances
- Nature of the application in which hazardous substances are used.
 - Closed system
 - Semi-open system
 - Open system

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The meaning of the term NT and its distinction from biology and chemistry

NT in Chemical Substitution

- The term NT encompasses a wide range of tools, techniques and potential applications
- Political background definition of NT
 - There is still not universal definition of NT
 - NT was accompanied by big promises and huge expectations
- Technical definition of NT
 - Most of the definitions of NT comprise a further aspect: the nm-size structure must enable new functionalities
 - In practice the new functionality is often unclear or not even mentioned
- Terms of size:

(0.1-100 nm)

Genetic engineering could be attributed to NT
Chemistry is not usually attributed to NT (< 0.001nm)
Nanosciences
Nanoelectronics

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The meaning of the term NT and its distinction from biology and chemistry

NT in Chemical Substitution

- Main characteristics of NT
 - Diversity
 - Enabling Technology
 - Early stage of development
 - Existence of a debate on NT
- Definition of NT in this project
 - As a first approach, everything is considered as NT which is claimed by proponents to be NT
 - Publications from journals carrying 'Nano'
 - All projects carrying 'Nano' in their title
 - Publications and projects dealing with typical NT objects

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The meaning of 'chemical substitution' in relation to NT

NT in Chemical Substitution

- Substitution is not restricted to the replacement of a hazardous substance by a less or non-hazardous substance
- NT provides new effects which are not based on chemical properties but on the physical properties caused by SIZE and SHAPE
- NT can be used to develop completely different processes or different products which serve the same purpose but in a completely different way

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Findings

NT in Chemical Substitution

Materials

- Coatings
- Flame retardants
- Flexibiliser
- Substitution or Reduction of solvents
- Catalysts
- Other Examples: Drug targeting
- Remediation

Conclusions

- At present: NT can not contribute in an exceptional manner to a large increase of substitution of hazardous substances
- For the future: NT has a considerable potential for substitution
- For a comprehensive assessment, each identified example has to be assessed case by case and in more detail as it was performed in this project
- To evaluate the benefit of the new nanomaterial in relation to the conventional one a life cycle assessment (LCA) has to be performed
- Which functionality of the hazardous substance could be provided by which NT.

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Nanologue project www.nanologue.net

European Forum on Nanosciences

Call for a dialogue on nanotechnologies

How will citizens benefit from NT ? ...

...and limit potential risks?

Seen through the properties of nano-materials

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Nanologue: Dialogue about what?

European Forum on Nanosciences

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Who is really in charge of policy making in cutting edge technology?

NT - threat or opportunity ?

Steffi Friedrichs, Director, Nanotechnology Industries Association	- No such thing as one NT - NT is an emerging technology that will help to advance emerging markets but will not have a market of its own - Existing regulations in appropriate areas (REACH) cover what is needed
Pat Mooney, Executive Director, ETC Group, Canada	- There should be a NT moratorium - Industrial revolution without having any rules and regulations at place
Cecilia Malmström, Minister for EU Affairs, Swedish Prime Minister's Office	- Need for transparency
Kjell Andersson, Managing Director, Karita Research	- European Transparency Arena for political insight and accountability
Anders Wijkman, MEP member of the STOA Panel	- Need to have some legislation on the issue of NT - It is unclear how such legislation would look like - Working group looking at this

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Thank you for your attention !

STOA website:
http://www.europarl.europa.eu/stoa/default_en.htm

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paula.hernandez@europarl.europa.eu

Working and Living with Nanotechnologies, 2 April 2009, European Parliament Brussels

ETUC resolution on nanotechnologies and nanomaterials

Final NanoCap Conference
Brussels, 2 April 2009

Joël Decaillon
Confederal Secretary ETUC



European Trade Union Confederation (ETUC)
Confédération européenne des syndicats (CES)

ETUC



ETUC is the European social partner representing workers. The Treaty of Maastricht (1992) guarantees this formal status.

Together with the employers, it is involved in consultation in areas such as employment, social affairs, macroeconomics, industrial and regional policy.

82 member organisations
36 European countries
12 industry federations
60 million workers



Preamble



The ETUC is convinced that nanotechnologies and manufactured nanomaterials might have considerable development and application potential.

- ✓ Technological improvements
- ✓ New jobs

Concerns about potential risks to human health & environment.

Health & Safety at work must be a priority

ETUC Contribution



- Members of the ETUC came together in a WG Nano and prepared a European Trade Union position .
- Resolution adopted by the ETUC's Executive committee in June 2008. It's the common position of all the trade unions in Europe. The ETUC represents 60 million workers.
- The contribution of the ETUC, its member federations and confederations is to point out essential elements of the European policy for a responsible and sustainable development of nanotechnologies.
- The ETUC Resolution is also a contribution to the EC Action Plan on Nanotechnologies and Nanosciences 2005/2009, which calls for a risk assessment on health, environment, consumers & workers.

ETUC Resolution



The regulatory challenge is to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained.
(EC: COM 2008.366)

The ETUC Resolution addresses the following issues:

- Marketing
- Workers Protection
- R&D
- Terminology
- Legislative framework in the EU
- Consumers protection
- Precautionary Principle & application

Marketing



REACH's "No data = No market" must apply: (Art. 5 REACH)

Nanometre forms of chemicals should not be allowed on the market unless, sufficient data are supplied by manufacturers to show there are no harmful effects for human health and the environment;

Registration procedure in REACH: (Art. 6, 7 ...REACH)

Must be modified in order to cover all nanomaterials, including those produced or imported in quantities below 1 tonne per year;

Chemical Safety Report: (Art. 14, Annex I REACH)

Chemical safety assessment must be done for all REACH-registered substances for which a nanometre scale use has been identified.

Communication & Implementation of risk management measures for human health & environment

Workers Protection



- **Risk assessment:** Involve workers and/or their representatives in the assessment and reduction of nanomaterial-related risks;
- **Risk reduction:** Amend Chemical Agents Directive 98/24/EC, to require employers to implement risk reduction measures when the dangers of substances used are still unknown;
- **Safety Data Sheets (Art. 31 REACH):** Improve workers' information about nanomaterials that may be present in products to which they are exposed: Safety data sheets must state whether nanomaterials are present;
- **Exposure controls:** Provide training and health surveillance for workers exposed to nanomaterials.

R&D



- **Increase budget for H&E aspects:**
Imbalance between budgets for the development of commercial applications and those for research into the potential impacts on human health and the environment:

To allocate at least 15% of public research budgets on nanotechnologies for health and environmental aspects;
- **H&S Reporting:** To require all research projects to include H&S issues as a compulsory part of their reporting.

Make health and safety at work issues a compulsory part of all research projects

Terminology



- A standardised terminology for nanomaterials is urgently needed to prepare meaningful regulatory programmes.
- ETUC calls on the EU Commission to adopt a definition of nanomaterials which is not restricted to objects below 100 nanometers in one or more dimensions.

To avoid nanomaterials already on the market be out of the scope of future legislation

Legislative Framework



- ETUC's examination of the current legislative framework has identified several loopholes. Some regulatory changes are needed.
- Amend Chemical Agent Directive & REACH for a better coverage to all potentially manufactured nanomaterials; (below 1Ton/year, Chemical Safety Report)

Precautionary approach: Meaning that the exposure should be avoided as much as possible. These substances must be considered as very hazardous chemicals.
- Voluntary initiatives & codes of practices are useful if some conditions are met, but nanotechnologies need proper legislation.

To avoid risks, avoid exposure

Consumers & Products



- **Label:** Right to know what's in a product. ETUC wants all consumer products containing manufactured nanoparticles which could be released under reasonable and foreseeable conditions of use or disposal to be labelled.
- **National Register:** ETUC calls on Member states authorities to set up a national register on the production, import and use of nanomaterials and nano-based products.

Easy to identify where responsibility lays for any harmful effect

Precautionary Principle



Priority Principle in REACH
Preventive actions must be taken where uncertainty prevails & given the deficit of knowledge.



This means that precautionary principle must be applied

This is the essential prerequisite for the responsible development of nanotechnologies and for helping ensure society's acceptance of nanomaterials.

Factual application of the PP



Shifting the burden of the proof to the proponent of the substance to demonstrate its safety.

This prevents damage while new information accumulates.

Examples of the application of the PP can be found in the ETUC Resolution in 2 areas, concerning:

- **The process of Registration of a Substance in REACH**
- **The implementation of Risk assessment for all nanomaterials**

Achieve the benefits of nanotechnologies while preventing a nano-disaster



"After the asbestos scandal, the ETUC finds it unacceptable that products should now be manufactured without their potential effects on human health and the environment being known unless a precautionary approach has been applied and made transparent to the workers".

Thank You

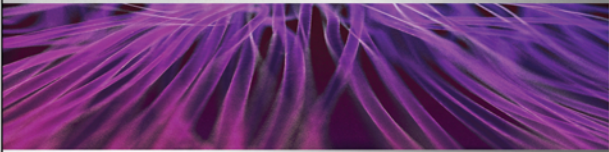


The voice
of workers
in Europe

NanoCap

Positions and perspectives of Environmental NGOs on Nanotechnologies and Nanomaterials

John Hontelez, Secretary General EEB
02 April 2009, NanoCap Final Conference



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Introduction

Herewith I am presenting the shared views and positions of five NGOs
Baltic Environmental Forum, EEB, LEGAMBIENTE, MIO-ECSDE and Natuur en Milieu
involved in the NanoCAP project

While the approach and analysis of the involved NGOs is different (due to varying objectives, visions and target audiences), the main common message of all NGOs is:


There is an urgent need for sustainable and responsible governance of the development and use of nanotechnologies, covering both nanomaterials and nanoproducts, at national and EU level

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Promises and Potential Benefits

Nanotechnologies promise to:


- bring about improvements to modern life
- provide new products and services with "wonder" properties
- enable increased and new human personal abilities
- reshape societal relationships through innovation in many different sectors



Healthcare	Environment	Energy	Electronics
<ul style="list-style-type: none"> Prevention Treatment Diagnosis 	<ul style="list-style-type: none"> Monitoring Reducing Impact Cleaning-up 	<ul style="list-style-type: none"> Insulation Improve efficiency of renewable energy sources Portable Power 	<ul style="list-style-type: none"> Computers Telecommunications Optics

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At present...



However, limited societal benefits have been brought about by most of the commercially available products currently on the market.

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The optimistic expectations of the benefits of nanomaterials may in some cases prove true. BUT meanwhile a strict regulatory framework should be adopted in order to ensure that these are developed and used following the precautionary and producer responsibility principles and that they are not posing threats to the environment and human health through their entire lifecycle

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Potential Risks

Nanomaterials

Have previously unknown properties & behaviour due to their small size (e.g. increased reactivity, conductivity, etc).

Risks

Environment	Health	Ethics & Society
may be eco-toxic after being discharged into the environment as their small size allows them to be easily taken up in organisms	can be inhaled, ingested or enter the human body via the skin, and then cause damage to cells and organs	surveillance and privacy, empowerment and control, nanotagging, diagnosis of predispositions to disease, etc. broaden the gap between the rich and the poor countries

EEB EEB EEB EEB EEB EEB EEB EEB EEB EEB

NGO vision for the responsible and safe management of nanomaterials

Effective, appropriate and enforced nano-governance

Sustainable
Development
Principle

Precautionary
Principle and Producer
Responsibility

should be adopted and put in practice before producing and introducing nanomaterials in the market

NGO Demands

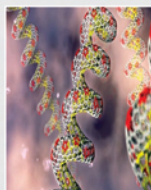
1. Policy & Regulatory Issues

- 1.1 Existing legislation needs to be amended to more explicitly and comprehensively address nanomaterials, and reinforced to ensure safety to human health and the environment envisioned in existing laws.
- 1.2 Development of a **regulatory and policy framework** for existing and future nanomaterials.
- 1.3 “No data, no market” principle in practice - no further market introduction should be allowed for products containing manufactured nanomaterials until appropriate impact and safety assessment tests are developed.
- 1.4 A clear, harmonised and internationally accepted definition of nano-technologies and nanomaterials should be adopted so as to avoid inconsistencies in risk governance and enhance the applicability of existing and future legal frameworks.

NGO Demands on nano governance

1. Policy & Regulatory Issues

- 1.5 Nanomaterials as a whole should be defined, treated and labeled as a **new class of substances**.
- 1.6 Develop a **pre-market registration and approval framework**.
- 1.7 Guarantee transparency, traceability and provision of information to consumers through **information on products** that contain nanomaterials.



NGO Demands

1. Policy & Regulatory Issues

- 1.8 **Full lifecycle analysis** including environmental, health, and safety impacts must be assessed prior to commercialisation.
- 1.9 Current **voluntary codes** for the safe development and the responsible use of nanoscaled materials should become **mandatory**.



Responsible Management of Nanomaterials and Nanoapplications Good practices

- Canadian Government: mandatory safety reporting scheme for companies producing nanomaterials (first country in the world to do so)
- French Grenelle Law (in discussion): measures for the declaration of products containing nanomaterials placed on the market

NGO Demands

2. Research & Development

- 2.1 Nano-research and development should be driven by real societal needs and based on ecological, social and sustainable development considerations and not on the ‘marketability’ of products.
- 2.2 Clearly identify the limitations of existing safety assessment and management tools in relation to nanomaterials.
- 2.3 In particular, there is an urgent need for additional toxicological and ecotoxicological studies, tests and protocols (all still very limited) in order to assess health and environmental impacts.



NGO Demands 2. Research & Development

- 2.4 All new nano-related projects receiving EU funding should be required to include a sustainability assessment and appropriate decision making mechanisms, including public participation.
- 2.5 A research strategy identifying a roadmap towards the safer development and use of nanomaterials in their different applications should be developed and implemented.
- 2.6 Sustainability assessment of (new) technologies tools should be developed, for their more systematic use in both research and product development.

NGO Demands 3. Public awareness, Public participation & Decision making

- 3.1 A transparent and effective communication of the risks of nanotechnologies to society is needed.
- 3.2 Environmental NGOs urge the European Commission and the Member States to immediately undertake an EU-wide public debate on nanotechnologies and nanomaterials. This should form part of a wider debate on technological innovation.



NGO Demands 4. Developing countries & countries with emerging economies

- 4.1 There is a need to place nanotechnologies and nanomaterials use in the context of development and employ these to meet internationally agreed poverty reduction goals, such as the Millennium Development Goals.
- 4.2 Assure that no new risks to environment and health are created in developing countries as a potential dumping ground for nano waste or as an "easy", not strictly regulated market.
- 4.3 Nanoproducts should not become expensive alternatives to existing effective local technologies, e.g. in water treatment.
- 4.4 Nanoproducts should not substitute the products traditionally produced by developing countries.

NGO Demands 4. Developing countries & countries with economies in transition

- 4.5 Attention should be paid to specific risks that might affect developing countries due to their particular environmental and social conditions.
- 4.6 Partnerships should be established in order to assist developing countries or countries with economies in transition to build scientific, technical, legal and regulatory policy expertise related to risks of manufactured nanomaterials.

Ultimately our demands lead to principle questions about the necessity of governance mechanisms on the sustainability assessment of technologies, sustainability objectives and targets in eco-innovation and on the continuing development of sustainable industrial policy.

Discussions on these elements are relatively recent at EU level and e-NGO's involvement in nanotechnologies policy development represents a practical example of these wider issues.

Clearly, much more work is needed on EU policy level to improve environmental and human health protection and to build governance structures based on the premise of public participation in decision-making, the precautionary principle and cradle-to-cradle product sustainability when addressing nano- and new technologies.

Thank you for your attention

Contacts to NanoCap NGOs:

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- Sandra Reintjes (SNM), s.reintjes@natuurenmilieu.nl
- Zita Dudutyte (BEF), Zita.Dudutyte@bef.lt
- Lidia Crivellaro (Legambiente), l.crivellaro@legambiente.org

Working and Living with Nanotechnologies

Conference Conclusions



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nanobüro

introduction to the reader



The following presentation does not offer a summary of the NanoCap conference but attempts to assess its significance.

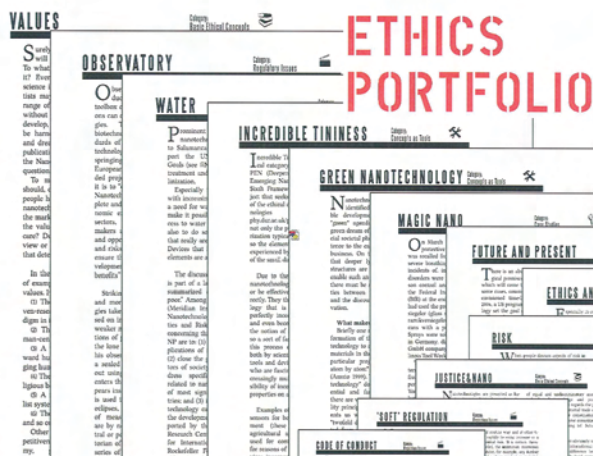
Since trade unions and environmental NGOs offered their conclusions of the NanoCap learning process, these are not repeated here. Instead, other concepts and insights from that learning process are highlighted here.

As for the significance of the conference, it has two dimensions:

- Within the predominant framework of „responsible development of nanotechnologies by all stakeholders“, trade unions and NGOs highlight specific genuine points of contention and decision making, e.g. regarding the standing of the REACH „no data – no market“ principle. Even as some discuss the applicability of REACH to nanoparticles, the genuine historical achievement of the REACH-framework is not to be questioned and any regulation of nanoparticles should be seen as an extension of REACH.

- Beyond the predominant framework of „responsible development“ with its emphasis on inclusion and open-ended conversation of citizen, consumers and other stakeholders, the involvement of powerful social movements raises the stakes for a political, deliberative negotiation of nanotechnologies.

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ethics portfolio



- a work in progress that will continue within and grow beyond NanoCap (Stefan Gammel and Astrid Schwarz invite you to participate)
- an open-ended loose-leaf collection of concepts, case-studies, tools, issues
- neither to do ethics nor to teach ethics ...
- ... but to enable deliberation to move forward beyond current limitations

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ethics portfolio



- it does not support the division of moral labor...
... but belongs into the background where it belongs
- in the end, it's not about lists of ethical concerns that are made by well-meaning and sensitive/aware individuals...
.... but about the representation of vital interests in face of a new way of doing things

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nano : a new way of doing things?



traditional precautionary and regulatory attitudes unwittingly imply a moratorium (which no one wants)

„do not market until proven safe“ – „approval based on risk assessment“ – „first of all proper characterization, standardization, classification“ – „we need to know and label what are nano-products and what are not“ – „apply the precautionary principle“ – „no market until sufficient data show that there are no harmful effects“

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nano : a new way of doing things?



„If it cannot be proved that a nano-substance is safe, it cannot be allowed onto the market.“

- Such demands seem consistent with the promotion of nanotechnology in a safe and sound manner.
- However, if these are straight-forward pre-conditions for the development, implementation, and marketing of nanotechnology – forget about nano!
- The message of nano: It can't wait for scientific evidence of safety or harm (which may never become available)! And: If nano has to be contained in closed systems, it won't flourish in the market.

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one expression of the dilemma



„In the current context, the only absolutely safe option would be a moratorium on the development of nanotechnology and a total ban on products containing nanoparticles until there is complete clarity on the risks to human health and the environment. In view of the speed and the dynamics of developments in nanotechnology, however, this is probably not a realistic objective. [Also,] nanotechnology is potentially a highly promising technology...“ (*Natuur en Milieu*)

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learning process



- I. Adapt the realities of nano (for now especially: nanoparticles) to regulatory expectations, safety concerns, precautionary approaches.
- II. Develop new strategies and criteria for „responsible development“ and „evidence-based policy-making“ which soften the demands and yet do not fail us in the end.

This is a learning process for European knowledge societies and within NanoCap.

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the nanoworld in limbo



An intermediary, transitional, uneasy space opens up:

between unknown but conceivable risks and unknown but presumed benefits

between current need to innovate and future availability of adequate methods, standards, and knowledge about health and safety impacts

How long do we need to stay in this transitional state?
No one knows, perhaps forever.

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strategies in limbo at work today



- I. „responsible (sustainable) development“ – including codes of conduct, observatories, public engagement, ELSI-research
 - these are instruments of vigilance
 - (even REACH appears today not so much as a regulatory framework but as an instrument to observe nanotechnology)
 - „we may not know enough about hazards but at least we are poised to catch them“
 - accompanying ongoing developments in the mode of conversation, not deliberation – in the language of „concern,“ not decision or prioritization

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strategies in limbo at work today



- II. precaution (*how far can one go without producing a moratorium, after all?*)
 - and if we don't know enough even to apply the „precautionary principle“ let's adopt a precautionary approach
 - if we don't know that a substance is hazardous, let's treat it as if it were
 - in the extreme form: containment in closed systems
 - (and the regime of permanent vigilance is doing its best to treat the whole life-cycle of nano-in-society as an observationally closed system)

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learning process



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This is a learning process for European knowledge societies and within NanoCap.

the limits of the balancing act



All of today's discussants engaged the tentative and careful balancing of unknown risks and unknown benefits.

- reassurance of good will on all sides and that we are, in fact, committed to vigilance
- different strenghts of commitment to necessary levels of risk-avoidance – but reluctance to question the shared commitment to the balancing act

E.g. everyone agrees to „no data, no market“ but it is difficult to turn differences of interpretation into clear-cut decision-items (applied to known hazardous materials or to all materials, applied to new products and processes or to all?).

deliberation beyond conversation



Concerted vigilance proceeds in the mode of conversation and mutual learning from all stakeholders,
but there were hints today of stronger political deliberative moments and possibilities.

deliberation beyond conversation



- I. Social movements assembled today –
 - stakeholders defined as advocates rather than being reduced to concerned individuals
 - mobilizing achievements that have become non-negotiable
 - bringing in historical knowledge of larger trends (nano may be new but it is also very old in the history of innovations)

deliberation beyond conversation



- II. Injecting hard principles into soft law
 - small point in ETUC-resolution: voluntary codes *if* they include workers's representaton in design and monitoring
 - more generally: social movements have the power to unilaterally apply the missing sanctions to the voluntary codes
 - drawing a line in nanotechnology conversations

deliberation beyond conversation



- III. (no-)nonsense products and projects
 - promoters of nanotechnologies produce long lists of benefits and potential applications
 - these lists are meant to impress us about all that nanotechnology can do
 - these lists should be taken up by social movements to create rankings
 - missing today almost altogether: agenda-setting, determing research priorities, ensure that societal benefits are actually realized

deliberation beyond conversation



IV. large-scale resources to enable a piecemeal approach

- a role for trade unions and NGOs to communicate with publics on informational resources and strategies for acting in the absence of knowledge
- allowing for piecemeal arrangements for specific production processes, consumer products
- old-fashioned „empowerment“ within power-relations

and this kind of process is to be supported by the ethics portfolio

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... which closes the circle, concludes the conference
but opens the political debate ...



ANNEX II: Description Speakers and Panel Members



SHORT DESCRIPTION SPEAKERS AND PANEL MEMBERS

Antonis Angelidis

Mr. Angelidis is chemical engineer who joined the Commission in 1990. He had been working for six years in the Directorate General of Energy and in particular in Euratom as a nuclear inspector. He then joined the Directorate General of Employment, Social Affairs and Equal Opportunities and since 1996 he is working in the Health and Safety at Work Unit. He is responsible for the development and the implementation of the Unit's prevention policy in the field of chemical substances. He is leader of the Unit's chemical group.

Frank Barry

Workers Representative member of AMICUS/ UNITE
President / Vice President for AMICUS Ireland and England 2000/2001
National Executive member for AMICUS /UNITE Ireland
Chairperson of the Sub- committee on developing a policy strategy for the HSA on the safe use of nano-materials in research and manufacturing by workers.
Member of the EU Nanocap project

Pieter van Broekhuizen

Pieter van Broekhuizen studied biochemistry at the Technical University in Delft and at the University of Amsterdam. He is manager of the unit Nanotechnologies and Chemical Risks of IVAM research and consultancy institute related to the University of Amsterdam. He was director of the Chemiewinkel, the Consultancy and Research Centre on Chemistry, Work and Environment at the same University. They merged with IVAM UvA BV in 2002. The unit Nanotechnology and Chemical Risks covers the interface between nanotechnologies, occupational health and safety, the environment and chemistry.
He is member of the Dutch Social Economic Council's subcommittee on the setting of occupational exposure limits.
He is involved in nanotechnologies and their possible impact on man and the environment. He coordinates the European project NanoCap and participates in different other nanotechnology projects.

Dorette Corbey

Dorette Corbey is member of the European Parliament for the Socialists Party. Member of the Committee on the Environment, Public Health and Food Safety and the delegation for relations with the People's Republic of China. She is the substitute in the Committee on Fisheries and in the Committee on Industry, Research and Energy.

Jan Cremers

Jan Cremers is member of the European Parliament Socialist Party. He is expert in the field of working conditions. In the end of the eighties he was chosen to become European trade union official, where he gave his support in the realisation of European social legislation concerning the free movement of workers and the occupational health and safety legislation. In 2000 he became director of the GBIO, the Dutch organisation for the education of works councils. He was senior researcher at the GTP advice and coaching institute and guest researcher at the Amsterdam Institute of Labour Studies (AIAS).

Joël Decaillon

Joël Decaillon is a graduate in European law from the University of the Sorbonne (Paris). He is a trade union official of nearly 30 years' standing, and was a member of the European Economic and Social Committee for 11 years. He is a member of the CGT's Executive Committee and, since May 2003, he is the Confederal Secretary of the ETUC.

Laura Degallaix

Laura DEGALLAIX is the Head of the Environment and Safety Department at BEUC, the European Consumers' Organisation. She is responsible for preparing and agreeing BEUC's positions and activities on all environment and safety issues. She works closely with the environment and safety officers in all 41 BEUC member organisations of 30 European countries. She represents BEUC at meetings and conferences in Brussels and around Europe. She is responsible for developing and implementing political strategy to force change to EU policy in the consumer interest. She is notably working on product safety, addressing both technical aspects of products and the content on chemical substances such as nanomaterials, and on environmental issues such as sustainable consumption and production and energy efficiency.



In relation to nanotechnologies, Laura Degallaix has been particularly active on nanomaterials contained in cosmetic products, in the context of the recast of the cosmetics Directive. She is also working closely with BEUC member organisations on consumer perception of nanotechnologies and risk communication. Laura Degallaix graduated in biochemistry and environment and worked in the French National Museum of Natural History in Paris. She then worked at the French consumer organisation UFC-Que Choisir, member organisation of BEUC, in Paris as policy advisor on environment and sustainable development issues.

Miklós Györffi

Educated in Romania and Hungary he got his doctor degree in physics in Debrecen and in technology assessment in Budapest. In 2005 he joined the European Parliament, DG Internal Policies Directorate A, Economic and Scientific Policy, Policy Department, administrator working for STOA (Science and Technology Options Assessment) Panel (previously also for ITRE Committee - on Industry, Research and Energy)

Malcolm Harbour

Malcolm Harbour was elected to the European Parliament in June 1999, and re-elected in June 2004. He has been re-adopted as a Candidate for the 2009 Elections. He is one of 3 Conservative members representing the West Midlands Region of the UK. He is a Member of the Internal Market and Consumer Protection Committee, and has served as elected Co-ordinator for the European Centre Right Group (EPP-ED) since 2004. He is also a Member of the Industry, Research and Energy Committee. He is Conservative spokesman on Internal Market issues, and specialist spokesman on IT issues. He is Vice-Chairman of the Parliament's Science and Technology Options Assessment Panel (STOA) and a Member of the Inter-Parliamentary Delegation to Japan, a country he visits regularly.

Malcolm Harbour takes a special interest in the EU single market, industry, science and technology policy. He is Chairman of the Forum for the Automobile and Society, the Ceramics Industry Forum and the Conservative Technology Forum. He is a Governor of the European Internet Foundation, a member of the Conservative Policy Review on Science and Innovation and the joint policy team with CDU and CSU MPs.

In 2005, he served on the CARS 21 High Level Group, a Europe-wide initiative to boost the automotive industry. He was named as a top 50 European of 2006 for his key role in broking agreement on the Services Directive. In May 2006, he was named the UK's most Small Business Friendly UK Parliamentarian by members of the Forum of Private Business.

Before his election to the Parliament, Malcolm Harbour spent 32 years in the motor industry, as an engineer, a senior commercial executive, a consultant and a researcher. He began his motor industry career in the BMC Longbridge Plant as an Austin Engineering Apprentice in 1967.

John Hontelez

John Hontelez has been the Secretary General of the European Environmental Bureau since December 1st, 1996
Other current positions:

- Member High Level Group on the Reduction of the Administrative Burden (Chaired by Mr. Edmund Stoiber) – advisory body to the European Commission.
- Member (on behalf of environmental organisations) of the Bureau of the Aarhus Convention (UNECE Convention on Access to Information
- Member Board Institute for Sustainable Development, Warsaw, since 1996.
- Member Coordination Board Ecoforum (a Pan-European network of Environmental Citizens Organisations), since 1994 and Chair of its Public Participation Campaigns Committee.

Lena Perenius

Lena Perenius was appointed Executive Director for the Programme Product Stewardship in November 2007; she joined Cefic in 2002 as Director REACH Implementation.

The core activities of the Programme Product Stewardship are focused on supporting the Chemical Industry with respect to proactive management of industry involvement at EU and International level in

- Chemical legislation
- Voluntary initiatives
- Management of emerging issues related to new or existing products
- Product Stewardship by improving interactions in the entire value chain on product safety.

A Swedish national, Lena Perenius has a degree in chemistry (biochemistry/microbiology) from the Stockholm University.

She has more than 25 years of work experience with industry, national authorities, the European Commission and trade associations. In Sweden she worked 8 years for the pharmaceutical industry and 11 years for Authorities, mainly for the Chemicals Inspectorate.

She joined the Commission, DG Industry, in 1996 with responsibility for harmonisation of chemicals legislation, notably restrictions on the marketing and use of dangerous substances.

Henrik Laursen

Henrik Laursen is administrator in DG Environment. He has been working with environment policy matters for the last 18 years and has covered a broad range of issues from climate change to phthalates in toys. Since November 2007 he has been working in DG Environment's Chemicals unit where he is the coordinator of DG Environment's policy on nanomaterials. His main tasks include being in charge of the Commission's input to the OECD Working Party on Manufactured Nanomaterials as well as working on the legal situation within the EU in the so-called "Competent Authorities Subgroup on Nanomaterials" (CASG Nano) which was established in 2008 under REACH.

Tony Musu

Tony Musu is a Chemical Engineer by education and he holds a PhD in Science from the Pasteur Institute in Paris.

Before his current position in the Research Institute of the European Trade Union Confederation (ETUI/ETUC), he spent five years in the industry dealing with the safety assessment of chemicals.

Since 2003, he has been participating on behalf of ETUC in various REACH-related Commission working groups. In 2007, he was appointed in the Management Board of the European Chemicals Agency (ECHA) where he represents European workers.

He is also a member of the Ad Hoc WG on Chemicals within the Luxembourg Advisory Committee on Health & Safety at work.

Ben Nemery

Professor Ben Nemery is head of the Research Unit of Lung Toxicology of the Department of Public Health, Faculty of Medicine, of the Katholieke Universiteit Leuven. This research unit is a joint-venture between the division of Occupational, Environmental and Insurance Medicine and the division of Pneumology. During the last decade, the laboratory has grown to a medium-sized group of about ten researchers at pre-doctoral and post-doctoral level. It has built up a good international reputation in the field of occupational and environmental pulmonary toxicology, including "nanotoxicology", and it is involved in various EU initiatives around the health and safety aspects of nanotechnology. Ben Nemery is actively involved in several national and international bodies, including the European Respiratory Society, where he holds positions in the scientific leadership, and the American Thoracic Society.

Alfred Nordmann

Alfred Nordmann is Professor of Philosophy and History of Science at Darmstadt Technical University, Germany. Since 2000, his research focused on nanotechnology as a symptom of larger changes of the culture of science and the relation of science and society. He served as rapporteur of the European Commission's expert group Converging Technologies – Shaping the Future of European Societies (2004).

Nordmann heads the nanoOffice which recently proposed an institutional model for the "regulation" of nanotechnology (www.nanoOffice.eu).

Recent publications include

- "Philosophy of Nanotechnoscience" in G. Schmid (ed.) Nanotechnology: Volume 1: Principles and Fundamentals, Weinheim: Wiley, 2008, pp. 217-244.

Dragomira Raeva

Dragomira Raeva has re-joined the EEB as the EU policy officer for Clean Air, Nanotechnology and Noise Reduction in September 2007.

Prior to joining the EEB, Dragomira has been working with the Lund Municipality in Sweden, where she helped the local mobility management team in developing and implementing environmentally friendly transportation services.

She has also been a long term trainee at the EEB assisting the works on air, noise and urban environment issues. Dragomira has been an active member of the environmental NGO Za Zemiata in Bulgaria, where she facilitated the organization of capacity building workshops, trainings and campaigns on various environmental topics.

Dragomira's academic training is in Environmental Science, Policy and Management. She completed her master's degree in a joint programme between the Central European University in Budapest and the Institute for Industrial Environmental Economics in Lund. Her thesis is in the field of sustainable urban transport and development and running of mobility management practices in European cities.



Lucas Reijnders

Prof dr. L. Reijnders (1946) studied biochemistry at the University of Amsterdam and got his PhD in molecular biology from that university in 1973. After that he worked in teaching positions at the Agricultural University of Wageningen and the State University of Groningen. Since 1988 he is professor of environmental science at the University of Amsterdam, and since 1999 he holds the same chair at the Open University of the Netherlands. His main publications in the field of nanotechnology are:

- Cleaner nanotechnology and hazard reduction of manufactured nanoparticles. *Journal of Cleaner production* 14 (2006) 124-133
- Biological effects of nanoparticles used as glidants in powders. *Powder Technology* 175 (2007) 142-145
- Hazard reduction for the application of titania nanoparticles in environmental technology. *Journal of Hazardous Materials* 132 (2008) 440-445
- Hazard reduction in nanotechnology. *Journal of Industrial Ecology* 12 (3) (2008) 297-306
- The release of TiO₂ and SiO₂ nanoparticles from nanocomposites. *Polymer Degradation and Stability* 2009; in press

Carl Schlyter

Carl Schlyter is chemical engineer specialised in biotechnology and the environment (at the Royal Institute of Technology, Stockholm). He is member of the European Parliament for the Group of the Greens/European Free Alliance (Verts/ALE). He is member of the Committee on the Environment, Public Health and Food Safety (Member) and the Delegation to the ACP-EU Joint Parliamentary Assembly (Member). He is substitute in the following committees: the Committee on Budgetary Control, the Committee on Fisheries and the Committee on International Trade. He is substitute for the delegation for relations with the countries of Southeast Asia and the Association of Southeast Asian Nations (ASEAN).

René von Schomberg

Dr. Dr.phil. Rene von Schomberg is an agricultural scientist and philosopher. He holds Ph.D's from the University of Twente (NL) (Science and Technology Studies) and J.W.Goethe University of Frankfurt (D) (Philosophy). He has been based at various universities and is now with DG Research of the European Commission. He is author/co-editor of 12 books, most recently:

- Implementing the Precautionary Principle, Perspectives and Prospects, co-edited with E. Fisher and J. Jones, E.Elgar Publishers, 2006 and the Working Paper of the services of the EC on the ethics of new technologies (see conference bag).

Willem-Henk Streekstra

Willem-Henk Streekstra is for 3 years now senior adviser environmental affairs for the Confederation of Netherlands Industry and Employers (VNO-NCW). Within VNO-NCW he coordinates the work on risk policy of nanotechnologies. VNO-NCW pursues an active approach on risk policies of nanotechnologies. This means she tries to turn the precautionary principle into concrete and workable measures to make risks of nanotechnologies manageable.

In former jobs he was a lobbyist for the Dutch agriculture.