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Published under the Nanologue project as deliverable D2 for work package 1.
Nanologue is funded by the European Commission within the 6th Framework Programme.
(FP6-2003-NMP-TI-3-main)

Nanologue Background Paper

on selected nanotechnology applications and their ethical, legal and social implications

Released September 2005

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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, Dagny Vedder, Dr. Christa Liedtke (WI), Dr. Hans Kastenholz, Andreas Köhler (EMPA), Hugh Knowles, Vicky Murray (FFF).

We would like to thank all those who provided comments and suggestions, in particular the Nanologue External Advisory Board as well as Torsten Fleischer, Asgeir Helland, Dr. Norbert Malanowski, Dr. Christoph Meili, Prof. Michael Metha and Rutger van Merkerk.

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1. Introduction

1.1 What is this paper about?

Nanologue's overarching objective is to facilitate a dialogue among researchers, business and civil society about the benefits and potential impacts of nanoscience and nanotechnology applications.

The first work package of the project was designed to prepare the ground for the subsequent discussion, providing an overview of current research into the ethical, legal and social aspects (ELSA) of nanoscience and nanotechnologies (NT) and identifying applications to be scrutinised in depth with regard to ELSA in the course of the Nanologue project. This document is one of the two deliverables from the first work package.[1]

This paper presents the main results of the research on ELSA for selected NT applications in the areas food, energy and medical diagnostics. The results are based on a broad and in depth literature analysis, input from the project's external advisory board (EAB) and other experts involved in the ongoing technology foresight studies of nanotechnologies.

The first chapter provides some background information on the Nanologue project. At first the issue why a dialogue is needed will be addressed. Second, the methodology used to select the NT applications and the set of ethical, legal and social aspects for the Nanologue project will be discussed. Finally, our understanding of nanoscience and nanotechnologies and ELSA will be introduced. The second chapter presents the main results of the screened application areas energy, food and medical diagnostics and their relationship to ELSA. Chapter 3 gives a brief project description of Nanologue as well as the role and the members of the External Advisory Board (EAB). The appendix provides a detailed description of the results summarised in the second chapter.

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[1] For the other deliverable check:
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.

It should be mentioned that this background paper, including its appendix, is a compilation of information, sources and quotes that primarily serves to inform the following work packages of the Nanologue project. We do not claim to provide a complete overview on ELSA for the selected NT applications, nor to have conducted a thorough analysis. However, the authors would like to share the current state of investigation with a wider audience in case they might find it useful.

The Nanologue project aims at raising awareness and stimulating discussion, not because we have a particular view about the potential opportunities and risks that NT presents. Our role is to encourage dialogue between stakeholders, facilitating constructive approaches for addressing the implications of NT.

1.2 Why a dialogue?

The field of nanotechnologies has attracted widespread attention and funding in recent years. Some applications have already entered the market, and applications based on today's basic research are expected by many to form the next industrial revolution. The unique properties of nano-technological applications suggest potential to solve some of the world's most pressing challenges, but they come with uncertainties and risks like all new technologies. Taking advantage of technological progress and preventing adverse side-effects requires analysis, evaluation and guidance to ensure technology is developed in ways that benefit the wider society and the planet.

Nanologue is a dialogue on nanotechnologies funded by the European Commission bringing together a wide range of technological experts, businesses and civil society representatives. This dialogue is driven by the need to understand ethical, legal and social implications of nanotechnologies – and communicate this understanding by raising awareness and providing information to societal actors.

Learn about opportunities and threats

There is very little knowledge in the wider European society about what nanotechnologies are and what impact they might have on how we live. Many experts acknowledge prevailing uncertainties about this. Innovative technologies based on multidisciplinary research provide an abundance of potential applications. While advocates preach a revolution, e.g. in chemical production methods, medicine, material science and energy systems, critics warn about unknown side-effects, e.g. allergies, and deliberate misuse of the technological solutions developed.

The dialogue processes in Nanologue aims at providing a neutral platform to gather recent knowledge and evidence about the multiplicity of potential impacts associated with selected nanotechnologies. It is driven by the need to understand the ethical, legal and social implications of nanotechnologies – and communicate this understanding by raising awareness and providing information to societal actors. Using scenario-building techniques, the projects findings will be assessed and translated into images comprehensible to the wider public and apt for communication.

> *A better dialogue between policy bodies, researchers, civil society actors is beneficial for understanding possible concerns and tackling them from the standpoints of science and of governance, and to promote informed judgment and engagement.*[2]

Spread information and raise awareness

Different societal groups have different information needs and perspectives regarding the ethical, legal and social aspects of nanotechnologies. By addressing these positions, Nanologue will help to spread information and raise awareness about the implications of nanotechnologies in the following relevant societal groups:

Scientists, students and product developers with a technical background possess the knowledge about the technologies they are working on, but seldom address ethical, legal or social implications.

Businesses are starting to commercialise of nanotech-based products. Experience in the development of bio-technologies has shown how the failure to adequately consider relevant ethical, legal and social issues can lead to long-term consequences on public trust and the public perception of those technologies.

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[2] Commission of the European Communities (2005): Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee. Nanosciences and nanotechnologies: An action plan for Europe: 2005-2006, p.2

Civil society actors lack information on and awareness of the basic properties, and sometimes even the existence, of nanotechnologies and the implications linked to them. However, a generally sceptical attitude among civil society groups prevails towards new technologies. The general lack of public knowledge has allowed unsubstantiated science-fiction visions to enter mainstream media. Public debates lacking a sound factual base are likely to get irrational and come to erroneous, potentially harmful, results. If concerns from societal actors are not listened to, insights on complex interdependencies get lost and hidden risks persist.

> *The consumer is exposed to the influence of streams of information, some of it contradictory. He not only hears the good news about product innovation, but also the warnings and consumer misgivings. Talking openly and responsibly about risks is the task of all those who possess the necessary knowledge and, above all, of those in the manufacturing industry. Dialogue is needed among science, industry, the authorities and the public.*[3]

Policy bodies are challenged by nanotechnologies as by all rapid technological and sociological developments. A 'window of opportunity' exists to shape NT research and applications through policy decisions. But information for policy makers and awareness of the implications of nanotechnologies is needed. For example, to answer the question whether regulatory frameworks specifically dedicated to nanotechnologies are needed?

1.3 Our approach

From the outset, the Nanologue project intended to base the dialogue on specific nanotechnology applications rather than on "Nanotechnology" in general. The term "Nanotechnology" is to our understanding a collective term, encompassing the various branches of nanosciences and nanotechnologies (see also section 1.5). Instead of discussing the ethical, legal or social aspects of such a broad area, we chose an **iterative approach** to narrow down the project's scope.

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[3] Swiss Re (2004). Nanotechnology. Small matter, many unknowns. Zurich., p.45

In a **first step** each consortium partner carried out a mapping of current literature to identify NT application areas of potential relevance for the project. The literature revealed a variety of categorization schemes for NT application areas, many of them with a smaller or larger overlap. With the aim of initiating a dialogue based on applications close to the market and with relevance to various ethical, legal and social aspects, the areas materials, medicine & life sciences, electronics & ICT as well as energy were identified as priority areas for the project. Within each NT application area, a multitude of specific NT applications was identified and listed.

In parallel, a first preliminary analysis of ethical, legal, and social aspects of NT applications discussed in the literature was carried out. More than hundred nanoscience- and nanotechnologies-related publications (studies, projects descriptions, articles and websites) were mapped in order to provide a first overview on the state of the art and on the ongoing debate. Studies and projects funded by the European Commission, national funding organisations in leading NT countries and other organisations were also considered.

In a **second step** 15 recently published overview reports related to NT and ELSA were chosen for more detailed analysis. Selection criteria were, amongst others, their scientific quality, their usefulness for ELSA discussion and their public availability. Summaries of the reports analysed are publicly available. [4]

Besides getting a deeper insight into the current discussion, this analysis step served two main purposes. First, for the NT application areas selected in step one, to identify specific NT applications within these areas that are already on the market or under current or prospective development. Acknowledging the overlaps between the four broad application areas, the applications mentioned in the literature have been categorised and priorities for selection.

Second, based on the first rough compilation of ELSA from step one, categories of ELSA have been formed, that appeared to be of relevance to various stakeholders (broadly business, policy makers, researcher, civil society). See the following section on “Our understanding of ELSA” for further details.

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[4] 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.

Supported by some members of the project's Expert Advisory Board, further desk research and expert interviews, the consortium selected in a **third step** three specific NT-application areas as well as a core set of seven ELSA as objects for investigation and dialogue for the course of the project. These are:

- **Selected NT application areas**: energy conversion and storage, food packaging, and medical diagnostics.
- **Selected ELSA:** environmental performance, human health, privacy, access, acceptance, liability, and regulation & control.

In a **final step**, the results of which are presented in this document, each NT application area and its relationship to ELSA was analysed in detail, starting with the information drawn from the overview reports and incorporating more application specific information drawn from supplementary sources in literature and the internet. A summary of the main results is presented in chapter 2 of this background paper, a detailed description in the appendix.

1.4 Our understanding of ELSA

As recent debates in the EU and elsewhere demonstrate, developments in science and technology do not take place in a vacuum, uninfluenced by social and ethical concerns. On the contrary, various actors with different views are shaping the process. Broad discussions of issues such as reproductive technologies, agriculture biotechnology and nuclear energy illustrate this point clearly. Against this background it seems very likely that some applications of NT will raise significant social, ethical, or legal concerns.

Whilst there is much excitement about the potential for NT to offer many benefits, such as increasing energy efficiency, better medical treatment, safer food, and lower costs for computing, some observers (stakeholders, scientists, media) have also expressed their concerns about possible risks associated with NT. This has resulted in a number of important questions about the future of the technology: What will society look like when nanotechnology becomes more mainstream? Will the products be profitable? Are there any negative environmental or health impacts? Who controls the use of NT? How to deal with liability? Whom will the technology benefit or harm? What are the ethical problems?

These ELSA related questions are not unique to NT. They have been discussed with varying levels of success in other areas of science-driven development of new technology (e.g. biotechnology, Human Genome Project). Having learned from these discussions, most NT exponents have realised that ELSA reflections should not be an adjunct to NT development, but an integral to it.[5]

But what exactly are the ethical, social, and legal aspects of NT? Engineers and scientists, social scientist, policy makers, regulators, business people, journalists, and science-fiction authors all seem to already have strong opinions about these aspects. Depending on the respective social group or scientific discipline engaged in the debate, different questions regarding the hopes and fears of NT are discussed.[6] They vary from the "nanodivide" to human enhancement, from civil liberties to military use, from environmental and human impact to technological convergence.

Given this backdrop, the Nanologue consortium has 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 the applications of nanotechnologies can pose to the society.

In an iterative procedure, based on literature analysis, expert interviews and internal evaluations, the consortium partners selected a core set of seven ELSA as basis. **The selected ELSA are:**

- environmental performance;
- human health;
- privacy;

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[5] The Royal Society (2004). Nanoscience and nanotechnologies: opportunities and uncertainties. London, pp 51.

Nanoforum (2004). 4th Nanoforum Report: Benefits, Risks, Ethical, Legal and Social Aspects of Nanotechnology

The COST Nanoscience and –Technology Advisory Group (NanoSTAG) (2001). ELSA Studies of Nanosience and Nanotechnology. ftp://ftp.cordis.lu/pub/nanotechnology/docs/nanostag-elsa.pdf

M. Roco, and W.Bainbridge (eds.) (2001). Societal implications of nanoscience and nanotechnology. Kluwer

[6] Schummer, J. (2004). „Societal and Ethical Implications of Nantotechnology": Meanings, Interest Groups, and Social Dynamics. Techne, 8/2, 56-87

- access;
- acceptance;
- liability; and
- regulation and control (see also chapter 1.3 and deliverable 1[7]).[8]

1.5 Our understanding of Nanoscience and Nanotechnologies

Nanotechnology has now become an umbrella term used to encompass the study, manipulation and application of matter based on its properties at the atomic scale. The "nano" prefix derives from the Greek noun nanos, meaning dwarf. A nanometer (nm) is one billionth (1×10^{-9}) of a meter: the length of about ten atoms placed side-by-side, or 1/80,000th of the thickness of a human hair. Nanotechnology is now generally considered to relate to the organization of atoms and molecules within a size range of 1 to 100+ nm, although much larger structures, devices and systems that incorporate or owe their existence to such entities are also described as nanotechnological.

Some definitions differentiate between nanoscience and nanotechnologies. The Royal Society & The Royal Academy of Engineering (2004) have agreed on the following definitions: [9]

"**Nanoscience** is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.

Nanotechnologies are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometre scale".

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7 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.

8 The consortiums is aware of the ongoing debate on military usage of NT (dual-use), but it was considered that this is out of the scope of this paper.

9 The Royal Society (2004). Nanoscience and nanotechnologies: opportunities and uncertainties. RS Policy document 19/04. London, p.5.

The Nanologue project consortium has decided to use these definitions as basis for discussion. It was also decided to use the term “nanotechnology” as a collective term, encompassing the various branches of nanosciences and nanotechnologies as proposed by the European Commission in the action plan “Towards a European Strategy for Nanotechnology”.[10]

[10] Commission of the European Communities (2004). Communication from the Commission. Towards a European Strategy for Nanotechnology. Brussels. p.4.

2. Results

2.1 Introduction

A summary of the main findings concerning ethical, legal and social aspects (ELSA) for the three application areas:

- energy conversion and storage;
- food packaging;
- medical diagnostics

will be presented. Extended versions with more detailed information can be found in the appendix. For some ELSA, no application specific information could be found in the literature, whereas information on a more general, not application specific level could be obtained. This information was excluded from the application specific descriptions but is made available in the appendix.

The absence of information does not indicate that a certain aspect is of no concern. To the contrary, it should rather be considered as an indication for areas that might deserve closer attention in the forthcoming debate and research. The information presented in the following not the result of an in-depth analysis but a compilation of different aspects and positions found in the literature.

2.2 Energy storage and conversion

"*Among the most important technical challenges facing the world in the 21st century is providing clean, affordable energy, whose supply is sustainable and universally available.*" (Baker A.J., 2005)

The challenge presented by climate change alone will require a complete rethink of the production and use of energy. There are three ways to address the issue 1) reduce energy consumption, 2) increase the efficiency of energy production and 3) use more distributed and environmentally benign energy systems. Nanotechnologies have the potential to revolutionise production, conversion, storage, distribution and use of energy.

2.2.1 Characteristics of the application

There are a number of areas where nanotechnology is expected to impact. Nano-layers could be used to make possible more efficient lighting and photovoltaic energy generation. Nano-clusters and tubes will impact on catalysis, hydrogen storage, artificial photosynthesis and lead to more efficient batteries and fuel cells. Finally, nanoporous membranes are expected to contribute to more efficient fuel cells and batteries.

For the following discussion of ELSA in the area of NT-based energy applications, three exemplary applications are discussed in the areas of energy production and storage:

Energy Production

1. FUEL CELLS (CONVERSION)

A fuel cell is an electrochemical engine (no moving parts) that converts the chemical energy of a fuel, such as hydrogen, and an oxidant, such as oxygen, directly into electricity. The principal components of a fuel cell are catalytically activated electrodes for the fuel (anode) and the oxidant (cathode) and an electrolyte to conduct ions between the two electrodes.

Applications of nanotechnology could transform fuel cells by increasing the efficiency of conversion through improved catalysts and membranes. It could also be possible to improve the construction of cells and storage of fuels such as hydrogen. NT-based solutions may also reduce the size and increase the lifetime of devices and enable the use of alternatives such as bio-fuels.

Resulting Applications and Products

Many analysts have suggested that fuel cells will not be commercially viable for a number of years due to material costs. There are several other barriers to progress including storage and distribution problems associated with fuels such as hydrogen and the impact of manufacturing hydrogen from non-renewable resources.

However, there have been rapid developments in fuel cell technology over the last 2-3 years and it is anticipated that $100 billion will be invested in this technology worldwide in the next 10 years.

- Toshiba has developed a miniature methanol fuel cell that was due for release in 2005 and could be used to power small electronic items such as laptops and mobile phones.

2. SOLAR CELLS (GENERATION)

A photovoltaic solar cell consists of a diode conventionally made of semiconducting materials sandwiched between two electrical contact layers. The sunlight passes through the top contact layer, is absorbed in the semiconductor and generates positive and negative charges, which diffuse to the different contacts. DC electricity is generated when the solar cell is connected to electrical equipment (or load) such as lighting, radio etc. The electrons and holes are separated by the diode and these charges drive a current in the circuit.

Resulting Applications and Products

Nanotechnology is already delivering improvements in solar technology. Dye-sensitised solar cells are already available but not commercially viable and advances in polymers should be seen in the Photovoltaic market imminently.

- There have been recent improvements in thin-film solar technology. This involves depositing a thin film of silicon on a substrate material. Polymers and nanotubes are being combined to create very thin active layers. The cells have a low efficiency but they are flexible and cheap.
- Nanostructured electrodes can increase the efficiency of organic solar cells by improving the efficiency and frequency range of light absorption.

Energy Storage:

3. BATTERIES (STORAGE)

Batteries store electric energy in a chemical form and most batteries work as follows: the electrolyte strips electrons off the cathode. These electrons gather in the anode and flow out, creating power, when the battery is put into use.

The surface area of the electrodes dictates the amount of power the battery produces. That is, the greater the area where the cathode contacts the electrolyte, the higher the current one can get out of the battery.

Resulting Applications and Products

In order to increase surface area, companies have been experimenting with “nanowire” batteries, which have the potential to dramatically increase surface area and hence improve performance. It is hoped this technology will cost less, last longer, be easier to make, smaller and more environmentally friendly.

Nanocrystalline materials and nanotubes have been demonstrated to greatly improve both power density, lifetime and charge/discharge rates of lithium batteries.

- Toshiba has developed a battery that can “recharge 80% of a battery's energy capacity in only one minute, approximately 60 times faster than the typical lithium-ion batteries in wide use today, and combines this fast recharge time with performance-boosting improvements in energy density.” Highly efficient batteries could meet the increasing power demand from portable products such as laptop computers, cell phones etc.
- Bell Labs is exploring the possibility of producing a micro battery that would still work 20 years after purchase by postponing the chemical reactions that degrade traditional batteries.
- The Endo Laboratory has significantly extended the charge/discharge lifecycle of lead acid batteries by adding carbon nanotubes.
- There is also the potential to dispense with batteries completely by developing nanotube-based ‘ultracapacitors’ powerful enough to propel hybrid-electric cars which would be more efficient, relatively more powerful, could be charged in seconds and function in more extreme temperatures.

Convergence

There have been developments in creating "biological" batteries which were created by encapsulating oxidant and reductant chemicals inside separate polymerized phospholipid membranes.

It is also mentioned, that nanotechnology could eventually allow scientists to mimic the process of photosynthesis.

2.2.2 Ethical, legal and social aspects

"Breakthroughs in nanotechnology open up the possibility of moving beyond our current alternatives for energy supply by introducing technologies that are more efficient, inexpensive, and environmentally sound." (Baker A.J., 2005)

Nanotechnology can potentially revolutionise the energy market and provide solutions to a number of challenges presented by increasing power demands and global climate change. However, it is essential that these advances are seen as part of the solution and not a solution in itself and it is important to be aware that "*enthusiasm for developing a "technical fix" to a range of global and societal ills might obscure or divert investment from cheaper, more sustainable, or low technology solutions to health and environmental problems.*" (Royal Society/Royal Academy of Engineering, 2004)

The following chart summarises the main benefits and risks for the use of nanotechnology in solar cells. Similar charts on fuel cells and batteries are not displayed, as many of the high level risks and opportunities are similar. The chart is followed by a more detailed overview including all three applications.

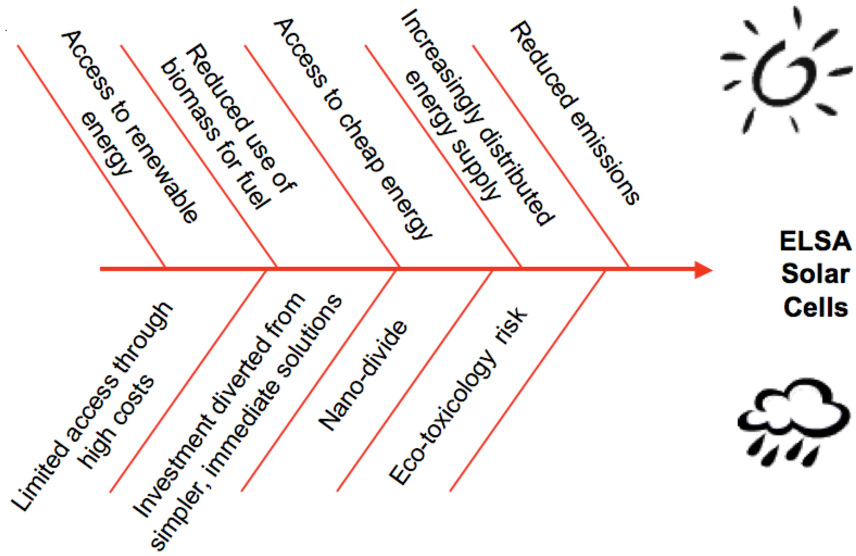

Figure 1: Main opportunities and risks for NT-based solar cells mentioned in the literature.

ELSA Environmental Performance

Opportunities

The development of cheaper and more efficient fuel and solar cells would lead to a reduction in pollution and emissions.

Use of nanomaterials in batteries is bringing about rapid decreases in charge time and improvements in performance. These all lead to decreased energy consumption and the ability to quickly and efficiently store energy from vehicles and renewable sources. This would indirectly lead to a reduction in the use of non-renewables.

Risks

There are concerns about the toxicity and chemical activity of the materials used in fuel and solar cells, particularly in nanoparticulate form. For example Nanorods, used in Solar PV, are very similar in shape to asbestos. It's possible that the same health risks apply.

Disposal at end of life is yet to be addressed and the advances in nanotechnology have to be assessed from a life-cycle point of view.

The complexity of the materials used could make them hard to reuse or recycle.

ELSA Human Health

Opportunities

The provision of cleaner energy would reduce pollutants and emissions and thereby improve human health.

Distributed, renewable energy supplies could help provide raise the standard of living and help provide localised healthcare.

Risks

There are general concerns over the use of nanorods and nanoparticulates in manufacture. Quantum dots used in photovoltaic technology, for example, were found to be cytotoxic in a study on their impact on human health. Some sources raise the issue that miniaturisation and increased efficiency in power devices could have military and surveillance applications.

One of the factors that will determine human health risks from nanotechnology in fuel cells is whether the nanomaterials are fixed or free, a distinction made in the Royal Society/Royal Academy of Engineering report. If the materials are fixed then it is unlikely that they will have an impact except in manufacture or disposal.

ELSA Privacy

There is no discussion of this ELSA topic in the material reviewed.

ELSA Access

Opportunities

If developed successfully on an industrial scale these technologies could provide access to sustainable energy and help developing countries avoid the destruction of local resources such as wood and the recurrent shortages and price fluctuations that come with the dependence on fossil fuels, as well as the environmental consequences of mining and burning oil and coal.

Use of renewable energy might contribute to negate the need for the development of expensive and wasteful distribution networks.

Risks

There is the risk that investing in a high tech solution could divert investment from other more suitable solutions. Also, the more complex the technology the harder it is for people to adapt to it and learn how to mend it. This takes control away from the user.

Aside from the current high cost of developing nanotechnology, there is a general concern that market forces might determine which technologies are developed and where, therefore limiting access for developing countries. For example, nanotechnology has the potential to deliver batteries that will cost less, last longer, be easier to make, smaller, quicker to charge and have less environmental impact. As energy storage is key to the development of renewable energies and a decentralised energy supply, it is important that this technology is as accessible as possible. However, development is likely to be biased towards storage for high tech devices in those countries with a market for them.

ELSA Acceptance

Fuel cells, solar cells and batteries are already on the market and therefore already largely accepted by the public, especially as they are seen as part of the solution to the energy problem. Despite the fact that nanotechnology is likely to have a large impact in this area, the negative aspects are likely to have a low profile in the pursuit of cleaner more efficient energy sources. As a result there has been little discussion in the public domain about the risks of this technology, apart from the safety of hydrogen storage. However, as the cells use developments in materials such as nanotubes, they are likely to be subject to the same scrutiny as many other uses of nanotechnologies.

ELSA Liability

There is no discussion of this ELSA topic in the material reviewed.

ELSA Regulation and Control

There is no discussion of this ELSA topic in the material reviewed.

2.3 Food packaging

Nanotechnology is attractive to the food industry as it promises to yield new solutions to key challenges. While far reaching visions such as nanotech food synthesizers or pathogen killing Nanobots are not expected to become reality within the next decades, nanotechnology related R&D for food processing, food engineering and food packaging is in the innovation pipeline of the food industry today. The authors of the RAND report highlight the growing importance of the converging technologies biotechnology, gene technology and nanotechnology in the food sector. Food engineering is one of the issues receiving highest attention in corporate R&D. It includes the development of functional food, nutrient delivery systems and methods for optimizing food appearance (colour, flavour, consistency). Another big issue in food industry-related R&D is food packaging and food monitoring.

2.3.1 Characteristics of food packaging

In the food-packaging arena, nanomaterials are being developed with enhanced mechanical and thermal properties to ensure better protection of foods from exterior mechanical, thermal, chemical or microbiological impacts. This would endow packaged foods with an additional level of safety and functionality. Additionally it would offer advantages along the supply chain and would potentially enhance the shelf life of foods. Examples for the use of nanotechnology in food packaging technology are:

- modified permeation behaviour of foils,
- enhanced barrier properties,
- improvements in mechanical and heat-resistance properties,
- active antimicrobic and antifungal surfaces,
- sensing and signalling microbiological and/or biochemical change.

One aim of innovative packaging solutions is the reduction of spoilage. Production, processing and shipment of food products could be made more secure through the development and implementation of nanosensors for pathogen and contaminant detection. Nanotechnology has the potential to provide a new solution to the tracking and tracing of goods and also to provide new monitoring techniques. Most of these technologies are still under development but have commercial potential.

For the discussion of ELSA in the area of nanotechnology-related food packaging, the examples listed below are chosen because they appear to be most prominent in the food industry's R&D pipeline:

- **Polymer nanocomposites for food packaging and wrapping**
  Foils or membranes based on nanocomposites offer adjustable gas permeability in food packaging which can help to better protect food in order to enhance quality and food safety.
- **Anti-microbial packaging materials**
  Packaging materials that exhibit anti-microbial properties caused by nanoparticular silver or other substances have entered the market recently. In the future, anti-microbial packaging is expected to become a mass application.
- **Self cleaning surfaces**
  Dirt-repellent coatings at the nanoscale can prevent the invasion of microorganisms and ensure food safety. Applying this so called lotus effect to the surfaces of food packaging could inhibit the settlement of microbes.
- **Smart packaging**
  Packaging materials with properties that can change depending on external or internal conditions such as temperature are under development recently. In the future, food packaging that can adjust its properties to pH, pressure, temperature and light or show self-healing properties when perforated may become available.
- **Tagging and monitoring of food items**
  Nanotechnology based anti-counterfeit technologies are in the R&D pipeline of various companies. Tagging of food packages will mean that food can be monitored from farm to fork. In the food sector the protection of brand authenticity may cause better food safety in certain cases.
- **Biomaterial characterization at the nanoscopic level**
  The application of the Atomic Force Microscope (AFM) in the area of food sciences is currently used to study the nanoscale structure of foods and other biomaterials.

2.3.2 Ethical, legal and social aspects

Few stakeholder statements concerning nanotechnology in the food sector have been voiced thus far. Most prominent in terms of ELSA discourse is the report 'Down on the farm', published by the ETC group - an international civil society organisation. The ETC group expresses general ELSA concerns about the use of nanotechnology in food and agriculture and scrutinises socio-economic effects. As a consequence, the ETC group calls for a moratorium, prohibiting the application of nanotechnology until the absence of health risks caused by nanoparticles will be scientifically evident. ELSA statements by other stakeholder focus merely on the uncertain health effects of nanoparticles and are not specific to the application in food and food packaging.

The following chart summarises the main potential benefits and risks for food packaging applications identified. A more detailed overview is given in the next sections.

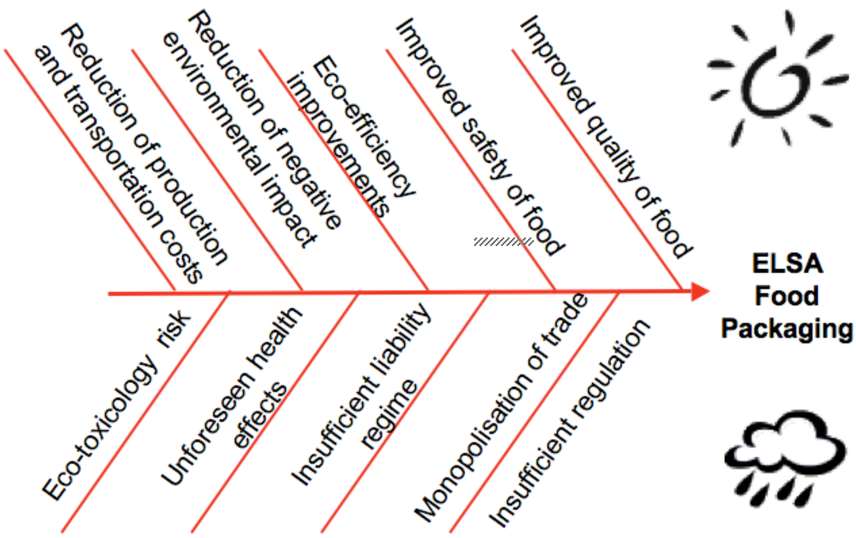

Figure 2: Main opportunities and risks for food packaging applications mentioned in the literature.

ELSA Environmental Performance

No specific statements regarding the environmental performance of nanotechnology in food packaging could be found. However savings in the total mass of polymer needed in the packaging sector caused by enhanced mechanical strength of packaging materials can be considered as an environmental advantage. More light-weight packaging could reduce environmental load of transportation. The longer shelf-life could on the other hand allow for longer distance distribution networks with associated negative environmental impacts. At the same time nanocomposites might pose both positive and negative challenges in the polymer recycling process, regarding efficiency and material quality.

ELSA Human Health

In addition to improve nutritional quality and safety of foods, opportunities are also seen in the usage of antimicrobial food packaging based on nanoparticles that can reduce the large-scale use of antibiotics and preserving agents in food processing as well as in processed food. Food might become healthier and microbial resistances might be avoided.

No information is available about how stable nanoparticles are fixed in a polymer matrix in the long term. But unintended diffusion of nanoparticles from packaging material into food might result in health risks. It is uncertain whether nanoparticulate antimicrobial agents in food packaging can cause adverse health effects such as allergies. So far no effects have been investigated.

ELSA Privacy

No privacy specific statements regarding nanotechnology in food packaging could be found. However, issues associated with tagging might occur, since it could provide e.g. seamless end-to-end surveillance of status, location, and consumer data.

ELSA Access

Nanotechnology related patents for food and food packaging could foster monopolization in the food sector. Smaller producers especially in less developed countries might be unable to afford the technology to implement it as source. This might lead to a two-class system and nano-divide effects in the long-term.

ELSA Acceptance

Acceptance might be directly linked to the question of health risk and secondly depend on whether any of the benefits outlined that impact on costs will be passed on to the consumers. Parts of these arguments are already known from the GM debate.

The ETC group states that nanotechnologies will dramatically change food production and processing as well as packaging, transportation and consumption. That can cause poor acceptability due to cultural concerns. It is unclear whether NT in food packaging benefits or affects naturally preserved (bio-) food.

ELSA Liability

No information is available about the long-term stability of antimicrobial, self-cleaning or other functional coatings so far. But product liability could be an issue. If nanoparticles from nanocomposites would be released into food due to wear and if they turn out to be harmful, this would cause claim for compensation in case of adverse health effects.

ELSA Regulation and Control

No regulation and control specific statements regarding nanotechnology in food packaging could be found. A gap in the current chemical regulation is reported in the case of nanoparticles.

2.4 Medical diagnostics

The health-sector is frequently mentioned as one of the most relevant and promising application areas for nanotechnologies. Regarding health aspects Farkas (2003) expects NT to be, "*the key technology for the 21st century*" and Wood et al (2003) claim that the *"…medicine and health area of NT applications is seen as one of the most potentially valuable, with many expected benefits to humanity. Fields mentioned are implants and prosthetics, diagnostics and drug delivery."*

2.4.1 Characteristics of the application

Within the medical field of medical diagnostics, methods and testing techniques for the analysis of molecular substances e.g. DNA and RNA are used to detect diseases or predispositions to diseases. There are several ways of analysing those substances with the aid of nanotechnologies. For the following discussion of ELSA in the area of NT-based diagnostic applications, two exemplary applications are discussed.

1. **Lab-on-a-chip (LOC**) as an example for in-vitro diagnostic:
   LOC represent a miniaturisation of chemical instrumentation integrating a multitude of processes, e.g. sample preparation, verification of reaction data, and detection of reaction products on one device.

What is nano about LOC? Although LOC is currently largely a microfluidic device, it is commonly mentioned in connection with nanotechnologies, as nanoparticles are frequently used for the detection of analyte molecules, and nanoscale structures can be found on the chip. Expectations for the future encompass a further miniaturisation of the chip down to a nanoarray level.

2. **NT-based in-vivo cancer detection**:
   In contrast to LOC in-vitro diagnostic, where molecular substances are analysed outside of the body, in-vivo diagnostic nanotechnologies detect potential cancer within the body.

The area of in-vivo diagnostic of cancer cells comprises NT-applications for molecular imaging (e.g. cantilever, nanopores, quantum dots) as well as applications trying to combine diagnosis and treatment (e.g. dendrimers, nanoshells).

Overall purpose of the application: Whereas the purpose of LOC-development is to gain fast, comprehensive, and reliable measurements of metabolic parameters from e.g. the human body with minimum invasion using one device, which is easy to handle and inexpensive (often disposable), the overall purpose of in-vivo diagnostic in cancer research is to observe the earliest molecular changes within cells, long before a physical exam or imaging technology is effective.

Resulting applications and products

LOCs are currently used amongst others for sample/tissue processing, genetic testing, biomarker discovery/detection and protein separation in the health sector. Application examples are DNA, protein and cell analysis for diagnostic purpose. A wide variety of NT-applications is expected for the short, medium and long term future, as highlighted by the figure below.

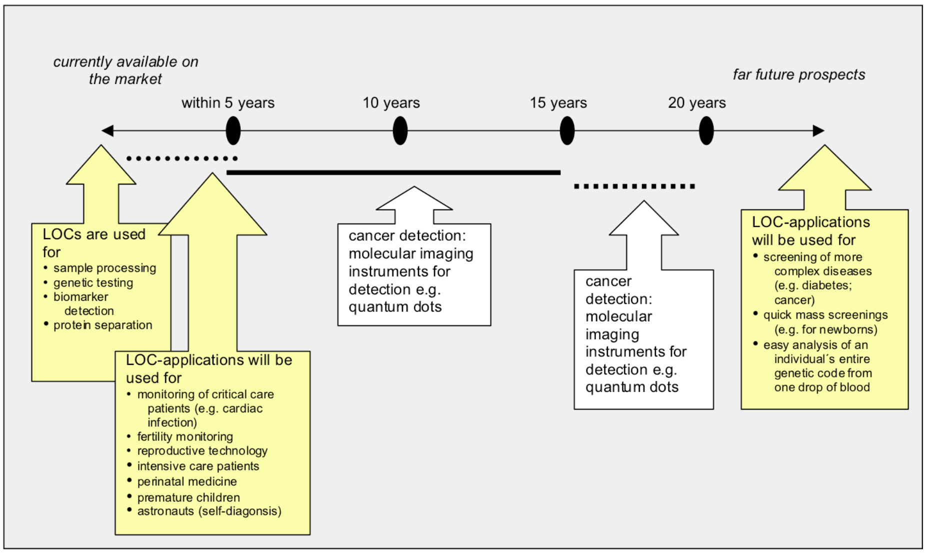

Figure 3: Market perspectives of LOC and NT cancer detection-applications (Sources: Venture Capital Magazin (2002), Wagner et al (2004), Paschen (2003), Hyder (2003)).

The applications chosen mirror different stages in the development of nanotechnologies. Whereas LOC are already in use, most in-vivo diagnostic applications of nanotechnologies are expected to reach marketability in the mid to long term.

Convergence

The report of the Royal Society claims that convergence of nanotechnology, biotechnology, information and cognitive sciences opens new horizons and holds potential for radical human enhancement. This holds also true for LOC technologies. In connection with ICT, LOC devices enable new possibilities in diagnostics. In particular telemedicine could reach a significant role. Patients will be able to inform the doctor about the current state of health. To realise the link between patient and doctor questions concerning data protection and data access have to be discussed.

2.4.2 Ethical, legal and social aspects

The application of nanotechnologies in the health sector, in particular for diagnostic purpose, promises big potential to enhance human health, for example regarding hopes to extent life expectancy or to win the fight against cancer. Next, the opportunities for human health, other ethical, social or legal aspects are also discussed. Concerns about the impact of new diagnostic devices on e.g. privacy may pose obstacles for the development of nanotechnologies. An overview on the potential ethical, legal and social implications of NT-based diagnostic devices is a first step to take full advantage of the technology.

The following chart summarises the main benefits and risks for LOC diagnostic devices. A similar chart on in-vivo cancer detection is not displayed, as less information on this application could be obtained. The chart is followed by a more detailed overview including both applications.

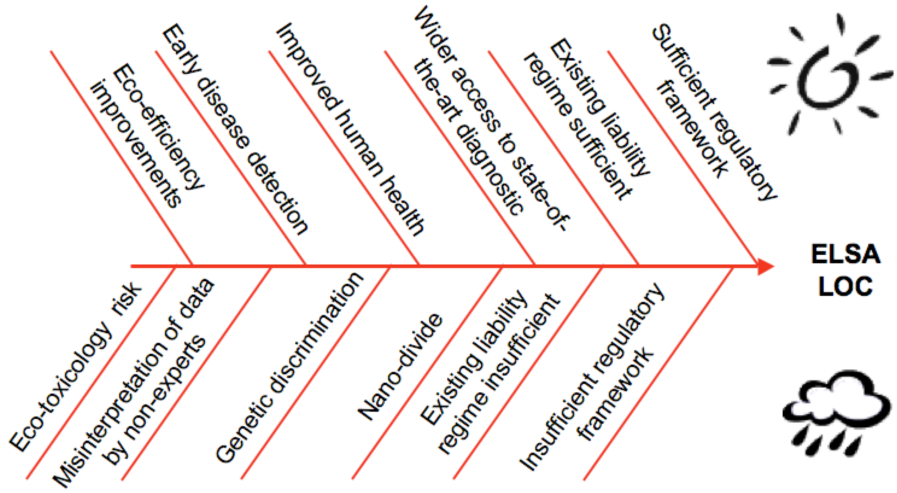

Figure 4: Main opportunities and risks for LOC applications mentioned in the literature.

ELSA Environmental Performance

Due to miniaturization effects, LOCs are perceived as a promising opportunity for **(eco-) efficiency gains** in terms of reductions in material and energy use.

While aspects of the environmental performance are not specifically mentioned for in-vivo applications, the end-of-life phase of LOC is mentioned as an area of concern regarding **eco-toxicological potential**.

ELSA Human Health

According to the literature screened, the main opportunities of LOC as well as in-vivo NT-applications for cancer detection can be found in the fields of **early disease detection** or **disease prevention** possibly leading to an extension of life expectancy.

LOC enables near patient diagnostic and personalised medicine (e.g. including patient-specific reactions to active agents), leading to a reduction of medicine consumption and thus **fewer drug side-effects**. LOC-related risks are mainly seen in terms of **mismanagement** like incorrect self-management with point-of-care/self-testing devices or misinterpretation of data because of insufficient device performance or false handling of devices.

In terms of early cancer detection NT-applications are perceived as a possible first step to **win over cancer** through an early identification of cancer or precancer, enabling treatment before symptoms of the disease become apparent. Additionally NT-based methods of diagnosis are expected to be less intrusive as they could be effective without surgery.

In contrast to fixed nanoparticles on LOC devices for in-vitro diagnostic, the in-vivo application raises questions of **toxicity** of free nanoparticles in the body [i.e. through accumulation] closely connected to the question of possible interactions with biological processes. First studies show that “nanomaterials can accumulate in the body, depending on the dosing route.” (Goldman/Coussens 2005)

ELSA Privacy

The collection of personal data always bears risks in terms of privacy. Data gathered with help of LOC-applications might lead to **genetic discrimination**. However, even without genetic discrimination fears remain that constant surveillance may become obligatory although the patient is in a good medical condition or the surveillance of the human body might lead to a new form of hypochondria. Discussed also as the “**right of non-knowledge**” it will become increasingly difficult as individual but also as the public to avoid knowledge about e.g. individual disease dispositions, except any regulations restrict the access.

ELSA Access

Decreasing costs per diagnosis through the use of NT products, may lead to a wider access and **increasing availability of state-of-the-art diagnosis** applications. In contrast, NT diagnostic applications carry the risk of a two-class system of medicine.

In general, NT is seen as a technology offering possibilities for health breakthroughs, yet many of them seem to be high-tech and thus quite costly. Discussing the **global nano-divide** it is stated, “it is hard to imagine their being used as health interventions among the poor” (Meridian Institute 2005).

Statements on opportunities and risks connected to the access of NT-applications for early cancer detection could not be found.

ELSA Acceptance

A wide acceptance of NT business institutions and the public bears the opportunity to spread existing nano-applications and to successfully introduce new applications to the market. Results of surveys on the public perception of NT affirm that applications such as LOC, which positively contribute to human health aspects help **pave the way for a wide acceptance of NT**.

However insufficient product performance e.g. development errors could yet lead to **rejection of NT** by the public. As LOC-technologies contribute to the substitution of processes usually performed in conventional medical laboratories, a wide acceptance and common use of LOCs could result in lower employment rates for workers in central medical laboratories.

ELSA Liability

Especially for the sector of medical diagnosis the interpretation of data gained by NT may lead to difficulties regarding liability: The earlier a diagnosis is given, the less clear the relationship to its causes becomes. Who would be **liable if a false prediction** were to be made?

ELSA Regulation and Control

For the field of medical diagnostics opportunities and risks in terms of regulation and control are not specifically restricted to the exemplary NT-applications previously introduced. In addition the need for regulation and control is interconnected with other ELSA-aspects previously mentioned, like, e.g. the need for regulation on the access to personal medical data is connected to privacy issues.

3. Nanologue Project

3.1 Project Description

Introduction

Nanologue brings together leading researchers from across Europe to facilitate an international dialogue on the social, ethical and legal benefits and potential impacts of nanosciences and nanotechnologies.

In the aftermath of the controversy and debate on genetically modified organisms it has become abundantly clear that in order to harness new technologies for economic and social benefit, governments and businesses will have to address a wide range of social, ethical and regulatory concerns. Nanologue will bring together current leading research on the social, ethical and legal implications of nanotechnologies, facilitate dialogue and produce guidance for stakeholders and developers of nanotechnologies in particular, on how to address the issues uncovered to the wider benefit of both society and the economy.

Nanologue aims at providing a common ground for discussion between actors from the civil society, academia and business. A deliberate consideration and elaboration of different positions regarding opportunities and risks of nanotechnology is a keystone of the Nanologue project.

Project steps

The project comprises three main steps.

1. A mapping study on recent developments regarding selected nanotechnology applications is currently undertaken to lay a common ground for the subsequent discussions.
2. Moderated dialogue sessions will be held allowing for an inclusive and neutral platform for information and opinion exchange and discussion. Interviews with experts will contribute to substantiate findings and opinions.

3. Insights will be translated into scenarios allowing for easy communication of the potential implications of these emerging technologies.

Dissemination

Results of the project will be disseminated by a variety of means, ranging from media workshops, a website and an online quick checker, to a project pamphlet and conference attendances.

The partners

Nanologue is led by the Wuppertal Institute (Germany) and conducted in cooperation with its consortium partners EMPA (the Swiss Federal Laboratories for Materials Testing and Research) in Switzerland, Forum for the Future in the UK and triple innova of Germany.

The project is a Specific Support Action in the NMP work programme (Nanotechnology and nanosciences, knowledge-based multifunctional materials, new production processes and devices) of the European Commissions sixth Framework Programme.

Further information

For further information on the Nanologue project check www.nanologue.net.

3.2 The External Advisory Board

The Nanologue project established an External Advisory Board (EAB) as an external advisory and review body working throughout the different phases of the project. Tasks of the EAB are:

1. Complement the expertise of the project consortium, on ethical, legal and social aspects as well as on technical and scientific properties of nanotechnologies;
2. Critically review and substantiate the projects findings;
3. Complement the consortiums network and contacts to media, education and other information gatekeepers to support outreach activities.

Members of the EAB are:

- Tim Aldrich, KPMG LLP
- Antoine Ducrocq, Avocat à la Cour
- Dr. Chris Ewels, Institut des Matériaux Jean Rouxel, Nantes
- Dr. David Rejeski, Woodrow Wilson International Center for Scholars
- Prof. Dr. Rainer Schweizer, University of St. Gallen
- Dr. Donald Bruce, Church of Scotland - Society, Religion and Technology Project
- Dr. Thomas Epprecht, Swiss Reinsurance Company
- Tim Harper, Cientifica Ltd.
- Prof. Dr. Ortwin Renn, University of Stuttgart

4. Appendix

See separate document