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Nanologue

Opinions on the Ethical, Legal and Social Aspects of Nanotechnologies

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Results from a Consultation with Representatives from Research, Business and Civil Society

Released May 2006

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This paper is a joint publication of the Wuppertal Institute (WI), EMPA, Forum for the Future (FFF) and triple innova (TI). It was written by Volker Türk, Claudia Kaiser, Dr. Christa Liedtke (WI), Hugh Knowles, Vicky Murray (FFF), Stephan Schaller, Dr. Holger Wallbaum (ti) and Dr. Hans Kastenholz, Andreas R. Köhler (EMPA).

We would like to thank all those who provided comments and suggestions, in particular the Nanologue External Advisory Board.

Glossary

ELS	Ethical, legal, social
ELSA	Ethical, legal, social aspect
GMO	Genetically modified organisms
LOC	Lab-on-a-chip
Nanoparticle	represent all forms of engineered nanoparticles
NT	Nanotechnologies
R&D	Research and Development
WP	Work package

1. Introduction

This paper presents the results from the Nanologue projects second phase: the engagement and dialogue on the societal benefits and risks of nanotechnology (NT) applications with representatives from research and civil society. Building upon the first project findings[1], it aims at establishing a deeper understanding on the ethical, legal and social (ELS) benefits and risks of NT-applications in the view of civil society and researchers. Using interviews and stakeholder workshops the main objectives were to:

- engage with representatives from research and development as well as marketers, users and accommodators of NT in a dialogue on the benefits and potential ethical, legal and social impacts of NT applications in order to capture their perspective on the issue;
- interview the societal groups engaged in this project phase in order to further develop and substantiate the benefits and potential impacts of NT (identified in the first project phase [1]);
- facilitate the process of prioritising the benefits and potential impacts identified;
- contribute to the development of the subsequent project work, including the development of scenarios exploring how business, civil society and public institutions can engage effectively in a dialogue on the ethical, social and legal aspects of NT and a web-based tool to quickly assess possible ELS issues for NT-products and research proposals.

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[1] See:
Nanologue Mapping study. Summary of key findings from a literature study on ethical, legal, and social aspects of nanotechnologies. A joint publication of the Wuppertal Institute, EMPA, Forum for the Future and triple innova. Available at www.nanologue.net.

Nanologue Background Paper on selected nanotechnology applications and their ethical, legal and social implications. A joint publication of the Wuppertal Institute, EMPA, Forum for the Future and triple innova. Available at www.nanologue.net.

As with the first Nanologue deliverables[1], the paper primarily serves to document the work that has been conducted and to inform the following Nanologue project work. However, the authors would like to share the current state of investigation with a wider audience in case they might find it useful. We welcome any comments or feedback.

1.1 Structure

Following the introduction, including a short description of the methodology applied, the project results are presented.

- Chapter 2 summarises the target groups awareness of ethical, legal, social aspects (ELSA), and
- chapter 3 gives evidence on the benefits and risks mentioned during the interviews and the workshop.
- Recommendations and actions that according to the target group should be taken in order to increase the benefits and minimise the risks are recorded in chapter 4.

Chapters 2 to 4 largely serve as a documentation of the target groups positions during the interviews and the workshop, which explains why some issues are mentioned several times throughout the document.

- Chapter 5 goes a step further by taking the insights gained throughout the project and translates them into a selected number of recommendations that are expected to facilitate the dialogue on nanotechnologies and ultimately a better integration of ELSA into the NT-development.

Further details about the interview guidelines and the interviewees can be found in Annex I-V.

1.2 Target group, scope and methodology

Based on an intensive literature research in the previous project phase, this phase was aimed at identifying the stance of researchers and civil society with regard to social, ethical, and legal aspects (ELSA) of NT-applications by means of telephone interviews and stakeholder workshops.

1.2.1 Target group

The term "researcher" is seen as a synonym for scientists/technologists involved in research and development of NT-based applications, both in university and business. Those working on basic research questions have not been in focus. Building upon previous project work, researchers working on the three NT-application areas medical diagnosis, food packaging and energy conversion and production have been selected. Each group has been asked for their position on ELS benefits, risk as well as potential actions to be taken with respect to their application area. In addition, one group was invited to participate in the interviews disregarding their specific NT-area of expertise. This "generic group" has been interviewed on ELSA and nanotechnologies in general.

Civil society can be defined as "the totality of voluntary civic and social organisations or institutions which form the basis of a functioning society as opposed to the force backed structures of a state (regardless of that state's political system)."[2] However, for the purposes of this project this group was widen to include those who are involved or interested in understanding, marketing, regulating, monitoring, writing about nanotechnologies or helping to develop market-relevant products using nanotechnology applications. As a result this group was expected to have a better understanding of the issues surround NT than a more traditional group of representatives from civil society. The involvement of civil society representatives was not meant as a representation of the public's perception of NT, but to ensure to balance the views from a wider group than just researchers.

Several researchers contacted by the Nanologue team reported to be either overloaded with interview requests and therefore not able to participate or were simply not interested. From this the conclusion

[2] http://en.wikipedia.org/wiki/Civil_society

can be drawn that the group of experts who agreed to participate in the interviews takes an above average interest in NT-related ELSA-aspects. Some explicitly named the importance of the Nanologue project aims as primary reason for their participation.

1.2.2 Methodology

Potential participants and interviewees for both groups were identified using a combination of desk research and communication with networks in the field. In addition members of the project consortium attended scientific conferences such as Nano4Food 2005 (Wageningen, NL) or the EuroNanoForum 2005 (Edinburgh, GB) and international fairs such as the EuroNano (St.Gallen, CH) in order to get in touch with experts in the field.

Using the results of the first project phase as guidance, interview questionnaires were drawn up to discuss the ethical, legal and social aspects according to the scheme described in chapter 1.2.3 and for the researchers complemented by a section on economic issues.

The interviewee was also asked a set of questions aimed at providing material for the scenarios in WP5 (see questionnaire in Appendix). Apart from a few exceptions, participants were interviewed by telephone. Where language was an issue participants were sent the interview protocol prior to the interviews and in three cases the protocols were filled out, sent in and then any issues and clarifications were discussed over email. Some participants were interviewed face to face. All interviews were summarised and subsequent drafts sent to the interviewee for their consent and comments.

For the dialogue with the civil society participants were invited to a one-day workshop in Edinburgh on the 5th September 2005. The workshop was held as one of the “Workshops-on-demand” for the EuroNanoForum 2005 Conference on ‘Nanotechnology and the Health of the EU Citizen 2020’. The workshop was used to further explore the ethical, legal and social aspects of NT and to develop recommendations for communication of ethical, social and legal issues between different actors in EU in future. During the workshop the delegates were asked to:

- list the main risks and benefits of nanotechnologies;
- vote for the most important risks and benefits and prioritise them;
- vote on how certain they were that these risks and benefits would be relevant by 2015;

- discuss the barriers to better communication between stakeholders concentrating on the role of scientists;
- make recommendations to overcome these barriers.

Finally, the results from the interviews and the workshop were analysed and compared.

It should be mentioned that due to the limited sample size – both the interviews and workshop results – a deeper statistical analysis was neither intended nor feasible. The figures and statistical diagrams displayed should be seen as illustrations/snapshots from the field for information purpose only.

However, the interview and workshops results combined with the Nanologue mapping study on recent NT studies do show interesting tendencies concerning societal expectations, opinions, and awareness with regard to nanotechnologies.

1.2.3 Defining ELSA - Ethical, legal and social aspects

The Nanologue Background Paper[3] concluded that there is no common understanding on what exactly ELSA of NT means. Strand writes "The question remains, however, what exactly are the ELSA of nanotechnology, and what to do about them. Indeed, we should expect this question to remain open for a long time."[4] Given this backdrop, the Nanologue consortium decided not to focus on ELSA from a specific discipline approach, but to use ELSA as a proxy for all different kinds of opportunities and threats applications of NT can pose to society.

Aspect in the context of this project is understood to describe characteristics or features of an area of opportunities and threats mentioned in connection with NT components or applications. The following seven aspects have been selected for the Nanologue project:

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[3] Nanologue Background Paper on selected nanotechnology applications and their ethical, legal and social implications. A joint publication of the Wuppertal Institute, EMPA, Forum for the Future and triple innova. Available at www.nanologue.net.

[4] Strand, R: Ethical Aspects of Nanotechnology. NANOMAT International Conference, 3 June 2004.

Environmental performance

Where the NT component or application has a direct or indirect impact on the natural environment. Relevant issues discussed are amongst others: eco-efficiency, eco-toxicity, bioaccumulation, or NT-applications in energy or environmental technologies.

Human health

Where the NT component or application has a direct or indirect impact on the human wellbeing. Relevant issues discussed are amongst others: Toxicity, particle accumulation, disease diagnosis and treatment, or drug delivery.

Privacy

Where the NT component or application has a direct or indirect impact on the generation of or access to personal information that an individual or group might want to restrict.

Access

How do individuals or societal groups get access to, and benefit from, NT applications. This aspect includes access within a society/country, between societies and countries (NT divide) as well as between current and future generations. The question of access goes beyond the mere physical access, but includes issues such as affordability, intellectual property rights, concentration of power and transparency, the integration into daily routines, trust etc.

Acceptance

Level of (public) acceptance to the introduction of nanotechnologies and nanotechnology applications and the influence that this might have on the development, production and marketing of NT-applications.

Liability

What direct or indirect impact has the NT components or applications on the legal responsibility for an act or failure to act. From an insurance perspective it includes the quantification (and “insurability”) of risks related to NT-based products.

Regulation & Control

Governmental and public services regulation as a process to control or steer the development, testing, marketing, usage, and disposal of NT-applications.

2. Awareness for ethical, legal and social aspects

Notably influenced by the debate on potential risks of NT-particles, there is a wide awareness among the target groups that the development and marketing of NT-based products is associated with ELS issues. The following chapter reports on the responses from researchers and civil society representatives.

2.1.1 Researcher

Researchers are aware of the discussion on societal opportunities and risk

All researchers interviewed were aware of the discussion about societal opportunities and risks of nanotechnologies and more than half felt well or at least adequately informed. Only one interviewee from the generic group explicitly stated that he did not feel well informed, while another said that nobody could ever be fully informed due to the complex nature of ELSA. However, to conclude that the general awareness and level of information amongst researchers is high might be misleading, since the total number of interviewees is rather low. Unprompted with questions on specific aspects, most of those that claimed to be adequately informed mentioned only a few benefits and risks, many of rather technical or economic nature. Moreover, about half of the researchers contacted were not willing to participate at the interview. Even though the interview request explicitly stated that no expertise on ELSA is required, some might have not responded simply because they felt not comfortable with or well informed about the topic. Considering this it can be assumed, that the interviewees had an above average awareness and knowledge.

The researchers used a variety of information channels to inform themselves on the current thinking and insights on ELSA in their fields of expertise. Exchange with colleagues during conferences was mentioned as prevailing source, followed by participation in research projects and internet searches. Several interviewees mentioned scientific publications and some other surveys or questionnaires.

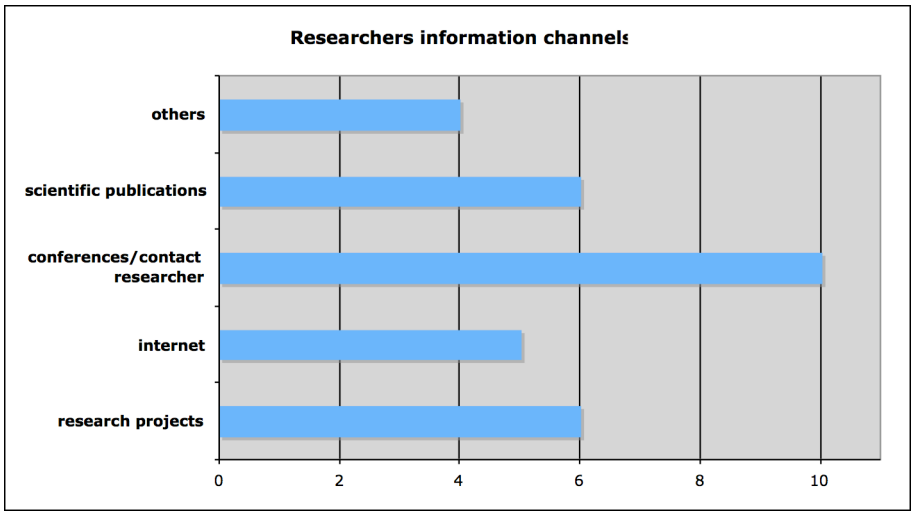

Figure 1: Information channels mentioned by representatives from research by numbers.

2.1.2 Civil society

The interviewees were asked if they felt adequately informed on ethical, legal, and social aspects associated with the development of nanotechnologies.

Civil society representatives felt less informed

Roughly a third said yes, but mostly with a caveat. Many of the interviewees commented that they follow the nanotechnology debate closely as part of their work or interests, but felt that the information had not yet reached the wider public domain. So whilst *they* felt informed, they were not necessarily representative of the general public, who might not be adequately informed.

There was a call for industry to be more transparent and release information on research already conducted, particularly around human toxicity. It was also posited that whilst there was an adequate amount of information 'out there' this did not mean that the ELSA were well understood [i.e. information itself is not enough].

Another third gave no specific answer or were not sure they were adequately informed. They all felt that there was a lot of information out there but either there was too much information and they were not sure of where to take the lead from, or they did not know where to look. There was a general feeling that the current debate had no structure and had not advanced.

The final third said no, they did not feel adequately informed, arguing that no-one had a great deal of knowledge in this area. A number of

interviewees mentioned that there was a particular shortage of information on legal issues associated with NT.

The internet was seen as the most important information source for the representatives of civil society. Several interviewees mentioned that many websites also provided email alerts, encouraging people to return to sites and view the latest information. Scientific conferences, discussions, research projects and publications were also a valuable source of information. Contact with government and authorities/EU, industry (through technical assessment reports and trade associations for example) and NGOs was also mentioned. There was some mention of more informal information sources, such as conversations with colleagues and some reliance on more mainstream sources e.g. newspapers, popular literature and TV.

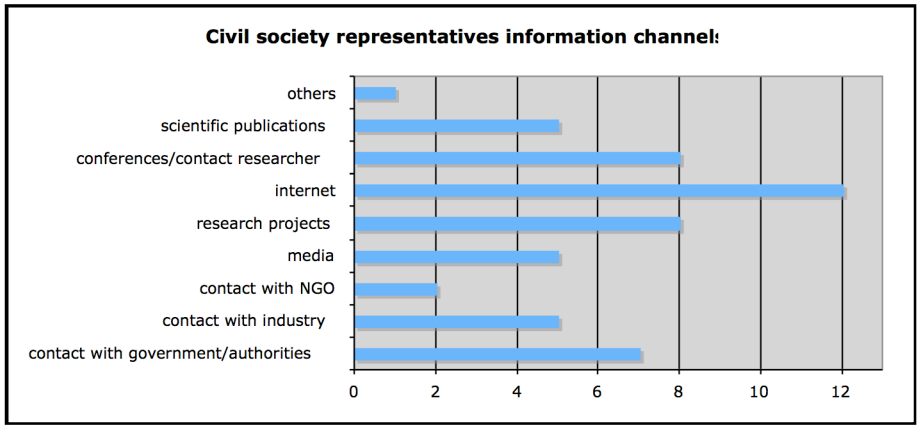

Figure 2: Information channels mentioned by representatives from civil society by numbers.

3. NT Benefits and Risks

Chapter 3 reports on the ELSA benefits and risks mentioned during the interviews and the workshop. The seven ELSA described in chapter 1.2.3 were used as a guiding categorisation scheme throughout the interviews. In addition, questions on the economic potential of NT-applications were posted. All issues raised by the target group could be related to one of these aspects[5]. This chapter largely serves as a documentation of the target groups positions, which explains why some issues are mentioned several times throughout the document. A comprehensive and summarising overview is given in Chapter 3.1.5 for the researcher, chapter 3.3.3 for civil society, and 3.4.2 as a final and integrated overview across both target groups.

3.1 Researcher interviews

The following chapter describes results gained from conducting twenty interviews with researchers from different application areas. Five interviewees participated in each group (medical diagnosis, food packaging, energy conversion and production, NT in general). A summarising overview of all interviews is provided at the end of this chapter.

3.1.1 Medical diagnosis

Five researchers, all of them experts for lab-on-a-chip (LOC) applications in the field of medical diagnosis, have been interviewed. The questionnaire focused on NT-based applications in medical diagnosis, more specifically on lab-on-a-chip, but covered also questions on NT-applications in general.

Most interviewees felt well or adequately informed on ELSA connected with NT-based LOC; two expressed that they felt more or less informed. All had discussed these issues with colleagues before.

[5] The discussion on possible dual use of NT-applications for civil and military purposes was raised a few times; however the Nanologue consortium decided at the projects beginning to consider this aspect out of scope.

Like the members of the general expert group, all interviewees in the application area of medical diagnosis were asked for their appraisal of their own understanding of ELSA and their estimate of the general public´s current perception.

For each of the seven ELSA they were asked whether it deserved much, more or less or little attention.

All aspects were considered to deserve between much and more or less attention from the interviewees perspective as well as from their appraisal of the general publics´ opinion.

Benefits are expected to outweigh the possible risks

Benefits of NT-based LOC applications were especially expected from an overall improved diagnosis performance. Attributes mentioned were “faster”, “portable” (point of care testing), and “more sensitive”. It was also expected that screening for a variety of (dispositions for) diseases would become routine and that enhanced diagnostics would enable more personalised treatment.

Only a few risks were mentioned for LOC. In general the benefits of NT-based LOC applications were perceived to outweigh possible risks. One interviewee explained there the availability of NT-based monitoring devices might lead to a change in the overall perception of human health if an increasing number of parameters could easily be monitored. Others highlighted the possibility of malfunctions or data misinterpretation resulting in wrong treatment.

The majority felt that the same benefits and risks would also be relevant for other NT-based applications in the medical sector

Asked if the benefits described would not only apply for NT-based LOC applications but for NT-applications in the medical area in general, four out of five interviewees agreed. One interviewee explained: “since the intrinsic properties of nano-bio devices are similar, one can deduce the same for the expected benefits”. Asked if this holds also true for the risks, responses were more cautious. Nevertheless, three out of five felt that most aspects also applied for the general area’ and one added that the discussion did not differ much from any discussion about the introduction of new technologies.

In order to better understand if the risks are largely a result of the application area or rather the NT-component as such, the interviewees have been asked “which of the risks mentioned are directly associated with the nanotechnological component/feature of the technology?” Responses were quite mixed. Some explained they didn’t see any risks directly associated with the NT component, while others explained the NT-feature was the enabling component, which was why all risks were bound to it.

One of the last interview questions opened a discussion which of the ELSA benefits or risks mentioned in the media were actually relevant for the debate on Nanotechnology. Issues connected with nanoparticles impacting on human health and the environment were mentioned as most relevant. One interviewee felt there was already some confusion with the GMO-debate, while another explained not to differentiate between the wide variety of applications might be dangerous as all potential risks tended to be "lumped together" and thereby posing an obstacle for each specific application.

Lacking differentiation of risks connected with different NT-applications may lead to confusion in the public NT-debate.

The following passages provide a more detailed description of the answers received.

Environmental Performance

The majority of interviewees felt that NT-based LOC-applications would reduce the environmental impact of medical diagnostics thanks to lower material, chemical and energy intensity compared to traditional applications. Some expected this to hold true even if LOC were designed as one-way disposable devices, while others doubted this, highlighting that materials would not be biodegradable or even toxic. Further environmental risks were not mentioned. Overall the aspect of environmental performance was not perceived to be of high priority and NT-based LOC-applications were expected to pose no major environmental difficulties.

Overall environmental performance was not seen as a top priority

Human Health

Being involved in the medical sector the interviewees considered human health to be the most important ELSA. Benefits to human health were expected to derive from medical NT-applications in diagnosis (and treatment) through

Human health considered as most important ELSA.

- improved analytical performance allowing cheap routine tests on a multitude of parameters;
- higher sensitivity and analysis automation allowing an earlier diagnosis;
- shorter response times, e.g. in emergency cases;
- portable and simple use, enabling point-of-care diagnoses;
- overall improved and more personalised health care.

Failures in the diagnosis process or the misinterpretation of data, subsequently leading to wrong medications or treatments, were seen as main risks by almost all interviewees. Reasons mentioned related to malfunctioning devices, pirated or fake products as well as the fact that once point-of-care testing kits are on the market, non-experts are expected to conduct tests for a wide range of diseases and disease dispositions. One interviewee put it the following way: "If a person discovers a cancer disposition with a cancer quick test, but would have no access to a doctor, how would this person react?" Referring to the possibility of increased health monitoring one mentioned the risk of a change in the general perception of health. He remarked: "it becomes a question of what is regarded to be healthy: If everything can be monitored all the time, people may feel, they have to do something on their present health state while it is not really necessary. […] - In a way there is always something wrong with everybody every time."

Will an increased health monitoring change our perception of health?

Risks deriving from nanoparticles used in LOC applications in the use phase were not seen and only one interviewee mentioned the importance of safety standards in the production phase.

Privacy

Privacy was seen as one of the most important ELSA

The protection of data (health data or even genetic information) generated with help of LOC-applications, i.e. the aspect of "privacy", was considered to be one of the most important ELSA next to "human health". One interviewee called it "one of the biggest issues" and highlighted "bearing in mind the convergence with other technologies, in particular ICT, the protection of data as well as the possible manipulation of the same deserve[d] special attention". However, one participant remarked specific regulation on these issues was required no matter if LOC-applications were used or not. Another interviewee explained privacy would only become an issue if samples were taken without notification of the person. He mentioned an LOC-based monitoring application build in a toilet as an example where a person might undergo monitoring for diseases, drugs or other substances without his/her knowledge.

Access

While most interviewees expected LOC to become available to all societal groups in industrial countries in the long term, others plainly doubted it. Only one of the interviewees explicitly mentioned the issue of "intellectual property rights" (IPR) stressing that ethical issues were

of “highest importance” and that questions about patents and intellectual property rights “remained unsolved”.

Asked for the likelihood for a nanodivide to happen within a country or society, one interviewee explained with regard to point-of care and home use applications there was a risk of exclusive use in terms of skills. Even the usage of conventional pregnancy tests required “certain abilities such as to read”, he explained.

Acceptance

Acceptance was in general considered to be a very important issue and crucial to the development of nanotechnologies. When asked to provide their vision of nanotechnology-development until 2015 two interviewees named “lack of public acceptance” as one of the main hurdles for the technology.

The general public hardly know about LOC applications.

However, the general public hardly knows about LOC applications, not to mention the connection to NT. The usage of NT-based applications was not considered to be at risk due to lacking public acceptance in the medial sector in general.

Liability

Diverging opinions were voiced whether special attention was needed in the areas of product and environmental liability. While two out of five experts considered current regulative frameworks to cover liability-aspects sufficiently, two others called for special attention in this area.

Regulation and control

Interviewees call for a more harmonised regulation.

In general the interviewees considered regulation and control to be an issue of medium importance. For LOC all but one interviewee felt the current regulative frameworks in general were sufficient, “if not overregulated in Germany” as one participant added. One of the interviewees felt unsure about a “need for additional regulation” however added “a better harmonisation of the regulation in EU, USA and Asia” was needed.

Economic potential

Efficiency improvements with positive economic effects were expected due to:

- decreasing pressure on hospitals as patients would less frequently be required to be physically present;

- faster and cheaper analysis;
- an earlier detection of diseases allowing less intense and costly treatment.

No impact on employment expected.

LOC-devices were also expected to become wide-spread in other application areas such as environmental or food quality monitoring. While most interviewees expected LOC applications to contribute to the EU's competitiveness, only one out of five interviewees expected a positive contribution to employment levels.

3.1.2 Food packaging

In order to investigate the benefits and risks of nanotechnology in the area of food packaging five experts were interviewed. All participants of the survey were directly involved in the research, development and commercialisation of nanotechnology based materials for packaging. They are employed at research institutions or companies.

When asked for their appraisal of their own understanding of ELSA, most of the interviewees stated they felt informed, while two felt inadequately informed. However, none of the interviewees felt actually fully informed about all ELSA.

For each of the seven ELSA the interviewees were prompted with the question whether a certain ELSA (at the time of the interview) deserved much, more / less or little attention for NT-based food packaging. The question was posed taking two angles: First the interviewees' own perspectives and second their estimate of the general public's current perception.

Environmental aspects and aspects of human health were rated as the most important issues from the interviewees´ perspectives, whereas the aspect of accessibility was considered to be less important. All remaining aspects were considered to deserve more or less attention. In general the civil society is expected to call for less or the same amount of attention for each ELSA-aspect except for accessibility. This aspect is considered to be of more importance in the public opinion than it is from the researchers´ perspective.

NT-based food packaging - an area of limited societal concern

In general the interviewees indicated that they did not consider food packaging as an application area of particular societal concern. Several added that only few risks are associated with that area. Pointing at NT based food additives, some mentioned this as an area of potentially much higher societal debate. A minority of interviewees

did not expect any specific risks caused by nanotechnology. One of them complained that the term “nanotechnology” was a misleading concept that created confusion in the public’s perception of risks since it was associated with nano robots or gene technology.

Potential benefits for food safety

The majority of interviewees pointed out that the benefits and risks of nanotechnology application in food packaging needed to be evaluated case by case. According to the experts interviewed, applying nanotechnology in food packaging would first of all benefit shelf life and the safety of packaged food. On the other hand the toxicology of certain nanoparticles might be an issue; however, not as a general rule. Nanoparticles which are used or expected to be used in food packaging (such as nano clay or nano silver) are - based on the current state of knowledge - thought not to be dangerous to human health.

Nanoparticles might pose toxicological problems if released into food.

The following provides a more detailed description of the answers received:

Environmental Performance

For NT enhanced packaging materials several environmental benefits and risks were mentioned. However, overall the interviewees indicated that these benefits and risks were of minor importance.

Benefits:

- Reduced usage of energy and raw materials (polymers) as a result of replacing heavier packaging materials by light weight polymer nano composites;
- NT could improve the mechanical properties of biodegradable polymers and make them attractive for being used for food packaging (advantages for plastic disposal);
- NT polymer composites may be beneficial for reusable packaging due to improved mechanical strength;
- Using nanotechnology for reinforcing recycled polymers, making them more capable for technical use, could help to reduce the amount of packaging waste and save resources at the same time.

Risks:

- Release of nano particles into the environment during the production and disposal phases of a product;
- Knoweldge about the effects of engineered nano-materials in the environment is still insufficient;
- Risk of environmental pollution by nanoparticles (persistence and unknown catalytic effects);
- Uncontrolled incineration of nanocomposites could cause emissions of nanoparticles into environment;
- Nanocomposite materials could disturb plastic recycling processes. Recyclers will have to deal with nanoparticular fillers, which eventually will be found in recycled materials.

The impact of nanocomposites on the recycling of food packaging plastic is not clear at the moment.

Human health

All interviewees expected various benefits for food safety resulting from NT enhanced packaging materials. Improvements were expected to come about as follows:

- enhanced barrier properties of polymer nanocomposites would inhibit gas diffusion;
- antimicrobial coatings can inhibit microbial settlement on packaging surfaces and could potentially be substituted for other preserving agents;
- more rapid detection of pathogens or toxins and indication of spoilage.

Food safety is expected to be significantly improved by Nanotechnology.

These features will delay spoilage and therefore enhance the shelf life of packaged food. It is questionable whether this can be seen as a contribution to food safety. Rather than improvements in food safety enhanced shelf life constitutes an economic benefit for distributors and retailers.

Rapid indication of spoilage could certainly contribute to better disease prevention especially for vulnerable consumer groups such as children or elderly people.

As for potential health risks, the interviewees voiced diverging standpoints. While some argued there was no nano specific risk to be expected, others pointed out nanoparticles could potentially pose a

health risk in case they migrate from the packaging into the food. They concluded that further research is necessary in this respect.

Worker safety in the production phase of polymer nano composites could be an issue depending on process parameters.

Another issue was the increasing sterility of everyday objects (including food) due to the widespread use of nanosilver. This might raise the risk of allergies because the human immune system would be unaccustomed to that and might tend to overreact in the long term. However this was not regarded as a nano-specific problem. Nanosilver was also suspected of possibly promoting the emergence of new superresistance among micro organisms.

Privacy

The aspect of privacy was not regarded as relevant for NT-based food packaging. NT based sensors to be applied on food packaging in combination with RFID were sporadically mentioned as potentially problematic in terms of consumer privacy. However this privacy issue was related to the RFID system and independent of the use of nano sensors.

Access

Cost sensitive mass products such as materials for food packaging will only be commercially successful if they are cheaper than existing packaging solutions. Therefore no disadvantage was expected for developing countries.

Technological dependence of developing countries from industrialised countries may be reinforced.

With regard to the general effects of NT on developing countries, benefits were expected, but not further specified. Risks of a “nano-divide”, i.e. an increasing technological gap between developing and industrialised countries as a result of a lack of patents in the former, the expense of R&D etc. were also seen.

Acceptance

Some interviewees warned of a backlash in public acceptance in case benefits and risks are communicated to the public in a non-transparent way. A backlash similar to that in the case of GM food was stressed as the major risk to nanotechnology. This point of view suggested that a lack of public acceptance would hamper the future development of nanotechnology, resulting in a loss of potential benefits of the technology. In addition, public and private investments in R&D would not be amortised as a result. Most experts considered

an honest communication of risks associated with NT to be essential. One interviewee however stated the public debate about potential risks was a risk in itself, claiming that a public and open risk communication could destroy public acceptance of nanotechnology.

Whether labelling of food products using nanotechnology could be an adequate way of communication was judged differently by the experts. On the one hand labelling could support the consumer's freedom of choice. On the other hand it could raise confusion as the term nanotechnology is not clearly defined in the reception of the general public.

Liability

Liability aspects of nanotechnologies were regarded as not different from the liability for any other new product.

Regulation and Control

None of the experts supported the idea of a general NT moratorium as a strong precautionary measure. One interviewee considered a debate about regulation in the area of NT as a risk for innovation since it made investors feel insecure. Another agreed partially by stating regulation activities not based on an unambiguous definition of the subject of the regulation would undermine innovation and commercialisation. Ultimately there was no consensus on which form of nanotechnology was to be regulated and which was not.

Other experts considered careful regulation or standardisation of nanotechnology to be preferable. The uncertain situation today resulting from the absence of a sufficient regulatory framework was preventing companies from bringing new innovative products onto the market.

Economic Potential

Only a few products using nanotechnology are on the marked so far.

Even though food packaging materials were discussed as a promising application area for NT in several news services, the interviewees were not aware of a significant market for sophisticated NT packaging applications today or in the near future. Especially nanoclay polymer composites with enhanced barrier properties were mentioned as being commercially used today. A few products such as food containers coated with nanoparticular silver are on the market.

Generally speaking the majority of interviewees considered the application of nanotechnology in the food packaging sector to be promising as it provides considerable opportunities to the European economy. However nanotechnology will only be successful on the market if NT based products are as cheap as or cheaper than existing solutions, and provide better performance at the same time. NT based food packaging is expected to remain cost intensive in the next 1-2 years. Large retailers are the key players; they will determine the diffusion of NT-based applications for food packaging on the market.

Nanotechnology solutions will only be of interest if they provide a better performance and are not more expensive. than existing solutions.

Asked about the potential for job-creation, some interviewees felt that NT-food packaging might have a moderately positive effect. A new sector of nanotech industry is not expected to emerge.

3.1.3 Energy conversion and production

From the five researchers interviewed in the area of NT-based energy production two mainly concentrate on solar cells while the remaining work more generically in the area of material science and its contribution to solar and fuel cells.

The interviewees felt well (2x) or reasonably well informed (3x) on ELSA with regard to NT-based energy production. When questioned about the main information channels, some mentioned the Internet while studies, education/training or projects appeared to have minor relevance. They observed that conferences on NT do not typically address ELSA as the technical focus is usually predominant. Furthermore, those conferences that do include sessions on ELSA were regarded as addressing these aspects only to a certain (often limited) extent. Nanotechnologies in energy conversion were perceived rather as a result of advanced material sciences (group of very small materials with large surface structures) than as a new scientific discipline itself.

The interviewees identified human health and environmental performance as the most important ELSA. Increasing environmental performance is clearly regarded as most important benefit from NT-based energy applications with important indirect implications for developing countries due to its decentralised nature and expected impact on price reductions. With reference to human health nano-toxicity is mentioned as the only relevant concern.

The researchers' estimation of the general publics opinion reflect their assumption that for some issues such as human health, access, acceptance, regulation & control there is no broad public awareness yet, but can increasingly be expected in the future. For the remaining aspects environmental performance and liability some researchers assume currently a high public concern that will decrease as soon as more sound information on risks is available.

The overview below enlists the main ELSA-related issues and expectations discussed by the experts during the interviews.

Environmental Performance

Enhancement of applications, especially in the area of energy production, conversion, and storage was perceived as one of the primary benefits by the researchers interviewed. They regarded NT as enabling technology offering new and revolutionary opportunities to realise more efficient (i.e. less material intense and/or higher energy efficient) energy production, conversion and storage. Asking for the relevance of NT for sustainable energy production the researchers agreed that it would definitely have an important role to play as enabling technology for combating climate change, but were cautious to announce NT as *the* technical solution to mainstream renewable energy supply. For the future they expect the increasing use of NT-enhanced energy applications to contribute to the reduction of emissions.

"Such increases in efficiency can hardly be realised without the use of nano-structured materials due to its physical properties."

On the risk side, the interviewees showed awareness for potential negative effects resulting from free nanoparticles (e.g. toxicity effects) although they generally agreed that there was currently no evidence that negative environmental effects would need to be expected. Some researchers expressed concern that cheap mass-produced and heavily consumed NT-applications might pose a major environmental impact during end-of-life as disposal strategies and recycling paths had not yet been defined. The challenge of recycling was mentioned by four out of five interviewees and regarded as very important as NT was increasingly becoming an integral part of many different products.

The recycling of nanoparticles/ NT-based applications is one of the primary challenges of NT.

Human health

The interviewees regard human health as most important aspect, closely followed by environmental performance. While risk issues dominate this aspect benefits are seen as well, but are expected to occur rather indirectly.

All researchers (more or less) agreed that the issue of potentially harmful free nanotubes and particles would deserve specific attention and was primarily relevant during production and recycling as particles were expected to be securely encapsulated in applications during the use phase. Although no information about negative health effects were currently available, factors such as the similar shape of nanorods and asbestos and a number of human allergic reactions to small sized particles pointed at possible risks that could not be ruled out.

Toxicity risk during production or disposal

The interviewees expect benefits from renewable distributed energy (e.g. solar cells, fuel cells, enhanced batteries) for the provision of healthcare and the general improvement of the standard of living, primarily in developing countries.

Privacy

The aspect of privacy was not regarded as relevant for NT-based energy application.

Access

From all ELSA discussed with energy researchers the aspect of access was evaluated as requiring the lowest average level of attention.

NT-based solar cells as promising leapfrogging technology for developing countries?

The interviewees agreed that access of developing countries to NT-based energy production applications deserved attention, but rather as an opportunity than a risk. Most expect the costs for energy production to drop significantly due to cheaper energy production. Furthermore a new generation of solar panels produced in low-tech processes could serve as “leapfrogging technology”. On the other hand some argued that such developments required time and efficient mass-production ability, which would not be available within the next 10-15 years.

Intellectual property rights (IPR) were by most researchers seen as part of the solution to benefit from research investments rather than an obstacle that slowed down the use of NT-based applications. Nevertheless minor slow downs due to IPR were expected.

This question whether NT might obscure or divert investments from cheaper, more sustainable, or low technology solutions to health and environmental problems evoked very diverse answers from the interviewees. While some (more or less) agreed that there was always a competition for funding and that technological hypes were successful in attracting money in the short term, others argued that the funding for solar cells or fuel cells has not been changing significantly now that NT was involved. In general the interviewees agreed that the involvement of NT in R&D would not cause hype anymore so that potentials were assessed (and funded) more realistically.

Acceptance

The interviewees regarded acceptance as generally being of major importance at present. They considered the public acceptance of nanotechnological energy applications to be crucial for further R&D. There was agreement that the creation of benefits would significantly contribute to enhance public acceptance.

While there is general agreement that NT-based energy solutions help to increase the acceptance for NT or will equally be affected by societal concerns concerning NT in general, one expert does not see strong linkages between NT-based products.

Liability

Although not agreeing on the level of attention liability deserves at present all interviewees expect this aspect to gain increasing significance in the future as soon as considerable numbers of NT-based products are on the market.

Liability will be of high importance in the next 10-15 years.

The researchers in general expect that NT-based products are be sufficiently covered by product or producer insurance. Uncertainties about risks from nanotoxicity and nanopollution will not prevent insurance companies to insure such products. Additionally, the majority of energy researchers considered it being likely that nanoparticles could be traced back to the polluter due to their specific production-related structure. This would lay the ground for practically enforceable liability obligations.

Regulation and Control

The majority of energy researchers agreed that the current regulatory framework addressed safety standards sufficiently as most national laws on customer health & safety were applied from the impact side and would hence automatically cover impacts/accidents resulting from new technologies. One interviewee was concerned that due to its physical properties NT-based applications might require additional regulation. He also made the observation that most technology-focussed regulation lagged well behind technological developments.

Laws are assumed to be sufficient.

There is a considerably high level of agreement among energy researchers that shared principles of the safe, sustainable, responsible, and socially acceptable development and use of NT should be addressed by a framework on the EU-level.

Researchers agree on need for shared NT principles on the EU level.

Economic Potential

The interviewees stated that a technology-based leading research position generally tended to result in positive economic benefits in terms of economic growth and most likely regarding job creation. They agreed that NT plays a central role as enhancing/enabling technology that would substantially influence an increasing number of products.

NT will enhance a wide range of products.

The interviewees expected many NT-based/-enhanced energy applications to be of great economic potential, including enhanced rechargeable batteries, fuel cells, and solar cells/panels. Furthermore, NT-based energy applications would influence a wide range of commercial applications including mobile devices (laptops, cell phones etc.), vehicle engines, and stationary equipment (e.g. decentralised household energy supply). Additionally, such NT-based applications would stimulate and enable new inventions and development and other industries.

From the interviewees' perspective the EU would currently not take the lead in the development of fuel cells and NT-based solar photovoltaic. One expert pointed out that Europe had a leading position in NT research, but would miss out on developing marketable applications. Instead new NT trends were more often set in Asia.

3.1.4 Nanotechnologies in general

Five researchers, from various application backgrounds, were interviewed about their perspective on nanotechnologies in general. Unlike in the groups discussed above, no applications were specified in advance and the interviewees were asked to try answering the questions at a more general level. Obviously, their personal area of expertise influenced the answers.

Regarding their fields of expertise, most researchers interviewed were personally interested in ELSA and felt well informed. Many had already discussed ELSA-topics with colleagues.

However, leaving their area of expertise and being asked about ELSA of NT in general most participants expressed they lacked an overview and would only be able to provide a few examples. Most interviewees highlighted the vast number of NT-applications made it almost impossible to sufficiently answer general questions.

Being researchers in a certain application area most interviewees clearly see a necessity for increased cooperation with other disciplines. They also demanded additional information on nanotechnology for non-experts e.g. if these non-experts were involved in the process of creating regulation. Most interviewees appreciated the approach taken in the Nanologue project and showed great interest in the envisioned deliverables.

Human health and environmental performance of highest relevance

Overall the aspects human health and environmental performance were considered to be of highest relevance for the current debate. Benefits from applications in both areas as well as potential risks associated with nanoparticles to human health and the environment were mentioned.

When asked to provide a vision on NT-development until the year 2015 aspects of public acceptance e.g. scandals like fraud, ethical concerns, clarification of health risks were mentioned on several occasions and stressed to be important factors. Other issues like funding, regulation and control and technical hurdles e.g. the time demand to assess the long time stability of nanoparticles and –products were mentioned once.

For each of the seven ELSA all interview partners were asked whether from their point of view the aspect deserved much attention, more or less attention or little attention. In addition they were questioned about their impression on the importance each ELSA-topic had within the public opinion[6].

While most members of the generic expert group agreed that aspects of environment, human health, public acceptance, and regulation and control (including liability) deserved much attention, aspects of privacy and accessibility of nanotechnologies were considered to deserve only more or less attention.

Asked about their sense for the publics perception on these aspects, they considered it to be more or less on the same level.

The following passages provide a more detailed description of the answers received within the interviews.

[6] i.e. if it deserved much, more or less, little attention from the point of view of the civil society

Environmental performance

NT applications expected to benefit the environment

Most interviewees felt that generally speaking NT applications would benefits the environment and contribute to improvements in the overall environmental performance of products. Main reasons mentioned were

- eco-efficiency gains due to miniaturisation effects e.g. “cleaner manufacture […] with less emissions and less waste”;
- the ability to build devices bottom-up;
- and NT-based environment technology applications like devices for waste water treatment.

All researchers interviewed were aware of the current discussion on risks that nanoparticles might pose to the environment and most interviewees considered it to be an important issue. However, the overall risk was considered to be minor and to level off in future if nanoparticles were handled properly and additional knowledge about reactions of individual nanoparticles to the environment could be gained. One interviewee said “I don’t see too many problems with negative environmental impacts of nanoparticles in the long run. In the short run we might encounter some problems, since we don’t know how to handle them”. Two interviewees pointed out that combustion processes already emitted large amounts of nanoparticles, but that these risks were (at the time of the interview) not included in the debate on nanoparticles.

Human health

Next to “environmental performance” and “regulation and control”, “human health” was perceived as the most important ELSA by this group.

Human health considered one of the most important ELSA

Benefits expected in the medical sector

Benefits to human health were expected by all interviewees through medical NT-applications in diagnosis and treatment, while the most prominent risk mentioned related to toxic effects of certain types of nanoparticles[7]. Workers at production sites as well as consumers using NT-based applications were highlighted as groups in danger of being exposed to toxic particles. Moreover, risks associated with possible failures or malfunctions of NT-applications e.g.

[7] The term ”nanoparticle” has been used in this report to represent all forms of engineered nanoparticles.

misinterpretation of diagnostics data or side effects during treatment were mentioned.

Privacy

Unprompted, none of the interviewees felt "privacy" was an important issue within the general debate on nanotechnology. When specifically asked to which extent they agreed to the statement "The potential impacts of NT applications on privacy deserve much more attention" most participants considered it to be of medium relevance.

Access

Developed and developing countries are expected to benefit from NT in the long run, but will dual safety standards be applied?

All interviewees felt nanotechnologies would benefit both developed and developing countries in the long run, however most of them expect applications to be introduced in developed countries first. A technology divide was expected by some participants. Two interviewees pointed out the risk that lower health and safety standards could be applied if production facilities operated in less developed countries. Issues around the access to NT-applications for different societal groups within a certain country or region have not been mentioned.

Acceptance

Public acceptance was regarded to be a crucial factor for NT-development. Four out of five interviewees mentioned the aspect of public acceptance when asked to name the three main hurdles of NT-development until year 2015. When discussing the necessity of additional information campaigns, opinions varied whether it was sensible to conduct additional campaigns before additional information on toxic effects of certain groups of nanoparticles could be obtained.

Liability

Diverging opinions were voiced whether special attention was needed in the areas of product and environmental liability. While two out of five experts considered current regulative frameworks to cover aspects of liability sufficiently, two others called for special attention in this area. A fifth interviewee considered regulation on product liability to be sufficient, but indicated in the area of environmental liability special attention was needed. He suggested implementing a general obligation to conduct technological impact assessments as a way to address this problem.

Regulation and control

"Most of the time regulation comes up once an accident has happened. That's what I expect to happen with nanotechnology as well."

A wide and diverging array of responses was given with regard to regulation and control. Some interviewees stressed the importance of learning from the GM-debate and amending regulation, but doubted this would happen in time: "…because most of the time accidents […] happen, and after that regulation comes up. That is, what I expect to happen with nanotechnology…"

Others expressed the need for developing less general and more specific regulation to sufficiently address safety concerns. Opposing the need for additional regulations, one expert explained that business would refuse to market applications without sufficient safety standards anyway. Other participants considered the current standards to be sufficient.

Economic Potential

Diverging opinions about the potential of NT-applications on employment levels.

All interviewees expect NT-applications to bear significant economic potential, mainly in terms of new or improved products and applications. Two out of five researchers expect NT to become an important factor for strengthening the EU's competitiveness. Asked about the potential impact on employment levels in the EU, some interviewees await a positive impact while others remain sceptical.

3.1.5 Summarising overview researcher

Having described the responses gained per expert group, the following chapter intends to present a more holistic perspective, looking for differences and commonalities as well as certain patterns between the different groups.

Most interviewees had some insights in the ELSA discussion, but lacked a comprehensive overview.

Confronted with the question "To your understanding, which are the potential benefits/risks and problems NT-based applications might bring to society" most interviewees came up with two or three issues. For getting a broader picture, the interviewers continued by explicitly asking for the experts' position with regard to a pre-selected number of ELSA (see interview guide). Judging from these responses as well as from general remarks in the course of the interviews, it appears that although almost all experts interviewed already informed themselves about ELSA and considered it important, most lacked a comprehensive overview on the variety of aspects possibly of relevance.

Generally speaking, the opinions and perceptions of the different groups interviewed did not differ to a large extent, but rather varied with regard to the applications in focus. Common statements found for all groups relate to:

- Environmental risks (eco-toxicity) and environmental opportunities (resource efficiency gains);
- Human health risks (toxicity) and opportunities (disease treatment and diagnostics);
- Parallels to the GM-debate.

Almost all of the issues mentioned in course of the interview, could be classified according to the seven ELSA. Only the possibility to use NT-applications for military purposes was not covered from the beginning. However, the consortium explicitly decided at the projects start to consider this aspect out of scope. As an application area the pursuit of military purposes with the help of nanotechnologies cannot be compared with conventional industrial applications as they go along with different ethical, legal, and social incentives and priorities. While for most industrial applications ELSA aspects include a preservation of values as the environment, human health, privacy, and equal accessibility, main goals of military purposes can include to harm human health and the environment while accessibility should

rather be restricted than promoted, and aspects of privacy are often set aside at a situation of war.

The figure below shows the interviewees average responses now aggregated for all interview groups when prompted with the question, if a certain ELSA (at the time of the interview) deserved much, more or less or little attention. The question was posed taking two angles: First the interviewees own perspectives and second their estimate on the general publics current perception.

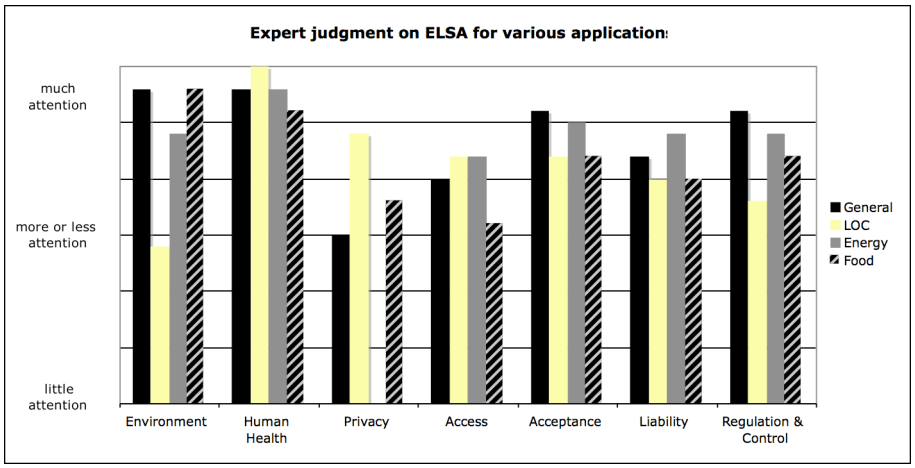

Figure 3: ELSA priorities as perceived by the experts (temporary)

The overview below enlists the main issues discussed by the experts during the interviews:

Environmental Performance

Overall, a positive impact of NT-applications expected.

Most interviewees felt that nanotechnologies would eventually contribute to improvements in the overall environmental performance due to eco-efficiency gains, miniaturisation effects or enhanced mechanical properties as well as through NT-based environment technology applications, e.g. testing and monitoring systems. Although the eco-toxicity potential of nanoparticles was perceived as a risk, the interviewees expected the overall impact of NT to remain positive, especially as cautious handling of nanoparticles was expected for the future.

Human health

Human health was perceived as one of the most important ELSA issues by most of the interviewees. Benefits were expected to derive from NT-applications in the area of medical diagnosis and treatment

as well as a result of improved food safety and water treatment which was perceived especially important in developing countries. A possible drawback mentioned several times are risks of misinterpretation of diagnostic data and the possible wrong treatment of diseases. This however was seen as no NT specific problem. Almost all experts were aware of risks discussed in connection with free nanoparticles, however felt it could be minimised through proper handling and efficient safety standards.

Privacy

Relevance of privacy depends on the application in focus.

The extent to which the aspect of "privacy" was considered important depended very much on the application in focus. While the experts interviewed on energy and food applications as well as those on general NT did not consider privacy as to be an important issue, the LOC group considered it to be one of the most relevant ELSA.

Access

While the aspect of accessibility of nanotechnology was overall considered to be an issue of medium relevance, most experts expected that the access to sophisticated NT-applications such as LOC would be limited to industrialised countries at the beginning.

Only for the area of medical diagnostic "access within a country or society" was subject to discussion. Statements whether the applications would be available to all societal groups disregarding their income or health insurance ranged from the expectation of NT-based LOC to become standard diagnosis tools helping to reduce the overall costs of the medical sector, to the statement that at first LOC-applications would only be available for a privileged group of people. No mention by any interviewee found the discussion about the access and abuse of NT by e.g. criminals or political regimes.

Acceptance

Impact of (lacking) public acceptance seems to differ from application area to application area (cp. medical applications)

Researchers from all application areas considered public acceptance of nanotechnology to be crucial for NT-development and a risk in itself. Some even felt that it was more important to deal with than the potential adverse effects of the technology. However, the impact (a lack of) public acceptance for NT in general is expected to have on the development in certain application areas differs. Whenever the use of NT results in personal benefits for the consumers, e.g. in the area of medical diagnostics, public acceptance is expected to be of lower relevance.

Liability

Not having interviewed persons with specific knowledge on the topic, liability issues were not considered to be of high priority, even though it was acknowledged to be an topic that needed more careful consideration in the future.

Regulation and Control

Widely diverging responses on the need for regulation.

A wide and diverging array of responses was given with regard to regulation and control. Doubts were voiced if sufficient regulation would or could be developed in time, others expressed the need for less general and more specific regulation, and yet again others (such as the majority of energy researchers) opposed the need for additional regulations arguing that most safety laws were applied from the impact side and hence automatically covered impacts/accidents resulting from new technologies.

Economic Potential

While all experts saw economic potential in terms of improved or new products, only a minority of experts believed NT would positively contribute to the overall job situation on long term basis. About half of the experts expect NT to contribute to the EU's' competitiveness in the future.

3.2 Civil society interviews

This chapter reports on the results of the civil society interviews. As well as questions on NT in general all participants were asked if they had a particular interest or expertise in food, energy conservation and storage or medical diagnostics. Only a small minority of interviewees felt they did not have a specific area of interest. Medical diagnostics was a slightly more popular topic, with a third of interviewees answering further questions in this area.

All of the interviewees discussed and understood a variety of both potential benefits and risks of NT. There was also an awareness that although benefits were potentially great, the risks could 'take over' if not managed and communicated properly. As one interviewee put it, there is potentially "97% benefit, 3% risk, but that 3% could kill the technology if not communicated".

"97% benefit, 3% risk, but that 3% could kill the technology if not communicated".

3.2.1 Nanotechnologies in general

When the participants were asked unprompted (i.e. not from a pre-determined list) for their opinion on which ELSA benefits or risks discussed in the media (or elsewhere) were relevant for the debate on Nanotechnology, they listed three times more risks than benefits (although this might have been as a result of the way the questions was framed).

No positive discussion - public discussion currently concentrates on risks of NT rather than benefits"

However, as one interviewee noted, this may be due to the fact that NT tends to sit in the business to business (B2B) relationship. The message about the benefits of NT tend to be discussed formally during the B2B transaction, but these discussions do not reach the public. "Instead, the public discussion about NT concentrates on potential problems – the risks not the benefits", i.e. what tends to be reported in the media.

When discussing benefits the interviewees focused on the potential for NT to improve the efficiency of resource use i.e. the ability to do more with less. Grouped by ELSA, the following is a summary of the general risks and benefits discussed during the interviews. The only risk that was cited that sat outside the ELSA defined in the first project phase was military and security applications of NT.

In addition to the initial unprompted discussion, interviewees were also asked the extent to which they agreed or disagreed with a set of statements related to the seven ELSA (See interview protocol in

Annex III). The responses that where relevant to this section are also outlined below.

Environmental Performance

Resource efficiency gains expected.

The majority of interviewees fully agreed that the application of NT will help to improve resource efficiency e.g. through the use of less materials or energy. General benefits listed included potential improvements in nano-filtration of water and improved energy storage and transfer.

Although toxicity was seen as the most pressing risk in this area, with a third of all interviewees concerned about the environmental impact of nanoparticles, there was less agreement with the statement that "nano-materials present an eco-toxicological risk, in particular in the disposal phase."

Human Health

Health benefits among the top listed.

Of the benefits listed, medical and health benefits were cited most often with the majority of interviewees fully agreeing that applications of NT will enhance human health through earlier disease detection and better-targeted application of treatment.

A third of all respondents expressed concern over toxicity and human health, with occupational hazards and the use of NT in food, particular concerns.

Privacy

In the initial discussion there was no mention of this issue from interviewees. However, when asked specifically about privacy the majority of interviewees more or less agreed that applications of NT will lead to issues around the collection of data e.g. through military/espionage devices or medical technology.

Access

Social justice and the nanodivide, the use of patents, corporate power and economic disruption were all cited as potential risks in this area.

The majority of those interviewed either fully or more or less agreed that developments in NT are key to addressing challenges such as provision of clean water for all and sustainable energy production.

Acceptance

Several interviewees noted that there were possible risks associated with media communication of NT threats in general. This included hype around “grey goo” and the vision of NT destroying the world, which several interviewees commented was not based on sound science.

The majority of interviewees were also more or less sure that there would be a public backlash against the use of nanomaterials in areas such as food and medicine.

Public backlash expected.

Liability

There was no mention of this issue from interviewees in initial discussion apart from a general sentiment that information and guidance on legal issues was lacking. There was no consensus on whether environmental liability regulations were sufficient to deal with the introduction of nanomaterials.

Regulation and Control

Several interviewees raised the ethical risks of medical applications using NT with a specific concern that current pharmaceutical regulation is not sufficient to cover NT.

There was no agreement as to whether additional regulations were necessary to deal with the use of nanomaterials and one interviewee also raised the possibility of additional legislation hindering progress.

No agreement on need for additional regulation.

Numerical Results

During the interviews the delegates were asked to score ELSA criteria and statements on those ELSA reflecting their importance (See questionnaire in Appendix IV). This section summarises those results.

The graph below clearly demonstrates that there was a high level of agreement that human health and environmental performance deserve more attention. This contrasts with the low level of agreement about the issue of access. Acceptance is obviously another area of concern.

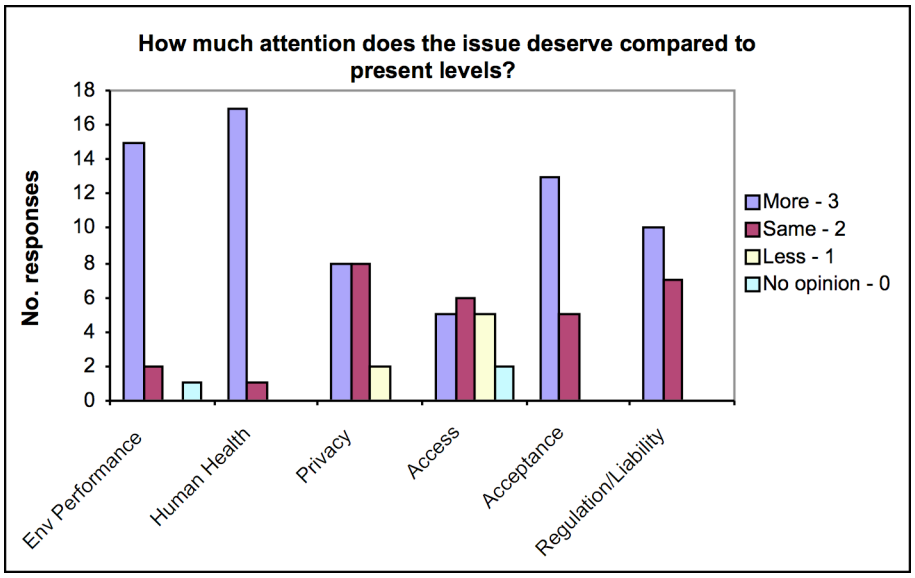

Figure 4: ELSA priorities of interviewees

The next figure shows the interviewees agreeing that civil society should call for action on human health and environmental performance. However, there is disagreement as to whether society should be concerned about areas such as privacy, access and liability.

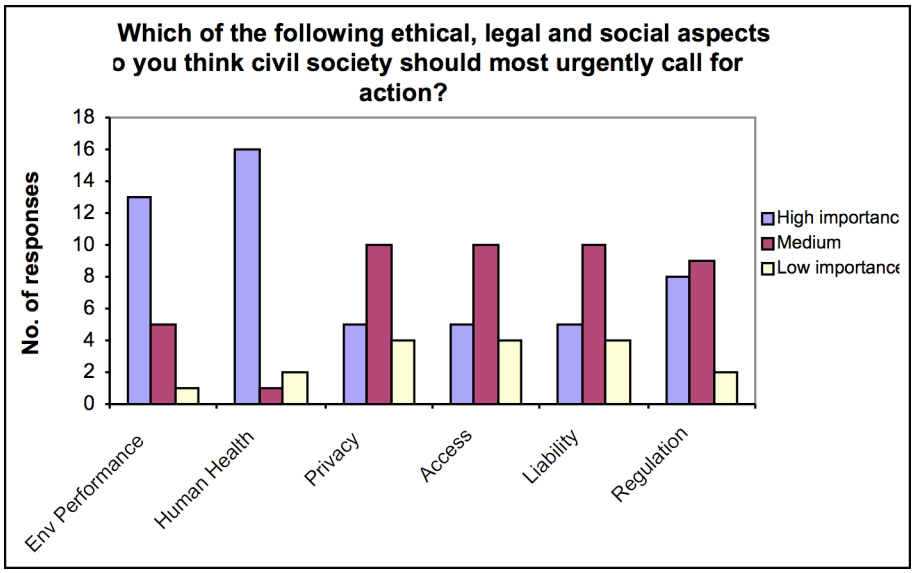

Figure 5: ELSA of civil society

Figure 6 shows that the majority of interviewees feel that attention will increase on all the ELSA mentioned with a unanimous vote on human health

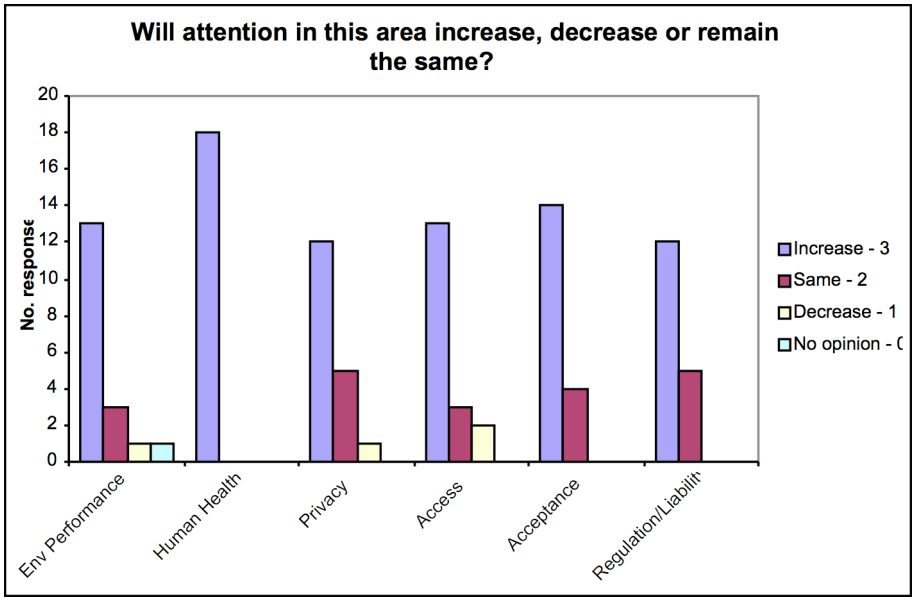

Figure 6: Will attention increase, decrease or remain the same?

The majority of those interviewed were not happy to answer this question as they felt that public level of knowledge was generally poor. However, there does seem to be some differentiation with most interviewees marking the level of knowledge on Access lower.

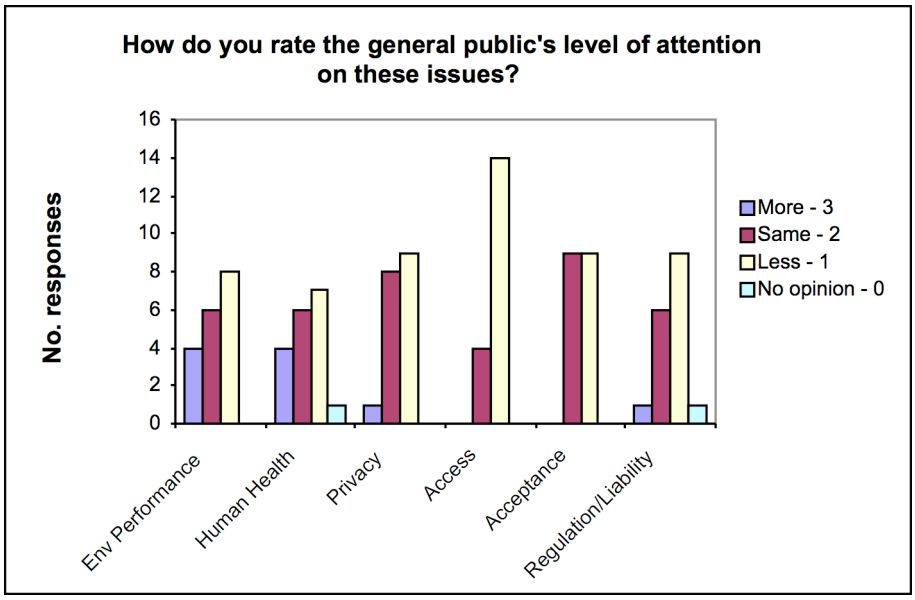

Figure 7: the general public's level of attention

3.2.2 Medical Diagnostics

Next to questions on NT in general, the interviewees have been asked if they had a particular interest or expertise in the food, energy or medical sector. Seven interviewees chose to talk about the medical sector, 5 about food and 4 about energy. As for the medical sector, most interviewees felt that the use of NT in sector was inevitable, as one interviewee commented, “the only way industry can go is smaller”.

Human Health

Interviewees were asked about the potential benefits and risks of NT in the medical sector in general. In terms of potential benefits, several interviewees talked about drug delivery, specifically increasing performance through targeted drug delivery and “smuggling” drugs past immune system.

It was felt that NT could contribute to raising the standard of health in general, enabling a reduction in costs of screening, diagnosis and treatment as well as less invasive procedures. NT could increase capacity to reach an early diagnosis, providing a more available service through shorter waiting times.

Will screening programmes change our perception of health?

Whilst it was felt that NT could bring about cost reductions in some areas, there might be a demand for services in greater volume, which could, as one participant noted, in fact mean more costs; “the danger is that this development leads to big screening programmes which could be problematic if it leads to costly screening for everyone ‘just in case’. People may no longer feeling assured that they are not ill just because they do not display symptoms!”

Other benefits mentioned for medical applications in general included; the use of NT for tissue and organ engineering and implants, improvements in imaging technology and benefits to the development of stem cell therapy.

On the other hand, there was a fear expressed that diagnosis will advance faster than treatment, with cancer treatment noted as an importance exception.

There was a specific concern over the potential negative impacts on human health through the use of NT in medical diagnostics, for example the use of quantum dots in *in-vivo diagnostics*.

Privacy

There was a concern over the lack of protocols for ethical issues around human research e.g. will ethics develop as fast as the technology and will data collection and privacy issues be sufficiently dealt with?

Access

There was little discussion apart from concerns over a nanodivide developing in this area through unjust distribution of resources.

Acceptance

One interviewee commented that the conservative habits of medical profession could hinder developments in this area.

Regulation and control

Apart from the question of ethics (see privacy) there was no mention of this aspect in this area during our interviews with civil society representatives.

3.2.3 Food

Potential benefits listed by interviewees can be split into the use of NT in food itself or "nano-inside" and the use of NT in food production, transport and packaging or "nano-outside".

In terms of applications of NT, interviewees raised specific examples including films or barriers to prevent oxygen and ethylene contributing to the deterioration of food, nanosensors for pathogen and contaminant detection and nanodevices to track shipments.

There was also some general discussion of the use of NT in food and the fundamental question of whether further industrialisation of food and agriculture is necessarily a good thing? One interviewee asked the extent to which this is a "nanofood" debate or whether it is it about the future of food systems?

Environmental Performance

There was a feeling that there has not been enough research into possible risks, particularly in terms of environmental performance.

Human Health

Benefits mentioned included 'smart food' to deliver drugs and nutrients and the potential of NT to make products cheaper and safer e.g. get rid of bacteria. The future possibility of self-assembly of food from basic elements was also mentioned.

There were concerns over the negative health impacts e.g. free nanoparticles entering body by ingestion and then bioaccumulating. One interviewee gave the example of colloidal fullerenes potentially polluting aquifers demonstrating a negative impact on fish and potentially humans.

Acceptance

""NT near our food sounds crazy"

Possible risks included the general fear that the use of NT in food could go the same way as GMOs. As one interviewee commented, the "GMO experience is one of the most awful ghosts in the NT community, especially in Europe. NT used near our food sounds crazy."

3.2.4 Energy

The only response that cannot be grouped according to ELSA was the potential geo-political implications e.g. less dependence on oil and gas in the Middle East.

Environmental performance

NT-based energy systems expected to help overcome the impacts of today's energy production systems

There was a focus on the potential for NT to help improve environmental performance and to help overcome the negative impacts of today's energy production and use. For example, according to the interviewees, NT will help with the development of technologies to fill the gap left by shrinking oil resources and the optimisation of new structures, which could improve use of sustainable energy sources. The potential to produce more efficient fuel cells and flexible solar cells was discussed, along with the reduction of pollution and improvements in the storage of hydrogen.

Despite these potential benefits, one interviewee sounded a note of caution: “the technical risks are substantial, and there is no guarantee that any of the huge advantages will be realised”.

There were also concerns over **eco-toxicology** and the risks from production and use of new materials.

Human Health

The main concern was around toxicology and safety issues arising from using hazardous materials (environmental and human risk).

Access

It was hoped that the application of NT may improve access to energy i.e. more people able to use energy at lower cost.

3.3 Civil society stakeholder workshop

The following section is a summary of the results from a one-day workshop. For a full breakdown of the workshop results please see Annex V.

3.3.1 Risks

The main topics of concern were toxicity of nanoparticles and the social impact of nanotechnologies under the banner “the nanodivide”. There was also a concern about the “nanobubble”, a term coined during the workshop.

Toxicity

Potential toxicity seen as greatest risk.

The issue that was considered the greatest area of risk was the potential impact of nanotechnologies on human health and the wider environment. However, the participants were not certain that these impacts would be an issue by the year 2015 due to lack of information and research in this area.

Nanodivide

The term nanodivide was used as a collective term to cover a number of concerns including:

- Concentration of power and access to nanotechnologies (cost of medical treatments for example);
- Access and equal distribution of the technology globally;
- Access within society or between societies.

Nanodivide highly likely to happen.

The delegates scored the “nanodivide” as highly likely to be an issue by 2015. There was recognition that this is not specific to NT and stems from a wider societal problem around the introduction of technology. However, there was a concern that government is limited in the actions it can take to prevent the introduction of nanotechnologies widening the divide.

The Nanobubble

Lacking focus of investments in NT.

Delegates believed that the massive investment in nanotechnology lacked focus and was going to create “products that we don’t want” and society does not need It was felt that private and public investment in the technology is not publicly driven enough and there

was a risk that the development of these unnecessary products would be at the cost of developments that would be of benefit to society as a whole. This lack of focus combined with huge investment and the hype surrounding the technology would result in a "bubble" that would eventually burst.

These risks were mentioned but not discussed in detail at the workshop:

- Consumer acceptance of the technology e.g. in food;
- Regulatory Framework is unable to keep up with new technology and a lack of current legislation;
- Concerns about military and terrorist uses.

3.3.2 Benefits

The key benefits discussed were improvements in medical diagnostics and the potential to reduce environmental pollution/impacts through the use of NT.

Medical Diagnostics

While the group did not discuss the topic in detail it was generally felt that society would see benefits from application of nanotechnologies in this area by 2015. Improved medical diagnostics and better-targeted drug delivery would result in improvements in health and wellbeing and possibly a reduction in healthcare costs.

Reduction in Environmental Pollution/Impacts

The delegates believed that application of nanotechnologies would eventually result in improved industrial processes with less impact and cost and greater efficiency. However, these improvements were deemed less certain to occur within the time frame stipulated.

- New possibilities for "new economies" and diversification of Technology;
- Improvement of living conditions through reduction of environmental pollution;
- Reduction of social conflicts due to more efficient use of resources such as water and energy.

3.3.3 Summary of civil society interviews and workshop results

This section provides a summary of the main risks and benefits discussed in the interviews and the workshop and highlights the key areas of interest.

Human Health and Environmental performance

Uncertainty about impacts to human health and environment.

The concern surrounding human health and the environment was expressed clearly in the interviews and confirmed through the workshop, though delegates seemed to be uncertain as to whether we would see any environmental or human impacts by 2015. The uncertainty was due to not having enough information on the possible impacts on human health and the environment and all the delegates called for a concerted effort to increase funding and research in this area. It is essential that society has more knowledge in this area before widespread introduction of the technology.

Privacy

Privacy was rarely discussed but was mentioned in conjunction with medical applications and concerns about data collection. This was not considered a major issue.

Access

Though it was not raised as a major issue in the interviews the strength of feeling about the issue of a nanodivide became far more evident in the workshop. The issue of "Access" was discussed in the interviews and was an area where the interviewees felt public knowledge was poor but likely to increase. However, in the workshop, the nanodivide was voted as key risk and likely to have an impact by 2015. There is a possibility that this may have been down to how the questions were framed in the interviews but it is also possible that there might have been a "social effect" of discussing the issue in a group that raised the profile of the nanodivide. The participants also commented that this issue was based on a much wider issue of the introduction of technology into society and perhaps the discussion around nanotechnologies was the ideal platform to tackle this broader topic What is the framework that should be used to guide the introduction of technologies to ensure wider benefit for society?

Access seen as a key risk for the development of the technology during the workshop

Acceptance

Public acceptance of the technology was mentioned in the discussions about food but did not really feature in the general discussion. However, there was a general consensus that the topic deserved more attention and there where several references to the GMO situation and what lessons could be learnt particularly around corporate power and transparency. There was also concern that the hype surrounding nanotechnology would create an attitude of mistrust and this could impact on acceptance of the technology.

Reference to the GMO debate.

Liability

A number of interviewees felt that there was a lack of information available on the legal aspects of nanotechnologies. Hence, there was little discussion.

Regulation and Control

A number of participants felt that current legislation was not sufficient to deal with the introduction of nanotechnologies. Most of the discussion on this area was in the recommendations made later in the discussion on how to mitigate risks and maximise benefits.

3.4 Integrated overview - benefits and risks perceived by research and civil society

3.4.1 Effects on different levels – 1st to 3rd order

Discussing ethical, legal and social issues arising from NT-applications shows that only few issues become matters of concern as an immediate result of the underlying NT-component/technology. More typically, the ELSA are associated with specific applications. The research also shows, that a significant number of issues is not new or unique to nanotechnologies, a finding confirmed by the RSA "most of the social and ethical issues arising from applications of nanotechnologies will not be new or unique to nanotechnologies. However, the RSA takes the view that effort will need to be spend whenever significant social and ethical issues arise, irrespective of whether they are genuinely new to nanotechnologies for not.[8]"

Research to date into NT and ELSA has failed to create a commonly accepted analytical framework to capture the different opportunities and impacts as well as their underlying causes. Without such a framework, determining how to maximise the opportunities and minimise the impacts is problematic. Adapting the categorisation scheme applied to capture the opportunities and impacts of Information- and Communication Technologies and sustainable development[9] [10], the following levels of effects can be differentiated:

First order effects: Impacts and opportunities created directly by the physical properties of NT-components. One example would be the (potential) toxicity of NT particles.

Second order effects: Impacts and opportunities that derive from applications using NT-components and/or NT-based solutions. The performance of these NT-applications should be significantly influenced by the NT-component or NT-solution. For example: Higher

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[8] Royal Society/Royal Academy of Engineering: 'Nanoscience and Nanotechnologies: Opportunities and Uncertainties', Report of the Royal Society/Royal Academy of Engineering Working Group, 2004, p. 51.

[9] Geibler, J.v.; Kuhndt, M. & Türk, V.: Virtual Networking without a Backpack? The Resource Consumption of Information Technologies. In: Hilty, Lorenz M., Seifert, Eberhard K. & Treibert, René (Eds): Information Systems for Sustainable Development. IDEA Group Publishing, Hershey PA (USA), 2005, p. 109-126.

[10] EITO: European Information Technology Observatory 2002, p. 253.

efficiency of energy conversion or storage due to the use of nanomaterials with large surface structure or saving of polymer raw-material resulting from enhanced mechanical stability of polymer nano-composites.

Third order effects: Impacts and opportunities created by applications using NT-components and/or NT-based solutions that are not genuinely associated with the NT-application but rather with the introduction of a new technology application in general. For example the discussion about a potential NT-divide is not unique for NT, but for new resource and knowledge intensive technologies in general.

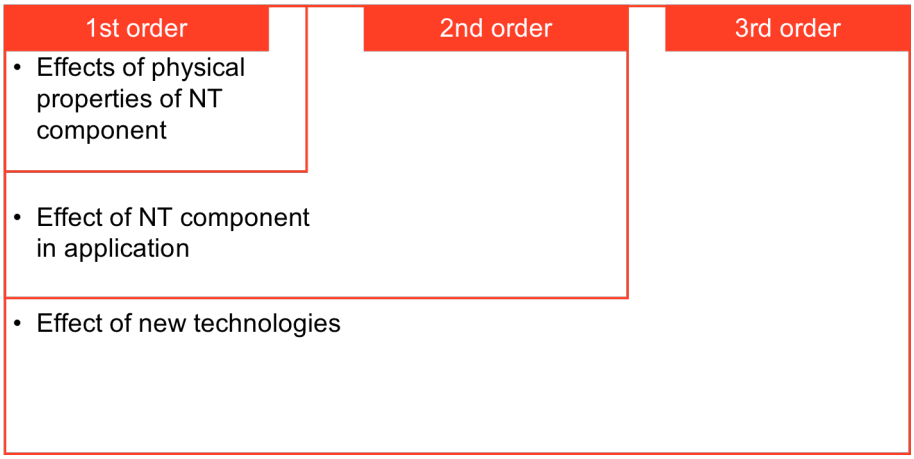

Figure 8: first to third order effects of nanotechnologies

Without differentiating between the different application areas discussed, the following table provides an overview on the benefits and risks described in the previous chapters categorised according to 1st to 3rd order effects. In that sense it is a condensed summary for ELSA discussed. It does explicitly not mean that all these aspects will be relevant for the debate on a certain application area. For more information on these effects the reader is referred to the sections above.

Though not necessarily applicable for each specific aspect the order of effect can be related to the level of awareness researchers and the civil society have regarding each aspect. As first order-effects are direct effects of the nanotechnology-component within an application these aspects are most likely to be thought of first,

Second order effects are connected with a specific application could accordingly be expected to be discussed only in connection with these applications. Actions deriving from second-order-effects could

therefore tend to affect only specific researchers or areas and can therefore be expected to be measures on the micro level.

Third order effects can apply to most evolvements of new technologies. These effects are mainly discussed on the macro-level and are often of a dynamic nature. It will be hard to define specific measures and groups responsible to react to third-order-problems. Therefore most reactions will result in requests for political actions.

(B) = Benefit; (R) = Risk

Environmental performance	Human Health	Privacy	Access	Acceptance	Liability	Regulation & Control
1st order						
Eco-, energy-, resource-efficiency gains, e.g. by building materials bottom-up (B) Eco-toxicity of nanoparticles (R) End-of-life treatment of particles unsolved (R)	Toxicity of nanoparticles (R) Evolving of new microbial resistances (R)					

Environmental performance	Human Health	Privacy	Access	Acceptance	Liability	Regulation & Control
2nd order						
Improved performance of environmental technologies (B) Technological solutions for climate protection, such as improved energy conversion and production (B) Improved water purification technologies (B) Env. Risk at end-of-life (R)	Improved diagnostics performance (B) Improved food safety (B) Risks of malfunctions or false handling of NT-based applications e.g. misinterpretation of testing results in diagnostics (R) Occupational hazards of working with NT (R)	Increased availability of personal health data e.g. genetic testing results (R)	Cheap, decentralised energy supply (B) Access to improved medical diagnostics (B/R) Technologies too expensive for 3rd world (R)	Improved performance of e.g. NT-based medical applications or clean energy technologies will help acceptance of NT (B) Cost savings in health care due to NT-based diagnosis applications improve acceptance (B) NT-based risks in applications that don't really benefit society are a risk for acceptance (R)	Is the current liability regime sufficient for NT-applications? Opinions diverge (R/B)	Current regulatory framework largely considered sufficient on general level (B) Adaptation of regulation on a specific application level might be needed (R)

Environmental performance	Human Health	Privacy	Access	Acceptance	Liability	Regulation & Control
3rd order						
Eco-efficiency gains e.g. due to raw-material or energy saving (B) Rebound effects cause increasing demand on resources (R)	Increasing pressure on health care due to toxicity (R) Expensive and knowledge intense applications lead to "health-divide" (R) Shift in the general perception of what can be considered "healthy" through extended monitoring abilities (R)		Technology divide within and between societies and countries (R) Limited access to NT-based solutions through IPR (R) Risk transfer to 3rd world countries due to dual standards and regulations (R) Increasing concentration of economic and corporate power (R)	Public perception on and agreement to NT-based applications including the debate on ethical and social issues (R/B) A nano-hype might lead to public backlash (R)		Lack of sufficient legal framework (R)

3.4.2 Commonalities from researchers and civil society

Summarising the findings from researchers and civil society, it can be concluded that:

- all participants had a general awareness for certain ELSA of NT;
- one of the key commonalities was that the discussion concentrated more on risks than benefits. The representatives from both groups seemed to be in agreement that there was more work to be done mitigating potential risks than promoting benefits;
- there was also strong agreement on the most important areas, with concerns around the impact of nanoparticles on the environment and human health consistently raised;
- the majority of participants expressed the concern that the life cycle impact of nanotechnologies is not presently taken into account and there is little understanding of end of life impacts;
- there was a general expectation that developments would lead to improvements in efficiency both in material and energy use and that this could lead to economic benefits;
- there was a recognition that the information on ELSA is not comprehensive or centralised and that public awareness is low;
- there was a general consensus on the importance of a discussion on ELSA, however there where doubts about level of detail needed in the public domain;
- there was a concern that a public backlash is almost inevitable;
- there was strong agreement that transparency is key to ensuring a constructive dialogue and business needs to share as much information as possible;
- if asked for a sector where significant ELS benefits of NT-applications are expected in the timeframe presented, the most common answer was the medical sector. Benefits are also expected from energy-conversion applications, while food-packaging was considered less beneficial;
- while NT are seen as a key technology for the EU's competitiveness, big benefits for employment are not expected;
- there was little agreement within or between the groups as to whether new regulation was needed.

4. Actions to increase benefits and reduce risks

This chapter reports on the recommendations made and actions suggested by researchers and civil society representatives in order to increase the benefits and reduce the risks of nanotechnologies. Similar to chapter 3, it serves largely as documentation of the target groups positions. Unlike the previous chapter, the recommendations are presented in a more integrated manner, i.e. not formally structured in those made by researchers working at different application areas such as medical or energy applications. The reason for this is that even though the interviewees have been asked to suggest actions specific to the application areas, there was a large overlap across the different application areas. All recommendations that are not labelled otherwise apply therefore to all application areas, Application specific recommendations are mentioned where available.

4.1 Actions suggested by researcher

After having identified the potential benefits and risks the interviewees where asked about appropriate actions to maximize the benefits and minimize the risks, first in an unprompted way "from your point of view, what actions should be taken today to minimise the risks and maximise future potentials", followed by more specific questions concerning the regulatory framework, information/ education activities, public and environmental liability, and the role of governments and the industry.

"When considering the funding of NT, areas expected to be most beneficial to society should be prioritised."

When asked generically about actions to maximize potentials, a considerable high number of interviewees mentioned research funding without further specification as primary means. Some argued that funding should focus more comprehensively on pressing human problems such as medical diagnostics and treatment as well as sustainable energy production.

Concerning actions to minimize risks energy and food packaging researchers consistently argued for life-cycle analyses on nanomaterials and NT-based applications. Production and disposal/recycling were seen as most relevant as particle release could occur during those stages. As one researcher put it "research focuses on the technical development of new efficient solar cells – the

recycling/disposal issue is crucial, but completely neglected." Others implicitly argued in favour of such approach: "As soon as research activities lead to the identification of promising application areas life-cycle analyses need to be carried out to better assess the overall benefits and risks." Furthermore, studies addressing health and environmental issues would need to keep up with fast technological developments and clarify the most important risks before products are launched on the market. Again funding was mentioned as important means to steer and stimulate such studies.

The following section provides the interviewees responses when asked about specific issues (see heading titles).

4.1.1 Need for additional specific regulation?

Whether there is a need for additional regulation is perceived differently among and between representatives of the different application areas.

Interviewees are cautious to call for new regulation per se

Generally speaking researchers were cautious to call for new regulation per se. Instead, they tended to call for an approach to assess specific regulatory needs case by case or sector by sector. Areas mentioned that might require additional regulation include the food sector as well as the potential impacts on the environment. Also the importance of keeping pace with technological development has been highlighted. One interviewee put it the following way: "One has to be aware of what the particular risks of nanotechnologies are and put them in the context of existing regulations."

Among energy and LOC interviewees there appeared to be a major consensus that the current regulatory framework was sufficient as it already covers other materials of potential risk (e.g. hazardous chemicals) and as all new products/technologies (including those based on NT) were subject of extensive review and mandatory testing procedures.

While some food-packaging researchers argue likewise, others pointed out that the current state of not having any nano-specific regulation obstructed innovation because incalculable liability risks would prevent the commercialisation of applications. Difficulties for additional regulation were expected concerning the exact definition of "nano", i.e. the particles, materials, and applications that are subject of such regulatory supplements. Furthermore, it remained unclear how engineered particles could be regulated in contrast to non-engineered ones (such as dust or combustion exhaust).

Actions recommended include:

Call for internationally harmonised regulation and standardisation

- **International harmonisation** of regulation including standardization of review and testing procedures for NT-based products. This includes an adaptation of existing regulation frameworks such as REACH on specific properties of nanoparticles;
- One expert argued politics and governments should put pressure on **industry** in order to motivate the establishment of **self regulation and self restriction**. Companies should conduct risk management according to the ALARA principle (as low as reasonably achievable) if they work with nano materials;
- **Additional sector regulation** for sensitive application areas (e.g. food, health care etc.) and work areas (e.g. nano-specific worker health & safety requirements and guidelines);
- The **precautionary principle** should be utilised in a moderate way but as early as possible in order to deal with nanoparticular substances in a cautious manner;
- Call for a **legal obligation to publish clinical studies**. This point was emphasised by medical experts and aimed at the central and comprehensive provision of health risks-related information.

4.1.2 The need for information campaigns and educational initiatives

Diverging opinions on the need and value of information campaigns

Different opinions were voiced with regard to the need or even meaningfulness of information campaigns and educational initiatives. The majority of interviewees pointed out that a balanced view on the opportunities and risks of NT were the most important content for information and education. As NT was emerging information efforts would need to be continued and to include results of recent research and testing besides technological advancements. Varying views were articulated concerning the target group and the related content and information channels to approach them:

General public / consumers: While most experts agreed that the general public (also in its role as consumer) were an important target group others expressed concern about conflicting messages that might cause confusion rather than providing guidance. Another concern expressed was that “to be understood by the general public information campaigns require a simplification of content, which in itself may cause a problem given the complexity of NT.” A few

interviewees challenged the importance of informing the general public pointing out that the general public "will hardly realise products enhanced through the use of NT".

One expert summarized the discussion about appropriate information channels for the general public by pointing out that "information is always considered not sufficient. The challenge is to choose the right communication channel to assure that important and balanced information is perceived. Scientific TV programmes for instance currently succeed in educating a wider society on current scientific research."

Several experts agreed that the responsibility to inform the public lied with public science and industry that should more actively present their findings on conferences and work closely with media.

Journalists were by many interviewees perceived as primary information gatekeepers. As a consequence an important action proposed addressed the comprehensive information and education of journalists – or as one interviewee put it: "If journalists don't feel comfortable with the topic, how can we expect the media coverage about NT to be positive?"

"If journalists don't feel comfortable with the topic, how can we expect the media coverage about NT to be positive?"

Workers possibly exposed to NT particles were as well identified as important target group. Interviewees commonly saw the need to comprehensively inform them on the topic of nanotechnologies – especially about potential risks.

Governments / policy-maker: Some interviewees from the generic and LOC group pointed out that there was a need for political advisory and education of decision makers.

Research: Across the expert groups interviewees recognised a need for additional information on NT for different kinds of non-expert-groups (such as lawyers and politicians involved in the evolvement of new regulation, journalists, and/or consumers/general public). One idea that emerged was to set up a central clearing place on ELSA and NT so that potential risks can more clearly be identified based on the aggregation of recent research projects and studies.

4.1.3 Public and environmental liability

Diverging opinions on the need for extended liability regulations

Again, diverging opinions exist if special attention is needed in the areas of public and environmental liability – also within the application areas examined. In general two different perspectives were prevailing:

A significant portion of interviewed researchers argue that the liability obligations in Europe do also cover NT aspects accurately as they are not technology specific, but look at the effect instead. As a result new products would undergo extensive and sufficient review and testing. From this perspective, existing liability would not require to be further complemented. One interviewee pointed out that from his perception there is “no difference between NT-applications and other products”.

Other experts put emphasis on the lack of information and the risks for human health and the environment that would need to be further clarified first. From their perspective it should be carefully evaluated if additional liability regulation is needed as soon as NT-based products are introduced to the market. Some experts for instance considered the product liability regime to be sufficient, but voiced some doubts about the area of environmental liability.

A further individual opinion mentioned included the recommendation to extent the liability for limited liability companies in order to reinforce the incentive for corporate risk governance. Finally, a small group of experts simply did not feel competent to comment on the subject.

4.1.4 Further actions to be taken by the Government

Government is expected to support and govern research on NT

Being asked about governmental actions to be taken by the government next to setting the legislative framework, most interviewees – being researchers themselves – mentioned support and governance of research. Further governmental tasks mentioned include monitoring, information, and setting the market framework for sustainable applications – activities that are interrelated in many ways:

Provision of funding: Governments take a central role as supporter of (basic) research. Energy interviewees stressed that European research spending often lacked continuity (e.g. compared to Japan) and co-ordination between different sciences and sectors as well as between basic and application-oriented research. Participants from

the group of general and LOC also highlighted the need for a continuous funding.

Furthermore funding should be used to better steer research activities towards the most important issues, e.g. risk assessment of nanoparticles, recycling option for materials containing nano-particles, and encourage the formation of multidisciplinary teams comprising of researchers, technologists, legal experts, experts for public perception and ELSA, business developers and "to a certain degree" politicians. A number of researchers expressed the concern that funding of public risk research was unsatisfying yet.

Monitoring/governance of research: With respect to the public funding policy in nanosciences and nanotechnologies some interviewees pointed out that there was an overall tendency to declare research as nano related in order to maximise the prospects for funding. According to these researchers public funding policy should be prioritised on technologies that promise to be advantageous from a societal point of view and support sustainable development.

While energy researchers stressed the funding requirements in the area of sustainable energy production (and NT as integral part) LOC-experts pointed to the special funding needs of small and medium sized businesses resulting from licensing and admission procedures of up to five years for medical applications.

Other suggestions are to control "delicate research areas such as weapons" or to provide guidelines on how to conduct assessment studies.

Information: A few experts proposed that governments should take a lead on public outreach and information about ELSA and NT and participate (again through funding) to structure and balance the public debate. Mentioned only once but probably a suggestion that is expected to help addressing the root of several issues is the call on administrations and politicians to stay informed about NT developments.

Market-based instruments: On the political level interviewees from the energy area demanded accompanying measures and incentives (e.g. of fiscal nature) to foster the use of more sustainable forms of energy production, especially as they will at first not be able to compete with non-sustainable/non-renewable forms of energy supply that are based on comparably cheap resource depletion.

4.1.5 Actions to be taken by the industry

While most of the actions mentioned can be summarised under the heading of transparency and accountability, their scope and specific focus varied widely. It spanned an area from legal compliance to information provision and dialogue up to the establishment of standardised measurement approaches. While the call for a closer collaboration with universities was mainly motivated by the wish for closer research cooperation, it could also contribute to many of the transparency and accountability actions suggested:

Businesses expected to act more transparently.

Transparency and accountability: Special emphasis should be given to the areas of transparency and accountability of businesses. Mentioned several times were issues such as the participation in the ongoing dialogue and the constant information about risks and benefits of NT-based products. Prior to production applications need to be tested comprehensively.

Risk assessment: The industry needs to keep on participating in assessing the risks and benefits of NT (e.g. through long-term and life-cycle-wide studies) und publish their results as soon as products are released. Additional actions proposed include the training of staff and a closer cooperation between industry and university researchers.

R&D investments: To maximise benefits European participants from the LOC groups suggested that companies should be willing to spend more venture capital and drive the development of NT through own funding. Some energy interviewees pointed out that European companies lacked some of the entrepreneurial risk taking spirit that can be observed with US companies.

Standardisation and voluntary commitment: Some experts finally called for more (sector-specific) self regulation. Food experts for instance argued that the chemical industry should set up specific in-house regulations, depending on what kind of nanotech application a company deals with.

4.2 Actions suggested by civil society

Sections 4.2.1 to 4.2.3 cover the specific recommendations that emerged from the workshop held in Edinburgh. The first recommendations cover the main risks identified during the session. The delegates believed that the priority was mitigating risks rather than maximising benefits, and therefore the recommendations

provided concentrate on tackling these main issues rather than maximising the potential benefits. The delegates also briefly tackled the issue of engaging with scientists (4.2.2) and taking the dialogue to the general public (4.2.3).

Further recommendations drawn from the civil society interviews are presented in sections 4.2.4 to 4.2.7. Interviewees responded more to the issue regulation and the role of government, industry and education than on public and environmental liability, which reflects the lack of information on legal issues.

4.2.1 Addressing risks

The Nanodivide

There was a call for all stakeholders involved to identify and clarify possible policy options that could prevent a "nanodivide". Government and NGOs should take a lead in initiating education on the issue and starting a public debate about the role of technology in our society. Government would also need to demonstrate political commitment to tackling the issue and work with other countries on developing common ground. It might require the formation of an international organisation to facilitate this process.

Call to all stakeholders to prevent a nanodivide.

There was also a call for business to realise opportunities of selling to the bottom of pyramid market and to develop applications to meet societal needs and address challenges such as provision of clean water.

Toxicity (Environmental and Human)

The participants called for scientists and government to develop and standardise the measurements and assessment procedure for nanotechnologies. They also believed that government needed to:

Standardised measurement and assessment procedures needed.

- Clarify its position on the need for further regulation and if necessary revise existing regulation frameworks;
- Ensure that information on toxicity is shared and lead on the creation of an open database to achieve this;
- Monitoring R&D and life cycle of NT-applications in order to recognise early warnings. Funding of research institutions capable of interdisciplinary independent assessment;

- Revise investment and funding framework to ensure that testing of the human and environmental impact of nanotechnologies are prioritised;
- Use the precautionary principle if necessary i.e. limit production of nanoparticles in case of evidence of their toxic effects.

Business must also respond to this issue buy scaling up testing and participating in the completely transparent sharing of knowledge. Parallel to this businesses must work on responsible product development and find thorough methods to manage risk in development and production.

NGOs must be involved from outset and continue to pressure the other stakeholders.

The Nanobubble

Caution needed to not fuel the "nano-hype".

Stakeholders involved in the development of and communication on nanotechnologies should beware of fuelling the "nano-hype" to an extent that causes unrealistic expectations of the technology from consumers. The media and general should be provided with balanced and concise information to prevent this from happening.

Governments should assess present publicly funded R&D programs and ensure that development is better targeted to meet societal needs. There needs to be an open and frank public conversation about what NT can deliver and how we should use this technology to prevent a social and financial "nanobubble".

4.2.2 Engaging scientists in a dialogue

The workshop delegates were also asked to explore the role of scientists in the dialogue on ELSA, what where the barriers where to their further involvement

The participants understood that there are always going to be other priorities for scientists that will prevent them dealing with ELSA of their work and that the attitude to ethical issues may vary between the generations - it was believed that interest is highest with those at start and end of career. There is a general hesitancy perceived amongst scientists to engage due to lack of time and support.

The delegates proposed a comprehensive list of measures that might facilitate scientist's engagement in ELSA of their work. This is a

summary of the main recommendations. The full list can be found in Appendix II.

- Engagement on and communication of ELSA should be a condition of all grants and there has to be a move "beyond publishing" to get away from just publish or perish. Those in management positions should also provide encouragement to staff to work on ELSA;
- Ensure that scientists have training in media, communication and ethics;
- There should be independent funding for ELSA communication and funding for dialogue between Government, business and wider society;
- The science education system needs to be updated to integrate discussions around science and society.

4.2.3 Taking the dialogue to the public

The delegates were also asked to consider how the dialogue could be taken out to the general public. It was felt that training the public in popular science and science literacy was key to encouraging public involvement in the dialogue. It might also help if examples used in education centre on examples of applications that are of benefit to society and the discussion needs to be reframed. Obviously this will require considerable facilitation and the correct use of mass media.

4.2.4 Smarter and clearer regulation

Present regulation considered not sufficient.

Although only one person interviewed called for a short term moratorium until a draft of safety tests had been developed, the majority felt that present regulation was not sufficient and needed to take into account the novel properties of nanoparticles and nanomaterials.

- Regulation needs to immediately concentrate on high-risk areas to prevent high impact.

One of the key concerns is the difference between regulation in Europe and Asia and whether this might become a competitive issue.

- There should be international cooperation on regulation and governance on nanotechnology to ensure that this does not affect markets.

Countries with political and economic clout should be taking the lead on investigating behaviour of nanoparticles and sharing information but they are “sitting on their hands”.

- There should also be a move to regulate patents to prevent a “nanodivide” occurring.

4.2.5 A need for improved governance

Lacking guidance on liability: a barrier to market NT-applications.

The lack of guidance on liability is making it very difficult for companies developing the technology to proceed and one interviewee knew of companies that had moved from medical applications to areas such as waste as they could manage the risk. It is also important that there is a level playing field and that the publication of risk assessment is no longer a competitive issue. Governments also have a role to ensuring that public interest is upheld through the regulation of patents. There is a need to initiate a dialogue with civil society and ensure that the risk is communicated sufficiently.

- Governments need to move swiftly to deal with the lack of guidance on regulation and liability;
- Governments must clarify their position on regulation and provide guidance on how we evaluate new materials and properties;
- Government must ensure that there is focus, sufficient funding and delivery on key areas and prevent a scattergun approach to funding. This must also include further research on human and environmental impacts as a priority.

Public needs positive NT-vision

An example of where this focus has been applied is in Israel, where there has been heavy investment in desalination technology. This provides an important context and vision for the public.

4.2.6 A more participative role for industry

There was consensus that it is important for industry to cooperate with other stakeholders, be a participative stakeholder in the discussion and make information (particularly on risk assessments)

available in the public domain. Industry must look into ensuring protection (from nanoparticles) in the work place and should be encouraged to use precautionary measures if necessary.

- A public database should be created and business must be more transparent with research information particularly around toxicity. Greater transparency is required;
- Industry must comply with legislation and self regulate where necessary.

4.2.7 Framing the Information and education campaigns

Call for more educational initiatives and information campaigns.

The majority of interviewees expressed a need for more educational initiatives and informational campaigns on the potential and risks and benefits of NT. There was a further comment from several participants that there is a need for interaction and dialogue, not just information i.e. stakeholder engagement. Due to market conditions the benefits of NT will only be realised if there is enough public interest in them. However, it was also recognised that it is essential to achieve a balance of information and it must have the right context.

- The best way to engage the public will be to put benefits in context e.g. around specific problems and applications that have societal benefit;
- The vision should be refocused, not around risks (e.g. Drexlers vision) but around a vision of sustainable development, which can be used as a framework to maximise benefits and minimise risks. It is essential that this framework be used as early as possible in the development process.

Participants in both the interviews and workshop felt that a dialogue on NT is a platform/opportunity to discuss the wider issue of how society engages with science and technology.

5. Recommendation for a dialogue on nanotechnologies

From the background research and interviews it has become evident that many expect nanotechnologies to deliver significant societal benefits. However, the majority of benefits and risks differs from application to application and takes place at different levels (first to third order, see chapter 3.4).

For example while the main benefits for energy production conversion and storage applications are seen in the environmental domain, medical diagnostic technologies promise benefits with regard to human health and raise concerns on privacy issues (second order effect). Common to almost all applications is the discussion about the so called first order effects such as potential human- and ecotoxicological risks of nano-particles. Other effects are discussed in the context of specific applications but are not genuinely associated with nanotechnologies but rather with the introduction of new technologies in general (third order effects).

In order to ensure that the technological development delivers the benefits at low levels of risk, a process needs to be initiated that takes into account the diversity of effects and expectations, as expressed by various stakeholder. Its ultimate goal would be to work towards a societal consensus on a responsible development of NT. While there seems to be a general support for such a process by policy makers, business and other societal actors, suggestions for the best means, it's scope etc. differ. However, there is little doubt that such a process should start at an early stage of technology development and would include or even based on a public dialogue.

Based on the background research and engagement with researchers and civil society representatives, five recommendations for the dialogue on nanotechnologies – and thus ultimately for the development of the technologies - are presented below:

5.1 Frame the dialogue

To ensure that nanotechnologies deliver maximum benefit to society an ongoing discussion about its social and environmental implications should run in parallel to the advancements of the technology.

Debate on ELSA should run in parallel to the technological advances.

Obviously funding distribution and criteria play a key role but a dialogue at the right level can be used to challenge the fundamental direction the technology can take. As the delegates at the workshop suggested the NT 'vision' should be refocused, not around risks but around a vision of sustainable development, which can be used as a framework to maximise benefits and minimise risks. It is essential that this framework be used as early as possible in the technology development path and a discussion needs to take place to understand how this can influence policy and funding mechanisms. Such a NT-vision might also help to attract media attention on the technologies potentials.

This would also give the technology a context in which to communicate the benefits and demonstrate the economic, social and environmental potential. Yet, caution to not fuel the nano-hype is needed as otherwise the nano-bubble might meet the New Economies fate and burst.

5.2 A dialogue in context

Much of the discussion and coverage about NT-based applications is on a level that does not differentiate at all between the sometimes profound differences of the wide array of applications currently captured under the term "nanotechnology".

Contextualisation in terms of need for certain applications is important. We might not need NT-golf balls, but we might need NT-based energy systems or medical applications, for example as one route to meeting the UN's millennium development goals or as an important contribution to the Commissions Environmental Technology Action Plan (ETAP). This would also justify the huge amounts of public money that have already been spent on developing the technology. For some applications, e.g. in the medical sector, we might also be willing to accept a higher societal risk than in others.

Benefits but in particular risks discussed for single NT-based applications are often lumped together as "risks of Nanotechnology" in the public discussion, making a public backlash more likely.

The debate of risk often does not differentiate between applications.

However not only the general public, but also other non-expert decision-makers in politics, business and society might also mix things up. The dialogue and communication need context, i.e. to focus on specific applications rather than NT in general, and providing a framework for assessing potential benefits and risks for all applications and levels. Acting on recommendations that result from such an assessment, the need for an application specific regulatory framework should be evaluated.

5.3 An open dialogue

Too much information might lead to confusion; however too little will almost certainly lead to a public backlash

While doubts have been voiced about the value of public engagement in the current discussion it is clear from previous situations (biotech etc) that the process must be as open and transparent as possible. Whilst there is a danger that too much information could lead to confusion or disengagement from the issue, there is a far greater danger that a lack of transparency will result in a lack of empowerment and a backlash from the public. The discussion on GM raised serious questions mainly but not exclusively about corporate transparency in particular, and this must be overcome.

Call for a clear distinction between facts and "nano-fiction" in the public debate.

If stakeholders are united over an objective to ensure that the development of the technology follows as sustainable a path as possible and it is clearly and consistently couched in terms of societal benefit (sustainable development), then acceptance will be much greater amongst the public. In addition, there needs to be a clear distinction between fact and fiction in communication about NT. Any dialogue should early refer to the current state of R&D in nanotechnology. "Nano-fiction" like visions (e.g. nanorobots) should be highlighted as not practically relevant within the next decade.

5.4 Assessing the risks

While there are a number of studies already conducted or currently under development, the risk that nanoparticles and other nano-based components might cause to human health and the environment is still not clear. These 1st order risks have been discussed by both researches and civil society for all application areas covered in this project. Given the current bias of the dialogue towards risks, some answers are urgently needed.

Part of the solution may be an international standardisation of measurement for nanoparticles and nanomaterials as a basis to assess the risks.

International measurement standardisation

There also needs to be a more consistent approach to assessing the risks of NT applications. Assessments using the 7 ELSA identified as part of this project could run alongside/include more traditional risk assessment procedures (level of exposure, hazard identification, risk characterization for example). Risks that originate directly from the NT-components (1st order) should be distinguished from those specific to NT-applications (2nd order) and the general societal context (3rd order).

A consistent approach for assessing the risks needed.

Integrated analysis based on life cycle perspective can help to systematically investigate indirect (2nd and 3rd order) effects of NT applications in the context of their future use. It appears that many interviewees only focussed their thoughts on the production phase, with less thought for the use- and disposal phase. If nano-materials are bound in e.g. plastic, then the potential exposure to these materials is limited. However, potential health and safety impacts might hit workers in factories. David Rejeski from the Woodrow Wilson International Center for Scholars said “the idea that this is super-clean manufacturing, moving atoms around, that's not right. The input chemicals are not clean. A lot of this stuff is done by milling and it's really dirty[11].” At the end-of-life phase no one knows if nanoparticles accumulate in human tissue or ecosystems and whether nano-pesticides might pose some future DDT-like problem.

Part of the NT risk discussion can be traced back to risk controversies in the past (e.g. GMOs). Retrospective analyses of past risk controversies can be useful for risk communication of NT. However, retrospective studies should be used with care, as one has to be careful to judge from hindsight alone.

Acknowledging the importance of a sound risk assessment on all levels and across the entire life-cycle, one should be aware that not pursing the technologies potentials might be a risk in itself. Developing nanotechnologies while simultaneously assessing its societal risks is a tremendous challenge, but excluding all possibilities of doubt before advancing with the technology might also not be the answer.

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[11] AlterNet : The Evolution of Frankenfoods? Available at: http://www.alternet.org/envirohealth/23534/ [2005, October 21].

5.5 Making information accessible

Even the most transparent dialogue will do nothing to avoid a backlash if no one is aware that it is happening, or cannot get access to the information easily enough to be involved. Lack of knowledge about nanotechnologies as well as ELSA of NT-applications can not only be attributed to the complexity or novelty of the subject. Quite some information is already available and many interviewees were also aware of the large amount of information "out there". However, they felt that this information is not available in a central, and even more important, accessible way.

Making this information available at the internet is an obvious choice, since the interviews showed that both target groups use it as a prime information source. For the research community, conferences played an important role.

Some solutions raised during our research include:

- A 'clearing centre', hosted by an institution with high social legitimacy, could be set up;
- Activities could be initiated that involve the general public via museums or science centres for example[12];
- Producers of products that contain NT-components should inform and engage with retailers;
- Labelling of NT products has been suggested, while others were cautious about this. A public discourse on this issue might be needed;
- Journalists and the media should be directly targeted with information both about benefits and risks.

[12] The NanoDialogue project appears to be a good example (http://www.nanodialogue.org/)

Appendix I – Interview guidance document

Interview guideline for medical diagnosis (LOC) Interviews

Entrée

The European Commission highlights the need to "respect ethical principles, integrate societal considerations into the R&D process at an early stage and encourage a dialogue with citizens" (European Commission 2005) within the action plan "nanosciences and nanotechnologies" for Europe 2005 – 2009. However this demand/need is not entirely new. In the context of NT-based projects the consideration of ethical, legal, and social aspects (ELSA) has gained increasing importance throughout the last five years. When in 2000 the US National Nanotechnology Initiative was launched, the program from the very beginning included funding for analyses of societal and ethical implications of nanotechnology.

1. Do you feel adequately informed on ethical, legal, and social aspects associated to NT within your field of expertise?

2. Through which information channels did you gain your present knowledge on ethical, legal, and social aspects? (e.g. schooling/training, professional work, own initiative)

Benefits of NT-based LOC applications

3. To your understanding, which are the potential benefits NT-based LOC applications will bring to society?

- ❑ Do LOC devices contribute to an overall decrease of the environmental burden/impact (e.g. lowered resource consumption) associated with medical diagnostic?
- ❑ (What are the benefits LOC-applications can bring with respect to human health?)
- ❑ Will simple and low cost LOC-applications make fast disease-screenings available for the broad public?
- ❑ What are the economic potentials of LOC applications? (e.g. strengthening the EU's competitiveness; job creation/employment creation)?

4. To what extent do you believe the benefits discussed in terms of LOC applications above are also relevant for NT-applications in the medical area in general?

Risks of NT-based LOC applications

5. To your understanding, which are the potential risks and problems NT-based LOC applications might bring to society?

- ❑ Does the production or use of NT-based LOC-applications bear the possibility to provoke negative environmental impacts? If yes, what kind of impacts are possible?
- ❑ What are risks in terms of human health connected with the use of NT-based LOC applications?
- ❑ Does the information (possibly) gathered through NT diagnostic-applications raise an extraordinary demand on data protection and respectively bear the potential to have negative impacts on private spheres? […a danger of genetic discrimination might arise e.g. through employers or insurers…]
- ❑ Will NT-based diagnostic applications be available to all societal groups [disregarding their income and health insurance (i.e. private or public insurance)]?

6. We have been discussing potential risks connected with LOC-application. Which of the risks mentioned is directly associated with the nanotechnological component/feature of the technology?

7. To what extent do you believe the risks discussed in terms of LOC applications above are also relevant for NT-applications in the medical area in general?

Actions to maximize potentials, and minimize risks of NT-based LOC-applications

8. From your point of view, what actions should be taken today to minimise risks and maximise future potentials of NT-based LOC-applications?

- ❑ Is there a need for additional specific regulation for LOC-applications or is the existing regulatory framework sufficient?
- ❑ Do you feel that more information campaigns and educational initiatives on the potentials and risks of NT-applications are needed?
- ❑ Do you think that special attention is needed in the areas of public liability and environmental liability?
- ❑ Next to setting the legislative framework, which actions should be taken by the government?
- ❑ What role should the industry play to maximise the potentials and minimise the risks?

ELSA-priorities of NT-based LOC applications

9. Within each of the 7 ELSA, different issues are addressed in the literature. To which extent would you agree/disagree to the following statements?

   Please assign:
   - 3 points if you fully agree with the statement,
   - 2 points if you more or less agree with the statement,
   - 1 point if you disagree with the statement, and
   - 0 if you don't have an opinion on the statement.

Environmental Performance		
	The application of LOC technologies in medical diagnosis contributes to improve resource efficiency, as LOC technology requires smaller amounts of e.g. materials or energy than traditional technologies.	
	LOC devices pose an eco-toxicological risk, in particular in the disposal phase.	
	Studies investigating the life-cycle wide environmental impacts of LOC applications are required.	
	Summarising your answers: at present, does the aspect of environmental performance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Human Health		
	The use of LOC devices in diagnostics contributes to enhance human health through earlier disease detection.	
	LOC allows personalising medical treatment, e.g. by knowing which active agent suits which patient.	
	Inappropriate handling like the misinterpretation of data by the potential LOC user poses a risk for human health.	
	Summarising your answers: at present, does the aspect of human health deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Privacy		
	The availability of more health related information through LOC will in future cause genetic discrimination (e.g. a known disposition for a certain disease might in future change the individual cost classification for insurances etc.).	
	The development of LOC applications will make it increasingly difficult to avoid knowledge about individual disease dispositions.	
	Summarising your answers: at present, does the aspect of privacy deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Access		
	Even in affluent nations LOC based diagnostic will only be available for a privileged part of society due to the high costs involved (two-class system medicine)	
	Developing countries will be excluded from the use of LOC as (financial and human) resource restrictions limit the access to the technology.	
	Summarising your answers: at present, does the aspect of accessibility deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Acceptance		
	LOC will become a mainstream medical diagnosis tool, paving the way for public acceptance.	
	There is a risk that LOC-based diagnostic is rejected by the public due to concerns about the increasing availability of personal data.	
	LOC will help to increase the acceptance of NT applications in general.	
	Summarising your answers: at present, does the aspect of acceptance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Liability		
	Current environmental liability regulations are sufficient to encompass LOC.	
	Current product liability regulations are sufficient to encompass LOC.	
	Summarising your answers: at present, does the aspect of liability deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Regulation and Control		
	The current regulatory framework sufficiently addresses safety standards of NT-based LOC devices.	
	NT-based LOC applications are associated with concerns that need to be addressed in a framework of shared principles for the safe, sustainable, responsible and socially acceptable development and use of nanotechnologies e.g. on the EU-level.	
	Summarising your answers: at present, does the aspect of regulation and control deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for "no opinion")	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public's opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Nanotechnology in general

10. To your opinion, which ELSA benefits or risks discussed in the media are relevant for the general debate on Nanotechnology?

11. With regard to NT-applications in general: To your opinion, in the context of which of the following ethical, legal and social aspects would the civil society most urgently call for action?

    Please assign

    - 3 points for aspects, that are especially important from your point view (as and expert),
    - 2 points for those you consider to be "not unimportant", and
    - 1 point for aspects of minor importance.
    - 0 if you don't have an opinion on the statement.

ELSA-Criteria	Score
Environmental Performance	
Human Health	
Privacy	
Access	
Liability	
Regulation	

12. Which events, product launches/developments, and publications do you consider to be the key landmarks of the development of NT up to the present day?

13. Imagine it is the year 2015.
    a. What have been the 3 main factors driving the development of NT?
    b. What have been the 3 main hurdles to NT-development that had to be overcome?
    c. How were those factors hurdles overcome?

Interview guideline for food packaging expert interviews

Entrée

The European Commission highlights the need to "respect ethical principles, integrate societal considerations into the R&D process at an early stage and encourage a dialogue with citizens" (European Commission 2005) within the action plan "nanosciences and nanotechnologies" for Europe 2005 – 2009. However this demand/need is not entirely new. In the context of NT-based projects the consideration of ethical, legal, and social aspects (ELSA) has gained increasing importance throughout the last five years. When in 2000 the US National Nanotechnology Initiative was launched, the program from the very beginning included funding for analyses of societal and ethical implications of nanotechnology.

1. Do you feel adequately informed on ethical, legal, and social aspects associated to NT within your field of expertise?

2. How/Where did you gain the information you needed on ethical, legal, and social aspects? (e.g. schooling/training, professional work, own initiative)

Benefits of nanotechnology (NT)-based applications

3. To your understanding, which are potential benefits nanotechnology based food packaging applications will bring to society? If possible, mention the application you expect to deliver these benefits.

   - ❑ What are the benefits nanotechnology based food packaging applications can bring with respect to environmental performance?
   - ❑ What are the benefits nanotechnology applications can bring with respect to human health?
   - ❑ Will NT benefit developing countries in areas such as health, environment and economy? Please explain your answer, can you give some examples for possible applications?
   - ❑ What are the economic potentials of NT applications? (e.g. strengthening the EU's competitiveness; job creation/employment creation)?

Risks of nanotechnology (NT)-based applications

4. To your understanding, which are the potential risks and problems NT-based applications for food packaging might bring to society? If possible, mention the applications you expect to led to these benefits.

- ❑ Does the production or use of nanotechnology applications for food packaging bear the possibility to provoke negative environmental impacts? If yes, what kind of impacts are possible?
- ❑ What are risks in terms of human health connected with the use of nanotechnology based applications for food packaging? Please give some examples.
- ❑ Do you expect the development of nanotechnology applications will negatively impact on developing countries? Please, provide examples.
- ❑ If the regulation framework turns out to be insufficient to address safety standards what will be the risk for society?

5. We have been discussing potential risks of nanotechnology applications in the food sector. Which of the risks mentioned is directly associated with the nanotechnological component/feature of the technology?

Actions to maximize potentials, and minimize risks of NT-based applications

6. From your point of view, what actions should be taken today to minimise risks and maximise future potentials of NT-applications?

- ❑ Is there a need for **additional specific regulation** for NT-applications or is the existing regulatory framework sufficient?
- ❑ Do you feel that more **information campaigns** and **educational initiatives** on the potentials and risks of NT-applications are needed?
- ❑ Do you think that special attention is needed in the areas of **public liability** and **environmental liability**?
- ❑ Next to setting the legislative framework, which actions should be taken by the **government**?
- ❑ What role should the **industry** play to maximise the potentials and minimise the risks?

ELSA-priorities of NT-based applications for food packaging

7. Within each of the 7 ELSA, different issues are addressed in the literature. To which extent would you agree/disagree to the following statements?

   Please assign:

   - 3 points if you fully agree with the statement,
   - 2 points if you more or less agree with the statement,
   - 1 point if you disagree with the statement, and
   - 0 if you don't have an opinion on the statement.

Environmental Performance		
	Nanoparticles fixed within the product cause problems in disposal and recycling.	
	Free nanoparticles, which are not fixed within the product will be an eco-toxicological threat (e.g. causing direct damage to organisms).	
	Due to miniaturization effects nanotechnologies generally contribute to decoupling of economic growth and resource consumption, as NT-applications need smaller amounts of materials and energy.	
	Summarising your answers: at present, does the aspect of environmental performance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for "no opinion")	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public's opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Human Health		
	Free nanoparticles, which are not fixed within the product, have a toxic impact on human health.	
	Current knowledge does not allow to draw conclusions to the effects of free nanoparticles on the human body. Much more research is needed to understand possible risks, and benefits connected to these effects.	
	Summarising your answers: at present, does the aspect of human health deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Privacy		
	The potential impacts of NT applications on privacy deserve much more attention.	
	At present, does the aspect of privacy deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Access		
	Developing countries will be excluded from the use of nanotechnologies as (financial and human) resource restrictions limit the access to the technology.	
	NT-applications will become mainstream and be available to anyone at low cost.	
	At present, does the aspect of accessibility deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Acceptance		
	A positive public perception of nanotechnologies is crucial for further diffusion of the technology.	
	The lack of knowledge on negative effects possibly connected to NT-applications is a risk for public acceptance.	
	Summarising your answers: at present, does the aspect of acceptance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Liability		
	Current environmental liability regulations are sufficient to encompass NT.	
	Current product liability regulations are sufficient to encompass NT.	
	Summarising your answers: at present, does the aspect of liability deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Regulation and Control		
	The current regulative framework is sufficient to address all health and safety requirements of NT.	
	If the current regulation proves to be insufficient, it will not be possible to establish the necessary regulatory framework timely to prevent negative effects to humans and environment.	
	Summarising your answers: at present, does the aspect of regulation and control deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Nanotechnology in general

8. With regard to NT-applications in general: To your opinion, in the context of which of the following ethical, legal and social aspects would the civil society most urgently call for action?

Please assign

- 3 points for aspects, that are especially important from your point view (as and expert),
- 2 points for those you consider to be “not unimportant”, and
- 1 point for aspects of minor importance.
- 0 if you don’t have an opinion on the statement.

ELSA-Criteria	Score
Environmental Performance	
Human Health	
Privacy	
Access	
Liability	
Regulation	

9. Which events, product launches/developments, and publications do you consider to be the key landmarks of the development of NT up to the present day?

10. Imagine it is the year 2015.
    a. What have been the 3 main factors driving development of NT?
    b. What have been the 3 main hurdles to NT-development that had to be overcome?
    c. How were those hurdles overcome?

Interview guideline for energy expert interviews

Entrée

The European Commission highlights the need to "respect ethical principles, integrate societal considerations into the R&D process at an early stage and encourage a dialogue with citizens" (European Commission 2005) within the action plan "nanosciences and nanotechnologies" for Europe 2005 – 2009. However this demand/need is not entirely new. In the context of NT-based projects the consideration of ethical, legal, and social aspects (ELSA) has gained increasing importance throughout the last five years. When in 2000 the US National Nanotechnology Initiative was launched, the program from the very beginning included funding for analyses of societal and ethical implications of nanotechnologies.

1. Do you feel adequately informed on ethical, legal, and social aspects associated to NT within your field of expertise?

2. Through which information channels did you gain your present knowledge on ethical, legal, and social aspects? (e.g. schooling/training, professional work, own initiative)

Benefits of NT-based energy production applications

3. To your understanding, which are the potential benefits NT-based energy production applications will bring to society? (production = generation [solar cells] as well as conversion [fuel cells])

- ❑ Will nano-energy applications contribute to combat climate change (e.g. sustainable hydrogen economy)?
- ❑ Will low cost nano-energy applications significantly contribute to secure the supply of energy (e.g. decentralisation of supply, use in developing countries, hydrogen economy)?
- ❑ What are the economic potentials of nano-energy applications? (e.g. strengthening the EU's competitiveness; job creation/employment creation; reduced dependence on fossil fuels)?

Risks of NT-based energy production applications

4. To your understanding, which are the potential risks and problems NT-based energy production applications might bring to society?

- ❑ Do the production, use, and disposal of NT-based energy production applications bear the possibility to provoke negative environmental impacts? If yes, what kinds of impacts are possible? (e.g. nano-particles with large surface areas being released into the environment)
- ❑ Will the efficiency gains due to nano-materials likely be offset by an increased (energy) resource need throughout the production? (high energy consumption for the production of solar cells, production of conversion inputs such as hydrogen from non-renewable sources → problem shifting)
- ❑ Will the production, use, and disposal of NT-based energy production applications pose a risk to human health? (e.g. nano-particles, nano-tubes during production and storage)
- ❑ Will NT-based energy production applications be available to all countries and societal groups (disregarding their state of development)?
- ❑ Is there a risk that NT-based energy applications divert focus and investments from more simple solutions?

Actions to maximize potentials, and minimize risks of NT-based energy production applications

5. From your point of view, what actions should be taken today to minimise risks and maximise future potentials of NT-based energy production applications?

- ❑ Is there a need for **additional specific regulation** for NT-based energy production applications or is the existing regulatory framework sufficient?
- ❑ Do you feel that more **information campaigns** and **educational initiatives** on the potentials and risks of NT-applications are needed? If yes, what would be their most important content?
- ❑ Do you think that special attention is needed in the areas of **public liability** and **environmental liability**? If yes, what aspects need to be focused at?
- ❑ Next to setting the legislative framework, which actions should be taken by the **government**?
- ❑ What role should the **industry** play to maximise the potentials and minimise the risks?

ELSA-priorities of NT-based energy production applications

6. Within each of the 7 ELSA, different issues are addressed in the literature. To which extent would you agree/disagree to the following statements?

   Please assign:
   - 3 points if you fully agree with the statement,
   - 2 points if you more or less agree with the statement,
   - 1 point if you disagree with the statement, and
   - 0 if you don't have an opinion on the statement.

Environmental Performance		
	Nanotechnological improvements will mainstream environmental-friendly energy production and assist in combating climate change.	
	Energy production, enhanced through the application of NT, will help to reduce pollutants and emissions.	
	Nanorods, used in fuel cells and solar PV, will lead to negative environmental effects not anticipated.	
	Studies investigating the overall environmental impacts of NT-based energy production applications from production to disposal are required.	
	Summarising your answers: at present, does the aspect of environmental performance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Human Health		
	Potentially harmful free nanotubes and nanoparticles particles might occur during manufacturing and disposal of fuel cells and solar PV.	
	Nanorods, used in fuel cells and solar PV, are very similar in shape to asbestos. It’s possible that the same health risks apply.	
	Distributed, renewable energy supply helps to provide healthcare and raise the standard of living.	
	Summarising your answers: at present, does the aspect of human health deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Access		
	Nanotechnology will enable efficient distributed energy supply at lower costs that will benefit poorer parts of the world without energy infrastructure.	
	Due to high investment and development costs concerning nanotechnologies, developments will be patented and subject to intellectual property rights (IPR). This will significantly slow down the wider distribution of technological solutions pressing problems.	
	Heavily investing in NT to provide solution to a range of global and societal problems might obscure or divert investment from cheaper, more sustainable, or low technology solutions to health and environmental problems.	
	Summarising your answers: at present, does the aspect of accessibility deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Acceptance		
	Nanotechnology will lower the costs of solar energy by 10 fold and the costs of fuel cells by 10 to 100 fold, making them commercially viable	
	NT-based energy production solutions will help to increase the acceptance of NT applications in general.	
	Fuels cells and NT-based solar panels are not seen as nano-products and will not be affected by society concerns regarding nanotechnologies.	
	Summarising your answers: at present, does the aspect of acceptance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Liability		
	Companies who use applications containing nanoparticles will not be held responsible for accidental release due to limited ability to trace back the origin of particles.	
	Uncertainty about risks from nanotoxicity and nanopollution will prevent NT-based energy production applications from being sufficiently covered by product or producer insurance.	
	Summarising your answers: at present, does the aspect of liability deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Regulation and Control		
	The current regulatory framework sufficiently addresses safety standards of NT-based energy production applications.	
	NT-based energy production applications are associated with concerns that need to be addressed in a framework of shared principles for the safe, sustainable, responsible and socially acceptable development and use of nanotechnologies e.g. on the EU-level.	
	Summarising your answers: at present, does the aspect of regulation and control deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Nanotechnology in general

7. To your opinion, which ELSA benefits or risks discussed in the media are relevant for the general debate on Nanotechnology?

8. With regard to NT-applications in general: To your opinion, in the context of which of the following ethical, legal and social aspects would the civil society most urgently call for action?

Please assign

- 3 points for aspects, that are especially important from your point view (as and expert),
- 2 points for those you consider to be “not unimportant”, and
- 1 point for aspects of minor importance.
- 0 if you don’t have an opinion on the statement.

ELSA-Criteria	Score
Environmental Performance	
Human Health	
Privacy	
Access	
Liability	
Regulation	

9. Which events, product launches/developments, and publications do you consider to be the key landmarks of the development of NT up to the present day?

10. Imagine it is the year 2015.
    a. What have been the 3 main factors driving development of NT?

    b. What have been the 3 main inhibiting factors for the development of NT?

    c. How were those inhibiting factors overcome?

Interview guideline for generic expert Interviews

Enter

The European Commission highlights the need to "respect ethical principles, integrate societal considerations into the R&D process at an early stage and encourage a dialogue with citizens" (European Commission 2005) within the action plan "nanosciences and nanotechnologies" for Europe 2005 – 2009. However this demand/need is not entirely new. In the context of NT-based projects the consideration of ethical, legal, and social aspects (ELSA) has gained increasing importance throughout the last five years. When in 2000 the US National Nanotechnology Initiative was launched, the program from the very beginning included funding for analyses of societal and ethical implications of nanotechnology.

1. Do you feel adequately informed on ethical, legal, and social aspects associated to NT within your field of expertise?

2. How/Where did you gain the information you needed on ethical, legal, and social aspects? (e.g. schooling/training, professional work, own initiative)

Benefits of NT-based applications

3. To your understanding, which are potential benefits NT-based applications will bring to society? If possible, mention the application you expect to deliver these benefits.

- ❑ What are the benefits NT-based applications can bring with respect to environmental performance?
- ❑ What are the benefits NT-applications can bring with respect to human health?
- ❑ Will NT benefit developing countries (DC) in areas such as health, environment and economy? Please explain your answer, can you give some examples for possible applications?
- ❑ What are the economic potentials of NT applications? (e.g. strengthening the EU's competitiveness; job creation/employment creation)?

Risks of NT-based applications

4. To your understanding, which are the potential risks and problems NT-based applications might bring to society? If possible, mention the applications you expect to led to these benefits.

- ❑ Does the production or use of NT-applications bear the possibility to provoke negative environmental impacts? If yes, what kind of impacts are possible?
- ❑ What are risks in terms of human health connected with the use of NT-based applications? Please give some examples.
- ❑ Do you expect the development of NT-applications will negatively impact on developing countries? Please, provide examples.
- ❑ If the regulation framework turns out to be insufficient to address safety standards what will be the risk for society?

5. We have been discussing potential risks of NT- applications. Which of the risks mentioned is directly associated with the nanotechnological component/feature of the technology?

Actions to maximize potentials, and minimize risks of NT-based applications

6. From your point of view, what actions should be taken today to minimise risks and maximise future potentials of NT-applications?

- ❑ Is there a need for additional specific regulation for NT-applications or is the existing regulatory framework sufficient?
- ❑ Do you feel that more information campaigns and educational initiatives on the potentials and risks of NT-applications are needed?
- ❑ Do you think that special attention is needed in the areas of public liability and environmental liability?
- ❑ Next to setting the legislative framework, which actions should be taken by the government?
- ❑ What role should the industry play to maximise the potentials and minimise the risks?

ELSA-priorities of NT-based applications

7. Within each of the 7 ELSA, different issues are addressed in the literature. To which extent would you agree/disagree to the following statements?

   Please assign:

   - 3 points if you fully agree with the statement,
   - 2 points if you more or less agree with the statement,
   - 1 point if you disagree with the statement, and
   - 0 if you don't have an opinion on the statement.

Environmental Performance		
	Nanoparticles fixed within the product cause environmental problems in disposal and recycling.	
	Free nanoparticles, which are not fixed within the product will be an eco-toxicological threat (e.g. causing direct damage to organisms).	
	Due to miniaturization effects nanotechnologies generally contribute to decoupling of economic growth and resource consumption, as NT-applications need smaller amounts of materials and energy.	
	Summarising your answers: at present, does the aspect of environmental performance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for "no opinion")	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public's opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Human Health		
	Free nanoparticles, which are not fixed within the product, have a toxic impact on human health.	
	Current knowledge does not allow to draw conclusions to the effects of free nanoparticles on the human body. Much more research is needed to understand possible risks, and benefits connected to these effects.	
	Summarising your answers: at present, does the aspect of human health deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Privacy		
	The potential impacts of NT applications on privacy deserve much more attention.	
	Summarising your answers: at present, does the aspect of privacy deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Access		
	Developing countries will be excluded from the use of nanotechnologies as (financial and human) resource restrictions limit the access to the technology.	
	NT-applications will become mainstream and be available to anyone at low cost.	
	Summarising your answers: at present, does the aspect of accessibility deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Acceptance		
	A positive public perception of nanotechnologies is crucial for further diffusion of the technology.	
	The lack of knowledge on negative effects possibly connected to NT-applications is a risk for public acceptance.	
	Summarising your answers: at present, does the aspect of acceptance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Liability		
	Current environmental liability regulations are sufficient to encompass NT.	
	Current product liability regulations are sufficient to encompass NT.	
	Summarising your answers: at present, does the aspect of liability deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Regulation and Control		
	The current regulative framework is sufficient to address all health and safety requirements of NT.	
	If the current regulation proves to be insufficient, it will not be possible to establish the necessary regulatory framework timely to prevent negative effects to humans and environment.	
	Summarising your answers: at present, does the aspect of regulation and control deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

8. Which events, product launches/developments, and publications do you consider to be the key landmarks of the development of NT up to the present day?

9. Imagine it is the year 2015.
    a. What have been the 3 main factors driving development of NT?
    b. What have been the 3 main hurdles to NT-development that had to be overcome?
    c. How were those hurdles overcome?

Annex II: List of researchers interviewed

Erased in the public version for confidentiality reasons

Annex III: List of civil society representatives

Erased in the public version for confidentiality reasons

Annex IV: Interview guide for civil society representatives

Entre

The European Commission highlights the need to "respect ethical principles, integrate societal considerations into the R&D process at an early stage and encourage a dialogue with citizens" (European Commission 2005) within the action plan "nanosciences and nanotechnologies" for Europe 2005 – 2009. However this demand/need is not entirely new. In the context of NT-based projects the consideration of ethical, legal, and social aspects (ELSA) has gained increasing importance throughout the last five years. When in 2000 the US National Nanotechnology Initiative was launched, the program from the very beginning included funding for analyses of societal and ethical implications of nanotechnology.

1. Do you feel adequately informed on ethical, legal, and social aspects associated with the developments of Nanotechnology?

2. Through which information channels did you gain your present knowledge on ethical, legal, and social aspects? (e.g. schooling/training, professional work, own initiative)

Nanotechnology in general

3. To your opinion, which ELSA benefits or risks discussed in the media are relevant for the general debate on Nanotechnology?

4. With regard to NT-applications in general: To your opinion, in the context of which of the following ethical, legal and social aspects should civil society most urgently call for action?

   Please assign

   - 3 points for aspects, that are especially important from your point view (as and expert),
   - 2 points for those you consider to be "not unimportant", and
   - 1 point for aspects of minor importance.
   - 0 if you don't have an opinion on the statement.

ELSA-Criteria	*Score*
Environmental Performance	
Human Health	
Privacy	
Access	
Liability	
Regulation	

INFORMATION FOR SCENARIO BUILDING

One of the key deliverables of this project is a number of scenarios looking at the future of NT in our society. These questions will inform that section.

Please think about the development of NT in its widest sense, including technological developments, market developments and the public perception of NT, up to the present day

5. Please identify up to five key points in that process that have been critical in influencing where NT is today. These landmark points could be publications, product launches, articles or anything that you feel is relevant. Please take your time and then tell me each key point. For each key point, please explain briefly why you chose it.

    1.

    2.

    3.

    4.

    5.

6. I'd like you now to use your imagination, and think forward ten years to the year 2015. Between the year 2005 and the year 2015,
    a. In 2015 what three main factors do you feel have been the strongest driving forces behind the development of NT?
    b. What have been the three main factors inhibiting the development of NT?
    c. How were those inhibiting factors overcome?

Specific Applications

For the purpose of the Nanologue project we have concentrated our research on the following application areas:

ENERGY CONVERSION and STORAGE

FOOD

MEDICAL DIAGNOSTICS

7. Do you have a particular interest /expertise in any of these areas (One area of discussion only)
8. What do you think are the key benefits associated with NT applications in this area? (Refer back to ELSA list)
9. What do you think are the key risks associated with NT applications in this area? (Refer back to ELSA list)

Actions to maximize potentials, and minimize risks of NT-based applications

10. From your point of view, what actions should be taken today to minimise risks and maximise future potentials of NT-based applications:

- ❑ Is there a need for **additional specific regulation** NT applications or is the existing regulatory framework sufficient?
- ❑ Do you feel that more **information campaigns** and **educational initiatives** on the potentials and risks of NT-applications are needed?
- ❑ Do you think that special attention is needed in the areas of **public liability** and **environmental liability**?
- ❑ Next to setting the legislative framework, which actions should be taken by the **government**?
- ❑ What role should the **industry** play to maximise the potentials and minimise the risks?

ELSA-priorities of NT-based applications

11. Within each of the 7 ELSA, different issues are addressed in the literature. To which extent would you agree/disagree to the following statements?

Please assign:

- 3 points if you fully agree with the statement,
- 2 points if you more or less agree with the statement,
- 1 point if you disagree with the statement, and
- 0 if you don't have an opinion on the statement.

Environmental Performance		
	The application of NT will help to improve resource efficiency e.g through the use of less materials or energy than traditional technologies.	
	Nano-materials present an eco-toxicological risk, in particular in the disposal phase.	
	Studies investigating the life-cycle wide environmental impacts of nanotechnology applications are required.	
	Summarising your answers: at present, does the aspect of environmental performance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Human Health		
	Applications of NT will enhance human health through earlier disease detection and better-targeted application of treatment.	
	Nanomaterials if allowed into our environment will have negative health impacts	
	There has been too little research into the possible impacts of nanomaterials on human health	
	Summarising your answers: at present, does the aspect of human health deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Privacy		
	Applications of NT will lead to issues surrounding the collection of data e.g. through military/espionage devices or medical technology	
	Summarising your answers: at present, does the aspect of privacy deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Access		
	Developments in NT are key to addressing challenges such as provision of clean water for all and sustainable energy production.	
	Developing countries will be excluded from the use of these technologies as (financial and human) resource restrictions limit the access to the technology.	
	Summarising your answers: at present, does the aspect of accessibility deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Acceptance		
	Although the technology is already in use there will be a public backlash against the use of nanomaterials in areas such as food and medicine.	
	Use of nanotechnology to revolutionise areas such as energy production will pave the way for public acceptance of the technology in other areas such as food and medicine.	
	The actors involved (e.g. Government and industry) need to do far more with regards to acceptance to prevent a repeat of the GM backlash.	
	Summarising your answers: at present, does the aspect of acceptance deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Liability, Regulation and Control		
	Current environmental liability regulations are sufficient to encompass the introduction of nanomaterials into the environment.	
	Present legislation such e.g. REACH can be amended to encompass the use of nanomaterials.	
	The use of nanomaterials requires the immediate creation of new legislation.	
	Summarising your answers: at present, does the aspect of liability deserve much (assign 3 points), more or less (assign 2 points), or little attention (assign 1 point): (assign 0 pts for “no opinion”)	
	Do you expect this to increase (assign 3 points), level off (2 points) or decrease (1 point) in the future?	
	Coming back to your estimation for the present situation, do you think that the general public’s opinion differs from your estimation? If so, does the general public call for much (3 points), more or less (2 points) or little (1 point) attention?	

Annex V: Workshop documentation

This Annex contains some of the results from the interviews in more detail. Section 1 lists the Benefits and Risks as prioritised by the delegates at the workshop. Section 2 contains a table describing how certain or uncertain the delegates were that the risk or benefit highlighted would become relevant by 2015.

Benefits and Risk Prioritised

Benefit	Votes
Better medical diagnosis	11
Reduction in environmental pollution / impacts	10
Better drug delivery	5
Food safety (improved packaging)	3
Reduced Cost / Material use = Improved efficiency	3
Greater Access to Resources (reduction in conflict)	2
Reduced cost of Healthcare	2
New technologies / New economies	1
Next generation information technology	0

Risk	Votes
Toxicity of Nanoparticles	12
The Nanobubble*	9
Nanodivide	7
Use of NT for military applications / terrorism	5
Products we don't want	4

Economic Dislocation	2
Privacy	1

*The Nanobubble – a concern held by the majority of the delegates that there was not enough focus and too much hype surrounding investment in nanotechnologies and this would result in a "bubble" that would eventually burst.

Uncertainty of Risks

The top rated risks were rated from certain (1) to uncertain (4) to occur by 2015

RISKS

The Nanodivide	**1**	2	3	4
Toxicity of Nanoparticles	1	2	**3**	4
"The Nanobubble"	1	**2**	3	4

BENEFITS

□ Environmental Pollution	1	2	**3**	4
Better Medical Diagnosis	**1**	2	3	4
Better Drug Delivery	1	2	**3**	4

Full list of recommendations

- Make engagement / communication a condition of grant (as with BBSRC funding)

- There has to be a move “beyond publishing” to get away from just publish or perish
- Give more time / rewards / publicity
- Ensure the scientists have training in media, communication and ethics. *There was the suggestion of using role-plays*
- Those in management positions should provide encouragement to deal.
- Create a forum with an international remit to bring together Scientists/Media/Public/Business.
- There should be independent funding for including ELSA communication and funding for dialogue between Government, business and wider society.
- Career development and assessment to include ELSA
- The dialogue must be facilitated.
- The education system needs to be updated to integrate the discussions around science and society, cost / benefit. Critical thinking introduced into all levels of education. (Obviously this is not unique to NT)
- Trans-disciplinary education of Natural / social scientists
- In corporate science there needs to be close co-ordination between those responsible for ELSA at board level and the technicians.
- Scientists should be encouraged to engage with educational institutions at all levels
- Information about new tech e.g. NT should be available at schools even early levels. This can be used to get through to parents as well.