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Benefits, Risks, Ethical, Legal and Social Aspects of NANOTECHNOLOGY

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Benefits, Risks, Ethical, Legal and Social Aspects of Nanotechnology

Abstract

In this report, the Nanoforum consortium presents the present state of the art of the public and scientific debate on benefits, risks, and ethical, legal and social implications of nanotechnology in Europe and other parts of the world. It also gives an overview of relevant research groups, funding programmes, projects and networks in Europe. Finally it reviews position papers of NGO’s, industrial associations and political parties, which are already participating in the emerging political debate on nanotechnology, as well as debates initiated by governments, the European Commission and parliaments, and gives access to media coverage of nanotechnology.

Nanotechnology is showing promising developments in many areas and may benefit our health and welfare. However, we should be aware of possible unwanted side-effects. Nanotechnology means new materials and components, which can be included in many different existing products or enable new products. Applications include sustainable energy, healthcare, cars, information and communication, and household products. The main concern is currently the health and environmental impact of small nanoparticles. Risk research is ongoing. In the public debate also long term scenarios and science fiction including nanorobots play a role, as well as ethical and social aspects of priorities in research such as military applications and the nanodivide between haves and have-nots. The political debate on regulating nanotechnology is just beginning.

Nanoforum is a thematic network funded by the European Commission, aiming to promote and raise the standard of nanotechnology activities throughout Europe. Nanoforum comprises a consortium of leading European nanotechnology organisations led by the Institute of Nanotechnology (UK) and including VDI Technologiezentrum (Germany), CEA-LETI (France), Nordic Nanotech (Denmark), Malsch TechnoValuation (Netherlands), METU (Turkey), Unipress (Poland), Sofia University (Bulgaria), BIT (Austria) and NanoNed (The Netherlands). Nanoforum is an information source for the European Community that unites disciplines and countries. Nanoforum provides a resource for business, research, government and financial institutions across Europe. This report has first been published end of June 2004 on www.nanoforum.org. This update has been published in October 2005.
Table of contents

1. Executive Summary

2. Potential Benefits of Nanotechnology Currently under Debate
   2.1. Introduction
   2.2. Energy
     2.2.1 Reduction of energy consumption
     2.2.2 Increasing the efficiency of energy production
     2.2.3 The use of environmentally friendly energy systems
     2.2.4 Recycling of batteries
   2.3. Life sciences and health care
     2.3.1 Diagnostics
     2.3.2 Drug delivery
     2.3.3 Tissue engineering
   2.4. Automotive Industry and Mobility
     2.4.1. Environmental aspects
     2.4.2. Safety aspects
     2.4.3. Outlook
   2.5. Information and Communication
     2.5.1. Top down strategies, how far can we go?
     2.5.2 Novel semiconductor devices
     2.5.3 Novel optoelectronic devices
     2.5.4 Displays
     2.5.5 Quantum Computer
   2.6. Chemistry and Environment
     2.6.1 Production of nanoparticles
     2.6.2 Catalysis
     2.6.3 Filtration
   2.7. Consumer goods
     2.7.1. Foods
     2.7.2. Household
     2.7.3. Optics
     2.7.4. Textiles
## Potential Risks of Nanotechnologies

### 3. Potential Risks of Nanotechnologies

#### 3.1. Introduction

#### 3.2. Initiatives, centres and projects dedicated to risks assessment of nanotechnologies

#### 3.3. Potential impacts of nanotechnologies on health

##### 3.3.1. Potential risks of nanoparticles

1. **Size effects**
2. **Shape and composition effects**
3. **Examples of consequences**
   1. **Experiments on animals**
   2. **Extrapolation to humans**

##### 3.3.2. Potential risks of fullerenes and carbon nanotubes

1. **Examples of studies on animals**
   1. **Experiments on rats and mice**
   2. **Experiments on rabbits**
   3. **Experiments on fish**
2. **Extrapolation to humans**

##### 3.3.3. Potential risks of other nano-elements

#### 3.4. Potential impacts of nanotechnologies on environment and the food chain

1. **Consequences of nanotechnologies on environment and the food chain**
   1. **Impact of the dispersion of nanosized materials in the environment**
   2. **Impact on environment of the adsorption phenomenon on nanosized materials**
   3. **Effects of aggregation of nanosized materials on environment**
   4. **Biotic uptake of nanomaterials**
2. **Methodologies considered for risks assessment of nanotechnologies on environment**
   1. **Measurement of accumulation**
   2. **Measurement of viability/mutagenic effects**
| 3.5. | Conclusions of Part 3 |
| 4. | Public Perception of Nanotechnology |
| 4.1. | Introduction |
| 4.2. | Media and scenarios influencing the public perception |
| 4.2.1 | Media |
| 4.2.2 | The space elevator |
| 4.2.3 | Nano-submarines |
| 4.2.4 | Molecular assemblers |
| 4.3. | Public Dialogue Projects |
| 4.4. | Conclusion |
| 5. | The Ethical Aspects and Political Implications of Nanotechnology |
| 5.1. | Introduction |
| 5.2. | Ethical Systems |
| 5.3. | What are the ethical considerations of nanotechnology? |
| 5.3.1. | Risks – known and deduced |
| 5.3.2. | Sharing knowledge |
| 5.3.3. | Achieving public acceptance and ensuring equity |
| 5.4. | The politics of nanotechnology – a balance of power |
| 5.4.1 | Human: machine interface |
| 5.4.2 | Military uses of nanotechnologies |
| 5.4.3 | Lessons from the past and present |
| 5.4.4. | Funding social science research |
| 5.4.5. | Legislation and regulation |
| 5.5. | Conclusions |
| 6. | Invited contributions to the debate on ethical and societal implications of nanotechnology |
| 6.3. | Douglas Parr: preprint version of “Will Nanotechnology make the world a
6.4. Sylvia Speller: “From science fiction to science fact – a nano-scientist’s views on the current debate on nanotechnology”

7. The need for new legislation and regulation caused by the emergence of nanotechnology

7.1. Introduction

7.2. European regulations and directives

7.2.1. European Union regulatory activities

7.2.2. Other European regulatory activities

7.3. National regulatory institutions and discussion groups

7.3.1. Germany

7.3.2. Switzerland

7.3.3. United Kingdom

7.3.4. The Netherlands

7.3.5. France

7.3.6. Belgium

7.3.7. The United States

7.4. Global regulatory activities and global action groups

7.4.1. Miscellaneous Action Groups

7.5. Standardisation and testing

7.5.1. European Union metrology advices

7.5.2. Other European metrology institutes

7.5.3. Other European Standardisation activities

7.6. National metrology institutes

7.6.1. Germany

7.6.2. United Kingdom

7.6.3. China

7.6.4. USA

7.7. International Metrology Institutes

7.8. Patenting

7.9. Industrial Initiatives

7.10. Conclusions
Part 1: Executive Summary.

This report is intended for non-experts in risk analysis and in technology assessment, or ethical, legal and social aspects of nanotechnology, to get a quick insight in what these areas of research have to say about nanotechnology. It also includes an overview of the emerging political and public debate on nanotechnology in Europe. The Nanoforum consortium hopes this will be interesting to the following user groups:

1) Nanotechnology researchers interested in international collaborations with experts in risk analysis and the ethical, legal and social aspects of nanotechnology;
2) Experts in risk analysis and technology assessment interested in issues related to nanotechnology;
3) Politicians, NGO’s and lay persons interested in what nanotechnology may mean for society.

This report includes parts on potential risks and benefits of nanotechnology; on public perception; on ethical and political aspects; and on the current status of the debate on legislation for nanotechnology. It also includes a list of European research organisations active in risk research specific for nanomaterials, and in ethical, legal and social aspects of nanotechnology. A continuously updated list of these organisations can also be found in the online database of institutions accessible at www.nanoforum.org. No glossary is included in this report, but readers who are unfamiliar with nanotechnology can check the online glossary at www.nanoforum.org.

What is nanotechnology?

In microelectronics, energy technology and biomedicine, some of the most crucial technological needs of today are related to nanotechnology. For example we would like to have more compact high-capacity lightweight batteries, more efficient solar energy technologies, less expensive high-resolution flat panel displays and more efficient means to transport drug molecules to targeted cells. Solutions to these problems are likely to be based on methods that border on nanotechnology.

Nanotechnology describes the creation and utilisation of functional materials, devices and systems with novel functions and properties that are based either on geometrical size or on material-specific peculiarities of nano-structures. Purely geometrically, the prefix "nano"
(Greek: dwarf) describes a scale 1000 times smaller than that of current elements of the micrometer-sphere (1nm corresponds to the millionth part of a mm). This scale has become accessible both by application of new physical instruments and procedures, and by further diminution of current microsystems. In addition, structures of animated and non-animated nature have been used as models for self-organising matter. Only if the mastery of this atomic and molecular dimension succeeds, can the prerequisites for the optimisation of product properties within socioeconomic areas such as energy engineering, environmental technology as well as in information technology, health and ageing be developed.

The world-wide industrial conquest of nanoscale dimensions began with the discovery of techniques to organise, characterise, and manipulate individual elements of matter as well as increasing insights into the self–organisation principles of these elements. In the meantime the speed of innovation has led to the situation that physical fundamentals are still being investigated while first product groups are already entering the world markets. Their sales impacts are caused by the implementation of nanoscale architecture with new macroscopic functions.¹

This report

In this report, the Nanoforum consortium presents the current state of the European and global debate on risks, benefits, ethical legal and social aspects of nanotechnology in October 2005. We have also included an overview of the government related, research, political and non-governmental organisations which are taking part in this debate, and of which we are aware. We would appreciate to be informed of other relevant organisations and news to be included in future updates of this report, and welcome your contribution. Please contact

mark@nano.org.uk

Part 2 discusses the potential benefits of nanotechnology in the application areas of energy, life sciences and health care, automotive industry and mobility, ICT, chemistry and environment and consumer goods. We present benefits of nanotechnology which are already available or are expected in the next decade or so. We conclude that nanotechnology can lead to improvements of a wide range of products and technologies. Nanomaterials, coatings etc. can be applied in new and more sustainable energy storage, conversion and saving technologies. Biocompatible materials and other nanotechnologies will also be used in tissue
engineering, implants, diagnostics and drug delivery. The automotive industry is already and will be a large market for nanomaterials, sensors etc. In ICT, nanoelectronics is already part of the international technology roadmap of the Semiconductor Industry. Nanotechnology will be taken up in computer CPU’s and memories. Nanomaterials will also lead to innovation in the chemical industry, and nanotechnology can contribute to environmental technologies including sensors and air, soil and water cleaning technologies. Nanotechnology can also become part of consumer goods for example in ‘smart textiles’.

The risks covered in part 3 of this report are subdivided into human health and environment. Health impacts of nanoparticles currently under investigation include risks of lung and heart diseases from inhaled nanoparticles, accumulation of non-biodegradable nanoparticles in the liver and uptake into the brain. Nanoparticles may also enter the food chain. These can be either existing particles such as soot (a product of burning coal or wood), or manufactured nanoparticles which are present in consumer goods and could be released in the environment during or after the use of the goods. We present the current state of research on risks for health and environment of nanoparticles. This is now the most pressing issue in the political debate on nanotechnology. We conclude that at the moment, research on health and environmental impacts is ongoing. So far, there is no significant evidence that nanoparticles present risks for humans, but it should be noted that no sufficient proof could be collected yet. Studies should continue.

In part 4, public perception of nanotechnology is explored, as this will influence the acceptance and hence market chances of nanotechnology. Public perception is influenced by many factors including published scenarios of nanotechnology’s long-term impacts on society. In this part, we discuss these scenarios from the perspectives of proponents and opponents of nanotechnology, including science fiction writers. These long term scenarios are not very relevant to the present day risks, benefits, and ethical, legal and social implications of nanotechnology. However, they do influence how the general public reacts to nanotechnology. These scenarios should therefore realistically be taken into account in a public debate on nanotechnology.

In part 5, we discuss current ethical aspects and political implications of nanotechnology. After an explanation of different ethical systems relevant to nanotechnology, this part reviews some ethical considerations of nanotechnology, including the risks debate, sharing knowledge
and public acceptance of nanotechnology. Nanotechnology is already the subject of public
debate and social science research in the EU and some other countries, because politicians and
industrialists have learned from the public opposition against GMOs¹ food and other recent
debates about new technologies. We analyse the present state of the global debate on ethical
aspects and political implications of nanotechnology. We base this on an analytical
framework of three types of ethical systems, borrowed from Chris Phoenix: guardian,
commercial and information. We conclude that nanotechnology should be managed using all
three types of ethical systems.

Part 6 consists of four contributions by social and human scientists and stakeholders on
ethical and societal aspects of nanotechnology.

Part 7 discusses the need for new legislation for nanotechnology. This includes recent
initiatives to standardise and test nanotechnologies, EU actions and directives which are
relevant to nanotechnology and the positions of different lobby groups and parties on
nanotechnology. It is clear that the discussion on whether or not nanotechnology leads to a
need for new legislation is only just beginning. Issues include safety of nanoparticles,
boundaries between laws governing market introduction of different kinds of technologies,
military applications of nanotechnology, patenting and standardisation. It is too early to say
what the outcome of these debates will be.

Research institutes in risk analysis and technology assessment in Europe dealing with
nanotechnology, and lobby groups and political organisations which have already shown
interest in nanotechnology and society are listed in part 8 and included in the database of
institutions on www.nanoforum.org. The database will be continuously updated.

What’s new in the October 2005 version?

Totally new is part 6, which comprises a debate forum on ethical and societal implications of
nanotechnology. This part consists of four invited contributions from external authors. Two of

¹ Genetically Modified Organisms. The introduction of genetically modified food such as corn, soy beans or
food crops which are resistant to pesticides or include terminator genes has been confronted with public
resistance, especially in Europe. This has slowed the development of a European biotechnology industry, and
increased awareness among policy makers, industry and researchers of the need for public debate about new
technology in early phases of development.
these authors are experts in ethics and social science and have resubmitted articles which have been published elsewhere on ethics and nanotechnology. These experts are Professor Jean-Pierre Dupuy of Ecole Polytechnique, Paris and Stanford University, USA and Professor Armin Grunwald of TAB and ITAS in Germany. Jean-Pierre Dupuy’s contribution looks at: “Complexity and Uncertainty; A prudential approach to Nanotechnology” (published as A contribution to the work in progress of the “Foresighting the New Technology Wave” High-Level Expert Group, European Commission, Brussels.) Armin Grunwald discusses: ”Nanotechnology – A New Field of Ethical Inquiry?” (published in Science and Engineering Ethics (2005) 11, 187-201)

The other two authors represent stakeholder groups to Nanotechnology, and write about ethical and societal aspects of nanotechnology from their viewpoint. These are Dr Douglas Parr of Greenpeace UK and Professor Sylvia Speller from the Radboud University in Nijmegen, The Netherlands (a Physicist). Douglas Parr submitted a preprint version of the article “Will Nanotechnology make the world a better place?” published in Trends in Biotechnology Vol.23 No.8, August 2005, pp.395-398, and Sylvia Speller submitted “From science fiction to science fact – a nano-scientist’s views on the current debate on nanotechnology”, as original peer reviewed work.

By publishing these contributions, Nanoforum hopes to open up the debate on these issues on our website. Peer reviewed contributions from other invited authors will also be published here in the future. We are also open to suggestions for authors.

Other changes to the 2005 edition of the Nanoforum report on Benefits, Risks, Ethical, Legal and Social Implications of Nanotechnology are in Part 2. These consist of minor changes to the paragraph on Information and Communication. Part 3 is also updated, including results of health and environmental risk studies on nanotechnology published between June 2004 and September 2005. The conclusion, that there is not enough evidence to decide if nanoparticles present a risk to humans or the environment remains the same. Toxicology and environmental impact research should continue. Part 7 (formerly 6) is also updated and includes information on international and national activities on regulation and standardisation of nanotechnology which have taken place since June 2004. New since the first version are public debate on nanotechnology in France and Belgium, the activities of the OECD Chemicals Committee, the installation of nanotechnology standardisation committees by ISO and CEN and work on nanopatenting classifications by EPO and other patent bureaus. We also include information
on new events and publications of the EU, countries and relevant organisations which were already active on nanotechnology regulation and standardisation before June 2004.

Parts 4, 5 and 8 have not been updated. We have decided not to update parts 4 and 5 on public debate and ethics as these chapters present merely one perspective to the broad spectre of viewpoints which are currently being discussed. We therefore opened the debate forum for invited authors in Part 6 to facilitate the exchange of visions. Part 8 is not updated, but instead we are continuously including more groups with expertise in social and economic studies of science, humanities and standardisation in universities and research organisation in our online database of organisations at www.nanoforum.org.

\[\text{www.nanoforum.org}\]
4th Nanoforum Report:

Benefits, Risks, Ethical, Legal and Social Aspects of NANOTECHNOLOGY

Part 2: Potential Benefits of Nanotechnology Currently under Debate

2nd Edition - October 2005
Benefits, Risks, Ethical, Legal and Social Aspects of Nanotechnology

Part 2: Potential benefits of nanotechnology currently under debate.

2.1 Introduction

This part will briefly focus on the achievements of nanotechnology in all relevant sectors and gives an outline for the future. Many promising features of nanoscaled objects have been identified leading to superior product functionality and thus providing means for a better life. In general, nanotechnologically improved products rely on a change in the physical properties when the feature sizes are shrunk. Nanoparticles for example take advantage of their dramatically increased surface area to volume ratio. Their optical properties, e.g. fluorescence, become a function of the particle diameter. When brought into a bulk material, nanoparticles can strongly influence the mechanical properties, such as the stiffness or elasticity. Such “nanomaterials” will enable a weight reduction accompanied by an increase in stability and an improved functionality, such as “easy-to-clean”, “anti-fog”, “anti-fingerprint” or “scratch-resistance”, to name a few. The most prominent change can be found in the area of information and communication, where the semiconductor industry is following its predicted path (Moore’s Law). In the beginning of 2004, Intel released its latest CPU “Prescott” manufactured in the 90 nm process, which clearly falls into the domain of nanotechnology.

An enormous improvement for a variety of product properties due to nanoscale effects has been achieved over the past years; although a distinct onset of nanotechnology in the past can be hardly defined. This apparent contradiction is based on the fact that today’s common definitions of nanotechnology enclose long existing products, which are based for example on thin layers or small particles. Therefore, products which are either based on nanosized features or on nanoscale properties might just match the current “nano” requirements by chance. Wide-spread products like computer hard drives are indeed based on nanotechnology, but which were not associated with the term “nano” when they were launched. Modern hard disk drives, with their enormous capacity of up to several 100 Gb would not be possible without the so called GMR-Effect (Giant Magneto Resistance), which is based on the coupling of magnetic layers, separated by an ultrathin “nano”-spacer and was discovered in the late 1980s¹.
Therefore, it is clear that the boundary between products related to the prominent term “nanotechnology” and others is fuzzy. Nevertheless, the overall nanotechnology market is optimistically estimated to reach 1 trillion dollars by 2015\(^2\), emphasising the claim of being an “enabling” technology and playing a key role in the 21\(^{st}\) century.

Besides the traditional fields of high-technology, life sciences are supposed to undergo a vivid change due to the impact of “nanobiotechnology”. Especially, in biology the word “nanotechnology” is of particular importance: it is nature’s intrinsic way to build on the nanometre scale molecule by molecule through self-organisation. This “assembling” method is extremely efficient and could be helpful for the conservation of nature and natural resources. It is expected that the concept of “self-assembly” could be an approach for a sustainable development in the future. However, such futuristic concepts are far from being realised at present or in a medium term view.

Beside this long term vision of a biomimetic nanotechnology, an earlier positive influence on health care and medicine can be foreseen. Several different realistic approaches have been reported for diagnosis and therapy. Furthermore, nanotechnology will provide better means for a sustainable power supply, a reduction in air pollution and a sustainable environmental protection. Nevertheless, the world-wide energy consumption is increasing due to the rising industrialisation of less developed countries. This increasing need for energy is accompanied by a surge in air and water pollution. There, nanotechnology provides solutions for improving renewable energy systems, such as fuel cells, solar cells or hydrogen storage and will help to foster their implementation in the future.
2.2. Energy

The current generation has the responsibility to leave coming generations a viable environment. According to the National Academy of Sciences, the Earth's surface temperature has risen by about 1 degree in the past century, with accelerated warming during the past two decades. There is strong evidence that most of the warming over the last 50 years is attributable to human activities. Human activities have altered the chemical composition of the atmosphere through the build-up of greenhouse gases – primarily carbon dioxide, methane, and nitrous oxide. The content of the greenhouse gas carbon dioxide has increased since the beginning of the industrial era by about 30%.

At the moment more than 50% of the total energy consumption of the world is caused by the countries of the OECD. Although the developing countries have a much higher growth rate in energy consumption (and will reach the level of the OECD countries in approximately 2015) it is widely accepted that the industrial countries bear the responsibility to lower the emission of greenhouse gases. Therefore, many countries are trying to complete the environmental guidelines of the Kyoto protocol. The European Union has committed itself to reducing greenhouse gas emissions by 8% during the period of 2008 to 2012 in comparison with 1990 levels, whereas projections indicate that the total gas emissions of the 15 member states will increase by at least 5.2% between 1990 and 2010 if no new drastic measures are taken.

There are different possibilities for reaching these goals.

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1 Organisation for Economic Co-operation and Development
2.2.1 Reduction of energy consumption

The total world energy consumption rose from 4551 Mtoe\(^2\) in 1973 to 6905 Mtoe in 2000. A reduction of energy consumption can be reached by better insulation systems and by the use of more efficient lighting or combustion systems. The energy consumption in the mobility sector (see chapter 2.4.) can also be reduced by use of lighter and stronger materials. Currently used light bulbs only convert approximately 5% of the electrical energy into light. Nanotechnological approaches like LEDs (Light Emitting Diodes) or QCAs (Quantum Caged Atoms) could lead to a strong reduction of energy consumption for illumination.

2.2.2 Increasing the efficiency of energy production

Today's best solar cells have layers of two different semiconductors stacked together to absorb light at different energies but they still only manage to use 30 percent of the Sun's energy\(^4\). Commercially available solar cells have much lower efficiencies (less than 20%). Nanotechnology can help to increase the efficiency of light conversion by specifically designed nanostructures. The degree of efficiency of combustion engines is not higher than 15-20% at the moment\(^5\). Nanotechnology can improve combustion by designing specific catalysts with maximised surface area.

2.2.3 The use of more environmentally friendly energy systems

The EU is committed to doubling the share of renewable energy resources from 6 to 12% by 2010\(^6\). An example for an environmentally friendly form of energy is the use of fuel cells powered by hydrogen, which is ideally produced by renewable energies. Probably the most prominent nanostructured material in fuel cells is the catalyst consisting of carbon supported noble metal particles with diameters of 1- 5 nm. Suitable materials for hydrogen storage contain a large number of small nanosized pores. Therefore many nanostructured materials like nanotubes, zeolites or alanates are under investigation. Also more environmentally friendly is an increased use of renewable energies. A widespread use of solar cells suffers from the high costs of purchase. A nanotechnological approach, currently under discussion, is low cost solar cells using titanium dioxide nanoparticles as light absorbing components (Grätzel cells).

\(^2\) Million tons of oil equivalent
2.2.4 Recycling of batteries

Because of the relatively low energy density of these systems the operating time is limited and a replacement or recharging is needed. The huge number of spent batteries and accumulators represent a disposal problem. The consumption of batteries and accumulators has, for example, doubled in Germany in the last ten years\(^7\), whereas the rate of return is only 40%. The use of batteries with higher energy content or the use of rechargeable batteries or supercapacitors with higher rate of recharging using nanomaterials could be helpful for the battery disposal problem.

2.3. Life sciences and health care

A strong nanotechnological impact on health care is inevitable and several approaches in using nanotechnology for therapy as well as for diagnostic purposes have already been presented. A long-term vision of a nanotechnological improved medicine is to overcome human weaknesses and to cure severe diseases. However, quite a few popular visions of a futuristic “nanomedicine” currently in vogue emanate solely from science fiction scenarios and lack any serious scientific background.
Nevertheless, since all diseases are based on mechanisms at the cellular and molecular level, gaining a better control of nanoscopic dimensions seems to be a meaningful task.

2.3.1 Diagnostics

A future disease diagnosis will be fast and comprehensive, making use of miniaturised analysis systems (“Lab on a Chip”) which will cut costs and time consuming lab cycles.

![Figure 2.3: A “Lab-on-a-Chip”](www.infineon.com)

The patient will benefit from this “near patient” diagnostic through an optimised therapy with fewer drug side effects. A targeted or personalised medicine reduces the drug consumption and treatment expenses resulting in an overall societal benefit by reducing the costs to the public health system. In a further step, the potential health risk or genetically probable diseases of a patient might be identified: defeating a potential disease before it is able to become a real one. The world market for Lab-on-a-Chip systems has been estimated to reach about 60 million dollars in 2005. On the other hand, this scenario induces a privacy problem: Identifying a potential genetic disease could have implications for the employment opportunities of the individual. Furthermore, it is of social concern because of its direct impact on insurance cost. In fact, a patient with a known probability of being affected by a certain disease may be uninsurable.

2.3.2 Drug delivery

Drug delivery is another major field of science where nanotechnology is expected to be of future importance. The world market for drug delivery is about 40 billion dollars. The overall drug consumption and side-effects can be lowered significantly by depositing the active agent
in the morbid region only and in no higher dose than needed. This highly selective approach reduces costs and human suffering. An example can be found in dendrimers and nanoporous materials. They could hold small drug molecules transporting them to the desired location. Another vision is based on small electromechanical systems: NEMS (Nano electromechanical systems) are being investigated for the active release of drugs. Some potentially important applications include cancer treatment with iron nanoparticles or gold shells.

2.3.3 Tissue engineering

Nanotechnology can help to reproduce or to repair damaged tissue. This so called “tissue engineering” makes use of artificially stimulated cell proliferation by using suitable scaffolds and growth factors. Tissue engineering might replace today’s conventional treatments, e.g. transplantation of organs or artificial implants. On the other hand, tissue engineering is closely related to the ethical debate on human stem cells. Thus, their tremendous capabilities bear a great health and economic potential as well as being ethical dynamite.

2.4. Automotive Industry and Mobility

The mobility sector could be a pioneer for a wider application of nanotechnology. The automotive industry is an economically important high-tech sector where new technologies are implemented relatively early because of high economic competition. The demand for safety, environmental and economic aspects are increasing and therefore the automotive industry invests a relatively large amount for R&D. The automotive industry expects advances from nanotechnology in all relevant aspects like ecology, security and comfort.

The most important ethical aspects of the mobility sector concern environmental and energy issues. Besides these ecological aspects there are also some societal aspects of nanotechnology in automotives concerning the safety of the passengers.

2.4.1. Environmental aspects

The mobility sector has a strong influence on environmental aspects because the transport sector accounted for 32% of the total energy consumption (steadily increasing from 17% in

3 In Germany appr. one third of all industrial R&D expenses.
1960) and for 44% of the total CO₂ emissions from fossil fuels in the EU in 2001. Industry, households and services decreased their CO₂ emissions between 1991 and 2001 by 6 to 8%, whereas the emissions of the transport sector increased in the same period by 22%. Despite all the improvements in car technology, a further increase in pollutant emissions is expected because of the steadily rising traffic density and the trend towards heavier cars for safety reasons.

The mechanisms by which the mobility sector can reduce emissions are the following:

- **Reduction of energy consumption**

Currently used metals can be replaced by lighter alternatives manufactured from aluminium or magnesium. However, these materials suffer from a lack of strength. This can be addressed through the addition of nanoparticles to improve the strength of lighter metals or of steel, so that less metal is necessary.

An increased use of plastics and new nanomaterials bring real benefits in terms of waste and energy saving. Used plastics generally consist of traditional polymers reinforced with nanoparticles making them stronger per unit weight.

Combustion can be improved by homogenous and large area spraying of petrol. At present, an injection system with very fine holes (Nanojets) is under discussion.

The rolling resistance of tyres can be lowered and the durability improved by the use of nanoscaled carbon black.

Engine lubrication can be optimised by new nanoparticle-based lubricants and through micro- and nanostructures on the inner surface of the cylinders.

Engine efficiency can be optimised by the use of higher temperatures and pressures. Nanotechnology can help to develop materials which are resistant to these conditions.

- **Use of more environmentally friendly energy systems**

Thermoelectrical elements based on nano-crystalline layers of semiconductors with low bandgaps may use a part of lost heat in the future.

Cheap (e.g. Dye solar cells) or more efficient types of solar cells (e.g. by the implementation of Nanodots) can be used in the roof for operation of specific modules (e.g. for air conditioning systems). As a vision this can be enlarged to the whole chassis.

The influence of new systems like fuel cells and the importance of nanotechnology (catalysts, membranes, hydrogen storage) is discussed in chapter 2.2.

- **Reduction of air pollution caused by exhaust gas**
The main discussion regarding air pollution by road traffic is currently focused on CO₂ because other pollutants have been reduced very effectively in the last years. Nanotechnology can contribute to the further reduction of pollutants by nanoporous filters, which can clean the exhaust mechanically, by catalytic converters based on nanoscale noble metal particles or by catalytic coatings on cylinder walls and catalytic nanoparticles as additive for fuels. Nanotechnology provides the means for a reduction in fuel consumption concerning all relevant criteria.

2.4.2 Safety aspects

Road accidents claimed more than 40000 lives in the EU in 2000\textsuperscript{10}. More than forty times as many were injured. 55\% of all road casualties were the occupants of passenger cars. For people under 45, road accidents remain the prime cause of mortality, although the number of casualties have decreased in the last 30 years. Nevertheless, road traffic in the EU has doubled in the past 30 years and a further increase is expected for the future.

The following nanotechnology aspects are under discussion regarding safety concerns in the automotive sector:

- Nanoparticles as fillers in tyres can improve adhesion reducing the stopping distance when wet.
- The stiffness of the car body can be improved by use of nanoparticle-strengthened steels.
- New deposition methods like sol-gel methods make it economically possible to apply anti-reflection layers of silicon dioxide or other nanoparticles with nanometer thickness onto displays or panes.
- Ultra-thin transparent layers on a silver base can be used for heatable and therefore mist and ice-free front panes.
- Transparent and light materials could substitute car body parts that reduce all-round vision

\textbf{Figure 2.4.:} Concept car with a roof out of nanomaterials for a better all-round vision (Courtesy of DaimlerChrysler)
at the moment.

- Electrochromic layers for automatically dimmed rear-view mirror to avoid driver
distraction due to glare.
- Nanostructured layers are also being discussed for use as anti-reflection layers on car
dashboards.

2.4.3 Outlook

It is expected that fuel cells will replace the petrol system in the next 20 or 30 years at least
partially. Fuel cells will cause major changes to the fuel supply system. The use of hydrogen
(which is the ultimate goal because of its environmental advantages) requires an absolutely
new infrastructure for hydrogen generation, transport and petrol stations. A more
decentralised generation of hydrogen fuel is often proposed to avoid much of the transport
problems. Another vision of nanotechnology is related to the car body. They may have
switchable colours in the future, where the owner can freely choose the styling of his/her car
resembling today’s mobile phones equipped with different coloured casings.

2.5. Information and Communication

The field of information and communication is steadily advancing in the production of
electronic devices with increasing performance at continuously dropping costs. The entire
worldwide semiconductor market will reach 215 billion dollars in 2006\textsuperscript{11} with an estimated
share of nanoelectronics of 10\%. Current high-technology production processes are based on
traditional top down strategies, where nanotechnology has already been introduced silently.
Especially the shrinking size of powerful mobile computers, hand held devices and mobile
phones have led to an extensive dissemination of digital data processing. In this regard the
concept of “ubiquitous computing” becomes more and more important. This concept can be
understood as an expansion of the traditional personal computing, where a single person had
access to a single computer. Nowadays, data processing becomes more flexible and an
integral part of different classical areas, such as computer monitored houses or cars, mobile
offices and clothes with “wearable electronics”. Therefore a single person may have access to
various computers integrated in “smart objects” in the future. This scenario of ubiquitousness
enables a greater flexibility and induces new application possibilities based on an ongoing
miniaturisation of the current semiconductor devices and the introduction of entirely new concepts for digital data processing. In this sense, nanotechnology will play a key role, albeit all high-tech products have to maintain a manageable size with an increasing performance and functionality.

2.5.1. Top down strategies, how far can we go?

The semiconductor industry is following the predicted “top-down” path anticipated by Gordon E. Moore in 1965. It says that the density of transistors in integrated circuits will follow an exponential law. In order to keep that predicted pace, electrical devices have to shrink continuously with time, going from micro- to nanotechnology. The smallest lateral dimension of electronics will eventually reach the molecular or atomic range opening the relatively new field of “molecular electronics”. At present, the common structuring method is still based on photolithography with light of 193 nm wavelength, whereby today’s minimum structure features have already reached 90 nm. For the year 2009, the introduction of extreme ultraviolet lithography (EUVL) is intended by the roadmap of the semiconductor industry\(^\text{12}\). EUVL uses a wavelength of about 13 nm and is supposed to produce minimum feature sizes of about 30 nm. A limitation can be found in the steadily increasing costs for lithography tools, as for example in the production of masks and wafer steppers.

Although the mainstream method of lithography seems to be able to produce several future generations of semiconductor devices, the search for alternative methods has already begun. Some issues and problems will be addressed in the following:

A tool for the production of nanoscale structures is electron beam lithography (EBL). There, an electron beam of a scanning electron microscope (SEM) is used to write the desired structures directly in a resist. The method is comparatively slow and expensive, but EBL is able to write structures in a reproducible manner down to 10 nm. It is a suitable tool for the production of masks.

A more intuitive tool is nanoimprint lithography (NIL), where the structure of a master is directly transferred onto a thermoplastic material (resist) through elevated temperatures. This method is able to write fine patterns (\(<\ 10\text{nm}\)) with high resolution over large areas (“parallel” structuring).

The nanoimprinting method belongs to a class of structuring techniques which have been previously named “soft lithography”. Soft lithography is a generic term for methods which make use of a stamp or a master, whose structures are transferred onto to a surface either by stamping (e.g. NIL), inking or capillary forces. Another strategy is based on the scanning
force microscope (SFM), an analytical tool to image surfaces mechanically with a tiny sharp probe and at atomic resolution. This technique is currently under investigation to serve as a future hard drive with ultra-high data density (Millipede\textsuperscript{13}). With this technique storage densities of more than 1 Tb/in\textsuperscript{2} can be achieved.

### 2.5.2 Novel semiconductor devices

- **Downscaling today’s CMOS production technique**

The semiconductor industry encounters several problems while downsizing the common CMOS production line. The steadily increasing demand for higher computing power has been satisfied by reducing the feature size and increasing the clock rate simultaneously. In addition, we observe a boost in the overall heat dissipation, leakage currents and parasitic capacities. Material with a small dielectric constant, known as “low-k” material, has been introduced in the past to isolate the copper lines from the surrounding silicon and is widely applied today. This measure reduces parasitic capacities and prevents copper from diffusing into the doped silicon. The most important element in integrated circuits, the field effect transistor, suffers from leakage current through the transistor gate. The so called gate electrode switches the current between source and drain of a field effect transistor just by applying an electrical field and is electrically isolated from both other electrodes. In today’s transistors the gate oxide is made of silicon dioxide which is getting thinner with smaller gate length. The thickness has been reduced to less than one nanometer. Thus, tunneling of electrons through the gate oxide is becoming a serious issue in modern chip architectures. This problem could be overcome by introducing “high-k” material. A higher dielectric constant of gate isolation would allow the production of thicker gate oxides and thus preventing current leakage.

The source-drain current of the common CMOS architecture suffers from a parasitic current flowing through the underlying silicon substrate. This current increases the total power consumption and is leading to unnecessary high power dissipation. By introducing the so called silicon-on-insulator (SOI) technique, where the functional silicon layer is separated by an electrically isolating oxide barrier from the bulk material, power dissipation can be significantly reduced. The SOI-technique allows a higher integration density and a faster switching of transistors.

Another approach is aiming at the direct modification of the charge carrier mobility. By tuning the silicon lattice constant the intrinsic conductivity can be increased. This approach is
known as “strained silicon” and can be achieved by adding layers composed of a different material, e.g. Silicon-Germanium with thin Si cover on top. Further modifications of today’s CMOS technique will introduce double and multiple gate structures in the future. Another approach to overcome obstacles from miniaturization can be found in the parallel data processing. Double and multiple core processors are on the way.

- **Single Electron Transistors**

A smaller current means having fewer electrons. A further reduction ultimately leads to a single electron device or a single electron transistor (SET). SETs have been of strong scientific interest for quite a long time. Interesting phenomena such as single electron tunneling and the Coulomb blockade were studied intensively. However, the need for cooling to low temperatures and the strong sensitivity to background charges prevented the use of SET devices in electronic circuits up to now.

- **Spintronic, Hard Disks, Nonvolatile Computer Memory**

The dependence of the resistance of a material (due to the spin of the electrons) on an external field is called magnetoresistance. This effect can be significantly amplified (GMR – Giant Magneto-Resistance) for nanosized objects, for example when two ferromagnetic layers are separated by a nonmagnetic layer which is several nanometres thick (e.g. Co-Cu-Co). The GMR effect has led to a strong increase in the data storage density of hard disks and made the gigabyte range possible. The so called tunneling magnetoresistance (TMR) is very similar to GMR and based on the spin dependant tunneling of electrons through adjacent ferromagnetic layers.

Both the GMR- and the TMR-effect can be used to create a non-volatile main memory for computers, such as the so called magnetic random access memory or MRAM. A computer equipped with MRAMs will be instantly switched on, without latency.

- **Molecular Electronic, Nanotube Transistor**

In a future vision the size of electronic devices will continuously diminish and their computation power increase. This scenario makes use of single molecules and their electronic properties.

One example of such a combination can be found in the “nanotube” transistor shown in figure 2.5.
Carbon nanotubes (CNTs) are promising candidates for molecular electronics due to their large electrical conductivity and high stability. However, a simple composition as it is shown in figure 2.5 would not be a viable approach, because of the Schottky barriers between the metal and the CNTs. On the other hand CNTs could be used as so called “vias” or “interconnects” which contact different layers in chip architectures.

Recently, DNA molecules have been used as a template for a novel self-assembled nanotube transistor\textsuperscript{14}.

![Figure 2.5: A nanotube transistor. A CNT (red line) is connecting the Drain and Source electrode. Image from www.infineon.com](www.infineon.com)

### 2.5.3 Novel optoelectronic devices

In the modern communication technology traditional analog electrical devices are increasingly replaced by optical or optoelectronical devices due to their enormous bandwidth and capacity, respectively. Two promising examples will be mentioned in the following:

**Photonic crystals**

Photonic crystals are materials with a periodic variation in the refractive index with a lattice constant that is half the wavelength of the light used. They offer a selectable band gap for the propagation of a certain wavelength, thus they resemble a semiconductor, but for light or photons instead of electrons.

**Quantum dot laser**

Quantum dots are nanoscaled objects, which can be used, among many other things, for the construction of lasers. The advantage of a quantum dot laser over the traditional semiconductor laser is that their emitted wavelength depends on the diameter of the dot. Quantum dot lasers are cheaper and offer a higher beam quality than conventional laser diodes.
2.5.4 Displays
An impact of nanotechnology on the flat panel market is already reflected in existing products, e.g. in digital cameras. Two prominent examples will be shortly addressed: OLEDs. At present, the most common flat panel displays are based on the liquid crystal technology (LCD, TFT). Such displays suffer from a pronounced viewing angle dependency and persistence. Organic light emitting diodes (OLED) are promising candidates for the creation of flat panel displays, because of their brilliant colours, extremely large viewing angles and low persistence.¹⁵

Nanotube field emission displays, NFED
The production of displays with low energy consumption could be accomplished using carbon nanotubes (CNT). CNTs can be electrically conductive and due to their small diameter of several nanometres, they can be used as field emitters with extremely high efficiency for field emission displays (FED). The principle of operation resembles that of the cathode ray tube (CRT), but on a much smaller length scale. First prototypes of a CNT FED have been presented by Samsung and Motorola.

2.5.5 Quantum Computer
Entirely new approaches for computing exploit the laws of quantum mechanics for novel “quantum computers” which enable the use of fast quantum algorithms. Such algorithm would provide an extremely fast decryption method compared to classical computation.
2.6 Chemistry and Environment

In a sense, all chemical synthesis can be understood in terms of nanotechnology, because of it’s ability to manufacture certain molecules. Thus, chemistry forms a base for nanotechnology providing tailor-made molecules, polymers etc. and furthermore clusters and nanoparticles. Such nanosized objects have received increasing attention in the past decade due to their unique and selectable mechanical, optical and functional properties. Various applications for nanoparticles have already been realised, ranging from drug delivery in life sciences to chemical catalysis. Traditional polymers can be reinforced by nanoparticles resulting in novel materials e.g. as lightweight replacements for metals\textsuperscript{16}. In particular the production of lithium-ion batteries with higher capacity and reliability will benefit from novel nanoparticles or nanocomposite material. Therefore, an increasing societal benefit of such nanoparticles can be expected.

2.6.1. Production of Nanoparticles

Several different strategies of nanoparticle production have been reported in the literature. They can be classified into two different main categories: the sol-gel process and the gas phase synthesis. The sol-gel process is a wet chemical procedure based on an initial liquid and colloidal “sol”, which can be gelled or transformed into a more solid structure (“gel”). Different drying procedures will form a glassy or ceramic structure, whereby thin coatings, fibers, aerogels and powders can be obtained.

Similar to the sol-gel process, the gas phase synthesis is a generic term, where many different dry chemical strategies are involved. The overall principle can be summarised as an initial evaporation of the material, followed by a homogeneous nucleation and a further condensation and coalescence of particles. The evaporation can be achieved through various different methods including furnace evaporation, sputtering, laser ablation or plasma evaporation. Particles can be formed by creating a supersaturated gas for example by cooling. This method can be applied for example to the synthesis of carbon nanotubes.
2.6.2 Catalysis

Chemical catalysis benefits especially from nanoparticles, due to the extremely large surface to volume ratio. The application potential of nanoparticles in catalysis ranges from fuel cell to catalytic converters and photocatalytic devices. Catalysis is also important for the production of chemicals, where the world market accounted for 900 billion dollars in 1999.

2.6.3. Filtration

A strong influence on waste-water treatment, air purification and energy storage devices of a “nanochemistry” can be foreseen. Mechanical or chemical methods can be used for effective filtration techniques. One class of filtration techniques is based on the use of membranes with suitable hole sizes, whereby the liquid is pressed through the membrane.

Fig. 2.6 Nano-porous aluminium oxide membrane (Source: Department of Materials Chemistry, The Ångström Laboratory, Uppsala, Sweden, www.mkem.uu.se/MC/Mats_Group/nano-porous/Projects.htm)

Nanoporous membranes are suitable for a mechanical filtration with extremely small pores smaller than 10 nm (“nanofiltration”). Nanofiltration is mainly used for the removal of ions or the separation of different fluids. On a larger scale, the membrane filtration technique is named ultrafiltration, which works down to between 10 and 100 nm. One important field of application for ultrafiltration are medical purposes as can be found in renal dialysis.

Magnetic nanoparticles offer an effective and reliable method to remove heavy metal contaminants from waste water by making use of magnetic separation techniques. Using nanoscale particles increases the efficiency to adsorb the contaminants and is comparatively inexpensive compared to traditional precipitation and filtration methods. Various ferrites and
natural magnetites are suitable for heavy metal removal. Particles are either fixed by an external magnetic field or by a suitable support in a fixed-bed column\textsuperscript{17}.

\subsection*{2.7. Consumer goods}

Nanotechnology is already affecting our daily life in different ways\textsuperscript{18}. Typically, these changes are marginal and the customer may not be aware of buying a nanotechnologically improved product. Recently, Forbes published a list of the top ten nanotechnology products of the year 2003\textsuperscript{19}. This list shows that nanotechnology is already included in various products, where the customer would not expect it.

Nanotechnology plays a role in the following fields, too, with some selected application presented:

\subsubsection*{2.7.1. Foods}

Nanotechnology can be applied in the production, processing, safety and packaging of food\textsuperscript{20}. A hope is to control and improve agricultural production. One vision of nanotechnology is the manipulation of the molecules and atoms of food to design food with much more capability, lower costs and greater sustainability than at present\textsuperscript{21}.

Consumers demand fresh, minimally processed and naturally preserved foods. A nano-composite coating process should improve food packaging by placing anti-microbial agents directly on the surface of the coated film\textsuperscript{22}.

Nano-composites could increase or decrease gas permeability of different fillers as is needed for different products. They can also improve the mechanical and heat-resistance properties and lower the oxygen transmission rate. Research is being performed to apply nanotechnology to the detection of chemical and biological substances for sensing biochemical changes in foods. This control could be extended to the whole food chain in the future\textsuperscript{23}.

\subsubsection*{2.7.2. Household}

The most prominent application of nanotechnology in the household are self-cleaning or “easy-to-clean” surfaces on ceramics or glasses. Such a transparent, anti-stick coating for
sanitary ceramics is offered by the company Duravit (WonderGliss) in cooperation with Nanogate GmbH\textsuperscript{24}. Common household equipment like flat irons have improved smoothness and heat-resistance due to nano-ceramic particles\textsuperscript{25}.

2.7.3. Optics

The first sunglasses using protective and antireflective ultrathin polymer coatings are on the market. For optics, nanotechnology also offers scratch resistant coatings based on nano-composites. These coatings are transparent (hence optical performance is not affected) ultra-thin, simple care, well-suited for daily use and the price is reasonable for the durability.
2.7.4. Textiles

One trend in the textile industry is that more and more clothes are manufactured in low-cost countries. High-cost countries like western Europe can only compete in this industry if they produce high-tech clothes with additional benefits for users. This includes windproof and waterproof jackets, where nanotechnology already plays a role. For the future, clothes with additional electronic functionalities are discussed by the buzzwords “smart clothes”, ”wearable electronics”, etc. Modern technology, including nanotechnology, could provide features like sensors (which could monitor body functions or release drugs in the required amounts), self-repairing mechanisms or access to the internet.

Simpler realisations are readily available, which make clothes water-repellent or wrinkle-free. A ski jacket based on nanotechnology is produced by Franz Ziener GmbH&Co. The windproof and waterproof properties are not obtained by a surface coating of the jacket but by the use of nanofibres. 26

The company Nano-Tex produce wrinkle-resistant and stain-repellent fabrics by attaching molecular structures to cotton fibers. 27

Textiles with a nanotechnological finish can be washed less frequently and at lower temperatures. 28

High-performance functional clothing is an increasingly important feature of the workplace. For example Gore-Tex has developed an antistatic, weather-protective, outerwear fabric. Nanotechnology has been used to integrate tiny carbon particles membrane and guarantee full-surface protection from electrostatic charges for the wearer. 29

A first conference addressing the applications of nanotechnology in the textile industry was held in June 2004 in Barcelona. 30

2.7.5. Sports

A high-performance ski wax, which produces a hard and fast-gliding surface, is already in use. The ultrathin coating lasts much longer than conventional waxing systems. 31

The French tennis racket manufacturer Babolat introduced a racket with carbon nanotubes, which lead to an increased torsion and flex resistance. The rackets are more rigid than current carbon rackets and pack more power. 32
Long-lasting tennis-balls are made by coating the inner core with clay polymer nanocomposites. These tennis-balls, made by the company InMat have twice the lifetime of conventional balls.  

2.7.6. Cosmetics

One field of application is in sunscreens. The traditional chemical UV protection approach suffers from it’s poor long-term stability. A sunscreen based on mineral nanoparticles such as titanium dioxide offer several advantages. Titanium dioxide nanoparticles have a comparable UV protection property as the bulk material, but lose the cosmetically undesirable whitening as the particle size is decreased. L’Oréal offers an antiwrinkle cream, where a polymer capsule (Nanosomes™) is used to transport active agents like vitamins and a hair conditioner “Aqua-Oleum” where nanotechnology leads to improved care power.

2.8. Conclusion

The most advanced nanotechnology projects related to energy are: storage, conversion, manufacturing improvements by reducing materials and process rates, energy saving e.g. by better thermal insulation, and enhance renewable energies sources. For a more detailed description of the different energy systems and the potential of nanotechnology, please read the Nanoforum report “Nanotechnology helps solve the world’s energy problems“, which is available on [www.nanoforum.org](http://www.nanoforum.org). A short-term impact of nanotechnology on health care will concern biocompatible and structured surfaces for tissue engineering or implants. In the long-term nanotechnology will provide the means for optimized diagnostics and drug delivery. For a more detailed description of the impact of nanotechnology on healthcare, please read the Nanoforum report „Nanotechnology and it’s implication for the health of the EU citizens“, which is available on [www.nanoforum.org](http://www.nanoforum.org). A short-term impact of nanotechnology on the automotive industry will provide easy-to-clean surfaces (e.g. lacquer) and a surge of electronic systems. Already available are nanotechnologically improved scratch-resistant lacquers and lubricants containing nanoparticles. In the long-term, front-lights will be replaced by LEDs and the combustion
engine by an electric drive and a hydrogen storage system. In one vision, the lacquer works as a solar cell provides electricity and may allow colour change according to the customer’s demands.

The critical length scale of **integrated circuits** are about 50 nm regarding the gate length of transistors in CPUs or DRAM devices. In a short- and mid-term view non-volatile random access memory will allow the instant-on feature, without any loading time during start up.

In the long-term, integrated circuits will benefit from novel effects due to quantum laws. The overall energy consumption will be lowered providing significantly longer running times for mobile computing.

**Chemistry** provides the building blocks for many secondary processes, whereby the accomplishment is done in large scale volume processes. Chemical catalysis and filtration techniques are two prominent examples where nanotechnology already takes part. The synthesis provides novel materials with tailored features and chemical properties e.g. nanoparticles with a distinct chemical surrounding (ligands) or specific optical properties. In this sense, chemistry is indeed a basic nanoscience. In a short-term perspective, chemistry will provide novel “nanomaterials” and in the long run, superior processes such as “self-assembly” will enable energy and time preserving strategies.

Nanotechnology is already impacting the field of **consumer goods**, providing products with novel functions ranging from easy-to-clean to scratch-resistant. Modern textiles are wrinkle-resistant and stain-repellent; in the mid-term clothes will become “smart”, through embedded “wearable electronics”. Already in use are different nanoparticle improved products. Especially in the field of cosmetics such novel products have a promising potential.
Benefits, Risks, Ethical, Legal and Social Aspects of Nanotechnology

Part 3: Potential risks of nanotechnologies

3.1. Introduction

Nanotechnologies are of great interest for researchers and industrialists, with a huge development potential\(^1\). They promise to become a strategic field with numerous applications in medicine, chemistry, electronic, materials and the environment\(^2\). However some studies on nanosized particles give the impression that they could have negative effects on health and Environment. These results are relayed by some groups (ETC groups, Greenpeace) or people which warn nanotechnology developments could have possible toxic effects resulting from nanoparticles either free or which could escape from the manufactured nanomaterials\(^3\).

Past experiences (asbestos, DDT, GM’s) have shown that toxicity studies are essential: first to avoid and control the exposition of people and environment to risks, and then to make the new technology accepted. That is the reason why nanotechnology toxicity question is currently one of the most concrete questions concerning this field.

More and more scientific studies are devoted to nanotechnologies potential effect on health and environment (each month, 1 or 2 studies on nanoparticles toxicity are published). Indeed, some nanoparticle properties (penetration, reactivity…) raise many questions\(^4\). How will the chemical properties of nanoparticles affect the body\(^5\)? What happens to the accumulated particles that have already been detected in some organs? How many of them are excreted and via what channels?\(^6\) Such questions receive particular attention on a science point of view and studies are the keys for a responsible, controlled and safe way of using nanotechnologies.

Today, this question concerns consumers but especially workers in nanotechnology research or industry, which are already in contact with engineered nanoparticles.

The reality is that we are already exposed to several kinds of nanoparticles produced by combustion (e.g. particulates from diesel exhausts) and natural nanomaterials (e.g. old wood)\(^7\). Most known risks for health and environment are caused by these existing sources of
nanoparticles and materials. The first results which suggested that nanoparticles could have negative effects dealt with these natural nanoparticles or nanoparticles in pollution. Moreover, nanotechnologies concerns in essence a huge panel of technologies and products (cosmetics, for instance), and the various consciously engineered nanomaterials will exhibit different behaviours, effects and toxicities, etc...

Different groups and personality, as Pat Mooney from the ETC Group, called for a moratorium on commercial production of nanomaterials until their risks are better elucidated and regulations put in place.

Assessments are routinely carried out for all new products (with extensive references to potential risks, interactions with other chemicals, toxicity, etc), however it is now difficult to set up regulation or protocol to evaluate nanotechnology products because their definition is not clear enough and information is missing. Thus, the priority is to evaluate these materials, determine the relative risks and gather basic information needed to establish regulations for this new kind of products. (it will still be necessary to investigate existing products including nanoparticles, which have been launched on market after being tested according to a regulation which does not take into account nanoparticles characteristics.)

The goal of this part is not to present an exhaustive list of potential risks of nanotechnologies, but to present the first elements of answer. The part is divided into three main parts:

- a brief description of the main initiatives and projects dealing with risk assessment of nanotechnologies.

- the potential impacts of nanotechnologies, and more precisely nanomaterials, on health.

- And finally, a look at the potential impacts of nanomaterials on the environment.
3.2. Initiatives, centres and projects dedicated to risks assessment of nanotechnologies

Faced with questions from the general public, questions and opposition from some groups, many academic centres, institutions and governments are launching initiatives to investigate the potential risks of nanotechnologies. The following are examples of these international initiatives:

In Europe, policy makers have requested further investigation into the possible side effects of nanotechnology. The European Parliament's Industry, External trade, Research and Energy Committee called for a study on the need for new regulations on nanotechnology while the same subject is discussed by the UK's Parliamentary and Scientific Committee. The European Commission organised expert workshops to discuss risk analysis of nanotechnologies, resulting in a report. A workshop was held in Brussels in January 2005 “research need on nanoparticules”.

A number of research projects on the safety of nanotechnology had been funded by the European Commission within the Fifth Framework Programme (FP5) and projects funded under the Sixth Framework Programme (FP6) are on going.. In particular, Renzo Tomellini from the European Commission requested that the ethical and risks aspects for health and the environment must be integrated in every future project dealing with nanotechnologies, where relevant. Projects of the FP7 will also address the aspect of nanotechnology safety. The European Commission will evaluate project proposals in the form of specific support actions (SSA) and Co-ordination actions (CA) on the topic “Impact of nanoparticle on human health and environment” in the thematic priority “nanotechnologies”.(Deadline for this call for proposals : mid September 2005)

There is also a Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) which will advise the European Commission on human health issues not covered by other EU risk assessment bodies. This includes nanotechnologies and methodologies for risk assessment.

Among the projects funded by EC dealing specifically with the risks from nanotechnologies, there is for example the NANOSAFE 2 project (started in April 2005 for 48 month). This 7M€ integrated project aims at developing risks assement and management to secure industrial production. It follows up the 1st study supported by EC through the accompanying
measure Nanosafe funded under the 5\textsuperscript{th} framework program. The results are expected to indicate that there are risks to workers and consumers, and to recommend regulatory measures and codes of practice.

In 2005, the EC also launched two projects on nanotechnologies and human health and the environment: NANOTOX, a Specific Support Action providing investigative support for the elucidation of the toxicological impact of nanoparticles on human health and the environment; and IMPACT, a Coordination Action, favouring communication links between numbers of regional, national and international initiatives in order to reduce duplication of effort, pool expertise and facilitate co-operation between networks \textsuperscript{16}

In 2005, the European Commission also funded NANOLOGUE\textsuperscript{17} and NANODIALOGUE\textsuperscript{18}. NANOLOGUE gathers International researchers to favour dialogue on social, ethical and legal benefits, and potential impact of nanosciences and nanotechnologies; NANODIALOGUE project (launched in March 2005 and supported with a 850,000 euro) is currently developing a framework of basic channels for communication and social debate on N&N.

In 2004, the \textit{European Committee for Normalization (CEN)} established a working group named CEN Technical Board Working Group (BT/WG) \textsuperscript{166} on Nanotechnologies. This group is charged with developing a strategy for European standardization in the area of nanotechnologies. It recommends the formation of a new CEN Technical Committee coordinate European standardization activities in the nanotechnologies and to favour collaboration with the \textbf{ISO TC for nanotechnologies} to support the needs of the European single market and its regulatory requirements. (The \textit{British Standard Institution} had submitted a proposal to the \textbf{International Standard Organisation} (ISO) for the creation of a new ISO field: technical activity on nanotechnologies.)

A number of mechanisms have been implemented by different governments to understand the real consequences of nanotechnologies\textsuperscript{19}. For example in \textit{France}, the National programme ACI (\textit{Actions Concertées Incitatives}) has settled a thematic action called “\textit{ECODYN}”, the goal of which is to study the accumulation of contaminants within continental environments ("ecodynamic" approach), and precisely their transfer (dispersion) in living organisms
(“ecotoxicological” approach). The purpose of this action is to study and understand the consequences of nanomaterials as regards the environment.

In **Germany**, the **Office of Technology Assessment at the German Parliament (TAB)** has published in July 2003 a study about chances and risks of nanotechnologies from a German point of view. The German ministry has commissioned the conduction of three studies about effects of Nanotechnology

- Economical Potential of Nanotechnology
- Sustainability effects by production and application of nanotechnological products
- Innovation and Technology analysis on Nanotechnology - Health

The Federal Ministry of Research launched a call for proposal on Chemical Nanotechnology. One topic in this call was the toxicity of nanoparticles and their dermal penetration and inhalation.

The German Association for Chemical Technology and Biotechnology (DECHEMA) has implemented a working committee on “Responsible Production and Use of Nanomaterials” (http://www.dechema.de/DECHEMA_VCI_working_group_%3Cbr%3E_Responsible_Production_and_%3Cbr%3EUse_of_Nanomaterials_-_lang-en-design-1.html) where the need and the priorities for actions concerning the toxicity of nanoparticles are discussed. A discussion with the German ministry regarding a research project is on the way.

A web page presentation about chances and risks of nanotechnology is planned in conjunction with the NanoMat network, but is not realized yet. (www.nanomat.de )

In June 2003 the **UK Government** commissioned the **Royal Society, the UK National Academy of Science**, and **the Royal Academy of Engineering**, to carry out an independent study on the benefits and risks of nanotechnologies and find out whether nanotechnology is likely to raise new ethical, health and safety or social issues which are not covered by current regulation. It makes recommendations about regulation to control exposure to nanoparticles. In February 2005, the **UK Government** published its response. The government recognized the importance of developing regulation policies in the field of nanotechnologies, however, new findings for research devoted to the set up of this regulation have not been planned.

The **Better Regulation Task Force** also published a document called “**Scientific Research: Innovation with Controls**”, which made recommendations to the UK government about how
to handle ethical and social issues pertaining to new medical technologies and to nanotechnology (creation of a informed debate, transparency in decision making processes…)

In the USA, the Government is currently funding research to assess environmental and health impacts associated with nanomaterials. The National Nanotechnology Initiative makes the research on health and safety impacts of nanotechnology a priority. (The NNI is a federal R&D program established to coordinate the effort of the US agencies working in nanoscale sciences.). In 2006, the NNI plan to invest $39 million in Environmental, Health and Safety (EHS) R&D and $43 million in Ethical, Legal and Social Issue and in Education.

Among the NNI projects on Environmental and Health implication, the National Institutes of Health through The National Toxicology program, investigates toxicology of nanomaterials with a current or a future commercial importance. This program tackles skin uptake, inhalation, and oral route of exposure. Other US agencies, as NIOSH (National Institute of Occupational Safety and Health), EPA (Environmental Protection Agency), USDA (US Department of Agriculture) and the NSF (National Sciences Foundation), plan to develop an extramural research program dealing with environmental implications of nanotechnology. This research program could include European Commission.

Also in the US: The Pew Charitable Trust and the Wilson center launched a project on Emerging Nanotechnologies. This project, gathering Industry, Government, Research, Non Governmental, will give a review of what is known and unknown about potential health and environmental risks involved by nanotechnologies.

The International Council on Nanotechnology (ICON), based at Rice University, and affiliated to the federally funded Center for Biological and Environmental Nanotechnology (CBEN); has settled a database gathering all publication related to nanotechnology environmental and health risks. This database is available via ICON website: http://icon.rice.edu/research.cfm. Anyway Rice University is very active in the field of nanotoxicology, especially through the CBEN, many of its researchers published studies dealing with this field, such as Vicky Colvin, Richard Smalley, Mark Wiesner, Mason Tomson, Joseph Hughes…
In Asia, policy makers started to fund research on nanotechnology risk assessment. For example, in Japan, the New Energy and Industrial Technology Development Organization (NEDO) has recently launched a bid for a study on the safety of several nanomaterials, such as metals, carbon and organic chemical substances. The Ministry of Education and Research of Japan (Mext) announced on July 2005 the launch of a study relative to the possible effects of nanoparticles on health. The project is entrusted to the AIST laboratories (National Institute of Advanced Industrial Science & technology). 70 researchers are involved in this project to gather data and evaluate the danger of nanoparticles. The results are due in March 2006.

In June 2005, China created the “National Nanotechnology Standardisation Committee” (SAC/TC279) headed by Bai Chunli, director of the National Centre for Nanoscience and Technology. SAC/TC279 will be serve as the cross-sector coordinating body for the purposes of drafting fundamental standards regarding nanotechnology, including terminology, methodology and safety in the fields of nano-scale measurements, materials, devices and scale biomedicine.

A first international initiative “International Consortium for Environment and Nanotechnology Research (I-CENTR)” has also been created. This consortium gathers approximately 30 researchers from different universities: Rice University from US, CNRS-Montpellier, CEA-Saclay&Cadarache, Université Aix-Marseille, Université Pierre et Marie Curie-Paris, Université Paul Sabatier-Toulouse, Faculté de Pharmacie de Châtenay de Malabry and Université de Bordeaux from France, and it will add groups from Germany, Switzerland and the UK. The consortium studies the environmental applications of nanochemistry, nano-scale materials and processes in the environment; nanomaterial interactions with organisms and the environment and finally sustainable ways for nanotechnologies to be developed.

In December 2005 the OECD will organised a workshop on the Safety of manufactured nanomaterials in Washington. The main objective is to determine the state of the art for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context. In advance to the workshop, the joint Meeting members have started to work on a survey "the potential implications of Manufactured Nanomaterials for Human Health and Environment safety" (http://www.oecd.org/document/35/0,2340,en_2649_34365_35406051_1_1_1_1,00.html)
These examples show the importance given by many countries to the risk assessment of nanotechnologies; they also demonstrate that countries are aware that international cooperation and dialogue are essential to deal with this issue.

A more complete list of initiatives, centres and projects is given in the who’s who.
3.3. Potential impacts of nanotechnologies on health

Nanotechnological risks are often associated with objects able of independent action, an idea which still belongs in the realm of science-fiction\textsuperscript{28}. But, potential hazards relating to the manufacture of innovative material, already commercially available or just short of market launch, are much more important to evaluate\textsuperscript{29}. That is why, almost all current studies relate to the potential impacts of nanomaterials on health\textsuperscript{30}. These can be both already existing nanomaterials from natural sources or combustion, or consciously engineered nanomaterials. Potential health hazards may not only affect consumers, but also occur in the workplace. There is a need for more exposure data of workers, consumers and the general population.\textsuperscript{31}

A nanomaterial is any material that either contains at least a certain proportion of nano-elements. Specialists separate these into general nanoparticles, and what are known as nanotubes or fullerenes. In paragraph 2.6.1 in this report, production methods of consciously engineered nanoparticles are covered.

Concerning the potential risks of nanotechnologies on health, studies (as in Houston-Texas at \textit{Wyle Laboratories}, about the toxicity of carbon nanotubes in \textit{mice}; and in Newark-Delaware at \textit{DuPont Co’s Haskell Laboratory}, about the exposure of nanotubes in \textit{rats}) have been published and suggest that some nanomaterials containing carbon nanotubes could be toxic. Other studies are underway to observe the potential toxicity and general health risks of nanoparticles, with initial results in press.

Human contact with nanomaterials can take various forms: inhalation, ingestion, and absorption through the skin. These have the potential to cause damage to the human body in different ways:
The following sections illustrate some examples of the potential risks from nanomaterials (nanoparticles, nanotubes…) for human health that have been taken from toxicological studies performed in rats.

3.3.1. Potential risks of nanoparticles

Nanoparticles, according to the most widely-accepted definitions, must have at least one of their dimensions less than 100 nm. They are made out of a wide variety of materials such as metals, metal oxides, ceramics and silicates. The nanoparticles in metal and metal oxide ceramic nanopowders tend to be roughly the same size in all three dimensions with dimensions ranging from 2-3 nm up to a few hundred, whereas silicate nanoparticles currently in use are flakes about 1 nm thick and 100 to 1000 nm across.

Until now, the majority of tests deal with nanoparticles\textsuperscript{32}. Some public health studies have found links between engineered nanoparticles and a wide range of health impacts including for example, increased asthma hospitalizations, heart diseases, chronic bronchitis and even premature death\textsuperscript{33}. The miniaturization of material down to nanoparticle size yields a host of surprises: not only can the behaviour of small particles be changed, but so, too, can their mobility. In contrast to larger microparticles, nanoparticles have almost unrestricted access to the human body\textsuperscript{34}. The possibility of absorption through the skin is currently under discussion, while the entry of
certain nanoparticles into the bloodstream by inhalation via the lungs is almost certain. Some of the tiny particles can also get into the body via digestive tract.

To summarize, three channels for the uptake of nanoparticles are considered:

- **Inhalation**

  Today, some nanoparticles are already widespread in the air we breathe, largely due to the combustion of fossil fuels and vehicle exhaust. In a busy street, each breath we take contains around 25 million nanoparticles. Scientists have found that pollutant particles from traffic and industry can enter the bloodstream and the brain after being inhaled. At high exposure, these particles can be toxic and could exacerbate heart disease, asthma and other respiratory diseases.

- **Ingestion**

  As many engineered nanomaterials are prepared and processed in liquids, a more relevant exposure route for nanotechnology workers may be direct dermal absorption or oral ingestion. Up to now, few studies deals with this channel.

- **Absorption through the skin**

  Many studies regarding penetration of nanoparticle into the skin refer to the absorption of drugs through the skin. Few publications mentioning this penetration are available. Moreover studies dealing with these aspects do not indicate clearly that nanoparticles absorbed through the skin also penetrated in the circulatory system.

  It is likely that there will be different toxicity results with different types of nanoparticle. Indeed scientists see two potential problems specific to nanoparticles: one problem has to do with their size and another has to do with their shape or functionalization.

### 3.3.1.1. Size effects

According to Günter Oberdörster, professor of environmental medicine from Rochester University, New York, potential effects on the body depend on particle sizes. Indeed, clusters of nanoparticles of a few micrometers are relatively not reactive and are too large to be
absorbed in blood after being inhaled. In contrast, individual nanoparticles are more reactive and can be found in blood\textsuperscript{36}.

Toxicologist Chiu-Wing Lam of \textit{Wyle Laboratories}, Houston, arrived at similar results (2003): inoffensive components at the macroscopic scale can appear dangerous at the nanoscopic.

As a result, even substances that are normally innocuous can trigger intense chemical reactions and biological damage, as nanoscale specks. For example, gold is an inert metal. But nanoparticles of gold are extremely chemically reactive, with the potential to disrupt biological pathways\textsuperscript{37}.

Several pulmonary toxicity studies (hazard studies) in \textit{rats} show that nanoparticles administered to the lung produce more potent adverse effects in the form of inflammation and tumours, compared with larger sized particles of identical chemical composition at the same dose.

In August 2004, a study carried out by C.S Kim from \textit{The Environment Protection Agency (EPA)} compares the deposition of micro- and nano-size particles in a human upper airway model and shows that the deposition distribution of nanosize particles are much more uniform which implies a greater toxicity of nanoparticles compared to larger particles made of the same materials\textsuperscript{38}.

More details on these studies, especially those implemented by Pr Günter Oberdörster and Pr Chiu-Wing Lam are given in part 3.3.1.3.

\textbf{3.3.1.2. Shape and composition effects}

\textbf{Particle surface coatings} are also likely to play a leading role in the toxicity risks, and corresponding safety assessments of nanoparticles. In fact, several experiments have shown that different surface coatings on particles can influence the pulmonary toxicity of these particles.

For example, using a pulmonary bioassay toxicity method, Pr. David Warheit from \textit{DuPont Co’s Haskell Laboratory} investigated a large number of commercial formulations of
pigment-grade TiO$_2$ particles (which are low-toxicity particle type), with different surface treatments$^{39}$. He discovered that, subjected to this treatment, one of the TiO$_2$ particles produced increased pulmonary inflammation compared to the others on rats. (Feb 2004)

We can conclude that presence/absence, or composition of surface coatings could have consequences regarding the toxicity of nanoparticles. Studies on particles surface coating are all the more important as surface characteristics of particles influence the deposition of particles in the body and are essential issues for drug delivery system development.
3.3.1.3. Examples of consequences

Some studies have already been published on the eventual toxicity of nanoparticles:

3.3.1.3.1. Experiments on animals

Firstly experiments have been done that demonstrate in vivo mobility of such particles. In March 2005, during the Society of Toxicology 44th Annual Meeting and ToxExpo (New Orleans), Akimori Shimoda from Japan University, presented images of nanoparticles moving from lungs to blood.40

- For example, Ken Donaldson, professor of respiratory medicine at Napier University (Edinburgh) has studied particles of pure titanium dioxide and pure carbon. At 10 micrometers diameter, they cause no damage to rat lungs, but when they are crushed into ultrafines (< 100 nm), they become highly inflammogenic to the lungs. In other words, the size of particles could affect their toxicity. Ken Donaldson also showed that these ultra fine carbon black particles could travel to the brain after inhalation. He also conducted similar experiments on ultrafine particles of pure styrene, with similar results41. (Sept 2003)

- Jörg Kreuter, University of Frankfurt, found similar results by intravenous injection of dalargin bounded to coated poly(butyl cyanoacrylate) nanoparticles in mice. Fluorescent and electron microscopic studies indicated that the passage of the particle-bound drug occurred by phagocytic uptake of the coated nanoparticles by the brain blood vessel endothelial cells.42

- Günter Oberdörster, professor of environmental medicine from Rochester University, New York, showed that ultrafine carbon particles (particle size below 0,1 µm) appear to pass through the olfactory mucosa of rats in the upper nose and end up in the olfactory bulb43. Günter Oberdörster even thought that these particles might also be appearing in some adjacent structures such as the frontal cortex and the striatum, and travelling along neuronal axons44. (2002)
Professor Paul Borm at the Center for Environmental Medicine – University of Düsseldorf has demonstrated that nanoparticles are so small that they can appear in the cerebellum.\textsuperscript{45}

Vicki Colvin (Associate Professor of Chemistry at Rice University\textsuperscript{46} and Director of the Center for Biological and Environmental Nanotechnology -CBEN) observed that inhaled ultra-fine particles (with at least one critical dimension below 100 nm) not only exert respiratory effects, but they may also translocate, at least to some extent, from the lung into systemic circulation and this may result in cardiovascular and other extra-pulmonary effects\textsuperscript{47}. (Sept 2003)

- In 2005, a study from Rochester University on inhalation of carbon nanospheres by rabbits demonstrated an increase of susceptibility to clotting in rabbits which spent 3 hours in “bad urban air pollution”, air containing 70 microgram of nanosphere per m³. Clotting took less than half as long as it had taken days earlier with the same rabbits breathing clean air.\textsuperscript{48}

- In 2005, Menzel et al from Leipzig University carried out experimentations on pig and showed that TiO2 nanoparticles can penetrate through the stratum corneum (outermost layer of the epidermis consisting of dead cells that slough off) into the stratum granulosum with the first 8 hours after application. Other studies showed that ZnO nanoparticles may enter rats and rabbits skin. By penetrating into the stratum granulosum and with photocatalytic reaction on exposure to sunlight, these particles could damage cell components. TiO2 could also cause allergic reactions. TiO2 and ZnO nanoparticles are used in sunscreen.\textsuperscript{49}

\subsection*{3.3.1.3.2. Extrapolation to humans}

Currently, no one knows if the responses observed in animal experiments would be similar in the humans.

Professor Warheit determined that the process of particle inhalation in rats is very different compared with larger mammals, such as dogs, primates or humans\textsuperscript{50}; (Feb 2004)
Classical attributes and sequelae of lung overload

<table>
<thead>
<tr>
<th></th>
<th>Rats</th>
<th>Dog, monkey and human</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pulmonary inflammation</td>
<td>Yes</td>
<td>Not certain</td>
</tr>
<tr>
<td>Hyperplasia of macrophages and epithelial cells</td>
<td>Yes</td>
<td>Not certain</td>
</tr>
<tr>
<td>Altered pulmonary clearance</td>
<td>Yes</td>
<td>Probably not</td>
</tr>
<tr>
<td>Large pulmonary burdens of particles</td>
<td>Yes</td>
<td>Probably not</td>
</tr>
<tr>
<td>Increased interstitialization of deposited particles</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Increased translocation of particles from lung to thoracic lymph nodes</td>
<td>Probably</td>
<td>Probably</td>
</tr>
<tr>
<td>Interstitial lung disease (fibrosis)</td>
<td>Yes</td>
<td>Yes, but less severe</td>
</tr>
<tr>
<td>Production of lung tumors</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

So, on the one hand, rats seem to be more sensitive to nanoparticles than humans and therefore the generation of hazard data in rats could provide a margin of safety when attempting to develop risk assessment for human exposures to various particulate materials.

On the other hand, following inhalation of nanoparticles into the lung, rats demonstrate a faster particle clearance compared with large mammals, which indicates that the immune system of rats is more active than that of humans.

Thus, we can say that animal models alone are not sufficient to predict risk effects of nanoparticles in humans.

To address this some scientists are directly measuring effects on humans:

- For example, Ken Donaldson, at the University of Edinburgh - UK - observed that inhaled nanoparticles (< 100 nm) caused damage at the point of entry to the human body, and in also to the brain\textsuperscript{51,52}. (Sept 2003)

- In addition industrial workers who breathe particulate matter, such as silica dust (particles size < 1 µm) have a significantly higher risk of auto-immune disorders\textsuperscript{53}.

- David C Chalupa and Günter Oberdörster from Rochester University studied for the first time the consequences of ultrafine particles deposition during spontaneous breathing on people with asthma. The deposition was more important for people with asthma than in previous studies with healthy people. So the risk for health effects may also be more important for people with asthma. (June 2005)\textsuperscript{54}

Previous examples dealt with risks regarding inhalation of nanoparticles, however companies such as Beiersdorf, a producer of nanoparticles based sunscreens, have investigated dermal absorption by means of electron microscopy and found no evidence that titanium nanoparticles can penetrate the human skin\textsuperscript{55}. The Scientific Committee On Cosmetics and non food products of the European Union considered these particles (coated and uncoated) safe for use as an UV filter on the basis of a dossier with confidential data.
This is however, a contentious subject and although a lot of scientific work has been done on whether nano-(or micronized) TiO$_2$ can penetrate human skin, there is still no consensus. Analyses of the different results (from Menzel, Scientific Committee On Cosmetics and non food products and other studies) are not possible as scientific data from Scientific committee dossier are not in the public domain.

To summarize:

- Several tests on nanoparticles have already been performed in rats, rabbits and pigs, which have lead scientists to have some presumptions about their toxicity. But, extrapolation to humans is not straightforward.

- As far as humans are concerned, the first data is appearing but this is still preliminary; so nobody knows the real consequences on humans.

More work has to be done to understand in vivo transport, the mechanism of toxicity, and the process of elimination and accumulation in vivo.

### 3.3.2. Potential risks of fullerenes and carbon nanotubes

Fullerenes (also known as “buckyballs”) are a series of hollow carbon molecules made of a cage of interlocking pentagons and hexagons like the patches on a soccer ball. The basic fullerene is made of 60 carbon atoms (C$_{60}$) and has a diameter of approximately 1 nm. Carbon nanotubes are close cousins of fullerenes. They are a new form of carbon made by rolling up a single graphite sheet to a narrow but long tube closed at both sides by fullerene-like end caps.
3.3.2.1. Examples of studies on animals

3.3.2.1.1. Experiments on rats and mice

There have been two main studies on the potential risks of inhaled carbon nanotubes in rats and mice:

The first study, published in the journal “Toxicological Sciences”, was led by toxicologist Chiu-Wing Lam and his colleagues at Wyle Laboratories in Houston-Texas (2003). They investigated the toxicity of carbon nanotubes in the lungs of mice by introducing them into the trachea of mice under anaesthesia.

Five of the mice treated with high dose of one kind of nanotubes died within 7 days. All nanotube products induced epitheliod granulomas – tumour-like nodules of bloated white blood cells in the lining of the lungs - and in some cases inflammation of the lungs at 7 days. These persisted and became more pronounced in animals that were sacrificed at 90 days. The lungs of some animals also showed inflammation around the bronchi, and extensive necrosis (tissue death)\(^56\).

The team concluded that carbon nanotubes could be more toxic than quartz, which is traditionally considered to provoke serious damage in humans.

The whole experience is detailed on: http://www.i-sis.org.uk/nanotubestoxic.php.

The second study involved rats and was led by scientist David Warheit at DuPont Co’s Haskell Laboratory. The aim of this study was to evaluate the acute lung toxicity of single-wall carbon nanotubes (SWNT). For that, David Warheit instilled single-walled carbon nanotube soot mixture into the trachea of rats. For comparative purposes, he also instilled a group with carbonyl iron and quartz, respectively. 15% of the rats treated with the highest dose of carbon nanotubes suffocated to death within 24 hours due to clumping of the nanotubes that obstructed the bronchial passageways. All surviving rats developed granulomas as a reaction to the foreign substance. In contrast, the quartz and carbonyl iron-instilled rats had respectively some toxicity and no toxicity.

The main conclusion was that mortality resulted from mechanical blockage of the upper airways by the instilled nanotubes and was not due to pulmonary toxicity of the SWNT. \(^57\)
In the following figures, we can observe the effects of carbon nanotube accumulation during these experiments in the rat lung:

![Figure 3.2. Source: http://www.materialstoday.com/pdfs_7_2/warheit.pdf](http://www.materialstoday.com/pdfs_7_2/warheit.pdf)


The first picture is a scanning electron micrograph of the left lung of a rat, demonstrating a microdissection of the major airways (arrows) moving in a distal direction to the bronchoalveolar junctions – the preferential sites of inhaled particle and fiber deposition in the distal lung. In the second picture, carbon nanotubes that were introduced into the trachea have conglomerated and are blocking the bronchial tubes (black stains). In both cases, the rats died. However, there is no statistical data on the amounts, and any substance inhaled in such massive amounts can lead to the same results. Therefore the exposure could be too high and the rats could have died from suffocation rather than a toxic effect from carbon nanotubes.

Other studies from John T. James at the Nasa’s Johnson Space Center in Houston and from Petia Simeonova at the National Institute for Occupational Safety and health (NIOSH, USA) tackles the effects of carbon nanotubes on the respiratory tracts of mice. They noted that carbon nanotubes caused significant damages even killing a few animals, and observed creation of granulomas in mice lungs. Petia Simeonova also measured damages in mitochondrial DNA in heart and aortic artery. (2005)

In this case it is important not to draw the wrong conclusions (Pr. Warheit himself did not believe the deaths and diseases were indicative of any “inherent pulmonary toxicity” of nanotubes) and it will therefore be necessary to carry out further complementary studies. Moreover a study from the National Institute for Occupational Safety and health (NIOSH,
**USA)** showed that none or only a small fraction of nanotube presented in that air can be inhaled. In this respect, all researchers recommended that inhalation studies, as opposed to the instillation studies performed here, should be the next step.

3.3.2.1.2. Experiments on rabbits

A study at the University of Warsaw, on the dermatological effects of carbon nanotubes in rabbits “did not find any signs of health hazards related to skin irritation and allergic risks.”

3.3.2.1.3. Experiments on fish

An interesting study has been implemented by Eva Oberdörster from **Southern Methodist University** in **Dallas** and her colleagues, to measure the effect of waterborne fullerenes on aquatic animals. (April 2004)

In a confined laboratory, the researcher exposed nine juvenile largemouth bass, confined to 10 liter aquaria, to a form of water-soluble buckyball (C\(_{60}\)) at a dose of 0.5 parts per million. After 48 hours, the animals were still alive but developed significant brain damage as measured by lipid peroxidation, or the breakdown of lipids, as shown by laboratory analysis of brain tissue samples. The brain damage seen in the fish exposed to the nanoparticles was severe: 17 times higher than that seen in nine unexposed animals. But, until further studies are done, Eva Oberdörster explains that no one knows yet whether these and other buckyballs will cause similar brain damage in humans.

In addition to damage to the brain, the researcher also investigated altered gene expression in the livers of exposed fish. She found a variety of genes that were turned on or off, indicating a whole-body response to fullerene exposure. In particular, Oberdörster found chemical markers in the liver of the exposed fish that indicated the onset of inflammation, a process that has been implicated in an increasing number of diseases.

The researcher still does not know the mechanism by which buckyballs cause damage in the fish. She doesn’t know if the fullerenes are directly causing lipid peroxidation in the brain tissue or whether it is a secondary effect caused by inflammation. Pr Oberdörster is planning additional studies in the future to determine the mechanisms of action and to find out how many buckyballs get into the fish's body and where the particles are distributed. She
expressed concern that nanoparticles could begin to accumulate throughout the food chain, affecting not just fish, but other animals, plants and possible people. But, she declared that the fullerenes to which fish were exposed are more toxic than nickel, but less than benzopyrene that we could find in cigarette smoke and exhaust fumes from vehicles.63

3.3.2.2. Examples of studies: extrapolation to humans

Inhalation and respiration:
Some studies have also been established in order to understand the potential risks of nanotubes on human health.
For example, immunologist Silvana Fiorito at University of Montpellier - France, made a study on the consequences linked to the respiration of nanotube fibers. She observed that when a micro-metre particle of pure carbon is introduced into a cell, the cell responds by producing nitric oxide. This innate reaction shows that the immune system is working and the body is fighting back against an invading foreign substance.
In contrast, if a nano-sized particle of the same substance is added to cells (in the form of a fullerene or a nanotube), the cells do not respond which has unknown consequences for health64.

Moreover, some scientists have already compared nanotubes with asbestos in term of risks and danger. For example, Dr. Wiesner at Rice University pointed out that carbon nanotubes resemble asbestos fibers in shape: they are long and needle-like65 (2002), but their sizes are different (0.1 to 10 μm in length for asbestos and 10nm to 1μm for carbon nanotubes). So, the supposition that the potential for harm could be similar would appear to be obvious but is subject to discussion in expert circles.
Indeed, according to Dr. Wiesner, carbon nanotubes cannot pose much of a threat at present because, in our environment, they tend to clump together rather than exist as single fibers (which have the potential to cause serious respiratory problems as asbestos fibers have).

Dermal effects:
Studies dealing with the effects of carbon nanotubes on human skin cells have been published the last few months. Some of these experiments showed that it is possible to control carbon nanotubes cytotoxicity by changing their surface composition.
- Vicky Colvin from Rice University exposed human skin cells to a solution containing different concentration of Buckyballs for 48h. The conclusion of this first experimentation is that a dilute solution (20 parts per billion) could kill half the cells. But the team continued its studies: they coated the buckyballs with chemicals (hydroxyl or carboxyl) and discovered that with this coating they became less toxic. However, according to Eva Oberdörster, this solution is not efficient in all situations, for example in environment, ultraviolet damages the hydroxyl coating.

The Rice University’s team, highlight an explatation in this toxicity change: Buckyballs without coating form aggregates which involve free radicals. These chemical reactions can affect the membrane cells. 66 (May 2005)

Other experiments showed that aggregates of naked bukyballs did not damage DNA in the cells.

- Anna Shvedova of the National Institute for Occupational Safety and Health (NIOSH) noted that carbon nanotubes may caused dermal toxicity due to oxidative stress.67

- Two teams (Huajian Gao of Max Planck Institute and Nancy Monteiron-Riviere of North Carolina State University) investigated the effect of carbon nanotube on human skin cells. The first one studied the single wall carbon nanotubes and concluded that SWCNT hold up cells growth, producing apoptosis and a decrease of cellular adhesion ability. The second one dealt with Multi wall carbon nanotubes (without derivation), and showed that a detectable fraction of these nanotubes are able to enter the cells and caused irritation in keratinocytes. (Oct-nov 2004)

These two studies mentioned that further experiments must be carried out: first to evaluate exposure and then to determine risks in occupational or environmental circumstances.

3.3.3. Potential risks of other nano-elements

Sangeeta Bhatia (researcher from the University of California at San Diego - US) investigated the toxicity of semiconductor Quantum Dots to cells 70 (Jan 2004). The study showed that under certain conditions, CdSe-core quantum dots were cytotoxic. This cytotoxicity could be modulated by processing parameters, ultraviolet light and surface coating. Cytotoxicity was presumably caused by surface deterioration of the CdSe lattice and
subsequent liberation of Cd$^{2+}$ ions. Appropriate coating could avoid cytotoxicity in vitro, but in vivo, Cd release over time was possible. Note that the researcher doesn’t see his work as a signal for an end to the future of quantum dot labelling but much more as a stimulus for further research on appropriate synthesis, processing and coatings of quantum dots.$^{71}$

**Fluorescent compounds** are under development as diagnostic tools for internal imaging of the human body- allowing examination and more effective treatment. However adverse effects should be investigated carefully especially the distribution within and elimination from the body.$^{72}$

![Image of fluorescent nanocrystals](image)

Figure 3.4. Source : Mammalian cell structures tagged by fluorescent nanocrystals, courtesy of A. P. Alivisatos, UCB

In 2004, Mark Green of the King’s College and Emily Howman of the University of Oxford investigated the interaction of water soluble semiconductor quantum dots with supercoiled DNA. They show that these water soluble semiconductor quantum dots can nick DNA. They attributed the observation to free radicals. This result highlights the question of the uses of such a material in in vivo applications.$^{73}$

Another concern is the effects of nanoparticles generated in vivo, for instance by wear debris of biocompatible implants. These could involve **auto-immune disorders** (linked to small particulates).

### 3.3.4. Conclusion

To conclude this part 3.3 on “potential impacts of nanomaterials on health”, two main areas could impact on health:
- the first one deals with the entry of nanoparticles into the body
- and the second one is linked to the risks of implants or other invasive applications
There is however no absolute certainty or proof of the danger posed by nanomaterials to human health. Animal experiments begin to answer this; however these need some qualifications before being extrapolated to humans as there are variations between experiments and different animal models.

According to David Warheit, there are several reasons why it is still too early to draw far-ranging conclusions regarding hazards and risks of nanomaterials for humans:

- The inhalation toxicology database on nanomaterials is rather small, and it consists almost exclusively of data about titanium dioxide, carbon black and diesel particles.
- Toxicology studies are mainly carried out with rats, whose lungs process inhale particles very differently compared with larger mammals.

Not only are the size and composition of nanoparticles important for their toxicity but also their surface coating.

Moreover, this last month, many studies on nanotubes and nanoparticles cytotoxicity have been published, according to Kevin D. Ausman from Rice University “cytotoxicity should not be confused with full fledged toxicological risk assessments, risks assessment take into account exposure rates, uptake mechanisms, transport within the body and much more. More often cytotoxicity studies are used as indicators of whether more extensive toxicological study is needed”.

So, complementary studies must be continued to elucidate the real impact of nanomaterials on human health.
3.4. Potential impacts of nanotechnologies on environment and the food chain

Nanoparticles can occur naturally, through combustion for instance, but they are increasingly being manufactured for industrial and medical applications. The future large scale production will have consequences: a quantity of nanoparticles could reach the environment. As they are and will be used in consumer products, electronics, fuel cells, materials for environment remediation, nanoparticles can be released into water or air, and ultimately contaminate soil and groundwater. Indeed products including nanoparticles will, sooner or later, have to be recycled or removed as waste and thus could affect the environment, others could directly be in contact with the environment (remediation product).

So, how may people be exposed to nanoparticles, and more precisely to engineered nanoparticles and in what quantities?

Today, some environmentalists fear that nanotechnology may involve negative effects on environment, such as contamination. A report from ETC group untitled “Down on the farm” deals with the consequences of nanotechnologies on agriculture and food chain. This report underlines the lack of information regarding these consequences and recommends the setting of an international regulation specifically for nanoproducts, and the establishment of a public and social debate.75 (Nov 2004)

Up to now, few scientific studies are devoted to environmental impact of nanotechnologies, and to consequences on food chain. Information is only at an early stage. However, because of their extreme division and strong mobility and reactivity, it appears significant to evaluate the risks related to nanoparticles transfer and their persistence in the environment. Disseminated in the environment by the normal use of product including nanoparticles or in an accidental way, which impacts will these products have on the systems in terms of bio-accumulation, bio-toxicity and mutagenic effects?

What will happen if some toxic nanomaterials get into the environment? They could constitute a completely new class of non-biodegradable pollutants, with which scientists obviously are still unfamiliar.

Potential risks of nanotechnologies on the environment are the following:
- The primary risk involved in nanotechnology stems from the “invisible” size of the particles being developed. Environmentalists worry that such particles could accidentally enter into the **food chain**, initially causing damage to plants and animals while eventually becoming a hazard to humans.

- The second risk of nanoparticles is due to their large surface area, structure, composition and reactivity, which could facilitate transport in the environment or lead to harm because of their interactions with other elements.

The following section will try to present the first elements of the potential impact of nanotechnologies on environment and the food chain. It will illustrate the potential toxicity of nanomaterials with different examples on **fullerenes**, **carbon nanotubes** and **metallic nano-oxides**. This section focus in engineered nanoparticles, but natural nanoparticles should also be studied in order to balance relative hazard related to the first one.

### 3.4.1. Consequences of nanotechnologies on the environment and the food chain

As already mentioned in the previous section about potential effects of nanotechnologies on human health, differences in size, shape, surface area, chemical composition and biopersistence require that the possible environmental and health impact be assessed for each type of nanomaterial. Several studies have shown that closely similar compounds may induce different effects. This is the case of **engineered nanomaterials** that could influence different potential risks linked to the environment.

All substances can be toxic to cells, depending on the exposure level. The more important question is to characterize the expected concentrations of engineered nanoparticles that may be present in **soil**, **water** and **air**.

In these days, four forms of nanoparticles could potentially involve harmful effects on environment: **dispersed nanoparticles as they are in the environment**, **adsorbed with other substances**, **aggregated** or **uptaken by cells**.

For example, a study called « *Nanomaterial Fate and Transport in the Environment* » from **CBEN – Rice University** is observing the behaviour of nanomaterials in the atmosphere, hydrosphere and biosphere, with particular attention to interactions with other chemical
species: organic and inorganic pollutant adsorption with TiO$_2$ nanoparticles and carbon nanotubes, and the effect of these nanosized materials on nucleation of natural inorganic constituents of water. Following on these researchers will work on transport and aggregation of nanoparticles and their interactions with biological systems, such as bacteria.$^{77}$

3.4.1.1. Impact of the dispersion of nanosized materials in the environment

The small size of nanoparticles could lead to enhanced mobility. However, little is known about the fate, transport and transformation of nanosized materials after they enter the environment. Nobody knows if they are toxic or not today, or if they could be toxic within months or years. So, these nano-elements could be non-biodegradable pollutants. Some tests (Zhang W.X) concerning iron nanoparticles (used in the new generation of remediation technology) were made in USA. This test showed that this nanoparticle remains reactive in soil and water for several weeks and they can travel in groundwater as far as 20 meters.$^{78}$

In the case of nanomaterials, size matters could facilitate and exacerbate any harmful effects caused by the composition of the material. For example, Titanium Dioxide is a generally non-reactive substance used in many products, such as skin lotions or house paints. However, it is increasingly being made in nano-sized particles. And tests show that these nanoparticles of Titanium Dioxide are highly reactive, generating “hot” free radicals that can burn up bacteria. That is why some experts are worrying about impacts on soil ecology if the particles are released.$^{79}$

Some other experts are also worrying about impacts on soil ecology if fullerenes are released. For instance, Mason Tomson from the Center for Biological and Environmental Nanotechnology (Rice University, Texas) has studied how buckyballs travelled into the ground with unexpected consequences: dispersed buckyballs in water surrounded by a protective coating of water, migrate in the ground without being absorbed$^{80}$.(July 2003)

Regarding the potential impact of nanomaterials in water, for instance, researchers from Rice University also looked at the movement of different nanomaterials in aqueous systems. The conclusion of the study was that not all nanomaterials are mobile. The movement of nanomaterials in the environment is very case-specific. Wiesner and colleague Helene Lecoanet tested the mobilities of three fullerenes under pH and ionic strength conditions.
similar to those in many groundwater aquifers. They compared these mobilities with those of four oxide nanomaterials and found that the particles exhibited “widely differing transport behaviours”.

While the transport of mineral nanoparticles is well described by current models for particle transport in porous media such as ground waters, the transport of fullerenes cannot be described by these models and shows some unusual properties. And the form of buckyballs that has received the most attention in recent toxicity studies is the least mobile form of fullerenes tested, thus the potential for environmental risk should be somewhat reduced. Wiesner believes his work will help scientists to understand the potential efficiency of using nanoparticles to clean up groundwater pollution, as well as aiding the assessment of any environmental risks that nanomaterials might present. (April 2004)

Another study from M. Wiesner team focus on the electrokinetic behaviour of colloidal aggregates of C60 fullerenes (named n-C60) produced through two different ways: by solvent exchange (tetrahydrofuran – THF) and by mixing with water (this technique is closer of natural aquatic system conditions). Researchers show that n-C60 is able to acquire charge by mixing water (that is to say without the intervention of solvent). This has implications for the transport ability of these materials in environment. Researchers also note that the charge of n-C60 formed by solvent exchange is stronger, and thus conclude that more studies are necessary on materials derived from n-C60 using THF. (May 2005)

3.4.1.2. Impact on environment of the adsorption phenomenon on nanosized materials

![Figure 3.5](image)

Figure 3.5. Source: Nanotechnology: Environmental Impact – Vicki Colvin

The structure of nanosized materials has great properties in term of surfaces, strong cationic exchanges capacities as well as strong surface charge. The combination of these properties makes them potentially reactive. It thus should be considered that they can bind with other substances, possibly toxins, in the environment.

This is precisely the case of colloids (natural nanoparticles), which are known for their transport and holding capacity of pollutants (adsorption phenomenon).
Adsorption is the fixing of dissolved molecules by a solid phase. This fixing is due to the establishment of secondary surface connections between the adsorbent and the adsorbed molecule (attraction phenomenon). For example, the retention of metals by grafted surfaces such as **fullerenes** or **carbon nanotubes** is possible. In fact, **organo-metallic fullerenes** exist.

We can also note that adsorption occurs to a greater degree on hydrophobic and charged particles (i.e., **nanoparticles**).

It is interesting to observe and identify the fixing sites due to the adsorption of heavy metals (Pb, Zn, As…) to determine the potential toxicity of these particles. For that, it is necessary to detect the speciation of the adsorbed pollutants, which could be characterized by various spectroscopic and microscopic techniques (X-ray Absorption Spectroscopy, SEM, FTIR, NMR…).

Thus scientists would be able to characterize two types of nanoparticles, which interact with bacteria: nanoparticles alone (with a direct biological role) and nanoparticles in the presence of metals (indirect role). They could observe the degree of contaminants in each case.

On that subject, **Rice** researchers currently examine how effectively buckyballs, which are extremely stable and robust, adsorb toxic materials. Binding to buckyballs could potentially make the toxins themselves more chemically stable or enable them to travel further through air or water\(^{83}\).

MB Tomson from **Rice University** studies naphthalene (organic pollutant) adsorption and desorption from aqueous C60 fullerene. The objective was to investigate these interactions according to different aggregation forms (deposited as thin film, dispersed in water…). The conclusion is that dispersal of C60 could affect the adsorption effect: the more the C60 are dispersed the more the adsorption phenomenon is important, this may also mean that low concentrate is not a criterious of lower toxicity. \(^{84}\) (2004)

Other studies are dealing with the adsorption of cadmium, another pollutant.
3.4.1.3. Effects of aggregation of nanosized materials on environment

![Image of aggregation phenomenon](image)

Figure 3.6. Source: Nanotechnology: Environmental Impact – Vicki Colvin

Aggregation is a gathering phenomenon of organisms or substances to form a conglomerate (it is not the same attraction as for adsorption). Nano-object aggregation can be a source of problem concerning the environment, and could involve potential risks of toxicity. In fact, in complex aqueous environments, many types of nanoparticles undergo aggregation phenomena. It is possible that a particle considered as non toxic, meets a toxic one and the whole conglomerate becomes toxic.

Vicki Colvin showed that, in water, whether it’s a lake or an aquifer, nanoparticles or carbon nanotubes may experience a tendency to aggregate. Their aggregation may determine where and how far they may travel. Different experiments have been designed: some to minimize aggregation by developing strategies for getting nano-elements into water, and others by intentionally altering and affecting the chemical surface of nano-elements to facilitate their manipulation, aggregation and deposition.\(^{85}\)

A recent study from Vicky Colvin and Joseph Hugues tackles the interaction between C60 and ecosystem. As it is mentioned above, C60 forms a stable aggregate (nano-C60) upon contact with water. This study reveals that this aggregate is toxic to bacteria. Indeed, researchers exposed 2 different bacteria to nano-C60 and showed that this aggregate inhibited bacteria growth and respiration at very low concentration.\(^{86}\) (April 2005)

According to Vicky Colvin, this properties could be use for good applications, but more studies have to be done concerning the possible toxicity of nanoparticles or metals which aggregate within nanoparticles.
3.4.1.4. Biotic uptake of nanomaterials

The biotic uptake phenomenon includes the absorption and incorporation of a substance by living tissue. It could contribute to an internal contamination in which the toxic substance participates in the metabolism of the body.

Past industrial failures associated with bio-uptake accumulation have had huge environmental consequences (e.g., semiconductor industry (metals, solvents), synthetic chemicals (PCB, DDT, Freon), applications of natural compounds (chlorine, asbestos), transportation and energy (air pollution, global warming)…) and have had very costly effects.

Regarding nanotechnologies, nano-elements may enter cells via:

- **Endocytosis** (process in which a substance gains entry into a cell without passing through the cell membrane. It results in the formation of an intracellular vesicle by virtue of the invagination of the plasma membrane and membrane fusion.)

- **Membrane penetration** (generally occurs with very hydrophobic particles)

- **Trans-membrane channels** (may be seen only with very small nanoparticles: < 5 nm)
The main issue of bio-uptake is that toxic cells could interfere in the food chain.

Figure 3.8. Source: Organic sequestration and bioavailability control – Richard D. Luthy
(Department of Civil and Environmental Engineering – Stanford University)

So, if nano-elements enter organisms at early stage in the food chain, they may be expected to accumulate in organisms higher in the food chain.

Some researchers at Rice University are currently conducting studies on how buckyballs affect bacteria and simple organisms like worms.

In a separate study, they are exploring whether buckyballs tend to move up the food chain. First results seem to show that nanoparticles accumulate in living cells over time, with ever-increasing concentrations in microbes, in the worms that eat those microbes, and in animals higher up the food chain. So, it is possible that these nanoparticles could be able later on to reach humans.

Therefore, while nanotechnologies promise to have numerous benefits for society, many of the potential risks remain uninvestigated and it remains to be determined more precisely the danger associated with these particles in the environment.
3.4.2. Methodologies considered for risk assessment of nanotechnologies on environment

This sub-section gives some examples of envisaging ways for characterizing the bio-accumulation and biological breakdown of nanomaterials, and their possible mutagenic effects on bacteria according to their physico-chemical properties.

3.4.2.1. Measurement of accumulation

The long-term persistence of nanoparticles (carbonaceous in particular), will depend on their possible biological breakdown in grounds and water. These sites contain organisms able to degrade polluting or natural carbonaceous poly-aromatic substances. It is important therefore to test the capacity of these sites to bio-degrade nanoparticles, by exploiting the difference of isotopic composition of carbon between these nanoparticles and other current substrates.

It should be possible to quantify the presence of carbon in nanoparticles in the microbial metabolism by analysing the isotopic composition of the metabolic products. Thus, residence times of these nanoparticles in the ground will be given, and it will be possible to observe the consequences (and behaviour) of metals or associated metals with nanoparticles. This would allow chemists and scientists to determine the degree of potential toxicity of these nanoparticles. During these experiments, the transfer of nanoparticles within (inside) bacteria will be determined by microscopy. So, it will be possible to quantify bio-accumulation.

Moreover, it would be possible to compare different types of nanoparticles to determine their potential toxicity and estimate their degree of toxicity.

3.4.2.2. Measurement of viability/mutagenic effects

The impact of nanoparticles on bacterial viability could also be tested in culture and in natural conditions. Researchers can measure bacterial viability thanks to fluorescent markers allowing:
Either the marking of DNA by Syto9, when membranes could be intact (viable bacteria) or damaged (not-viable bacteria)
Or the single marking of DNA of damaged membranes, by propidium iodine.

The fluorescence emitted by these two markers allows the size of viable and nonviable populations to be assessed.
The ratio "viable/nonviable bacteria", which depends on nanoparticle concentrations and time, will permit their impact on bacteria viability in natural environments to be estimated.
These tests of mutagenic effects will allow the potential geno-toxicity of these products on bacteria to be assessed.
The behaviour of metals associated with nanoparticles must be studied in terms of toxicity and assessment of metal speciation.
For example, does chromium associated with a nanoparticle that penetrates a bacterium have the same mutagenic effect as dissolved or complexed chromium?
Complementary tests must be done.

3.4.3. Conclusion

To conclude the part 3.4 on “potential effects of nanotechnologies on environment”, it seems clear that differences in size, shape, surface area, chemical composition and biopersistence require that the possible environmental impact be assessed for each type of nanomaterial. The long-term behaviour of such substances and their effects on elements are thus extremely hard to foresee.

Indeed, impacts of nanotechnologies on the environment have not been studied thoroughly yet. A few studies have been carried out on this very complex subject and researchers currently have less concrete results on this subject than on health effects.

Some elements are known:
- The tendency of nanoparticles to aggregate in various aqueous environments.
  (different kinds of aggregations according to different nanoparticles and different environments)
The adsorption of contaminants to the surface of nanoparticles is strong, and the possibility to affect fate and transport of this contaminant in ecosystems.

But there is not enough information to predict the impact of nanotechnologies on environment and particularly on the food chain so it is necessary to continue research on their potential negative aspects.
3.5. Conclusion of part 3

Today, the first studies dealing with the impacts of nanotechnologies on health and environment are being achieved. Few data exist regarding the health risks of dermal or oral exposure to nanomaterials, and studies concerning nanotechnologies impact on environment are at an early stage.

For the moment, we do not have sufficient information to accurately assess the risks of nanotechnologies, and it seems necessary to step back from the results already available because:

- Most of them do not include important data of risks assessment (exposure rates, uptake mechanisms, transport…)
- They do not take into account all possible changes in composition of nano sized particles which can occur during their trip to environment or human organism…
- There are no regulations or protocols concerning nanotoxicology studies to ensure their validities. It is known that nanotechnologies present specific characteristics which need adapted methodologies and regulations.

Moreover in the framework of toxicity studies, definition of nanotechnologies is not clear. It would be difficult to define products which will have to be treated as “nanoproducts”.

Currently, some products including nanoparticles are already on the market (cosmetics, remediation products, pesticides): they have been studied according to current regulations and are considered as non toxic products. Nanotechnologies toxicity studies could bring back into question the use of these products (if they are defined as nanotechnologies products). That is the reason why discussion concerning nanotoxicology should involve all stakeholders: Government, Scientists, Industry, General Public, Non Governmental Organizations… It seems important to define actors’ role in nanotechnologies development. For instance, some nanotechnologies applications will be soon available, what will be the role of Industry in the control of product safety?

So many questions remain unanswered, showing the need to continue toxicology research. Anyway, numerous studies are ongoing on this subject and some of these results will be published soon. More studies and realistic tests in which nanosized materials are inhaled or transported in the environment have to be done. It is paramount that nano-experts realize...
these studies in order to understand and control all consequences linked to these new technologies. And, even if those tests are very expensive today, they have to be done. So, while waiting for these results, we should continue R&D to take advantage of the current dynamic in the field of nanotechnologies.

Fears which emerge must be calmed by implementing a real discussion between the different actors. The dialogue between scientists and the general public must avoid past mistakes, as was the case for GMOs, where the absence of distinction between various techniques, contempt of information and an incomplete study of the risks, legitimately caused a massive rejection by the general public and a great mistrust with respect to the “agro-business”\(^\text{90}\).

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4th Nanoforum Report:

Benefits, Risks, Ethical, Legal and Social Aspects of NANOTECHNOLOGY

Part 4: Public Perception of Nanotechnology

2nd Edition - October 2005
Part 4: Public Perception of Nanotechnology.

4.1. Introduction

The major technological landslides have always stirred people’s imagination and in the case of nanotechnology it has been no different. Since nanotechnology around the turn of the century was recognized as perhaps the technology of the 21st century with billions of dollars of funding in the US, Europe and Japan much thought has been given to how this technology might affect our future.

Much of the controversy about nanotechnology focuses around the subject of what is known as “molecular assemblers.” In 1986, one of the most significant books on the subject of nanotechnology: *Engines of Creation: The Coming Era of Nanotechnology* was written by K. Eric Drexler, now the chairman of the board of directors of Foresight Institute. In his book Drexler examines among other things the possibility of these "molecular assemblers" and predicts that their existence will completely change the world, as we know it. With “molecular assemblers” we would be able to build anything with perfect precision while at the same time avoiding all pollution. Ultimately, Drexler foresees, they would enable us to colonize the solar system and approach immortality.

Drexler has no doubt about the endless possibilities that nanotechnology entails, on the other hand he feels equally troubled by the potentially devastating negative consequences of such a technology. At one point in *Engines of Creation* he writes: “Replicating assemblers and thinking machines pose basic threats to people and to life on Earth." For Drexler the development of molecular assemblers and nanotechnology is inevitable, and as a result he finds it crucial that the implications of the technology is thoroughly examined before it is put to use and that society develops a system to ensure that this technology does not fall into the wrong hands. In an opinion article in June 2004, Chris Phoenix and Eric Drexler withdraw the prediction of uncontrolled self replicating nanobots, and warn instead for “weapon systems,
radical shifts of economic and political power, and aggregate environmental risks” to which nanotechnology may contribute.¹

Among those who have picked up on Drexler’s earlier predictions is the chief scientist and cofounder of Sun Microsystems Bill Joy. In 2000 Bill Joy wrote an article for Wired magazine entitled “Why the Future Doesn't Need Us.” In his article Bill Joy argues that the current pace of our technological progress - with specific reference to what he calls the GNR technologies; Genetics, Nanotechnology and Robotics – may pose a serious threat to the human race. One of his key points, quoting Ted Kaczynski, also known as the Unabomber, is that because our society has become more and more dependent on computers and other machines, this will eventually lead to computers being so complex that we will become slavishly dependent upon them making the decisions for us. If we do not set up some sort of ethical standard to guide future innovations within this field or maybe even stop potentially dangerous research, we will experience an oppressive propagation of robots and other forms of electronic life as a result of the obvious advantages (speed, strength, and longevity) that the electronical hold over the biological.

Another text that has enjoyed a great deal of attention since its publication in 2002 is the novel Prey, written by the hugely successful American science fiction author Michael Crichton. Crichton draws heavily on the theories of Joy and Drexler in this novel, describing an accident that leads to self-replicating nanomachines running out-of-control and rapidly trying to consume the world's resources in their quest for more organic material to sustain further replication and thus turn the world into a big lump of grey-goo. Although this might strike some as a bit far fetched, it has among other things led to Prince Charles asking the Royal Society, the UK’s national academy of science, to look into the "enormous environmental and societal risks" of nanotechnology, specifically voicing his concern over the so-called "grey goo" issue.

There are also some watchdog groups, such as the ETC Group based in Canada, who are advocating that all nanotechnological research should be put "on hold" until the comprehensive studies into the health risks have been conducted. The ETC group states: "We want to see a moratorium on the release of nanoparticles to the environment until evidence that it is safe (for the environment and human health) is clear." ¹

On the other side of this debate we find various people and groups who point out that the development of nanotechnology may solve most of the problems that confront the world today and therefore we cannot ignore the potentials of this technology. Among these are Mihail C. Roco and William Sims Bainbridge, both advisors on nanotechnology to the National Science Foundation in US. In 2002 Roco and Bainbridge edited a report entitled *Converging Technologies for Improving Human Performance*. In this report they foresee that if we are able converge what they see as the four major areas of science and technology - nanoscience and nanotechnology; biotechnology and biomedicine, including genetic engineering; information technology, including advanced computing and communications and cognitive science, including cognitive neuroscience, collectively referred to as NBIC – we would be able to achieve “a tremendous improvement in human abilities, societal outcomes, the nation’s productivity, and the quality of life.” According to Roco and Bainbridge this would need to be done with close attention to ethical questions and the needs of society, but if done correctly and the appropriate measures in terms of funding were taken immediately, they foresee that within 20 years this could lead to a dramatic development in areas like work efficiency and learning, enhanced individual sensory and cognitive capabilities, a ground-breaking transformation of our healthcare, new communication techniques including brain-to-brain interaction, the enhancement of human capabilities for defence purposes, etc. In other words “an age of innovation and prosperity that would be a turning point in the evolution of human society.”

Another important voice in this debate is Richard E. Smalley, University Professor and 1996 Nobel Prize winner in chemistry. Smalley contests the basic principles of Drexler’s theories, arguing that the molecular assemblers as predicted by Drexler are physically impossible. But Smalley also sees a risk in speculating about the potential dangers of nanotechnology as this might weaken public support for it and thus hinder the many positive aspects nanotechnology could bring about. Although Drexler and Joy take the same basic position in relation to the possible risks of nanotechnology (i.e. they could be considerable/radical, and must be taken seriously, addressed openly and in transparent ways, etc) in contrast with Richard Smalley, they at the same time differ as much as they can when it comes to the short-term conclusion. Joy advocates a moratorium whereas Drexler is in favour of “full speed ahead” both with respect to the technological development and to the debate/reflection of its implications/risks and so forth. But Smalley doesn’t seem to see this distinction; he rebuts Drexler in just the same way as he rebuts Joy without acknowledging that Drexler may have a point in
suggested an open discussion. It would have been possible for him to see Drexler as an ally here, as Smalley is worried (and seemingly much driven by this) for obstacles being raised for the further rapid development of NT. A more in depth analysis of the debate about the visions from Drexler and Joy will be introduced in a new publication planned to be published later this year by Professor Hans Glimell from Göteborg University.

As the study *Prospects for Theoretical and Disciplinary Unification* chaired by Astrid Schwarz notes, it is interesting when discussing these scientific disagreements among the scholars that part of the problem may stem from the lack of a shared paradigm within the scientific community. As the study argues, “science can only advance and articulate in ever greater detail a true picture of the world where there is common a language, where instruments and laboratory practices, background assumptions, an awareness of theoretical problems and an ability to recognize their solutions are shared,” and even on this question, whether such a paradigm exists, the experts seems to differ.

When addressing the issue of how nanotechnology is perceived by the general public one has to recognize that the vast majority of people still have little or no idea of what nanotechnology is or what the possible implications of this technology might be. Ed Regis, author of the book *Nano* points out nanotechnology probably will not make any big impression on the general public until it actually happens.

Bainbridge has conducted a qualitative analysis into the public perceptions of nanotechnology based on an Internet survey. His study revealed “a high level of enthusiasm for the potential benefits of nanotechnology and little concern about possible dangers.” As one might expect, the public mentally connected nanotechnology with other areas of science such as the space program, nuclear power, and cloning research, but viewed nanotechnology in a more favourable light.

As with any other technology, there is nothing intrinsically good or bad about nanotechnology. The key issue must be what is done with it. In view of this it seems important to remember that when talking about public angst towards any given technology, be it gene-, bio- or nanotechnology it is not the technology that raises public concern but the ethical standards of the scientists behind it and how it may potentially be abused for economical, military or other purposes. Thus one might argue that in many cases it is not the
technology itself, which is debatable, but the scientific community and those controlling the finances behind it that create the fear and the science fiction-like horror scenarios.

In 2003 the Royal Society and the Royal Academy of Engineering in the UK carried out an independent study of the likely developments that nanotechnology may bring about and whether these developments raises ethical, health and safety or social issues which would require new regulation. It was the view, among a Civil Society group that took part in this study, “that scientists and regulatory agencies needed to work together with other social groups, including non-experts, in order to draw on a wide range of knowledge and identify areas of concern.” The media would also play a very important part in this area. The Civil Society group argued the need for a very open system including a pluralist system of government, public peer review, and adaptive regulatory systems. The Royal Society in UK carried out a survey on how nanotechnology was recognized in the society today (Views of the public, January 2004). The survey deals with how nanotechnology is seen by the general public and gives great status on the awareness level in the society. This work is done in UK.

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Table 4.1 Awareness of Nanotechnology, Courtesy of Royal Society, www.nanotec.org.uk

In this report they also looked into how people understand the word nanotechnology and which picture and feeling people get from this. In the table below one can see that nanotechnology is seen as a “smalltech” field but still 81% of the people that had heard about nanotechnology can not describe what nanotechnology is about.
Table 4.2, Understanding of Nanotechnology, Courtesy of Royal Society, www.nanotec.org.uk

A similar study was conducted in Germany. According to Dr Peter Wiedermann (Research Centre Jülich, Germany), the German study concluded that nanotechnology is unknown to the public and that people who have heard about it are not hostile towards nanotechnology.\textsuperscript{ii}
4.2 Media and scenarios influencing the public perception.

A lot of projects, scenarios, and nanotechnology “myths” are also a great influence on the general public perception of nanotechnology. Some of the most popular themes will be introduced and discussed in the section below.

4.2.1 Media

In Germany the Association of Engineers (VDI) has carried out a small survey about nanotechnology in the media. They found out that at least 9 complete television programmes and 11 shorter film contributions were shown in Germany in the last 5 years. The spectrum of the programmes is broad but most described the visions and expected benefits of Nanotechnology.

The film contributions are partly about specific Nanotechnology institutions like the CeNTech Münster or regions like Nanotechnology in the Saarland. Several thematic contributions are about applications in health care (Cancer treatment, drugs, etc. but also about Nanotechnology in automobiles or in fire protection.

Furthermore they found out that there are more than 15 newspaper articles about nanotechnology per week in German nationwide newspapers. They are equally distributed about science rubrics and education/politics rubrics. Furthermore there is an increasing number in the economic parts of newspapers. The articles are predominantly very positive and describes as the television contribution the expectations and benefits of Nanotechnology. Nanotechnology is often mentioned as example of an advanced technology. If criticism is mentioned, it rarely address the risk of Nanotechnology but more often problems in the utilization of project results, a lack of funding or describes Nanotechnology as a momentary hype.

It is very hard to get such kind of information nationwide around European countries. Either there are no such statistics carried out or one can only get minor and not thorough enough details so it is hard to get a picture of the situation and therefore Germany are here shown as an example.
4.2.2 The Space Elevator:

Discoveries and developments within nanotechnology research and especially within carbon based nanotechnology (e.g. carbon nanotubes, and fullerenes) have led to some peculiar but also serious projects and thoughts on various applications. Best known and widely referenced is a project called “the space elevator” from NASA, a 62,000-mile twine of carbon nanotubes that would transport cargo into orbit.

Figure 4.1. Photo: Courtesy of HighLift Systems

Based on the research within carbon nanotechnology and the highly motivating factor of being able to travel to the moon in a cheap and easy way, High Lift Systems\(^2\) has been established in the US, devoted solely to the development of such a space elevator. This system is decades away- if it ever happens at all. But analysts like Brian Chase, vice president of the Space Foundation, see research like this as critically important\(^3\). "It's impossible to make breakthroughs if all you're funding is immediate, near-term applications," he said. The public acceptance of this project is quite high as it is something that everybody can relate to in the sense that everybody knows an elevator and everybody knows that we are able to travel in space. Projects such as the space elevator can provide the general public with a gentle introduction to nanotechnology developments and allow them to learn more about e.g. carbon

\(^2\) [http://www.americanantigravity.com/highlift.html](http://www.americanantigravity.com/highlift.html)

\(^3\) Wired May 07, 2004
nanotechnology. On the other hand, the negative view is that this project is decades away, almost impossible to achieve and it gives the audience a wrong view of what to expect from nanotechnology in the future and especially in the near future.

4.2.3 Nano-submarines

Another area that has met great acceptance as a nanotechnology theme for the broad audience is the Nano-submarine. This was introduced initially in 1966 by the movie “Fantastic Voyage”, where a surgical team is miniaturised and injected into the blood of a dying man. This theme has been kept in peoples’ mind’s ever since, and now when nanotechnology gets more popular and other sci-fi people talks about miniature “robots” injected into the body this movie pops–up in peoples’ mind’s again. It is of course impossible to shrink people to the nano-size, but the reality is that we will in the very near future create small, custom-made nanoparticles that will be able to detect and perhaps kill cancerous cells at an early stage. Such research is being carried out in many places in various ways, from Rice University in the US to the National Microelectronics Research Center in Cork, Ireland. But the wording “Nano-submarines” has no real meaning in relation to what has been carried out in actual research.

Vanishingly small machines like the ones envisioned here could someday serve as tiny mechanical doctors. These miniature devices would roam between the red cells of the bloodstream, seeking out and destroying harmful viruses (shown here as green geometric solids). The working parts of these machines would be built around gears no bigger than a protein molecule.4

4.2.4 Molecular Assemblers

Another popular theme is the picture of building e.g. consumer goods atom by atom by molecular assemblers. A large number of people, researchers as well, mention the possibility of creating molecular machines, gears and assemblers for the creation of almost anything. Of course it is nice to have some very long term goals to achieve even within the laws of physics and quantum mechanics, but the actual relevance to society is not very clear. If one does a small calculation of how many atoms are needed for building e.g. a new transistor for computing from scratch atom- by atom, a number of 50,000,000,000,000 atoms will have to be produced and aligned in the proper way to create a Pentium processor. Such an achievement for a nano-machine using molecular assembly is impossible at present and will not be so for a very, very, very long time, if ever. Yet one should not say that this is not possible and one should be aware of the theme as a lot of funding and research is determined to go along this road to achieve 100% control of matter, even at the large scale creation.

On the left a picture of a Fine-Motion Controller for Molecular Assembly created by K. Eric Drexler. As this is very early nanotechnology thought the views even from Drexler himself have changed a bit towards more reality based research.
Public dialogue projects

Governments are not only interested in funding nanotechnology and polling public opinion about it. They are also starting public dialogue projects to let scientists and lay people discuss about pros and cons of nanotechnology, and to enable the setting of a more societally relevant research agenda. As nanotechnology is among the first areas of research where such public dialogue is started in a very early stage of development, when there are still very few products on the market, these dialogue projects are an experiment in themselves. Mid 2005, such dialogue projects are ongoing in the EU, UK, Germany, the Netherlands and Switzerland. Outside Europe, relevant work is being done in the USA, and at a global level in the project Nano and the Poor organized by the Meridian institute, www.nanoandthepoor.org
4.3 Conclusion

Public perception of nanotechnology is a very important barrier for nanotechnology to be established successfully in society now and in the future.

As showcased in the above sections numerous sources influence the public perception of nanotechnology, some of them stimulate great expectations and some of them will leave great concerns as to ethical issues. But, as with any technology there is nothing basically good or bad about nanotechnology. What matters is what we do with it. Just as, thousands of years ago, our ancestors found that you can use fire to stay warm, sterilise food and make it tastier, so it can also burn people, torch their houses and ruin their crops. The one course that is not open to us is to abandon nanotechnology. It would be similar to banning macrotechnologies because bullets kill people. And, even if you could squeeze the nanogenie back into its little bottle, the opportunities lost by neglecting nanotech could, over the years, kill as many people as using it recklessly would.”

Dr Matsuura discussed at the Nanotech 2004 conference in Boston (March 7-11) that public perception of nanotechnology is perhaps developing along a similar track as with biotechnology “Like those of biotechnology, the first applications of nanotechnology will bring little obvious benefit to consumers. Better, cheaper materials, and hidden manufacturing efficiencies that benefit producers first, are redolent of the “advantages” of biotech—namely reduced applications of agricultural chemicals, which help to keep the cost down while raising yields. Obvious consumer benefits, such as improvements in medicine etc. etc., are further away”.

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5 Economist March 18 2004 Boston
4th Nanoforum Report:

Benefits, Risks, Ethical, Legal and Social Aspects of NANOTECHNOLOGY

Part 5: The Ethical Aspects and Political Implications of Nanotechnology

2nd Edition - October 2005
Part 5: The Ethical Aspects and Political Implications of Nanotechnology

5.1 Introduction

Nanotechnologies have the potential to pervade all aspects of life. This should be seen as desirable, and it is most likely unavoidable. The important question is how we as a global society react to this, control the development, regulate where needed, ensure that the benefits from nanotechnology are available to all and at the same time ensure that public concerns are fully addressed.

This part will examine the ethical aspects and political implications of nanotechnology i.e. what rules or regulations society could or should adopt to govern the development and use of nanotechnologies and how governments and other agencies should administrate these.

From the outset it is clear that the issues associated with the development of nanotechnologies and the impacts these will have on society must be made freely available to everyone in society. This requires a level playing field, which does not mean that everyone must have a degree in nanoscience, but it does mean that the scientists, technologists and industrialists involved must be prepared to discuss their work in language that is accessible to all. Through open and informed debate everyone in society can understand the basic principles behind this “revolution”, and therefore evaluate the risks and benefits more effectively. This will go much of the way to avoid the backlash and misinformation that has been seen with other technological advances such as genetically modified (GM) crops.

5.2 Ethical systems

The Oxford English dictionary defines “ethics” as the moral principles governing or influencing conduct or the branch of knowledge concerned with moral principles. More broadly speaking ethics can be said to be “the set of rules of behaviour applied to a person by a system or institution they participate in”.

According to Chris Phoenix, who authored the paper including this quote, there are at least three ethical systems:

**Guardian** – ensures security and maintains the status quo. Such a system is governed by tradition, loyalty and authority and must be incorruptible.
Commercial – ensures increased value through trade. Such a system is governed by negotiation, competition and industry and must be capable of adapting to new situations. Information – ensures increased knowledge through dissemination. Such a system is governed by honesty, cooperation and idealism and must be freely accessible to all. Healthy societies need all three of these systems to flourish, and for these systems to remain separated at the organizational level. Failure to do so can have disastrous consequences. An example quoted in the paper is of a police department that tried to become more efficient by offering its officers a bonus for making arrests (i.e. mixing guardian and commercial ethical systems), which resulted in an increase in false arrests.

Traditionally, science has fallen into the information ethics system i.e. scientists are motivated by discovery, and while results can be guarded, it is generally accepted that scientists will share information and materials with other scientists. The role of modern science however, is no longer solely that of advancing knowledge. It comprises both academic or public organizations and industrial companies, and, as a result of increased costs for equipment and consumables, these quite different entities are often allied. It is here that conflicts arise - industry by definition falls into a commercial ethics system, which is at odds with the accessibility of information ethics systems.

5.3 What are the ethical considerations of nanotechnology?

In his presentation at the EuroNanoForum conference, Professor Göran Hermerén of Lund University, Sweden, discussed the ethical considerations of nanotechnology. Basically these can be broken down into three parts: what are the risks (based on what we know and what we can deduce); how should this knowledge be shared (freely or only to selected groups) and lastly how to achieve public acceptance and ensure that access to nanotechnologies is equitable.

5.3.1 Risks – known and deduced

It is essential that a mechanism for assessing risk be established that takes account of the relative frequencies of risk and the gaps in our knowledge. It is important therefore that risk assessments are initiated early on to avoid negative imagery e.g. could nanoparticles and other nanomaterials have the same health and environmental impacts as asbestos or CFCs? At the moment the scientific community and current legislation appear to be at odds. On the one
hand we have scientific observations that nanomaterials have improved or markedly different properties to their bulk counterparts. On the other, that their effects on health and the environment have not been adequately studied and are currently assumed to be no different to existing guidelines based on studies of bulk compounds. To answer these questions various Institutes are examining such aspects as the biodegradability of novel nanomaterials and their toxicological effects in animal models (e.g. CBEN in the US are investigating the toxicology and biodegradation of carbon nanotubes and buckyballs).³

Many ethical discourses propound the value of the “Precautionary Principle” which originates from the German “Vorsorge” (meaning “precaution”) and evolved from German clean air environmental policies that were introduced in 1984 at the “First International Conference on the Protection of the North Sea”.⁴ The “Precautionary Principle” was later embodied in the Rio declaration of the UN in 1992 (principle 15) and states that:

“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”⁵ The European Commission has also issued a Communication on the Precautionary Principle.⁶

In the study of potential risks it is important to remember that any risks must be balanced with benefits, and that risks may only present in specific contexts. In certain circumstances inaction itself may lead to a worse outcome, e.g. forcing the development of technologies outside established regulatory bodies.⁷

In addition, it is important to take account of the viewpoints of different cultures and populations that have the potential to be radically different. What may be an acceptable risk to one group may be totally unacceptable to another. In this context one must account for public perception following media exposure i.e. if there is a risk assessment does this mean that there is something wrong? It is wrong to assume that people will automatically respond with suspicion, only if the reasons behind the risk assessments are shrouded in secrecy will this occur. A certain amount of honesty and transparency can provide faith and an understanding of the reasons behind decisions for the general public. In this regard, the Institute for Prospective Technological Studies recently published guidelines for risk management.⁸ Recently, the Swiss Reinsurance company Swiss Re published a report on risk perception of nanotechnology and its implications for the insurance industry. They also raise some interesting issues.⁹
5.3.2 Sharing knowledge

Acceptance of new technologies necessitates an understanding of not only the science behind them, but also the value of this technology to society. Therefore the public must be given sufficient information to make an informed decision. This information should be correct, should not be misleading and must address public concerns, in order to avoid deeply polarised debates. It is well documented that public concerns over scientific ignorance can cause deep mistrust e.g. thalidomide was used in the 1950s and 1960s as a sedative during pregnancy, however potential side-effects were not tested for before use and its effects on foetal development only became apparent later.

All too often we have heard that nanotechnology will cure all diseases, provide cheap energy and reverse the effects of pollution. While this is the belief and aim of many researchers it is often quoted in a Hollywood blockbuster style, with no associated time-tag. It is very easy for scientists to see where the logical progression of research will take us; what is important is conveying this to others that do not have the specific knowledge or language of science. What is often necessary is not to focus on a future development that may have a major and comprehensible impact on society, but to explain and describe the processes in between. Achieving this understanding gives ownership to the audience and promotes a better dialogue between all parties.

A recognition of what is known and what still needs to be determined is therefore essential, and so it is just as important that gaps in knowledge are conveyed to the general public as well as the facts about benefits.

5.3.3 Achieving public acceptance and ensuring equity

There are a number of issues that will affect public acceptance and again these may vary in importance between different societies and populations.

Developments in nanotechnology have the potential to vastly improve the level of patient care and therapy (for example smarter implants that can send patient information remotely to a central computer allowing care in the home or advances in tissue-engineering allowing replacement of defective organs etc) and to provide a safer environment for all in society (for example through enhancements in monitoring and surveillance systems). While ostensibly these should improve disease or injury prognosis, and cut down on crime etc, there are questions of invasion of privacy and sharing of information.
The maintenance of human dignity is firmly rooted in all societies, with most establishing systems to protect vulnerable members such as children, the elderly and the infirm. In all circumstances it should be recognised that individuals have the right to determine what information about them can be disclosed to third parties, and what information can be communicated to them by third parties. As such there must be regulations protecting the individual (especially those most vulnerable) from nanoscale objects, which must be established at the onset and must ensure that mental and physical integrity are not imposed upon without informed consent.

Nanotechnology may have the potential to improve the quality of life, but it can only do so with public acceptance of its validity and value. What must be remembered is that different societies, demographic groups and individuals may have quite different religious and philosophical beliefs, and physical needs. As a result, it is clear that within any society there will be a whole spectrum of feelings pertaining to advances in nanotechnology and their impact on such aspects as: personal integrity; safety and security; the well-being of future generations; health; economic growth; environmental impacts and freedom of research.

The financial costs of technologies will need to be explained carefully to the public in terms of priorities, associated costs, future markets and how such investments compare with other technologies. The people involved with the research, development and ultimate commercialisation of nanotechnologies are groups who all may have different agendas within the expansion of a new technology e.g. cutting-edge research is expensive which often necessitates industrial involvement. However this can lead to controversy over data access, patents, publications and so on. Finally the public will want to know who will have access to the new technology and if it will widen the gap between developed and developing countries.

5.4 The politics of nanotechnology: a balance of power

To consider the politics of managing nanotechnology one has to consider all the parties with a vested interest. These include the developers (scientists and innovators), the investors (industry and finance), the consumers (public) and regulatory organizations (action groups, health and safety, legal bodies). According to Dr Peter Eigen who is the chairperson of the anti-corruption organization “Transparency International”10 the arena of globalization has three players: governments, corporations and civil society, and it is the latter that is increasing in power and influence. Ultimately, it is governments which must initiate the debate and put in place the necessary regulatory bodies that in turn must be made up of experienced and
knowledgeable individuals who must be credibly independent of government influence or commercial interest. Nanotechnology development will require investment, but who will pay for this and how will this be regulated? Investors have one main interest- return on their investment. While this may be “clouded” by moral issues (i.e. many investors will not invest in projects that will result in societal or environmental damage), few investors will put money into a technology that will take many years or decades to pay out (though they may not be deterred by enterprises that have more ambiguous risks associated with them). These issues must be addressed, and this can only be achieved through a balance of power between government, regulatory bodies and industry. To quote MIT Professor Lester Thurow: “Changes in global finance overwhelm all but the largest governments. Governments have lost much of their influence over the movement of information and capital. They cannot control who crosses their borders either physically or culturally…as national governments shrink and global corporations expand, a second major problem emerges. Almost everywhere we look we see rising economic inequalities among countries, among firms, among individuals.”

As a result of the investment required for nanotechnology research and development (R&D), many countries will not be able to fully exploit these advances for the benefit of their citizens, which could result in a “nano-divide” (similar to the “digital divide” caused by advances in information technology). Furthermore, many developing countries rely on natural resources such as metals, minerals and oil for much of their income. Nanotechnology offers the potential to reduce the dependency on these resources or even circumvent their use entirely. While this may have advantages for the environment and, in the long-term, costs, what is considered less is the effect that this decreased dependency will have on the economies of these developing countries. Many a cynic might look at this and suggest that the West is removing its dependency on resources that it lacks, and that this is the driving force behind much of these advances. To address this, developing countries must be engaged in the debate and must be encouraged and assisted in the development of their own nanotechnology programmes that are targeted to issues of key importance to their needs. In addition, when advances in nanotechnologies are envisaged to have dramatic and beneficial effects for global societies, this must be tempered with other measures to offset detrimental effects on other countries’ economies.
5.4.1 Human: machine interface

Probably one of the most contentious issues is the development of the human: machine interface. Society must determine at the earliest stage whether it has the right to enforce new technologies on individuals in any circumstances. Many of the new technologies will aid disease diagnosis and treatment, and as a result improve quality of life: “Although many of the ideas developed in nanomedicine might seem to be in the realm of science fiction, only a few more steps are needed to make them come true, so the “time-to-market” of these technologies will not be as long as it seems today. Nanotechnology will soon allow many diseases to be monitored, diagnosed and treated in a minimally invasive way and it thus holds great promise of improving health and prolonging life. Whereas molecular or personalised medicine will bring better diagnosis and prevention of disease, nanomedicine might very well be the next breakthrough in the treatment of disease.”\(^{13}\) However, there has also been much discussion in the literature about developing nanotechnologies for human “performance enhancement”.\(^ {14}\) This includes improvements to humans in terms of augmenting mental ability, physical strength and engineering interfaces with electronic devices (e.g. control of equipment or communication by direct neural implants). (See also paragraph 4.1 in this report.)

Both aspects of the human: machine nano interface have ethical considerations. In terms of augmenting human performance the key will be whether it will always remain voluntary, or can we imagine a point in time when, to fulfil a work role efficiently, a worker must be “equipped” with a neural implant (e.g. to precisely control a machine)? Even if such implants are only employed on a voluntary and personal basis, what will be the broader implications for society? Will such enhanced individuals become an elite group? Will they be precluded from certain activities (e.g. athletics, as those that use anabolic steroids are now)? Or, will they be actively sought, by certain employers, to the detriment of “normal” individuals? Even the use of nanotechnologies for disease diagnosis and treatment has future ethical implications. DNA analysis and microarray technologies are one example of this. These were pivotal to the success of the human genome project and have continued to develop into highly rapid and sensitive platforms for genetic analysis. Most scientists believe that these advances will bring the cost and time required to sequence the complete genome of an individual within the reach of most clinics. This could allow the screening of individuals for genetic mutations and raises many moral and ethical questions: should a person be told that they have a genetic pre-disposition to a disease that might not affect them until later in life, or
not at all? Should a couple be told that if they have a child that child would have a non-life threatening disorder? Who would ensure that such information if it is obtained is kept strictly confidential and not passed to other parties, such as insurance companies (who then might refuse health or life insurance based on these findings)? Indeed, will it then be a pre-requisite that anyone requiring such insurance must be screened? And following on from that, will this exclude individuals who are unwilling or unable to be screened, from being “full” members of society?

5.4.2 Military use of nanotechnologies

Another major political issue to be considered in the balance of power is how nanotechnologies may affect the military and the future arms race.\textsuperscript{15} Augmenting human performance has obvious attractions, such as improving stamina, strength and the ability to deal with multiple situations and process information more effectively. History also shows us that technology advances have lead to the military developing smaller, more mobile and more powerful weapons, surveillance systems and other military equipment. While these may be developed under the auspices of safeguarding freedom and ensuring security, such devices if they continue to follow current trends could give rise to an arms race similar to that of nuclear weapons. To prevent an escalation there must be internationally agreed regulations. For instance, nanotechnology could one day make surveillance devices and weapons that are virtually undetectable and have advanced remote control capabilities, which raises issues of where the dividing line lies between ensuring security and infringing human rights. As a result, unilateral actions of one country on another could become more targeted and more difficult for the international community to police. Safe-guarding these technologies will be crucial- preventing their sale or distribution to, or theft by, other organizations.

At present the main country publicly declaring that it is developing military uses of nanotechnologies is the US. In 2001 the US invested 125 million USD in nanotechnology initiatives for the Department of Defense (DoD).\textsuperscript{16} The proposed budget for 2005 includes 276 million USD for the DoD and 1 million USD for homeland security (together this is approximately 28% of the total nanotechnology budget). For example, the Institute of Soldier Nanotechnologies (ISN) at MIT was established in 2002 with a five-year 50 million USD contract from the US military and is looking at producing a battle-suit that provides improved protection, monitors vital signs and (at the same time) is lighter than conventional equipment.\textsuperscript{17}
The UK Ministry of Defence (MOD) is also funding some military aspects of nanotechnology including new structural materials, electronic devices and quantum interference, however this is on a much smaller scale (approximately £1.5 million per annum).\textsuperscript{18} This research is mainly carried out through the Defence Evaluation and Research Agency (DERA) and its Corporate Research Programme, although the MOD recognises that close collaboration with academic research is essential to keep abreast of developments in nanotechnology that could have applications in defence.

Sweden is investing 11 million euros over 5 years in nanotechnology research for military purposes through FOI (the Swedish Defence Research Agency). The funding is divided between 7 research projects (involving universities, major defence companies and some high-tech start-up companies) and focussed during the first two years on feasibility studies before entering an application-oriented phase.\textsuperscript{19}

The EU has recently published a call for proposals and supporting activities in the scope of the preparatory action on “the enhancement of the European industrial potential in the field of security research”. While this does not specifically mention nanotechnologies, many of the areas have implicit nanotechnology connections (such as sensors, tracking devices) under the project themes of “Improving situation awareness” and “Protecting against terrorism (including bio-terrorism and incidents with biological, chemical and other substances)”.\textsuperscript{20} There is a budget of 65 million euros from 2004-2006, which is a precursor to a much larger Security Research Programme that will start in 2007.\textsuperscript{21}

### 5.4.3 Lessons from the past and present

It is always useful to learn from previous experience and when one considers nanotechnology there are many parallels with the debate over GM crops. For example in the UK in 2003 a public debate was initiated that highlighted the following concerns:\textsuperscript{22} mistrust over benefits (are these for society or for the multinational companies developing the crops); environmental impacts (both on animal species and possible transfer of genetic material to other plants); health risks (will there be transfer of genetic material to bacteria in the gut); aims of the technology (it appears to be a fix rather than a solution to global health and food problems); lack of understandable discussion from scientists (insufficient, unbiased information for the public to make up their own minds).
There are many ways in which these issues can be addressed in the context of nanotechnology to avoid the pit-falls of the GM debate and also to ensure that those involved in the technology development are fully protected.

5.4.4 Funding social science research

Probably one of the most important mechanisms by which this debate can be seen to have transparency is through the involvement of social scientists that have been specifically trained to research and analyse the societal implications of technological developments. Social science analysis provides a peer-reviewed mechanism by which probable effects can be ascertained by individuals that have an independent and objective stance to those performing the R&D and those making policies. Allied with the approach from the R&D scientists this will allow a balanced and thorough description of the state of the art and future directions for nanotechnologies. Through this many of the questions raised in previous sections could be answered, in particular the impact of nanotechnologies on different social groups. Social science is not however, a discrete discipline and so there are many individuals with skills that will prove invaluable to the effective analysis and communication of developing global policies, what public opinion is and how that is changing, and individuals who will be able to act as arbitrators in the public debate. So for example there are political and economic scientists that have been trained to analyse policy making and can provide clarity to the nature and dynamics of global economies and administrations, and how these will impact each other and future technology developments. There are others experienced in media studies who can offer an insight to the different biases within government, industry and indeed the media itself, which can shape the views and attitudes of society to particular issues. In addition, such individuals can assist in determining the best means by which to communicate new technological developments to society in general. Although this is not an exhaustive list, it goes some way to illustrate the fact that trained and experienced individuals (whether from the physical, life or social sciences) can, if they work together, inform society about what is happening, why it is important, and what the considerations and the long term implications are for nanotechnology developments. Technology has advanced ever more rapidly in the last century and when one considers that nowadays a larger proportion of society (particularly, but not exclusively, in developed countries) are better informed and more willing to question the judgement of authority, then it becomes clear that this “collaboration” between scientists, social scientists and policy makers will aid society as a whole in coming to agreement about
the legislation and regulation of new developments. The European Commission is currently evaluating social science project proposals for Specific Support Actions and Concerted Actions that were submitted in response to a call on the ethical, legal and social aspects of nanotechnology.

5.4.5 Legislation and regulation

Health and safety are paramount. Governments as guardian systems must ensure that the appropriate analyses and regulations are in place to prevent any detrimental effects to human health or the environment. By establishing independent, knowledgeable committees to act upon this prior to the industrialisation of nanotechnologies, this will go much of the way to allay public concerns over new developments and promote confidence that balanced and informed decisions are being taken.

At the other end are the developer and investor. Both require protection of intellectual and commercial rights. Many nanotechnologies will require significant investment to transfer from the laboratory to industrial application. As a result of the multidisciplinary nature of nanotechnology much of this development will involve several groups that could easily be from different universities, institutes or companies. This will require extensive legal agreements and potentially complex patents. In this respect, the Organization for Economic Cooperation and Development (OECD) held a meeting in January 2004 to discuss science and innovation policy. Although this covered all science and technologies, it was recognised that nanotechnology would be one of the key areas of innovation at the start of the 21st century. Intellectual property rights (IPR) were recognised as key to innovation however, while they should protect the rights of the inventor, it was stated that IPR policies should be developed by government agencies that do not stifle technology diffusion into the market. The current state of legislation in the EU is covered in more detail in part 5.

5.5. Conclusions

It is clear that there are a large number of activities worldwide that in principle are setting the stage for informed discussion between all parties. However, what is not clear is whether these discussions will be allowed to take place at a suitable rate for full public understanding and negotiation of where developments should go. The question of ethics is crucial and requires
time: “there is…a difference between simply delivering information on ethics to the public and engaging the public in “ethics talk” about a new technology.”

The management of nanotechnology must involve all three ethical systems (guardian, commercial and information). Many of the advances in nanotechnology will require investment and therefore commerce, however this must not occur in isolation. Advances in surveillance and military uses of nanotechnology for example must be governed by an incorruptible guardian system. Finally it is essential that information about and access to nanotechnology developments is made freely available to all, especially regarding those that give most benefit to humanity.

3 http://www.ruf.rice.edu/~cben/index.shtml
4 http://www.dep.no/md/html/conf/declaration/bremen.html
9 www.swissre.ch
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There’s an old saying: what the farmer doesn't know he doesn't eat. People have always been afraid of the unknown, and this fear has often led to irrational thinking and actions. Basically, the problem is that the public –at least in large parts of Europe - no longer trusts science, and does not believe in the future. Especially, when science leaps forward, ethics and acceptance lag behind. Then people tend to look to the past and take comfort in tradition and in all kinds of irrational beliefs.

But we need to believe in the future to confront the real problems in the world. It is therefore important for us as scientists to explain what we're doing and what it means for society. Scientists have tended to take their social identity for granted, so few have put much effort into promoting it. In my view, science needs to be made glamorous again (as it was in the 1920s and again in the 1960s), so that more young people want to study it and the public understands it better.

Nanoscience and, in particular, nanotechnology, are rapidly gaining public attention due to potentially far-reaching consequences for society. Nanoscience is the ability to measure, predict, construct and control objects on the scale of atoms and molecules, and to make use of the unique properties available at that scale. Nanotechnology involves devices, materials, and processes that embody nanoscience. Neither biomolecular
motors, nor the magnetic layers in the current read/write heads in our computers are nanotechnology in the narrower sense, since in the former there is no external control of the actuation and in the latter there is no lateral control of the atoms in the layer.

Self-assembly and organization, as well as scanning probe microscopy, are currently the most promising approaches in nano-science; they are used to fabricate nanostructures and to characterize and manipulate material on a nano-scale.

**You ain't seen nothing yet**

Nanotechnology is highly interdisciplinary, yet we have only just started to combine physical, chemical, biological and medical concepts. Many projects seek to combine the hard (physical) and the soft (bio-inspired) nano-worlds, for instance in protein-based transistors, proteomics and metabolomics chips, and artificial organels.

Nanotechnology is both an enabling and a disruptive technology, which worries established industries, given their difficulties with extrapolating current concepts to the future. For instance chip and hard-disk developers are almost at the limit of what they can achieve with current technology. Small, dynamic flexible start-up companies are usually in a better position to react to new developments.

As with earlier technologies such as nuclear fission energy, pesticides, (global) positioning systems and GM, it is precisely the power of nanotechnology that gives rise to the risks. For instance, the enhanced reactivity of nano-particles is beneficial in catalysis, but free-floating nano-
particles can be detrimental if they come in contact with organismal tissues. A couple of regulations on this are being prepared and scientists are acting as advisors. However, many regulation gaps have not yet been recognized.

We’ve seen a growing polarization between nano-optimists and nano-pessimists since 2001. This has been fed by the media on the one hand with scenarios such as those presented in science fiction thrillers like Prey [1] and on the other by true progress such as logic components on a molecular level [2] and the synthesis of complex functional bio-agents [3]. The latter really does represent progress because modified viruses can be used e.g. in medical treatments.

The public is confused and sceptical because it cannot assess the probability of scenarios such as the following:

- Nano-electronics could be developed to create ‘smart dust’ of electronic-grains that could be used for communication and surveillance purposes. This scenario raises issues of privacy as well as of pollution control.
- Artificial RNA/DNA sequences that can code for undesired proteins in organisms could be assembled from fragments and use cell biochemistry to function as a messenger or a switch. The possibility of run-away self-replication is usually raised.
- Biotechnological hybrid systems could be implemented to achieve unknown levels of remote-control capabilities (even of human beings), with deep implications for ethical accountability of individuals and a radical transformation of the way warfare (both manned and unmanned) is carried out.

Despite increasing interest in the social and ethical implications of
nanotechnology [see e.g. 4, 5], the dialogue between scientists and the public has not got very far, so acceptance of nanotechnology remains low. Scientists' opinions are governed by their research experience, sensing that progress towards true nano-devices is slow and awkward. The public, however, has the impression that scientists are acting like 'sorcerer’s apprentices' [6], playing with powerful procedures that are little understood, but dangerous and irreversible.

External factors which affect this perception are the widespread airing of irrational views on genetic manipulation and the slow response from politicians with regard to regulation of the abuse of such technologies. All this has exacerbated regressive views among the public.

An exact discipline such as nanophysics has a 'vertical' structure, i.e. without knowing the concepts at level (n-1), it is impossible to understand level n. So scientists must be exceptionally creative when attempting to explain the core issues. The dialogue also suffers from scientists taking too much for granted – scientific concepts have become an unconscious part of their language. They hardly recognize the knowledge gaps and so a conversation can easily degenerate into a slanging match.

**Let's sustain a culture of science**

Another part of the knowledge gap is due to ignorance among the general public. The interest in exact sciences is still disappointingly low in countries such as Germany, the UK and the Netherlands, and the numbers of those pursuing an education in physical sciences are extremely low.

The media, especially the movie industry, has tremendous potential to
develop a better appreciation of the exact sciences. Just look at the way it has improved the general public's understanding of disciplines such as forensics, medicine, law, history and art, and the social sciences. The problem is that Hollywood can make more money by exploiting peoples’ psychological and emotional need to retreat into illusion than by tackling the tough intellectual demands of understanding the world we live in. There is also the problem that the physics presented in movies is often wrong (for instance, explosions in space producing sound).

The extent to which nanotechnology will permeate our daily life will depend on the way in which the interaction of society with nanotechnology develops. There are a number of potential scenarios, all the way from a denial of technology to a technology-driven existence [see e.g. 7]. Where we end up between these two extremes partly depends on scientists’ ability to explain nanotechnology to the public as well as involving wider sections of society in technology assessment studies.

However, since governments are embedded in a global power play, there will always be a tendency to move towards the technology-driven scenario, even if the public does not favour it. This is because international political power depends on economic power. Other forces that shape technology, include funding, consumer choice, and geopolitical events.

Modern life is complex and abstract. People don't acknowledge the science and technology on which their lives depend, because it's invisible (only the user interfaces are visible). We love the devices we use every day, but are ignorant and oblivious of the technology that is needed to produce them. At the research stage in particular, the larger the knowledge gap, the more
everyone is suspicious. That’s more true in Europe and less true in US. This is the challenge facing us as scientists and interpreters of science. We need to make smarter use of the media to reach a wider audience. As a minimum, a modern nation should maintain an appropriate number of research facilities and expert teams on each type of technology in order to be able to react to new developments as well as to the catastrophes that may occur in other countries.

A universal ethical injunction for scientists might be to tackle the hard issues, to expel illusion and fantasy, and present the public with the facts as we know them. These should be communicated in captivating stories, accompanied with realistic, controlled future scenarios [8]. We should convey the wonder of the work we do without avoiding the tough questions about both the good and the ill that it can lead to. While stem cells may offer ways of curing a wide range of currently incurable diseases and handicaps, they can also be used to manipulate human beings in ways that are considered ethically unacceptable. There may well be similar dilemmas surrounding nanoscience and nanotechnology, but we must move the discussion from science fiction to science fact.

[8] Instruments for future scenario reflection should be elaborated jointly by exact nanoscientists and philosophers of science.
[~1400 words]
Abstract:
Nanotechnology could produce a revolutionary wave of innovation upon society. The form such a revolution might take will depend on many things, but certainly includes the context, content and purposes of research projects and agendas decided by existing political and corporate institutions. Lessons from the GMO affair indicate that behaviour of these institutions is at least as important as ‘risk’ in informing public acceptability. This article argues that current research priorities need to shift in favour of environmental and health protection to engender public support, and an ongoing need to remain sensitive to emerging societal preferences.

Introduction

Greenpeace can see that nanotechnology can be used for both good and bad purposes. We believe it is impossible to have a ‘view’ about nanotechnology as a whole because the applications are so broad and uncertainty about the final outcomes. We can see and endorse the possibilities for cheaper solar power, stronger more efficient materials, and possibly efficient energy use and cleaner production processes. However whilst there is much visionary rhetoric about a renewable energy revolution (e.g. http://smalley.rice.edu), much of the advances in nanotech in the energy field seem to be about expanding the use of fossil fuels which cause global warming. Nanotech could be used for military applications promoting a ‘nanotech arms race’ or by social pressure force ‘cures’ on those who don’t want them. It is also likely that as with any new technology, it is impossible at present to identify potential downsides, about which - at the moment - we can only guess.

If one recognises that there is potential for both good and bad how will it be possible to obtain the one without the other – and as a prerequisite agree on what the ‘good’ actually is. These issues are no different for nanotech than for any other part of science and technology - but if nanotech is as revolutionary as many expect then it makes these questions much more important and urgent than in other areas. If nanotech is all hype and no substance then there is no particular reason to attach special weight to the concerns here.

This article seeks to explore first the relationship between technology and society, and especially the wider lessons for nanotech from the GMO debate, then to look at the

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1 See for example possible efficient hydrogen generation from nanocrystaline solar cells, [http://www.hydrogensolar.com](http://www.hydrogensolar.com) and [http://news.bbc.co.uk/1/hi/sci/tech/3536156.stm](http://news.bbc.co.uk/1/hi/sci/tech/3536156.stm)
implications of those lessons for institutional arrangements and funding, and the relationship of science and technology with the public.

It may seem odd to have an article which is concerned with the future looking almost entirely at the present – but the scope of future upsides and downsides from nanotechnology will depend on decisions now. Further, the more radical innovations that nanotech may produce cannot yet be forseen, and the best way to handle this uncertainty and ambiguity is to develop robust social processes. One would not expect good experimental data from badly designed experiments – nor can one expect good social outcomes from dysfunctional social institutions. This is as true for technology’s interaction with society as it is for social welfare and policing.

Nanotechnology and society

The budding nanotechnology community is keen to ‘not make the mistakes of GM’. Well that might be a laudable aspiration but why is it that New Scientist can still say of nanotechnology “the same questions are being asked of it as were asked of GM crops, and once again the answers are not there”? Partly this is about the hazards of nanoparticles (see below) but it is also about the economic and social context for technology development of global multinational companies in an economically liberalised framework combined with rapid technology transfer.

The emerging questions about the relationship between technology and society prompted Greenpeace UK to co-host with the magazine New Scientist and the Royal Institution a series of debates about the limits to, and management of new technology as it relates to society. Our experience was that there was virtually no-one who could give an across-the-board assessment of nanotechnology and other new technologies in terms of their technical possibilities, likely impacts and emerging concerns. We commissioned a report to survey the scene from Imperial College, London.

Whilst identified near- and medium-term developments indicated uptake in certain sectors like IT, it remains too early to say with certainty what products would emerge that would be ‘revolutionary’ at least in the way that nanotech has sometimes been described. It was feasible to identify some potential issues including the development of a ‘nano-divide’, the destructive potential of nanotechnology and the new hazards that might emerge from nanoparticles. Nanoparticles provide the first case study of the receptiveness of nanotech policy formulators to respond to outside perspectives. See Box

In the longer term a bigger challenge for the nanotech policy community than dealing with nanoparticles will be to devise processes to integrate perspectives of a wider community of ‘users’ and the lay public where not all relevant aspects of the issues are known and understood. This may seem a curious need, but will be required if the lessons of the biotech controversies are to be understood and taken on board. And to do this requires an understanding of what those lessons actually are whilst recognising that nanotechnology is very different in terms of scope and possibilities from GMOs.
Lessons from the GMO debates

GMOs had a relatively long period of broadly positive media coverage across Europe from the end of the 1980s through to the mid-1990s\(^1\), and initial GM food offerings in UK were being accepted onto the market - proponents might have thought that ‘acceptance was going well’. In reality the deeper structural and institutional problems of biotech development were crucial to the scepticism with which it was later treated.

The most comprehensive analysis of public disquiet over the prospect of GM food is from the Public Perceptions of Biotechnology in Europe project (PABE) which looked at underlying public concerns in 5 countries; France, Germany, Italy, Spain and the UK. To the surprise of researchers the scepticism seemed to have origins in similar attitudes despite national cultural differences. The attitudes were not driven by ‘risk’ in the scientifically understood sense of hazard and probabilities, but were much more about institutional and cultural responsibilities. The researchers summarised public scepticism in the form of questions that were being asked – see Box. And they stated that “[predominantly] concerns expressed... were mostly based on empirical lay knowledge about the past behaviour of institutions responsible for the development and regulation of technological innovations and risks”\(^12\) This is a crucial understanding if the concerns of the public are to be properly met. It is not just the narrowly defined safety of the products that is at issue, but responsibility being taken for those products, and the choice of developments in the first place. In this case the concern was – with considerable justification – that GM crops were being used to extend a model of agriculture that was industrialised and out of keeping with other kinds of food production and manufacture. Yet frequently public concerns about GM food were described as being irrational fear about small risks\(^13\).

What can be learnt from this about potential public acceptance (or not) for nanotechnologies? Clearly the point about institutional responsibility (for which read Government, companies, and research establishments generally) is relevant to nanotech – what are the attributes of ‘the system’ into which new products and processes will emerge? Do they have public sympathy or not? Could new products act as ‘lightning conductors’ for wider concerns about the general thrust of economic and social developments? Can appropriate choice of product development mitigate these concerns? If so, how can the proper choice of developments, through R&D programmes, be made to happen?

Some clues have emerged from work in the UK over the past few years. The role of public values in setting ‘standards’ for institutional and corporate behaviour, and the need to treat such values with respect, has been recognised for some time\(^14\). In 2000 the House of Lords Science and Technology Committee\(^15\) urged a ‘dialogue’ between science and the public, promoting two-way communication rather than the didactic style previously favoured, on the basis that science was suffering a crisis of confidence at the public level. However it is a less well known report from University of Lancaster\(^16\) that has the most direct lessons for nanotech, as the authors point out that new technologies have their own ‘social constitutions’ and factors such as distribution of expertise, location of benefits, and availability of choices determine the likelihood of willing acceptance, so that a contrast can be drawn sharply between IT technologies and GMOs.
What drives nanotechnology? And what should?

Given these clear lessons about how GM technology developed and concerns not being simply about ‘GMOs’ but how it was developed, it is disappointing that predominantly debates about nanotechnology from Governments have been dominated by the simple metric of amount of money being put into nanotechnology for international competitiveness reasons – not whether it is being spent on the right things or whether the proposed science and technology developments carry a broader public support. A debate in UK Parliament about nanotechnology\textsuperscript{17}, and a select committee report\textsuperscript{18} that preceded it, contained essentially no mention of these. Clearly the quantity of money being invested in nanotech development is important, but characterising the success of innovation policy only in this way it is rather like deciding on the success of a trip to the supermarket purely on the basis of the weight of goods acquired. Similarly the UK 10-year strategy on science and technology investment framework\textsuperscript{19} and the EU Communication on nanotech\textsuperscript{20} tend towards a one-dimensional view of technology development with gestures towards public involvement and safety issues. In each case there are sections and sentences that seem quite innovative but overall the documents convey an impression of surging ahead in the funding race with the public (or ‘consumers’) as an afterthought or as a problem to be sorted out later. This kind of approach is definitely not taking on board the lessons from the GM controversies which requires a root and branch rethink of what is being researched and to what ends.

Significant amounts of the science and fundamental research under the banner of ‘nanotechnology’ is too speculative to fit into a box which has its potential use written on the lid. But there is a great deal that has some intention of a particular end use behind it. Perhaps every research result that can be written into a news report that reads “Scientists have revealed a new breakthrough that might one day mean that…..” fits into this second category. Because whenever research is begun or carried through with these end goals in mind it begs questions about why those goals were deemed priorities above other possible uses for the research cash, other ways of using the same science, or other ways of solving the problem the research is ostensibly addressing. Not to mention the question of who decided what to pursue and why. Shouldn’t the chosen end goals of these research priorities be something that is open to public scrutiny, debate and prioritisation? Or at least be justified against some direct determinations of public and societal aspirations in the area?

If public sector science is to be responsive to the aspirations of the public (who are, after all, paying for it) then research programmes should be mindful of what society is broadly seeking. Some of the social and environmental aspirations held widely by the public are pretty well known. It is now well established that there is a demand for clean, renewable energy\textsuperscript{21} and that there is a preference for public health interventions over drug treatment when people become ill\textsuperscript{22}. There is a clear mandate to search out how new science and technology, like nanotech, can contribute. Whether these goals are getting priority amongst new nanotech funding is quite hard to determine but there is little to indicate that they are.

The need for a more direct determination of public values has led several commentators to argue that engagement with the public needs to move ‘upstream’,\textsuperscript{23} The mechanisms could be through consensus conferences or citizens’ juries or other
mechanisms. Although finding the correct one at the correct time will not always straightforward, the most important thing is a receptiveness to the outputs from these processes by those who will still be charged with taking the decisions on what research is actually supported. This will mean prioritising some areas of research and, by implication, stopping others. If that receptiveness is not present, public dialogue processes will do little other than stir up cynicism.

For those sceptical of upstream public engagement consider the outputs from the first UK consensus conference held a decade ago, and before GM food was a term familiar to even media correspondents. The consensus conference panel said that there needed to be labelling of GM food, choice available to consumers, that the ethics and priorities of developing countries need to be taken into account, that patenting needed to be re-examined because of the advantages it gives multinational organisations, that Government should be doing research to maximise benefits to all rather than leaving it to companies. Tellingly they cited expected benefits of GM crops that are still not in prospect. Think how different the GM food debate in Europe might have been if those recommendations had been enacted. Instead when GM food arrived on a large scale they were ignored.

Conclusions

The prospects for controversies over nanotechnology are very dependent on the uses to which it is put. Addressing the underlying governance issues will be key. One of the most intelligent ways to address this is to dedicate further research to widely shared goals that are amenable to technological innovation like climate change and to take on board the lessons from a real engagement with public concerns. For those involved in scientific policy making and funding this may be uncomfortable but as recently pointed out “we cannot carry on ignorantly lurching from one mess to the next”.

Anyone who argues that this limits scientific freedom should note that this prioritisation happens already – it’s just that the decision-making is generally unaccountable and hidden.
The hazards of nanoparticles have been known for over a decade – since the identification of ultrafine airborne particles as a major cause of mortality and morbidity in urban environments. However the causal mechanism for these health outcomes is not well understood, nor (entirely) its relevance to the health threat of synthetic nanoparticles which may – or may not – behave differently compared to the nanoparticles of the existing atmospheric burden which are largely a by-product of combustion processes. As a scientific evaluation exercise, understanding the health and environmental impacts of nanoparticles is a formidable cross-disciplinary challenge. The state of understanding has recently been reviewed. However as a policy exercise regulation of nanoparticles is a relatively familiar exercise – it is about what to permit when there is plausible cause for concern and considerable scientific uncertainty about impacts; where should responsibility lie, who should take the lead in getting answers, where should liability lie etc. In that sense it is similar to the policy on chemical regulation with respect to endocrine disruption, or that of the impact of low-level radiation exposure.

Recently there has been a significant recognition of the need for some form of regulation – from the EU Commission and from the Royal Society/Royal Academy of Engineering report on nanotechnology commissioned by UK Government. UK Government has essentially accepted that there are new toxicology issues.

Currently personal exposure to nanoparticles will be dominated by those derived from the by-products of combustion. However dispersive uses of nanoparticles are growing. For example they are already being used in sunscreens (Titanium dioxide) and clothing (silver oxide). A fuel additive (4nm cerium oxide) is being used in 1000 diesel buses across the UK to improve fuel efficiency, although the fate of the nanoparticles is unknown. Whilst relatively slow to appreciate the potential problem in the first instance, the nanotech community is now experiencing growing calls for legislation to minimise or prevent exposure to nanoparticles. The jury is still out on whether such response to these calls will be seen as a welcome opportunity to demonstrate responsibility or generate obfuscation, denial and delay.
Box – Questions from public about GM crops and food arising from public attitude research across 5 countries

- Why do we need GMOs? What are the benefits?
- Who will benefit from their use?
- Who decided that they should be developed and how?
- Why were we not better informed about their use in our food, before their arrival on the market?
- Why are we not given an effective choice about whether or not to buy and consume these products?
- Do regulatory authorities have sufficient powers and resources to effectively counter-balance large companies who wish to develop these products?
- Can controls imposed by regulatory authorities be applied effectively?
- Have the risks been seriously assessed? By whom? How?
- Have potential long-term consequences been assessed? How?
- How have irreducible uncertainties and unavoidable domains of ignorance been taken into account in decision-making?
- What plans exist for remedial action if and when unforeseen harmful impacts occur?
- Who will be responsible in case of unforeseen harm? How will they be held to account?

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Nanotechnology – A New Field of Ethical Inquiry?

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Keywords: ethics of technology, nanotechnology, risks, equity, privacy, enhancement of human beings

ABSTRACT: Parallel to the public discussion on the benefits and risks of nanotechnology, a debate on the ethics of nanotechnology has begun. It has been postulated that a new “nano-ethics” is necessary. In this debate, the – positive as well as negative – visionary and speculative innovations which are brought into connection with nanotechnology stand in the foreground. In this contribution, an attempt is made to discover new ethical aspects of nanotechnology in a more systematic manner than has been the case. It turns out that there are hardly any completely new ethical aspects raised by nanotechnology. It is much rather primarily a case of gradual shifts of emphasis and of relevance in questions which, in principle, are already known and which give reason for ethical discussions on nanotechnology. In a certain manner, structurally novel ethical aspects arise through the important role played by visions in the public discourse. New questions are also posed by the fact that previously separate lines of ethical reflection converge in the field of nanotechnology. The proposal of an independent “nano-ethics”, however, seems exaggerated.

1. Introduction

In view of the revolutionary potential attributed to nanotechnology,1,2 it is not surprising that this technology has found great interest in the media and in the public at large. Ethical, legal, and social implications (ELSI) are already being elaborated by commissions and study groups. Ethical reflection on nanotechnology has, in fact, already coined new terms such as “nano-ethics”,3,4 but has, to date, hardly
accomplished more than to proclaim a need for ethics in and for nanotechnology. The ethical aspects discussed in the – to the present, few – treatises are much rather evidence of a tentative approach to a relatively new field of science and technology than of systematic analysis. Criteria for determining why certain topics, such as self-replicating nanorobots or nanoparticles, should be ethically relevant are not given. The normative fuzziness of unclear criteria joins the cognitive fuzziness caused by a lack of knowledge of the real possibility of the technical innovations concerned. The result, as the working hypothesis of this contribution has it, discloses, above all, a diffuse uneasiness regarding rapid scientific advances in nanotechnology.

In view of this situation, the purpose of this contribution consists primarily in studying current and foreseeable developments in nanotechnology from the viewpoint of ethics. Which developments are ethically relevant? Are there ethical questions which have already been answered by current discussions in the ethics of technology or in bioethics? Are there developments which pose completely new questions? To this end, it is necessary – besides inquiry into the present state of the discussion – to look for criteria for deciding when something is ethically relevant (sec. 2). These criteria are then applied to the field of nanotechnology, and the ethical challenges are “mapped out” (sec. 3). This is done on the basis of an evaluation of the current literature, and of pertinent references on the Internet. After answering the question on the necessity of nano-ethics (sec. 4), comments are subsequently made on the role to be played by ethics in the further development of nanotechnology.

2. Ethics for Nanotechnology – Relevance Criteria

It has been controversial for quite some time whether science and engineering have any morally relevant content at all (and could therefore be a subject of ethical reflection). Into the 1990's, technology was held to be value-neutral. In numerous case studies, however, the normative background of decisions on technology (even those made in the laboratory) have since been recognized and made a subject of reflection. The basic assumption of this development is not to see technology solely as a sum of abstract objects or processes, but to take its embeddedness in societal processes seriously. Technology is not nature, and does not originate of itself, but is consciously produced to certain ends and purposes – namely, to bring something about which wouldn’t happen of itself. Technology is therefore always embedded in societal goals, problem diagnoses, and action strategies. In this sense, there is no “pure” technology, i.e. a technology completely independent of this societal dimension.

Normative aspects of science and technology, in a morally pluralistic society, unavoidably lead to societal debates at the least, and often also to conflicts over technology. As a rule, what is held to be desirable, tolerable, or acceptable is controversial in society. Open questions and conflicts of this type in the context of science and technology are the point of departure for the ethics of technology. Technology conflicts are, as a rule, not only conflicts over technological means (e.g., in questions of efficiency), but are also conflicts over visions of the future, of concepts of humanity, and on views of society. The role of the ethics of technology consists of
analysis of the normative structure of technology conflicts and the search for rational, argumentative, and discursive methods of resolving them.

Even if technology is basically beset with values, most of the technically relevant decisions can be classified as the “standard case” in the following sense: they don’t subject the normative aspects of the basis for the decision (criteria, rules or regulations, goals) to specific reflection, but assume them to be given for the respective situation, and accept the frame of reference they create. In such cases, no explicit ethical reflection is, as a rule, necessary, even if normative elements self-evidently play a vital role in these decisions – the normative decision criteria are clear, acknowledged, and unequivocal. It is then out of the question that this could be a case of conflict with moral convictions or a situation of normative ambiguity – the information on the normative framework can be integrated into the decision by those affected and by those deciding on the basis of axiological information, without analyzing it or deliberating on it. The (national and international) legal regulations, the rules of the relevant institutions (e.g., corporate guidelines), where applicable, the code of ethics of the professional group concerned, as well as general societal usage, are elements of this normative framework.

The requirements to be set in the normative framework in order that it can be accepted as a “standard case” can be operationalized according to the following criteria:

- **Pragmatic completeness**: the normative framework has to treat the decision to be made fully with regard to normative aspects;
- **Local consistency**: there must be a “sufficient” measure of consistency between the normative framework’s elements;
- **Unambiguity**: among the relevant actors, there must be a sufficiently consensual interpretation of the normative framework;
- **Acceptance**: the normative framework must be accepted by those affected as the basis for the decision;
- **Compliance**: the normative framework also has to be complied with in the field concerned.

There are such well-established “standard” situations in many fields (e.g., in decision-making processes in public administration or in private businesses). Technical innovations and scientific progress, however, can challenge such situations by presenting new questions or by shaking views previously held to be valid. This is then the entry point for ethical reflection in questions of science and engineering, for the explicit confirmation, modification, or augmentation of the normative framework.

Whether there are new challenges for ethics in nanotechnology and what they might be, will be investigated against this background below. In order to clarify the question of ethical relevance, an examination of the topics treated in previous papers judged on the basis of systematic criteria for the ethical relevance of science and technology was carried out.
The guiding questions in this study were:

- Which are the ethical aspects in the sense defined above, especially which are the genuine ethical aspects in the subjects for ethics in nanotechnology named in current publications?
- Is relevant and sufficiently evident knowledge available for the assessment of scientific and technical developments in nanotechnology or of their use (as addressed with regard to ethics)?
- Which of the ethical aspects of nanotechnology are specific for nanotechnology?

This method permits a clear determination of the questions to which ethical reflection can make a real contribution. It then also permits an estimation about to what extent an independent “nano-ethics” would be justified. The resulting “map” of ethical aspects described below is a survey of the use of nanotechnology as regards aspects of content, and includes partially overlapping fields of content. These fields have the fact in common that nanotechnology will play a constitutive role in the foreseeable advances in their areas.

3. Ethical Aspects of Nanotechnology

In practical philosophy and in ethics, nanotechnology has to date seldom been made a subject of discussion. [NT = nanotechnology]: “While the number of publications on NT per se has increased dramatically in recent years there is very little concomitant increase in publications on the ethical and social implications to be found.”

Some postulate a need for ethics and make reference, above all, to remote visions (for example, the abolition of aging or “runaway nanorobots”). Certain terms, such as privacy, man-machine relationship, or equity are often cited (e.g., ). Systematic studies, which could do justice to the diversity and breadth of nanotechnology, haven’t yet been presented. At the same time, concern over the detrimental consequences of this deficit grows: “The lack of dialogue between research institutes, granting bodies and the public on the implications and directions of NT may have devastating consequences, including public fear and rejection of NT without adequate study of its ethical and social implications.”

3.1 Nanoparticles – Opportunities versus Risks

A vast potential market for nano-based products is seen in the field of new materials. By means of an admixture or specific application of nanoparticles, some new properties of materials can be brought about, for instance, in surface treatment. If making new technical functions and performance factors is a common motivation for scientific and technological progress, ethical questions on these advances pose themselves as the “classical” question of the possible side effects of these developments.
Artificially produced nanoparticles can be disseminated into the environment or enter the human body as emissions during production or by the daily use of products including nanoparticles. Nanoparticles could eventually be transported as aerosols over great distances and be distributed diffusely. They could enter the human body by way of the lungs, through the skin, or the digestive tract. How they interact in spreading, their impact on health and on the environment, in particular, potential long-term effects, are at present almost unknown. This applies also and above all for substances which don’t occur in the natural environment, such as fullerenes or nanotubes. As far as the potential proliferation of nanoparticles is concerned, aspects such as mobility, reactivity, persistence, lung infiltration, solubility in water, etc., have to be taken into consideration.

Questions of toxicity for the environment and for humans, on nano-material flow, on their behavior in spreading throughout various environmental media, on their rate of degradation, and their consequences for the various conceivable targets are, however, not ethical questions. In these cases, the pertinent empirical-scientific disciplines, such as toxicology or environmental chemistry, are competent. Their results would be of interest from the viewpoint of ethics as soon as the available empirical facts can be consulted to establish which practical consequences they have for working with nanoparticles:

- What follows from our present lack of knowledge about the possible side effects of nanoparticles? One radical consequence, namely, a moratorium on putting nanoparticles onto the market, as it would probably follow from Hans Jonas’s ethics of responsibility according to the priority of the negative prognosis, has already been demanded.

- More generally formulated: is the precautionary principle relevant in view of a lack of knowledge, and what would follow from the answer?

- Which role do the – doubtlessly considerable – opportunities of nanoparticle-based products play in considerations of this sort? According to which criteria can judgement of benefits and hazards be based when the benefits are (relatively) concrete, but the hazards are hypothetical?

- Are comparisons of the risks of nanoparticles with types of risk known from other areas possible, in order to learn from them? Can criteria for assessing the nanoparticle-risks be gained from experience in developing new chemicals or medicines? Which normative premises enter into such comparisons?

- Is the discussion on threshold values and environmental standards transferable to nanoparticles? What about the acceptability or tolerability of risks? Which methods of determining critical values come into question, and how do they relate to ethical questions or questions of democratic theory?

The contribution of ethics to this subject therefore lies in a value judgement of the situation (relationship of reliable knowledge to the degree of uncertainty), to
clarification of the comparability to other types of risk, and by disclosing the normative presuppositions and implications entering into it, as well as to the normative basis for practical consequences. These questions of the acceptability and comparability of risks, the advisability of weighing up risks against opportunities, and the rationality of action under uncertainty are, without doubt, of great importance in nanotechnology. A new field of application is developing here for the ethics of science and technology; the type of questions posed, however, is well-known from other discussions of risks (exposure to radiation; chemicals).

3.2 Sustainability: Just Distribution of Opportunities and Risks

Possible side effects of nanotechnology of a completely different type result from considerations of equity. In particular, in connection with sustainability are ethical questions of the distribution of opportunities for the use of as well as the spatial and temporal distribution of the opportunities and risks of nanotechnology: ‘Nanotech offers potential benefits in areas such as biomedicine, clean energy production, safer and cleaner transport and environmental remediation: all areas where it would be of help in developing countries. But it is at present mostly a very high-tech and cost-intensive science, and a lot of the current research is focused on areas of information technology where one can imagine the result being a widening of the gulf between the haves and the have-nots’. In this respect, we have to distinguish between intragenerational and intergenerational aspects.

The distribution of the use of natural resources between present and future generations belongs to the intergenerational aspects. Appreciable relief for the environment is expected from the use of nanotechnology: savings of material resources, reduction of the incidence of environmentally detrimental by-products, improvement of the efficiency of energy transformation, reduction of energy consumption, and the elimination of ecologically deleterious materials from the environment. Decisive for the assessment of nanotechnology or of product lines based on nanotechnology from the viewpoint of sustainability is that technology accumulates positive and negative contributions to sustainability throughout its entire “lifetime”, which extends from the primary sources of raw materials via transportation and processing to consumption, and finally ends with their disposal as waste. The entire life cycle of a technology is therefore decisive for the assessment of the technology’s sustainability. But nanotechnology is at present in many branches still in an early phase of development. For this reason, we can only speak of nanotechnology’s sustainability potentials. There is no guarantee that technical sustainability potentials will turn out to be real contributions to sustainable development. The discussion of sustainability potentials can, however, be employed constructively with regard to technological development, if further development is accompanied by ethical reflection on questions of distribution between present and future exploitation of nature.

Intragenerational problems of distributive justice present themselves basically in every field of technical innovation. Because scientific and technical progress requires considerable investments, it usually takes place where the greatest economic and
human resources are already available. Technical progress increases existing inequalities of distribution. This can be illustrated on the example of nanotechnology in medicine.\textsuperscript{18} Nanotechnology-based medicine will, in all probability, be expensive medicine. Questions of equity and of access to (possible) medical treatments could become urgent in at least two respects: within industrialized societies, existing inequalities in access to medical care could be exacerbated by a highly technicized medicine making use of nanotechnology, and – with regard to less developed societies – because likewise, already existing and particularly dramatic inequalities between technicized and developing nations could be still further increased. Apprehensions with regard to both of these types of a potential “nano-divide” (after the well-known “digital divide”) are based on the assumption that nanotechnology can not only lead to new and greater options for individual self-determination (e. g., in the field of medicine), as well as to considerable improvement of the competitiveness of national economies. Current discussions on distributive justice on the national and on the international level (in the context of sustainability as well) are therefore likely to gain new relevance with regard to nanotechnology.

Both of the aspects described are, however, not really new ethical aspects of technology, but are rather intensifications of problems of distribution already rife. Problems of equity belong in principle to the ethical aspects of modern technology.

3.3 The Private Sphere and Control

Another field regularly mentioned among the ethical aspects of nanotechnology is the threat to privacy through new monitoring- and control technologies.\textsuperscript{3,20} Nanotechnology offers a range of possibilities for gathering, storing, and distributing personal data to an increasing extent. In the course of miniaturization, a development of sensor and memory technology is conceivable which, unnoticed by its “victim”, drastically increases the possibilities for acquiring data.\textsuperscript{3} Furthermore, miniaturization and networking of observation systems could considerably impede present control methods and data protection regulations, or even render them obsolete. For the military, new possibilities for espionage are opened.\textsuperscript{21} Passive observation of people could, in the distant future, be complemented by actively manipulating them – for instance, if it would be possible to gain direct technical access to their nervous system or brain.

These scenarios are regarded by some to be not only realistic, but even certain: “But what is not speculation is that with the advent of nanotechnology invasions of privacy and unjustified control of others will increase.”\textsuperscript{3} Underlying this opinion is an only thinly veiled technological determinism: “When new technology provides us with new tools to investigate and control others we will use them.”\textsuperscript{3}

Within the private sphere, health is a particularly sensitive area. The development of small analyzers – the “lab on a chip” – can make it possible to compile comprehensive personal diagnoses and prognoses on the basis of personal health data. Stringent standards for data protection and for the protection of privacy therefore have to be set. Without sufficient protection of their private sphere, people are rendered
manipulable, their autonomy and freedom of action are called in question.1(p.363ff.) The “lab-on-a-chip”-technology can facilitate not only medical diagnoses, but can also make fast and economical comprehensive screening possible (op. cit.). The rapid decoding of complete individual genetic dispositions can come within the reach of normal clinical work or of clinic-external services. Everyone could let him- or herself be tested, for example, for genetic dispositions for certain disorders – or could be urged by his/her employer or insurance company to do so. In this manner, individual persons could find themselves put under social pressure, their freedom of action would be impaired. In addition, it would have to be clarified, how one has to deal with results which possibly depress the patients affected over longer periods of time, fearing the impending outbreak of a serious disease (which possibly never occurs). How to deal with – presumably sometimes considerable – uncertainties of diagnoses is, in this connection, also an important aspect.

Questions of privacy, of monitoring and controlling people are doubtlessly ethically relevant. The current discussions on restricting civil liberties for the sake of combatting terrorism are taking place against a background in which normative criteria play a pivotal role, and in which there are conflicts over this subject. On the other hand, the political dimension of these questions stands prominently in the foreground, for instance, on estimations of the immediacy of the danger and on statements on the assumed problem-solving capacity of measures proposed. If it should come to an endangerment of the private sphere through nanotechnology, the ethical dimension would be more tangible. And nonetheless, it would even in this case be more likely to be kept in the background, while the central discussion would certainly much rather be concerned with the context of data protection, in which we have already gained considerable experience.

But all of these questions of monitoring and of data protection are not posed exclusively by nanotechnology. Even without nanotechnology, observation technologies have reached a remarkable stage of development which poses questions on the preservation of the private sphere. Even today, so-called smart tags, based on RFID-technology (Radio Frequency Identification), are being employed for access control, as ticketing, e. g., in public transportation and in logistics. These objects have at present a size of several tenths of a millimetre in each dimension, so that they are practically unnoticeable to the naked eye. Further miniaturization will permit further reduction in size and the addition of more functions – without nanotechnology being needed –, but nanotechnology will promote and accelerate these developments.

The ethically relevant questions on a right to know or not to know, on a personal right to certain data, on a right to privacy, as well as the discussions on data protection and on possible undesirable inherent social dynamisms, and, in consequence, of a drastic proliferation of genetic and other tests, have been a central point in the bio- and medical-ethical discussions for quite a while. Nanotechnological innovations can accelerate or facilitate the realization of certain technical possibilities, and therefore increase the urgency of the problematic of the consequences; in this area, however, they don’t give rise to qualitatively new ethical questions.
3.4 Crossing the Border between Technology and Life

Basic life processes take place on a nano-scale, because life’s essential building-blocks (such as proteins, for instance) have precisely this size. By means of nanotechnology, biological processes are made nanotechnologically controllable. Molecular “factories” (mitochondria) and “transport systems”, which play an essential role in cellular metabolism, can be models for controllable bio-nanomachines. Nanotechnology on this level could permit the “engineering” of cells. An intermeshing of natural biological processes with technical processes seems to be conceivable. The classical barrier between technology and life is increasingly being breached and crossed. One speaks of elements of living organisms in classical mechanics’ language: as factories, rotors, pumps, and reactors.

This is, at first glance, a cognitively and technically extremely interesting process, with a great deal of promise. The technical design of life processes on the cellular level, direct links and new interfaces between organisms and technical systems portend a new and highly dynamic scientific and technological field. Diverse opportunities, above all, in the field of medicine, stimulate research and research funding. New ethical aspects are certainly to be expected in this field. Their concrete specification, however, will only be possible when research and development can give more precise information on fields of application and products. The corresponding discussions of risks could have structural similarities to the discussion on genetically modified organisms. It could come to discussions about safety standards for the research concerned, about “field trials”, and release problems. The danger of misuse will be made a topic of debate, such as, for example, technically modifying viruses in order to produce new biological weapons. A wide range of future ethical discussions is opening, for which at present there is insufficient practical background for concrete reflection. In this field of nanotechnology (not in that of the nanoparticles, [sec. 3.1]), similar developments concerning resistance in society could be feared as in the case of genetic engineering.

A new area that is practically as well as ethically interesting consists of making direct connections between technical systems and the human nervous system. There is intensive work on connecting the world of molecular biology with that of technology. An interesting field of development is nanoelectronic neuro-implants (neurobionics), which compensate for damage to sensory organs, or to the nervous system, or increase the performance capacity of these organs and broaden the spectrum of human perception. Microimplants could restore the functions of hearing and eyesight. Even today, simple cochlear or retina implants, for example, can be realized. With progress in nanoinformatics, these implants could approach the smallness and capabilities of natural systems. Because of these undoubtedly positive goals, ethical reflection could, in this case, concentrate above all on the definition and prevention of misuse. Technical access to the nervous system, because of the possibilities for manipulation and control which it opens, is a particularly sensitive issue.

Extrapolating these lines of development into the realm of speculation, the convergence of technology and humanity, the conceivability (in the sense of a pure
thought possibility) of “cyborgs” as technically enhanced humans or humanoid technology could be problematized.¹ Developments of this type raise the question of humanity’s self-concept, which is of great ethical relevance. In nanotechnological visions, aspects repeatedly occur which blur the boundary between what human beings are and what they create with the help of technical achievements and applications. Such visions pose the question, to what extent technical or partly technical can partly biologically-constructed man-machine chimeras lay claim to the status of a person. An entire spectrum of anthropological and ethical questions follows from out of this question aspect. In some US-American churches – in contrast to the Transhumanism discussion – precisely this aspect of nanotechnology is a central theme. Nanotechnology acts as a playing-field on which various philosophies of life compete.

In spite of the speculative nature of the subject, ethical reflection doesn’t seem to be premature. One needn’t see the main concentration of nanotechnology’s ethical aspects in this area, but one can certainly find enough indications that scientific and technical progress will intensify the – at present, non-existent – urgency of these questions in the coming years. In particular, advances in brain science and developments in “converging technologies”² lead to this expectation – and would justify ethical reflection “in advance”. But the insight that the questions raised aren’t really specific for nanotechnology also applies here. Since the 1980’s, these subjects have been repeatedly discussed in the debates on artificial intelligence and on artificial life.

3.5 The Improvement of the Human Being

With the transgression of the boundary between technology and living beings from both sides, our understanding of what distinguishes human beings and which relationship mankind assumes to be its natural physical and psychic constitution is also called into question. Within the tradition of technical progress that has, at all times, transformed conditions and developments – which, until then, had been taken as given, as unalterable fate – into influenceable, manipulable, and formable conditions and developments, the human body and its psyche are rapidly moving into the dimension of the Formable. The vision of “enhancing human performance” has been conjured up, above all, in the field of “converging technologies”.¹

If the wish to “improve humanity” – probably in view of the experience of the cultural and social deficits of “real human beings” – has been expressed often in history, the approach of bringing about these improvements by technical means – assuming that this is realizable – is apparently new (science fiction, as a rule, doesn’t lay any claim to future realizability). Formerly, improvement utopias were founded rather on the basis of “soft” methods – above all, upbringing and education. Technology had its place outside of human beings, as a means of augmenting mankind’s capacities for action. Technical enhancement of human beings themselves – if this would be possible at all – would in any case pose a series of new ethical questions.
Nanotechnology, in combination with biotechnology and medicine, opens perspectives for fundamentally altering and rebuilding the human body. At present, research is being done on tissue and organ substitution, which could be realized with the help of the nano- and stem cell technologies. Nanoimplants would be able to restore human sensory functions or to complement them, but they would also be able to influence the central nervous system. While the examples of medical applications of nanotechnology cited remain within a certain traditional framework – because the purpose consists of “healing” and “repairing” deviations from an ideal condition of health, which is a classical medical goal –, chances (or risks) of a remodelling and “improvement” of the human body are opened up. This could mean extending human physical capabilities, e.g., to new sensory functions (for example, broadening the electromagnetic spectrum the eye is able to perceive). It could, however, also – by means of the direct connection of mechanical systems with the human brain – give rise to completely new interfaces between man and machine, with completely unforeseeable consequences. Even completely technical organs and parts of the body (or even entire bodies) are being discussed, which, in comparison with biological organisms, are supposed to have advantages such as – perhaps – increased stability against external influences.

There are initial anthropological questions of our concept of humanity and of the relationship between humanity and technology.11 With them, however, and at the same time, the question poses itself, how far human beings can, should, or want to go in remodelling the human body, and to what end(s) this should or could be done. The difference between healing and enhancing interventions is on conceptual grounds – in particular the terms “health” and “illness” haven’t been clarified to date – and for practical reasons, a gradual approach would be prudent.22

The improvement of mankind could also include the postponement of death. According to the definition of health formulated by the World Health Organization (WHO), according to which health is a “state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity” (Charter of the WHO), aging could also be interpreted as a disorder. Overcoming aging with the help of nanotechnology would, then, in the sense of medical ethics, be nothing other than fighting epidemics or other diseases. Aging “as a disease” would be combatted medically as if it were the flu. Seen against the background of continuing and controversial discussions on the concept of illness in medical theory and in medical ethics, this is, however, not undisputed. Whether aging as a process and death are, in principle, acknowledged as a predetermined initial condition of human existence, and should only be made subject to medical treatment in their extreme expression, or whether aging and death are seen as conditions which are, whenever possible, to be abolished, depends on fundamental normative presuppositions, which, in view of the conflicts connected with them, are of great ethical relevance.3

Possible answers from ethics could, according to the respective school of thought, turn out quite differently. Liberal eugenics based on utilitarian ethics could draw the conclusion that it doesn’t acknowledge any difference between therapeutic and enhancing interventions and leave “the choice of purposes of interventions which alter
characteristic traits to individual preferences”, Kantian ethics would thematize the instrumentalization of human beings, religious morals would bring traditional human self-concepts (which are deeply rooted in culture) as a limited being (in time as well) to bear.

The practical relevance of such ethical questions in view of a – at least in the eyes of some protagonists – possible technical improvement of human beings (with the substantial participation of nanotechnology) may, at first sight, seem limited. Two considerations, however, contest this estimation: first, the vision of the technical enhancement of human beings is actually being seriously advocated. Research projects are being planned in this direction, and milestones for reaching this goal are being set up, whereby nanotechnology takes on the role of an “enabling technology”. Furthermore, technical enhancements are by no means completely new, but are – in part – actually established, as the example of plastic surgery as a technical correction of physical characteristics felt to be imperfections shows, and as is the case in the practice of administering psycho-active substances. It isn’t difficult to predict that the possibilities and the realization of technical improvements of human beings will increase; demand is conceivable. In view of the moral questions connected with this development and of their conflict potential, ethical reflection is needed in this field.

4. Is an Independent Nano-Ethics Necessary?

Nonetheless, we don’t have to reckon with a “Nano-ethics” as a new branch of applied ethics. The propagation of nano-ethics overlooks the fact that many of the ethical questions raised by nanotechnology are already known from other contexts of ethical reflection. The ethics of technology, bioethics, the ethics of medicine or also the theoretical philosophy of technology concern themselves with questions of sustainability, of risk assessment, of the interface between human beings and technology, especially between living beings and technology. These questions are in themselves not new, as the analyses of the individual formulations of the problematic definitions have shown.

Partially new, however, is their convergence in nanotechnology. Analogous to the well-known fact that nanosciences and nanotechnology are fields in which the traditional borders between physics, chemistry, biology, and the engineering sciences are crossed, various traditional lines of ethical reflection also converge in ethical questions in nanotechnology. The fashionable creativity in coining terms, as it precipitates itself in designations like “Neurophilosophy” or “Nano-ethics”, obscures the integrative and cross-sectional nature of many ethical challenges, rather than being particularly helpful. We don’t need any new sub-discipline of applied ethics called “nano-ethics” but because new topics and questions are concentrated in nanotechnology and because it accelerates scientific and technical progress, there is a need for ethics in and for nanotechnology. Presupposition is, in particular, willingness on the part of the ethicists for an open reflection on ethical aspects of nanotechnology beyond the scope of classical “hyphenated ethics” and to a dialogue with natural and engineering scientists.
5. Ethics as Concomitant Reflection of Nanotechnology

Ethics often seems to lag seriously behind technical progress and to fall short of the occasionally great expectations. The rapid pace of innovation in technicization has the effect that ethical deliberations often come too late; after all of the relevant decisions have already been made, when it is far too late to influence the course of technology development. Technological and scientific progress shapes reality which can no longer be revised after certain points of no return. Ethics in this perspective, could, at best, act as a repair service for problems which have already arisen.

The above is, however, a one-sided view. Ethics actually can provide orientation in the early phases of innovation, e.g., because even the scientific and technical basis includes certain risks which are ethically unacceptable. The opinion that one has to wait with ethical reflection until the corresponding products are on the market and have already caused problems can easily be refuted. This is because the technical knowledge and capabilities are known, as a rule, long before market entry, and can, with the reservation of the well-known problems of the uncertainty of predicting the future, be judged as to their consequences and normative implications. Due to nanotechnology’s early stage of development (many prefer to call it nanoscience), we have here a rare case of an advantageous opportunity: there is the chance and also the time for concomitant reflection, as well as the opportunity to integrate the results of reflection into the process of technology design, and thereby to contribute to the further development of nanotechnology.

These considerations don’t necessarily mean that ethical deliberations have to be made for absolutely every scientific or technical idea. The problems of a timely occupation with new technologies appear most vividly in the diverse questions raised by the visions of salvation and horror as regards nanotechnology. What sense is there in concerning oneself hypothetically with the ethical aspects of an extreme lengthening of the human life-span, or with self-replicating nanorobots? Most scientists are of the opinion that these are speculations which stem much rather from the realm of science fiction than from problem analysis which is to be taken seriously. We shouldn’t forget that ethical reflection binds resources, and there should therefore be a certain evidence for the realizability of these visions, if resources are to be invested in them which could then be lacking elsewhere. Ethical reflection is not necessary “in advance”, nor just for the sake of the intellectual diversion it provides. In this respect, we need our own “vision assessment”.

Ethical reflection and policy advice built on it are neither senseless nor premature in early phases of development if there are realistic possibilities for the practicability of the technology concerned. Then, there are possibilities for designing ethical assessments as concomitant processes of technological development. If, at first, only rather abstract considerations on the lines of technological development are possible, valuable advice for the further path of development can nonetheless already be given (e.g., by means of timely allusions to potential technology conflicts and to methods of de-escalation). Further, ethical judgement makes orientation for planning the process of technological development possible (for example, with regard to questions of
equity). In the course of the continuing development of possibilities for the application
of nanotechnology, it is then possible to continuously develop the – initially abstract –
estimations and orientations on the basis of newly acquired knowledge and, finally, to
carry out an ethically-based technology assessment: “Nanoethics is not something one
can complete satisfactorily either first or last but something that needs to be continually
updated.”

The added value in comparison with a later start for ethical reflection is obvious;
even the process of technological development profits from the assessment of the
consequences, and ethics avoids “coming too late”, which it is occasionally accused of
doing. Technology assessment and ethics have the responsibility, in view of the rapid
and momentous developments in nanotechnology, to make the societal process of
learning which is always connected with the introduction of a new technology as
constructive, transparent, and effective as possible by means of timely investigation
and reflection.

* This contribution is based partially on considerations made by the author as a member of the
study group “Nanotechnology” of the European Academy Bad Neuenahr-Ahrweiler. This study

group will present the entire report of its results in 2005.

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COMPLEXITY AND UNCERTAINTY

A PRUDENTIAL APPROACH
TO NANOTECHNOLOGY

Jean-Pierre Dupuy
March 2004

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1 A contribution to the work in progress of the “Foresighting the New Technology Wave” High-Level Expert Group, European Commission, Brussels.
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SUMMARY

We have become capable of tampering with, and triggering off, complex phenomena. As a consequence we have to confront a new kind of uncertainty. The "Precautionary Principle" is of little help in that task. Anticipating the consequences of our technological choices is at the same time more important and more difficult than ever. What is desperately required is a novel science of the future.
TABLE OF CONTENTS

1. The debate about molecular manufacturing
2. Complexity and Self-organization
3. Unchaining Complexity
4. A new kind of uncertainty and the irrelevance of the Precautionary Principle
5. Toward a new science of the future
   5.1. In Search of an Ethics of the Future
   5.2. A Critique of the Scenario Approach
   5.3. From Occurring Time to Projected Time
   5.4. Conclusion. Exploring the set of projected equilibria as a substitute for the scenario approach
1. The debate about molecular manufacturing

Eric Drexler, the inventor of the notion of nanotechnology, and Christine Peterson, the President of the Foresight Institute, are notoriously keen to make the distinction between "near-term nanotechnology" and "advanced nanotechnology". The former refers to any technology smaller than microtechnology, e.g. nanoparticles; the latter to "complete control of the physical structure of matter, all the way down to the atomic level." It is of course advanced nanotechnology, also known as molecular manufacturing, that will have major societal impact and possibly entail major risks, provided that ... it will see the light of day.

As is well known, controversy is still raging about the physical, technical, industrial, economical feasibility of molecular manufacturing. As Peterson puts it, "Until this issue has been put to rest, neither a funded molecular manufacturing R&D project nor effective study of societal implications can be carried out. [...] We urgently need a basic feasibility review in which molecular manufacturing's proponents and critics can present their technical cases to a group of unbiased physicists for analysis."  

In July 2003, the UK Economic and Social Research Council published a report entitled "The Social and Economic Challenges of Nanotechnology". It pointed to the current debate "about whether the radical view of nanotechnology, leading to molecular manufacturing, is feasible or practical, whether by the route sketched out by Drexler or some other means. Those who consider this radical view of nanotechnology to be feasible are divided as to whether it will lead to a positive or negative outcome for society. This debate takes for granted that nanotechnology will have a revolutionary effect on society, and the contrasting visions are correspondingly utopian or dystopian."

On 18 November 2003, the US Senate passed the 21st Century Nanotechnology Research and Development Act, "to authorize appropriations for nanoscience, nanoengineering and nanotechnology research, and for other purposes". It called for a one-time study on the responsible development of nanotechnology "including, but not limited to, self-replicating nanoscale machines or devices; the release of such machines in natural environments; encryption; the development of defensive technologies; the use of nanotechnology in the enhancement of

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3 Christine Peterson, a testimony given before the U.S. House of Representatives Committee on Science, April 9, 2003.
4 Ibid.
human intelligence; and the use of nanotechnology in developing AI.\textsuperscript{5} Many have interpreted this as an opportunity and a challenge to those who support Drexler’s vision of molecular manufacturing to make their case, or even as an endorsement of the feasibility of that program. In contrast, the studies performed by the UK’s Royal Society/Royal Academy of Engineering are still wondering what nanotechnology is all about, without the least mention of molecular manufacturing.

Richard Smalley, the Nobel laureate in chemistry who was one of the discoverers of the fullerene (C\textsubscript{60}), has been challenging Eric Drexler on the possibility of molecular manufacturing. Recently the former accused the latter of scaring children with stories of self-replicating nanobots going haywire, and the latter replied by saying, "U.S. progress in molecular manufacturing has been impeded by the dangerous illusion that it is infeasible. [...]Building with atomic precision will dramatically extend the range of potential products and decrease environmental impact as well. The resulting abilities will be so powerful that, in a competitive world, failure to develop molecular manufacturing would be equivalent to unilateral disarmament."\textsuperscript{6}

The debate between the two men has also been quite technical, and it is all about the limitations of chemistry. Smalley asserts that atoms cannot simply be pushed together to make them react as desired, in the manner fancied by Drexler, but that their chemical environment must be controlled in great detail, through a many-dimensional hyperspace, and that this cannot be achieved with simple robotics. Drexler rejoins that such components of cells as enzymes or ribosomes are able to do precise and reliable chemistry. Smalley agrees but adds that this can occur only under water. Drexler replies that his proposal does assert that chemistry in dry surfaces and a vacuum ("machine-phase chemistry") can be quite flexible and efficient, since holding a molecule in one place can have a strong catalytic effect. Drexler ends his statements by calling for further research, beginning with an independent scientific review of molecular manufacturing concepts.

An advocate of Drexler's program recently wrote:

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\textsuperscript{5} My emphasis.
\textsuperscript{6} "Nanotechnology. Drexler and Smalley make the case for and against 'molecular assemblers'", \textit{Chemical & Engineering News}, December 1, 2003. See \url{http://pubs.acs.org/cen/coverstory/8148/8148counterpoint.html}.  

Failure to anticipate the development of molecular manufacturing could have serious consequences. Simple physics theories, conservatively applied, predict that the technology will be dangerously powerful. A working molecular nanotechnology will likely require the design and enforcement of policies to control the use of compact advanced manufacturing systems and their products. But panicked last-minute policy will be bad policy—simultaneously oppressive and ineffective. The military implications are even more perilous. Molecular manufacturing systems are expected to be able to produce weapons as powerful as nuclear bombs, but much more selective, easier to manufacture, and easier to use. If a powerful nation suddenly realizes that molecular manufacturing is possible, and discovers that rival nations are already making material progress, they may react violently, or may enter into an arms race that will probably be unstable and thus may result in war with weapons of unprecedented power.

On the positive side, molecular manufacturing may be able to mitigate many of the world's humanitarian and environmental crises. Advancing its development by even a year or two could alleviate untold suffering, raising standards of living worldwide while sharply reducing our environmental footprint. However, rapid and effective humanitarian use may also depend on sound policy developed well in advance.\(^7\)

My opinion on this is the following. The Smalley – Drexler debate is a red herring, and we should refrain from taking a position about it, even if we had the scientific and technological expertise to do so. There is no doubt that molecular manufacturing is feasible once we regard molecular biology itself as a form of it. The issue is not one of essence but of point of view. As soon as we construe the cell as natural machinery, the possibility of tampering with it becomes a forgone conclusion. If the feasibility of molecular self-assembly is beyond question, it is because we have developed a view of nature and the living system that is akin to our own artifacts.

2. Complexity and Self-organization

It is often asserted that the starting point of nanotechnology was the classic talk given by Feynman in 1959\(^8\), in which he said: "The principles of physics, as far as I can see, do not speak against the possibility of maneuvering things atom by atom. [...] It would be, in principle, possible (I think) for a physicist to synthesize any chemical substance that the chemist writes down. Give the orders and the physicist synthesizes it. How? Put the atoms down where the chemist says, and so you make the substance." Today's champions of nanotech add: "We need to apply at the molecular scale the concept that has demonstrated its effectiveness at the macroscopic scale: making parts go where we want by putting them where we want!\(^9\)"

I tend to disagree. If such were the essence of (advanced) nanotechnology, the worries that it raises would rest on sheer ignorance. As Nature science writer Philip Ball puts it in his excellent essay, "2003: nanotechnology in the firing line"\(^10\):

In March [2003], the Royal Institution (RI) in London hosted a day-long seminar on nanotech called “Atom by atom”, which I personally found useful for hearing a broad cross-section of opinions on what has become known as nanoethics. [...] First, the worry was raised that what is qualitatively new about nanotech is that it allows, for the first time, the manipulation of matter at the atomic scale. This may be a common view, and it must force us to ask: how can it be that we live in a society where it is not generally appreciated that this is what chemistry has done in a rational and informed way for the past two centuries and more? How have we let that happen? It is becoming increasingly clear that the debate about the ultimate scope and possibilities of nanotech revolve around questions of basic chemistry [...]. The knowledge vacuum in which much public debate of nanotech is taking place exists because we have little public understanding of chemistry: what it is, what it does, and what it can do.

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8 "There's Plenty of Room At the Bottom".
10 Nanotechweb.org, December 2003. [http://www.nanotechweb.org/articles/society/2/12/1/1](http://www.nanotechweb.org/articles/society/2/12/1/1)
Writing about nanoethics, Ball goes on to say:

Questions about safety, equity, military involvement and openness are ones that pertain to many other areas of science and technology. It would be a grave and possibly dangerous distortion if nanotechnology were to come to be seen as a discipline that raises unprecedented ethical and moral issues. In this respect, I think it genuinely does differ from some aspects of biotechnological research, which broach entirely new moral questions. Yet it is perhaps the first major field of science, applied science or technology - call it what you will - to have emerged in a social climate that is sensitized in advance to the need for ethical debate in emerging technologies.

[...] Yet the pragmatic truth is that if nanotechnology does not acknowledge some kind of ethical dimension, it will be forced upon it in any case. Those working in the field know that nanotech is not really a discipline at all, that it has no coherent aims and is not the sole concern of any one industrial sector. But even funding agencies speak of it as though this were not so. To the public mind, organizations such as the US National Nanotechnology Initiative surely suggest by their very existence that nanotech has some unity, and it is therefore quite proper that people will want to be reassured that its ethical aspects are being considered.

Here I cannot follow Philip Ball. I believe him to be wrong on two major accounts. I believe there is indeed some kind of unity behind the nanotech enterprise and even behind the NBIC convergence; but that this unity lies at the level of the metaphysical research program that underpins such convergence. I also believe that the ethical issues raised by it are to a large extent novel and that they find their source in the very ideas that govern the field.

In order to substantiate those two claims, I submit that the origin of the new field is to be sought in another classic conference, the one John von Neumann gave at Caltech in 1948 on complexity and self-reproducing automata.

Turing's and Church's theses were very influential at the time, and they had been supplemented by cyberneticians Warren McCulloch and Walter Pitts' major finding on the properties of neural networks. Cybernetics'
Credo was then: every behavior that is unambiguously describable in a finite number of words is computable by a network of formal neurons---a remarkable statement, as John von Neumann recognized. However, he put forward the following objection: is it reasonable to assume as a practical matter that our most complex behaviors are describable in their totality, without ambiguity, using a finite number of words? In specific cases it is always possible: our capacity, for example, to recognize the same triangular form in two empirical triangles displaying differences in line, size, and position can be so described. But would this be possible if it were a matter of globally characterizing our capacity for establishing "visual analogies"? In that case, von Neumann conjectured, it may be that the simplest way to describe a behavior is to describe the structure that generates it. It is meaningless, under these circumstances, to "discover" that such a behavior can be embodied in a neural network since it is not possible to define the behavior other than by describing the network itself.

Von Neumann thus posed the question of complexity, foreseeing that it would become the great question for science in the future. Complexity implied for him in this case the futility of the constructive approach of McCulloch and Pitts, which reduced a function to a structure---leaving unanswered the question of what a complex structure is capable.\textsuperscript{11}

It was of course in the course of his work on automata theory that von Neumann was to refine this notion of complexity. Assuming a magnitude of a thermodynamical type, he conjectured that below a certain threshold it would be degenerative, meaning that the degree of organization could only decrease, but that above this threshold an increase in complexity became possible. Now this threshold of complexity, he supposed, is also the point at which the structure of an object becomes simpler than the description of its properties. Soon, JVN prophesied, the builder of automata would find himself as helpless before his creation as we feel ourselves to be in the presence of complex natural phenomena.\textsuperscript{12}

At any rate, JVN was thus founding the so-called bottom-up approach aka reverse engineering. In keeping with that philosophy, the engineers of the future will not be any more the ones who devise and design a structure

\textsuperscript{11} Here as elsewhere, the irony of intellectual history is great. Marvin Minsky, who wrote his doctoral thesis under von Neumann, regarded his teacher's attack on McCulloch's approach as an aberration, an admission of weakness, a lack of faith in what he himself, John von Neumann, had managed to accomplish. Now, as is well known, Eric Drexler wrote his dissertation on nanotech under Minsky's supervision!

\textsuperscript{12} On all that, see my \textit{The Mechanization of the Mind}, Princeton University Press, 2000.
capable of fulfilling a function that has been assigned to them. The engineers of the future will be the ones who know they are successful when they are surprised by their own creations. If one of your goals is to reproduce life, to fabricate life, you have to be able to simulate one of its most essential properties, namely the capacity to complexify itself always more.

Admittedly, not all of nanotech falls under the category of complexity. However, the scope covered by it, especially in the case of the NBIC convergence, is much wider and relevant than the implications of a possible Drexler-type molecular manufacturing. Even more importantly, the novel kind of uncertainty that is brought about by those new technologies is intimately linked with their being able to set off complex phenomena in the Neumannian sense.

3. Unchaining Complexity

"The unleashed power of the atom has changed everything save our modes of thinking, and we thus drift toward unparalleled catastrophe." Albert Einstein

It would be a mistake to think that, although novel, our current situation before the consequences of our technological choices is not the outcome of a long historical process. Discontinuities and ruptures must always be analyzed against the background of continuous dynamics. In her masterly study of the frailties of human action, *Human Condition*\(^\text{13}\), Hannah Arendt brought out the fundamental paradox of our time: as human powers increase through technological progress, we are less and less equipped to control the consequences of our actions. A long excerpt is worth quoting here, as its relevance for our topic cannot be overstated – and we should keep in mind that this was written in 1958:

[... ] the attempt to eliminate action because of its uncertainty and to save human affairs from their frailty by dealing with them as though they were or could become the planned products of human making has first of all resulted in channeling the human capacity for action, for beginning new and spontaneous processes which without men never would come into existence, into an attitude toward nature which up to the latest stage of the modern age had been one of exploring natural laws and fabricating objects out of

\(^{13}\) The University of Chicago Press, 1958.
natural material. To what extent we have begun to act into nature, in the literal sense of the word, is perhaps best illustrated by a recent casual remark of a scientist who quite seriously suggested that "basic research is when I am doing what I don't know what I am doing." [Wernher von Braun, December 1957].

This started harmlessly enough with the experiment in which men were no longer content to observe, to register, and contemplate whatever nature was willing to yield in her own appearance, but began to prescribe conditions and to provoke natural processes. What then developed into an ever-increasing skill in unchaining elemental processes, which, without the interference of men, would have lain dormant and perhaps never have come to pass, has finally ended in a veritable art of 'making' nature, that is, of creating 'natural' processes which without men would never exist and which earthly nature by herself seems incapable of accomplishing [...].

The very fact that natural sciences have become exclusively sciences of process and, in their last stage, sciences of potentially irreversible, irremediable 'processes of no return' is a clear indication that, whatever the brain power necessary to start them, the actual underlying human capacity which alone could bring about this development is no 'theoretical' capacity, neither contemplation nor reason, but the human ability to act – to start new unprecedented processes whose outcome remains uncertain and unpredictable whether they are let loose in the human or the natural realm.

In this aspect of action [...] processes are started whose outcome is unpredictable, so that uncertainty rather than frailty becomes the decisive character of human affairs14.

No doubt that with an incredible prescience this analysis applies perfectly well to the NBIC convergence, in particular on two scores. Firstly, the ambition to (re-) make nature is an important dimension of what I called the metaphysical underpinnings of the field. If the NBIC converging technologies purport to take over Nature's and Life's job and become the

engineers of evolution, it is because they have redefined Nature and Life in terms that belong to the realm of artifacts. See how one of their most vocal champions, Damien Broderick, rewrites the history of life, or, as he puts it, of "living replicators":

*Genetic algorithms* in planetary numbers lurched about on the surface of the earth and under the sea, and indeed as we now know deep within it, for billions of years, replicating and mutating and being winnowed via the success of their expressions – that is, the bodies they *manufactured*, competing for survival in the macro world. At last, the entire living ecology of the planet has *accumulated, and represents a colossal quantity of compressed, schematic information*.\(^{15}\)

Once life has thus been transmogrified into an artifact, the next step is to ask oneself whether the human mind couldn't do better. The same author asks rhetorically, "Is it likely that nanosystems, designed by human minds, will bypass all this 'Darwinian wandering, and leap straight to design success'?\(^{16}\)

Secondly, as explained before, it will be an inevitable temptation, not to say a task or a duty, for the nanotechnologists of the future to set off processes upon which they have no control. The sorcerer's apprentice myth must be updated: it is neither by error nor by terror that Man will be dispossessed of his own creations but by design.

There is no need for Drexlerian self-assemblers to come into existence for this to happen. The paradigm of *complex, self-organizing systems* envisioned by von Neumann is stepping ahead at an accelerated pace, both in science and in technology. It is in the process of shoving away and replacing the old metaphors inherited from the cybernetic paradigm, like the ones that treat the mind or the genome as computer programs. In science, the central dogmas of molecular biology received a severe blow on two occasions recently. First, with the discovery that the genome of an adult, differentiated cell can be "reprogrammed" with the cooperation of maternal cytoplasm – hence the technologies of nucleus transfer, including therapeutic and reproductive cloning. Secondly, with the discovery of prions, which showed that self-replication does not require

\(^{16}\) Ibid., p. 118.
DNA. As a result, the sequencing of the human genome appears to be not the end of the road but its timid beginning. Proteinomics and Complexity are becoming the catchwords in biology, relegating Genomics to the realm of passé ideas.

In technology, new feats are being flaunted every passing week. Again, the time has not come – and may never come – when we manufacture self-replicating machinery that mimics the self-replication of living materials. However, we are taking more and more control of living materials and their capacity for self-organization and we use them to mimic smart machinery or perform mechanical functions.

Examples are plenty. To name just a few: in December 2003, IBM managed to create silicon memory chips using a template provided by a plastic polymer that organizes itself naturally. One application of the technology could be to design flash memory chips with cells roughly 1/100th the size of the cells currently required to store a piece of data. More broadly, IBM said, "the successful research suggests that polymer-based self-assembly techniques could be used to build other kinds of microchips in the future, when more features shrink to such small scales that current production techniques become impractical". On the same month, scientists from DuPont, the University of Illinois at Urbana-Champaign and the MIT used the self-assembly of DNA to sort carbon nanotubes according to their diameter and electronic properties. DuPont said, “spontaneous self-assembly of nucleic acid bases occurs on a variety of inorganic surfaces. This phenomenon, considered as an important prebiotic process relevant to the origin of life, has led us to seek a new function for nucleic acids in the manipulation of inorganic nanomaterials, where interfacial interactions dominate.” The feat will have momentous applications, since “the separation of carbon nanotubes is the single greatest impediment to their technological application.” Last November, scientists in Israel built transistors out of carbon nanotubes using DNA as a template. A Technion-Israel scientist said, "What we've done is to bring biology to self-assemble an electronic device in a test tube [...] The DNA serves as a scaffold, a template that will determine where the carbon


nanotubes will sit. That's the beauty of using biology. And so on and so forth.

4. **A new kind of uncertainty and the irrelevance of the Precautionary Principle**

Our tampering with, and setting off complex processes, in the technical, Neumannian sense of the word "complex", brings about a kind of uncertainty that is radically novel. In particular, it is completely alien to the distinctions upon which rests the Precautionary Principle.

The precautionary principle introduces what initially appears to be an interesting distinction between two types of risks: "known" risks and "potential" risks. It is on this distinction that the difference between prevention and precaution is made to rest: precaution would be to potential risks what prevention is to known risks.

A closer look reveals 1) that the expression "potential risk" is poorly chosen, and that what it designates is not a risk waiting to be realized, but a hypothetical risk, one that is only a matter of conjecture; 2) that the distinction between known risks and hypothetical risks (the term I will adopt here) corresponds to an old standby of economic thought, the distinction that John Maynard Keynes and Frank Knight independently proposed in 1921 between risk and uncertainty. A risk can in principle be quantified in terms of objective probabilities based on observable frequencies; when such quantification is not possible, one enters the realm of uncertainty.

The problem is that economic thought and the decision theory underlying it were destined to abandon this distinction as of the 1950s in the wake of the exploit successfully performed by Leonard Savage with the introduction of the concept of subjective probability and the corresponding philosophy of choice under conditions of uncertainty: Bayesianism. In Savage's axiomatics, probabilities no longer correspond to any sort of regularity found in nature, but simply to the coherence displayed by a given agent's choices. In philosophical language, every uncertainty is treated as an *epistemic* uncertainty, meaning an uncertainty associated with the agent's state of knowledge. It is easy to see that the

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The introduction of subjective probabilities erases the distinction between uncertainty and risk, between risk and the risk of risk, between precaution and prevention. If a probability is unknown, a probability distribution is assigned to it "subjectively". Then the probabilities are composed following the computation rules of the same name. No difference remains compared to the case where objective probabilities are available from the outset. Uncertainty owing to lack of knowledge is brought down to the same plane as intrinsic uncertainty due to the random nature of the event under consideration. A risk economist and an insurance theorist do not see and cannot see any essential difference between prevention and precaution and, indeed, reduce the latter to the former. In truth, one observes that applications of the "precautionary principle" generally boil down to little more than a glorified version of "cost-benefit" analysis.

Against the prevailing economism, I believe it is urgent to safeguard the idea that all is not epistemic uncertainty. One could however argue from a philosophical standpoint that such is really the case. The fall of a die is what supplied most of our languages with the words for chance or accident. Now, the fall of a die is a physical phenomenon that is viewed today as a low-stability deterministic system, sensitive to initial conditions, and therefore unpredictable — a "deterministic chaos," in current parlance. But an omniscient being — the God of whom Laplace did not judge it necessary to postulate the existence — would be able to predict on which side the die is going to fall. Could one not then say that what is uncertain for us, but not for this mathematician-God, is uncertain only because of lack of knowledge on our part? And therefore that this uncertainty, too, is epistemic and subjective?

The correct conclusion is a different one. If a random occurrence is unpredictable for us, this is not because of a lack of knowledge that could be overcome by more extensive research; it is because only an infinite calculator could predict a future which, given our finiteness, we will forever be unable to anticipate. Our finiteness obviously cannot be placed on the same level as the state of our knowledge. The former is an unalterable aspect of the human condition; the latter, a contingent fact, which could at any moment be different from what it is. We are therefore right to treat the random event's uncertainty for us as an objective uncertainty, even though this uncertainty would vanish for an infinite observer.

Now, our situation with respect to the complex phenomena we are about to unleash is also one of objective, and not epistemic, uncertainty. The novel feature this time is that we are not dealing with a random
occurrence either. Neither random, nor epistemically uncertain, the type of "risk" that we are confronting is a monster from the standpoint of classic distinctions. Indeed, it merits a special treatment, which the precautionary principle is incapable of giving it.

We know today that what makes a complex system, (e. g. a network of molecules connected by chemical reactions or a trophic system) robust is exactly what makes it exceedingly vulnerable if and when certain circumstances are met. As Albert-László Barabási puts it, this "coexistence of robustness and vulnerability plays a key role in understanding the behavior of most complex systems. [...] topology, robustness, and vulnerability cannot be fully separated from one another. All complex systems have their Achilles' heel. Complexity gives those systems an extraordinary stability and a no less remarkable resilience. They can hold their own against all sorts of aggressions and find ways of adapting to maintain their stability. This is only true up to a certain point, however. Beyond certain tipping points, they veer over abruptly into something different, in the fashion of phase changes of matter, collapsing completely or else forming other types of systems that can have properties highly undesirable for people. In mathematics, such discontinuities are called catastrophes. This sudden loss of resilience gives complex systems a particularity which no engineer could transpose into an artificial system without being immediately fired from his job: the alarm signals go off only when it is too late. And in most cases we do not even know where these tipping points are located. Our uncertainty regarding the behavior of complex systems has thus nothing to do with a temporary insufficiency of our knowledge, it has everything to do with objective, structural properties of complex systems.

On the other hand, this uncertainty is not of the kind that is attached to random events and it is not amenable to the concept of probability. The key notion here is that of informational incompressibility, which is a form of essential unpredictability. In keeping with von Neumann's intuitions on complexity, a complex process is defined today as one for which the simplest model is the process itself. The only way to determine the future of the system is to run it: there are no shortcuts. This is a radical uncertainty: in contrast with a deterministic chaos – the source of randomness –, perfect knowledge of the initial conditions would not be enough to predict the future states of the system. Its unpredictability is irremediable.

When the precautionary principle states that the "absence of certainties, given the current state of scientific and technical knowledge, must not delay the adoption of effective and proportionate preventive measures aimed at forestalling a risk of grave and irreversible damage to the environment at an economically acceptable cost", it is clear that it places itself from the outset within the framework of epistemic uncertainty. The presupposition is that we know we are in a situation of uncertainty. It is an axiom of epistemic logic that if I do not know p, then I know that I do not know p. Yet, as soon as we depart from this framework, we must entertain the possibility that we do not know that we do not know something. An analogous situation obtains in the realm of perception with the blind spot, that area of the retina unserved by the optic nerve. At the very center of our field of vision, we do not see, but our brain behaves in such a way that we do not see that we do not see. In cases where the uncertainty is such that it entails that the uncertainty itself is uncertain, it is impossible to know whether or not the conditions for the application of the precautionary principle have been met. If we apply the principle to itself, it will invalidate itself before our eyes.

Moreover, "given the current state of scientific and technical knowledge" implies that a scientific research effort could overcome the uncertainty in question, whose existence is viewed as purely contingent. It is a safe bet that a "precautionary policy" will inevitably include the edict that research efforts must be pursued — as if the gap between what is known and what needs to be known could be filled by a supplementary effort on the part of the knowing subject. But it is not uncommon to encounter cases in which the progress of knowledge comports an increase in uncertainty for the decision-maker, something that is inconceivable within the framework of epistemic uncertainty. Sometimes, to learn more is to discover hidden complexities that make us realize that the mastery we thought we had over phenomena was in part illusory.
5. Toward a new science of the future

"We have met the Enemy and He is Us."
Pogo Possum

5.1. In Search of an Ethics of the Future

German philosopher Hans Jonas's fundamental work, *The Imperative of Responsibility*\(^{21}\), cogently explains why we need a radically new ethics to rule our relation to the future in the "technological age". This "Ethics of the Future" [*Ethik für die Zukunft*] - meaning not a future ethics, but an ethics for the future, for the sake of the future, i.e. the future must become the major object of our concern – starts from a philosophical aporia. Given the magnitude of the possible consequences of our technological choices, it is an absolute obligation for us to try and anticipate those consequences, assess them, and ground our choices on this assessment. Couched in philosophical parlance, this is tantamount to saying that when the stakes are high, we cannot afford not to choose consequentialism\(^{22}\), rather than a form of deontology\(^{23}\), as our guiding moral doctrine. However, the very same reasons that make consequentialism compelling, and therefore oblige us to anticipate the future, make it impossible for us to do so. Unleashing complex processes is a very perilous activity that both demands foreknowledge and prohibits it. To take just an illustration:

The unpredictable behaviour of nanoscale objects means that engineers will not know how to make nanomachines until they actually start building them\(^{24}\).

Now, one of the very few unassailably universal ethical principles is that *ought* implies *can*. There is no obligation to do that which one can not do. However, in the technological age, we do have an ardent obligation that we cannot fulfill: anticipating the future. That is the ethical aporia.

Is there a way out? Jonas's credo, which I share, is that there is no ethics without metaphysics. Only a radical change in metaphysics can allow us

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\(^{22}\) Consequentialism as a moral doctrine has it that what counts in evaluating an action is its consequences for all individuals concerned.
\(^{23}\) A deontological doctrine evaluates the rightness of an action in terms of its conformity to a norm or a rule, such as the Kantian categorical imperative.
\(^{24}\) *The Economist*, March 2003.
to escape from the ethical aporia. The major stumbling block of our current, implicit metaphysics of temporality turns out to be our conception of the future as indeterminate. From our belief in free will – we might act otherwise – we derive the conclusion that the future is not real, in the philosophical sense: "future contingents", i.e. propositions about actions taken by a free agent in the future, e.g. "John will pay back his debt tomorrow", are held to have no truth value. They are neither true nor false. If the future is not real, it is not something that we can have cognizance of. If the future is not real, it is not something that projects its shadow onto the present. Even when we know that a catastrophe is about to happen, we do not believe it: we do not believe what we know. If the future is not real, there is nothing in it that we should fear, or hope for.

The derivation from free will to the unreality of the future is a sheer logical fallacy, although it would require some hard philosophical work to prove it. Here I will content myself with exhibiting the sketch of an alternative metaphysics in which free will combines with a particularly hard version of the reality of the future.

Before I broach the metaphysical and final part of this discussion, I should like to add a further ethical reflection that compounds the need we are in to bestow some measure of reality onto the future.

I am referring to the concept of "moral luck" in moral philosophy. I will introduce it with the help of two contrasting thought experiments. In the first, one must reach into an urn containing an infinite number of balls and pull one out at random. Two thirds of the balls are black and only one third are white. The idea is to bet on the color of the ball before seeing it. Obviously, one should bet on black. And if one pulls out another ball, one should bet on black again. In fact, one should always bet on black, even though one foresees that one out of three times on average this will be an incorrect guess. Suppose that a white ball comes out, so that one discovers that the guess was incorrect. Does this a posteriori discovery justify a retrospective change of mind about the rationality of the bet that one

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made? No, of course not; one was right to choose black, even if the next ball to come out happened to be white. Where probabilities are concerned, the information as it becomes available can have no conceivable retroactive impact on one's judgment regarding the rationality of a past decision made in the face of an uncertain or risky future. This is a limitation of probabilistic judgment that has no equivalent in the case of moral judgment. Here we touch upon a second serious deficiency of the precautionary principle. As it is unable to depart from the normativity proper to the calculus of probabilities and the cost-benefit approach, it fails to capture what constitutes the essence of ethical normativity concerning choice in a situation of uncertainty.

A man spends the evening at a cocktail party. Fully aware that he has drunk more than is wise, he nevertheless decides to drive his car home. It is raining, the road is wet, the light turns red, and he slams on the brakes, but a little too late: after briefly skidding, the car comes to a halt just past the pedestrian crosswalk. Two scenarios are possible: Either there was nobody in the crosswalk, and the man has escaped with no more than a retrospective fright. Or else the man ran over and killed a child. The judgment of the law, of course, but above all that of morality, will not be the same in both cases. Here is a variant: The man was sober when he drove his car. He has nothing for which to reproach himself. But there is a child whom he runs over and kills, or else there is not. Once more, the unpredictable outcome will have a retroactive impact on the way the man's conduct is judged by others and also by the man himself.

Here is a more complex example devised by the British philosopher Bernard Williams, which I will simplify considerably. A painter — we'll call him "Gauguin" for the sake of convenience — decides to leave his wife and children and take off for Tahiti in order to live a different life which, he hopes, will allow him to paint the masterpieces that it is his ambition to create. Is he right to do so? Is it moral to do so? Williams defends with great subtlety the thesis that any possible justification of his action can only be retrospective. Only the success or failure of his venture will make it possible for us — and him — to cast judgment. Yet whether Gauguin becomes a painter of genius or not is in part a matter of luck — the luck of being able to become what one hopes to be. When Gauguin makes his painful decision, he cannot know what, as the saying goes, the future holds in store for him. To say that he is making a bet would be incredibly reductive. With its appearance of paradox, the concept of "moral luck" provides just what was missing in the means at our disposal

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for describing what is at stake in this type of decision made under conditions of uncertainty.

Like Bernard Williams' Gauguin, but on an entirely different scale, humanity taken as a collective subject has made a choice in the development of its potential capabilities which brings it under the jurisdiction of moral luck. It may be that its choice will lead to great and irreversible catastrophes; it may be that it will find the means to avert them, to get around them, or to get past them. No one can tell which way it will go. The judgment can only be retrospective. However, it is possible to anticipate, not the judgment itself, but the fact that it must depend on what will be known once the "veil of ignorance" cloaking the future is lifted. Thus, there is still time to insure that our descendants will never be able to say "too late!" — a too late that would mean that they find themselves in a situation where no human life worthy of the name is possible.

Hence the bold metaphysical move advocated by Hans Jonas. The idea is to project oneself into the future and look back at our present and evaluate it from there. This temporal loop between future and past I call the metaphysics of projected time. As we are going to see, it makes sense only if one accepts that the future is not only real but also fixed.

5.2. A Critique of the Scenario Approach

For the last half century, futurology has been equated with the scenario approach. If some credit is granted the foregoing, it appears that this method is no longer appropriate to tackle the kind of radical uncertainty that we are confronting.

Ever since its beginnings the scenario approach has gone to great lengths to distinguish itself from mere forecast or foresight, held to be an extension into the future of trends observed in the past. We can forecast the future state of a physical system, it is said, but not what we shall decide to do. It all started in the 50s when a Frenchman, Gaston Berger, coined the term "Prospective" – a substantive formed after "Retrospective" – to designate a new way to relate to the future. That this new way had nothing to do with the project or the ambition of anticipating, that is, knowing the future, was clearly expressed in the following excerpt from a lecture given by another Frenchman, Bertrand de Jouvenel, in 1964:
The purpose is to generate a habit, the habit of forward-looking. We feel that as this grows into a habit, we, or our successors, shall develop in this exercise greater skill, thanks to self-criticism and mutual criticism. At the outset we encountered in the authors we solicited a great reluctance to embark upon such speculation. They said it was unscholarly, which of course it is, but it happens to be necessary. It is unscholarly perforce because there are no facts on the future. Cicero quite rightly contrasted past occurrences and occurrences to come with the contrasted expressions \textit{facta} and \textit{futura}: \textit{facta}, what is accomplished and can be taken as solid; \textit{futura}, what shall come into being, and is as yet 'undone,' or fluid. This contrast leads me to assert vigorously: \textit{there can be no science of the future.}' 

\textit{The future is not the realm of the 'true or false' but the realm of 'possibles.'}

Another term coined by Jouvenel that was promised to a bright ... future was "\textit{Futuribles}"\textsuperscript{27}, meaning precisely the open diversity of \textit{possible futures}. The exploration of that diversity was to become the scenario approach.

Again, the premises on which the whole enterprise rests are at best arbitrary metaphysical presuppositions and ones, to repeat, that we can no longer afford to entertain. If we do not bring ourselves to believe in the reality of the future, we'll never be able to measure up to the challenges that lie ahead\textsuperscript{28}. And those who claim that those presuppositions derive from the freedom of the will are just committing a serious philosophical blunder. Thus Michel Godet, one of the foremost among today's "prospectivists", could write

All who claim to foretell or forecast the future are inevitably liars, for the future is not written anywhere – it is still to be built. This is fortunate, for without this uncertainty, human activity would lose its degree of freedom and its meaning – the hope of a desired future. If the future were totally

\textsuperscript{27} The tradition launched by Bertrand de Jouvenel continues today in a journal called \textit{Futuribles}, edited by his own son Hugues.

\textsuperscript{28} Another early proponent of "Prospective" was Robert Jungk. In 1960, as he was interviewing victims of the Hiroshima atomic bomb, he met a man under 50 who looked 80. That man said to him in a sedate manner: "How could all those intelligent people have dropped this bomb without thinking of the consequences?" That encounter was what prompted Jungk to devote his life to futures studies.
foreseeable and certain, the present would become unlivable. Certainty is death. Because the future has to be built, it also cannot be conceived as a simple continuation of the past.  

This passage is also typical of a confusion that spoils much of what is being offered as a justification of the scenario approach. On the one hand, the alleged irreducible multiplicity of the "futuribles" is explained by the ontological indeterminacy of the future: since we "build", "invent" the future, there is nothing to know about it. On the other hand, the same multiplicity is interpreted as the inevitable reflection of our inability to know the future with certainty. The confusion of ontological indeterminacy with epistemic uncertainty is a very serious one, as explained above.  

To underline the weaknesses of the philosophical foundations of the scenario method is not to deny its many virtues. There is no question that it has helped individuals, groups, and nations to find new ways to coordinate through a jointly worked-out image of the future shared by all. However that has been achieved in a paradoxical way. The method aimed at emphasizing the importance of the future while it denied its reality. Hence the essential question, is there a way to protect the democratic virtues of the scenario approach while jettisoning its flawed metaphysics?  

5.3. *From Occurring Time to Projected Time*  

If the future is ontologically indeterminate shouldn't we say the same about the past? After all, there was a time when our past was the future of

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30 The World Business Council for Sustainable Development (WBCSD) "Global Scenarios 2000-2050" Summary Brochure provides another illustration of this glaring confusion. On the one hand, we read that "Unlike forecasts, which impose patterns extrapolated from the past onto the future, scenarios are plausible, pertinent, alternative stories that are concerned more with strategic thinking than with strategic planning." We also read that "scenarios recognis(e) that possibilities are influenced by a wide range of people." Here we are clearly on the side of the indeterminacy of the future due to people's faculty to make (strategic) choices. On the other hand, we are also told that a crucial step in the making of scenarios is "to identify and analyse driving forces that will shape the environment. What will persist and can be forecast (for example, demography in many exercises), and what may change and is unknown? Following the identification of the driving forces, we can now contemplate a set of plausible storylines." The uncertainty is here clearly epistemic.
its own past. French biographer André Maurois once went so far as to write:

There is no privileged past (...) There is an infinitude of Pasts, all equally valid (...) At each and every instant of Time, however brief you suppose it, the line of events forks like the stem of a tree putting forth twin branches\textsuperscript{31}.

Dutch historian Johan Huizinga had already paved the way by writing:

The historian must (...) constantly put himself at a point in the past at which the known factors will seem to permit different outcomes. If he speaks of Salamis, then it must be as if the Persians might still win; if he speaks of the coup d'Etat of Brumaire, then it must remain to be seen if Bonaparte will be ignominiously repulsed\textsuperscript{32}.

The few historians who take this line of thought seriously are those who do not shy away from writing what goes today by the name of "Counterfactual History" or "Virtual History". Those "What if?" historians try and put forward more or less convincing answers to such questions as, What if there had been no French Revolution? What if Hitler had invaded Britain? What if the Soviets had won the Cold War? And, of course, the Pascalian one, What if Cleopatra's nose had been different?

Among professional historians, though, widespread is the opinion that this kind of exercise is a mere "parlour game" or a "red herring"\textsuperscript{33}. From Marxists and other materialists this opinion doesn't come as a surprise but it is much more widely shared than that. It is worth quoting British idealist philosopher Michael Oakeshott on this:

It is possible that had St Paul been captured and killed when his friends lowered him from the walls of Damascus, the Christian religion might never have become the centre of our civilisation. And on that account, the spread of Christianity might be attributed to St Paul's escape ... But when events are treated in this manner, they cease at once to be historical events. The result is not merely bad or doubtful

\textsuperscript{32} Ibid.
\textsuperscript{33} These dismissive phrases are from E. H. Carr. Quoted by Niall Ferguson, p. 4.
history, but the complete rejection of history (...) The distinction (...) between essential and incidental events does not belong to historical thought at all\textsuperscript{34}.

The opposition between historians who see only historical necessity and those who are sensitive to the metaphysical postulation that things might be different from what they turned out to be, can and must be transcended. The metaphysical tools exist that allow us to carry out this \textit{Aufhebung}. We owe them to French philosopher Henri Bergson and his brilliant student Jean-Paul Sartre. The idea is that as long as human beings live, they are absolutely free, and their freedom resides entirely in their capacity to choose, that is, to invent their lives. Future-oriented counterfactual propositions such as, "If I were to do this, the consequences would or might be that, and I am entirely responsible for them, whatever they turn out to be", make full sense. However, as soon as "death has turned life into destiny", to quote another famous existentialist, backward-looking counterfactual propositions such as, "Had I had more time to devote to my work, I would have written the novel of the century", are completely devoid of meaning and serve as mere alibis or cheap excuses – the stuff "bad faith" is made of\textsuperscript{35}.

In that kind of metaphysics, counterfactual propositions are admissible only when they are future-oriented. When we look back at the past, we see only necessity. There is nothing else than that which has happened, no possibility that never came to actuality. When history unfolds, then, possibilities become actual, but something strange happens to the branches that were not selected. It is not that they have become impossible: it turns out that they were never possible! As history proceeds in its course, it interjects necessity back into the past. Necessity is only retrospective.

In the framework of this metaphysics the parties to the debate about the meaning of virtual history appear to suffer from symmetrical blind spots. The "What if?" historians argue as if the possibilities that did not become actual kept existing forever, in a kind of eternal limbo. The mainstream historians who refuse to ascribe any meaning to counterfactuals reason as

\textsuperscript{34} Michael Oakeshott, \textit{Experience and its Modes}, Cambridge, 1933; quoted by Niall Ferguson, p. 6-7.

\textsuperscript{35} In Sartre’s plays, the dead keep talking to each other and even make definitive philosophical claims such as, "Hell is other people"! The only thing they wish to do, but can \textit{no longer} do, is "choose their past". The latter has become inert, sentenced to be forever part of the "In itself".
if agents endowed with free will didn't make any difference in the way events occur.

*Back to the future.* Following Hans Jonas, as explained before, my task has been to reestablish the future in its ontological status of a *real* entity. Bergsonian – Sartrean metaphysics permits exactly that: project yourself into the future and look back from there at the present. Seen from the present the future was open, but seen from the vantage point of the future, the path that led to it appears to have been necessary. We were free to choose, to be sure, but what we chose appears to have been our destiny. 36

At this stage non-philosophers are probably thinking that this is all speculative bla-bla-bla that has no bearing whatsoever on the real world. One couldn't be more plainly wrong.

The temporal experience I am trying to describe – and which, again, I call "projected time" -, is ours on a daily basis. It is facilitated, encouraged, organized, not to say imposed by numerous features of our social institutions. All around us, more or less authoritative voices are heard that proclaim what the more or less near future will be: the next day's traffic on the freeway, the result of the upcoming elections, the rates of inflation and growth for the coming year, the changing levels of greenhouse gases, etc. The futurists and sundry other prognosticators, whose appellation lacks the grandeur of the prophet's, know full well, as do we, that this future they announce to us as if it were written in the stars is a future of our own making. We do not rebel against what could pass for a metaphysical scandal (except, on occasion, in the voting booth). It is the coherence of this mode of coordination with regard to the future that I have endeavored to bring out.

A sine qua non must be respected for that coherence to be the case: a *closure condition*, as shown in the following graph. Projected time takes the form of a loop, in which past and future reciprocally determine each other.

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36 This is a famous Heideggerian *philosopheme.*
To foretell the future in projected time, it is necessary to seek the loop's *fixed point*, where an expectation (on the part of the past with regard to the future) and a causal production (of the future by the past) coincide. The predictor, *knowing that his prediction is going to produce causal effects in the world*, must take account of this fact if he wants the future to confirm what he foretold. Traditionally, which is to say in a world dominated by religion, this is the role of the prophet, and especially that of the biblical prophet.\(^\text{37}\) He is an extraordinary individual, often eccentric, who does not go unnoticed. His prophecies have an effect on the world and the course of events for these purely human and social reasons, but also because those who listen to them believe that the word of the prophet is the word of Yahveh and that this word, which cannot be heard directly, has the power of making the very thing it announces come to pass. We would say today that the prophet's word has a *performative* power: by saying things, it brings them into existence. Now, the prophet knows that. One might be tempted to conclude that the prophet has the power of a revolutionary: he speaks so that things will change in the direction he intends to give them. This would be to forget the fatalist aspect of prophecy: it describes the events to come as they are written on the great scroll of history, immutable and ineluctable. Revolutionary prophecy has preserved this highly paradoxical mix of fatalism and voluntarism that characterizes biblical prophecy. Marxism is the most striking illustration of this.

\(^{37}\)To his misfortune and above all that of his compatriots, the ancient prophet (such as the Trojans Laocoon and Cassandra) was not heeded; his words were scattered by the wind.
However, I am speaking of prophecy, here, in a purely secular and technical sense. The prophet is the one who, more prosaically, seeks out the fixed point of the problem, the point where voluntarism achieves the very thing that fatality dictates. The prophecy includes itself in its own discourse; it sees itself realizing what it announces as destiny. In this sense, as I said before, prophets are legion in our modern democratic societies, founded on science and technology. What is missing is the realization that this way of relating to the future, which is neither building, inventing or creating it, nor abiding by its necessity, requires a special metaphysics.

Perhaps the best way to bring out the specificity of the metaphysics of projected time is to ponder the fact that there is no such closure or looping condition as regards our "ordinary" metaphysics, in which time bifurcates into a series of successive branches, the actual world constituting one path among these. I have dubbed this metaphysics of temporality "occurring time"; it is structured like a decision tree:

![Occurring time diagram](image)

Obviously the scenario approach presupposes the metaphysics of occurring time. But that is also the case of the metaphysical structure of prevention. Prevention consists in taking action to insure that an unwanted possibility is relegated to the ontological realm of non-actualized possibilities. The catastrophe, even though it does not take place, retains the status of a possibility, not in the sense that it would still be possible for it to take place, but in the sense that it will forever remain true that it could have taken place. When one announces, in order to avert it, that a catastrophe is coming, this announcement does not possess the status of a prediction, in the strict sense of the term: it does not claim to say what the future will be, but only what it would have been had one failed to take
preventive measures. *There is no need for any loop to close here:* the announced future does not have to coincide with the actual future, the forecast does not have to come true, for the announced or forecast "future" is not in fact the future at all, but a possible world that is and will remain not actual.\(^{38}\)

By contrast, in projected time, the future is held to be fixed, which means that any event that is not part of the present or the future is an impossible event. It immediately follows that in projected time, prudence can never take the form of prevention. Once again, prevention assumes that the undesirable event that one prevents is an unrealized possibility. The event must be possible for us to have a reason to act; but if our action is effective, it will not take place. This is unthinkable within the framework of projected time.

Such notions as "anticipatory self-defense", "preemptive attack", or "preventive war" do not make any sense in projected time. They correspond to a paradox exemplified by a classic figure from literature and philosophy, the killer judge. The killer judge "neutralizes" (murders) the criminals of whom it is "written" that they will commit a crime, but the consequence of the neutralization in question is precisely that the crime will not be committed!\(^{39}\) The paradox derives from the failure of the past prediction and the future event to come together in a closed loop. But, I repeat, the very idea of such a loop makes no sense in our ordinary metaphysics.

5.4. **Conclusion. Exploring the set of projected equilibria as a substitute for the scenario approach**

We should take very seriously the idea that there is a "co-evolution of technology and society" (Arie Rip). The dynamics of technological development is embedded in society. The consequences of the development of nanotechnology will concern society as well as technology itself. Technology and society shape one another.

The future of nanotechnology, therefore, depends on the way society is going to react to the anticipations that are being made of this future. If

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\(^{38}\) For an illustration, one may think of those traffic warnings whose purpose is precisely to steer motorists away from routes that are otherwise expected to be clogged with too many motorists.

\(^{39}\) Here I am thinking of Voltaire's *Zadig*. The American science fiction writer Philip K. Dick produced a subtle variation on the theme in his story "Minority Report." Spielberg's movie is not up to the same standard, alas.
those anticipations are produced through the scenario method, they will be of no help in the resolution of the ethical problem. They won't restore the future in its status of a real entity of which our knowledge must be as precise as possible. I have argued that the most effective way to ascribe reality to the future is to reason in the framework of projected time. But, then, we are confronted with a problem of reflexivity. This "we" refers to all groups, lobbies, expert groups, administrations, institutions that purport to shape the future through its anticipation, anticipation made public. We are the "prophets" of today, in the technical sense explained above. We have to explore the fixed points of the temporal loop that links the future to the past and then to the future again. Those fixed points I have called "projected equilibria".

Alexei Grinbaum and I have called "ongoing normative assessment" the methodology that corresponds to the determination of these projected equilibria. One can succinctly capture the spirit of this approach with the following words: it is a matter of obtaining through research, public deliberation, and all other means, an image of the future sufficiently optimistic to be desirable and sufficiently credible to trigger the actions that will bring about its own realization. It is easy to see that this definition can make sense only within the metaphysics of projected time, whose characteristic loop between past and future it describes precisely. Here coordination is achieved on the basis of an image of the future capable of insuring a closed loop between the causal production of the future and the self-fulfilling expectation of it.

I have said before that prevention made no sense in projected time. What can take its place then? Are there projected equilibria that may protect us against a major disaster, if such a denouement is in the offing? The search for an answer to that question I have called "enlightened doomsaying".

From the outset it appears that this search is bound to run into an irremediable paradox. It is a matter of achieving coordination on the basis of a negative project taking the form of a fixed future that one does not want. One might try to transpose the above characterization of the methodology of ongoing normative assessment into the following terms: "to obtain through scientific futurology and a meditation on human goals an image of the future sufficiently catastrophic to be repulsive and sufficiently credible to trigger the actions that will block its realization" — but this formulation would fail to take account of an essential element. Such an enterprise would seem to be hobbled from the outset by a prohibitive defect: self-contradiction. If one succeeds in avoiding the undesirable future, how can one say that coordination was
achieved by fixing one's sights on that same future? The paradox is unresolved.

In order to spell out what my solution to this paradox is, it would be necessary to enter into the technical details of a metaphysical development, and this is not the place to do so.40 I will content myself with conveying a fleeting idea of the schema on which my solution is based. Everything turns on a random occurrence — but one whose nature and structure defy the traditional categories that I discussed in the first sections of this work.

The problem is to see what type of fixed point is capable of insuring the closure of the loop that links the future to the past in projected time. We know that the catastrophe cannot be this fixed point: the signals it would send back toward the past would trigger actions that would keep the catastrophic future from being realized. If the deterrent effect of the catastrophe worked perfectly, it would be self-obliterating. For the signals from the future to reach the past without triggering the very thing that would obliterate their source, there must subsist, inscribed in the future, an imperfection in the closure of the loop. I proposed above a transposition of our definition of ongoing normative assessment, in order to suggest what could serve as a maxim for a rational form of doomsaying. I added that as soon as it was enunciated, this maxim collapsed into self-refutation. Now we can see how it could be amended so as to save it from this undesirable fate. The new formulation would be: "to obtain... an image of the future sufficiently catastrophic to be repulsive and sufficiently credible to trigger the actions that would block its realization, barring an accident."

One may want to quantify the probability of this accident. Let us say that it is an epsilon, e, by definition weak or very weak. The foregoing explanation can then be summed up very concisely: it is because there is a probability e that the deterrence will not work that it works with a probability 1-e. What might look like a tautology (it would obviously be one in the metaphysics of occurring time) is absolutely not one here, since the preceding proposition is not true for e = 0.41 The fact that the

40 I will take the liberty of referring the interested reader to my Pour un catastrophisme éclairé.
41 The discontinuity at e = 0 suggests that something like an uncertainty principle is at work here, or rather an indeterminacy [Unbestimmtheit] principle. The probabilities e and 1-e behave like probabilities in quantum mechanics. The fixed point must be conceived here as the superposition of two states, one being the accidental and
deterrence will not work with a strictly positive probability $e$ is what allows for the inscription of the catastrophe in the future, and it is this inscription that makes the deterrence effective, *with a margin of error $e$*. Note that it would be quite incorrect to say that it is the *possibility* of the error, with the probability $e$, that saves the effectiveness of the deterrence — as if the error and the absence of error constituted two paths branching out from a fork in the road. There are no branching paths in projected time. The error is not merely possible, it is actual: it is inscribed in time, rather like a slip of the pen. In other words, the very thing that threatens us may be our salvation.

preordained occurrence of the catastrophe, the other its non-occurrence. I cannot pursue this line of reasoning any further here.
4th Nanoforum Report:

Benefits, Risks, Ethical, Legal and Social Aspects of NANOTECHNOLOGY

Part 8: Who's Who in Risk and ELSI research and public debate

2nd Edition - October 2005
Part 8: Who’s who in risk and ELSI research and public debate

8.1. What is being done?

Partly as a result of the furore over GM crops, most governments recognise the need to tackle what is a multidisciplinary subject with a multidisciplinary approach. What has been realized is that governments must understand public perception and ensure that everyone in society understands the key issues involved in the development of nanotechnologies. If this is achieved, technological advances will be democratically accepted and not perceived as being forced through as a result of massive investment. Therefore many governments have set-up committees, funded projects or commissioned reports to investigate the implications of nanotechnology on society. In this part, we give an overview of EU and government initiatives on risks and ethical legal and social implications of nanotechnology. We also identify the main players in research and public debate. The information is structured per country. This list will be updated as the debate unfolds.

8.2. The EU

8.2.1 Ethics in Science and New Technologies (EGE)¹

The EGE was established by the EC in 1997 as “an independent, pluralist and multidisciplinary body which advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies.” The EGE consists of 12 members who advise the EC on ethical questions such as human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research. The latest newsletter from the EGE states that it is “envisaging to give an opinion on the ethical aspects linked to nanotechnologies.”²
8.2.2 European Economic and Social Committee (EESC)³

The EESC is a consultative body set up by the Rome Treaties in 1957. It consists of representatives of the various economic and social components of organized civil society. Its main task is to advise the three major institutions (European Parliament, Council of the European Union and European Commission).

The EESC has adopted a resolution on the Lisbon declaration to help advance social, economic and environmental policies through its position as a link between European government, national government and public organizations. It achieves this through consultations with various groups, conferences, reporting on its findings and drafting its own opinions.

8.2.3 The sixth framework programme (FP6)

The third thematic priority area of FP6 is focused on nanosciences and nanotechnologies, knowledge-based multifunctional materials and new production processes and devices (NMP). It has a budget of 1.3 billion euros over the period 2002-2006 and its objectives are “to promote the creation of an RTD-intensive European nanotechnology related industry, and to promote the uptake of nanotechnologies in existing industrial sectors.”²⁴ Within the call it is stated that “whenever appropriate, societal, health, ethical and regulatory issues should be addressed”.

8.2.4 Workshops

As already noted public debate is important to the acceptance of new technologies. The EC together with the US NSF organized a workshop in 2002 to discuss the ethical and societal implications of nanotechnology (the 3rd Joint EC-NSF Workshop on Nanotechnology: “Nanotechnology – Revolutionary Opportunities and Societal Implications”).⁵ This not only covered ethical and societal implications but also had presentations on education, training, communication and the environment.

The second session of EuroNanoForum 2003 was devoted to the discussion of the societal, ethical and environmental implications of nanotechnology.
8.2.5. European parties, lobby organisations and standards bodies

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8.4. Germany

The EUROPEAN ACADEMY in Bad Neuenahr focuses its work on the analyses of transdisciplinary sciences with an expected influence on society. A project group works on the "status and the perspectives of nanomaterials, nanodevices and nanocomputing" and started with
working out a clear definition of that field (www.europaeische-akademie-aw.de/pages/arbeitsgruppen_forschung/projektgruppen_nanomaterialien.php).

The FRAUNHOFER INSTITUTE FOR SCIENTIFIC AND TECHNOLOGICAL TREND ANALYSES (FhG-INT) is mainly working in the military area, but views nanotechnological R&D and products not only under these viewpoints, but also via explaining the general importance of that field for industry and society (www.int.fhg.de/servlet/is/298/).

Mainly in the FUTURE TECHNOLOGIES DIVISION of the VDI TECHNOLOGY CENTER topics dealing with socioeconomic, health and public perception effects are actively pursued. The VDI acts as a consultant for the German research ministry in the field of nanotechnology and discusses the necessities for legislation activities.

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European Parliamentary Technology Assessment = TAB (Germany)
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Medical Institute of Environmental Hygiene
University of Düsseldorf
Paul J.A. Borm (Germany)
http://www.miu.uni-duesseldorf.de/mit/borm.htm

Technical University of Darmstadt
Institute of Philosophy
At the RESEARCH CENTER in KARLSRUHE the INSTITUTE FOR TECHNOLOGY ASSESSMENT AND SYSTEMS ANALYSES (ITAS) works on the general socio-economic description of the outcome of nanotechnological developments. Goals are the information of society, the description of the contents of the technological field and the support for decision makers (http://www.itas.fzk.de/deu/projekt/flei0350.htm)

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92296 CHATENAY-MALABRY
http://www.u-psud.fr/Chatenay/Pharmacie.nsf

Université de Bordeaux
351 cours de la Libération
33405 TALENCE CEDEX
http://www.u-bordeaux1.fr/

INERIS (Institut National de l'Environnement Industriel et des Risques)
Covers potential risks of nanotechnologies
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8.6. Hungary

Measurement and Testing:
OFFICE OF METROLOGY IN HUNGARY
H-1124 Budapest XII.
Tel: (+36 1) 458-5800
Fax: (+36 1) 355-0598
http://www.omh.hu/

8.7. Italy
Italian Institute for the Physics of Matter,  
Laboratorio die Biomateriali,  
Università di Modena e Reggio Emilia, Modena  
Via del Pozzo 71,  
41100 Modena  
Tel.: 0039 1 0659 8740  
Fax: 0039 1 0650 6302  
e-mail: arata@infm.it  
www.infm.it

Measurement and Testing:  
IMGC  
Istituto di Metrologia "G. Colonnetti" - C.N.R.  
Strada delle Cacce, 73  
10135 - Torino (Italia)

http://www.imgur.cnr.it/

8.8. Sweden

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8.9. The Netherlands

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RIVM, Laboratory for Toxicology, Pathology and Genetics
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NEDERLANDS Normalisatie Instituut
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NEN-Business Development
machiel.vandalen@nen.nl
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Postbus 5059,
2600 GB Delft
http://www.nen.nl/nl/act/specials/nanotech/

NMI
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NL 2628 VK Delft
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NL 2600 AR Delft
Telephone: +31 15 269 15 00
Telefax: +31 15 2612971
E-mail: NMi@NMi.nl
www.nmi.nl

NGO’s:
Friends of the Earth Netherlands
(Milieudefensie)
P.O. Box 19199
1000 GD Amsterdam
The Netherlands
www.milieudefensie.nl

Zuid-Hollandse Milieufederatie
P.O. Box 22344
3003 DH Rotterdam
The Netherlands
www.antenna.nl/zhm
info@zhm.milieu.net
Phone: +31 10 476 5355
Fax: +31 10 477 5562

8.10. United Kingdom

The ROYAL SOCIETY is an independent scientific academy of the UK dedicated to promoting excellence in science, www.royalsoc.ac.uk. The ROYAL ACADEMY OF ENGINEERING is a
publicly funded engineering body in the UK with the aim is to promote excellence in engineering
for the benefit of the people of the United Kingdom, www.raeng.co.uk. The Royal Society and
The Royal Academy of Engineering are jointly carrying out an extensive study on
nanotechnology. One of the topics in this study is to investigate whether there is a need for
legislative action for nanotechnology 6

Nuffield Council for Bioethics7 - funded by the Nuffield Foundation, the Wellcome Trust and
the Medical Research Council. Its remit is to “identify, examine and report on the ethical
questions raised by recent advances in biological and medical research.” In this context the
Nuffield Council for Bioethics has backed the use of genetic testing for tailored drug
administration (pharmacogenomics), a process which will be enhanced through advances in
nanotechnology.

School of Medicine & Dentistry - University of Rochester- Günter Oberdörster
http://www2.envmed.rochester.edu/envmed/TOX/faculty/oberdoerster.html

Department of Human Anatomy and Cell Biology - University of Liverpool - C.V.Howard (UK)
http://www.liv.ac.uk/hacb/staff/Howard.C.html

Nanotechnology and Nanoscience - the Royal Society (UK)
http://www.royalsoc.ac.uk/nanotechnology/

The Royal Society (UK)
http://www.royalsoc.ac.uk/

Centre for Cell Engineering (CCE) – University of Glasgow - Adam Curtis (UK)
http://www.gla.ac.uk/centres/cellengineering/adam/adam.html

University of Liverpool (UK)
http://www.liv.ac.uk/
The Better Regulation Task Force (UK)
http://www.brtf.gov.uk/

Lancaster University (UK)
http://www.lancs.ac.uk/

Centre for Economic and Social Aspects of Genomics (CESAGen) (UK)
http://www.cesagen.lancs.ac.uk/

Measurement and Testing:
NATIONAL PHYSICAL LABORATORY

Green party (UK) — the only UK political party with a publicised stance on Nanotechnology. It wants a moratorium on commercial nanotechnology developments.

8.11. Switzerland
Technology Assessment:
TA-Swiss
www.ta-swiss.ch

University of Basel (Switzerland)
http://www.unibas.ch/

Swiss Federal Institute of Technology (Switzerland)
http://www.ethz.ch/index_EN

Measurement and Testing:
METAS, SWISS INSTITUTE OF METROLOGY AND ACCREDITATION
8.12. Other regions and countries

The OECD, the organisation for economic co-operation and development, discusses the possible influence of transformative technologies of the 21st century in a report on governance in this century. The OECD plays a prominent role in fostering good governance in the public service and in corporate activity. The OECD produces internationally agreed instruments, decisions and recommendations to promote rules of the game in areas where multilateral agreement is necessary for individual countries to make progress in a globalised economy. In their report, OECD lists the new issues that new technologies raise: jurisdiction, definition of property right, prevention of terrorism, data protection and privacy, and health and safety and environmental regulation. The OECD groups 30 member countries from all over the world sharing a commitment to democratic government and the market economy, and has active relationships with some 70 other countries, NGOs and civil society.\(^9\)

At the World Conference on Science and the Use of Scientific Knowledge held by the United Nations Educational Scientific and Cultural Organization (UNESCO) and the International Council for Science (ICSU) in 1999, there was a declaration aimed to strengthen ethical standards within the scientific community:

“All scientists should commit themselves to high ethical standards, and a code of ethics based on relevant norms enshrined in international human rights instruments should be established for scientific professions. The social responsibility of scientists requires that they maintain high standards of scientific integrity and quality control, share their knowledge, communicate with the public and educate the younger generation. Political authorities should respect such action by scientists. Science curricula should include science ethics, as well as training in the history and philosophy of science and its cultural impact. (UNESCO 1999).”

In 1998 UNESCO established a Commission on the Ethics of Scientific Knowledge and Technology (COMEST). In August 2003 COMEST published a comprehensive report on “the teaching of ethics”.\(^{10}\) Included in this was a proposal that ethics be a constant and integral part of scientific training and continuing research. Crucially this should be interactive (rather than taught) and lead to a recognized and accredited qualification. It was also stated that an
international committee should be established that could assist in the global development of ethics programmes and their accreditation.

INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC, is a global organization that prepares and publishes international standards for all electrical, electronic and related technologies. These serve as a basis for national standardization and as references when drafting international tenders and contracts (www.iec.ch). No standards specifically aimed for nanotechnology were found.

USA

The societal implications of nanotechnology were explored in the US National Science Foundation (NSF) report “Societal Implications of Nanoscience and Nanotechnology”. 11 This report included the following recommendations: that social science research into nanotechnology implications should be a priority; that provisions should be made to educate nanotechnologists about the societal and ethical implications of their work and that openness and discussion with the public should be fostered. The US Congress last year allocated 850 million USD to nanotechnology research. Initially, a bill was proposed to reserve up to 5% of this for the study of the societal and ethical implications of nanoscience, however this was subsequently defeated. Instead there is provision "that ethical, legal, environmental, and other appropriate societal concerns, including the potential use of nanotechnology in enhancing human intelligence and in developing artificial intelligence which exceeds human capacity, are considered during the development of nanotechnology ..." As part of this the US (NSF) held a workshop on the societal implications of nanoscience and nanotechnology in December 2003. 12 13

Foresight Institute 14 - a not-for-profit educational organization whose purpose is to promote the understanding, discussion and dissemination of the economic, social and environmental outcomes of nanotechnology.
The Center for Responsible Nanotechnology\textsuperscript{15} - a not-for-profit organization that has published information on the risks and benefits of nanotechnology as well as its social, ethical and legal implications.

Center for Responsible Nanotechnology (CRN)

http://www.crnano.org/dangers.htm

Risks assessment of nanotechnologies – Example of US projects

http://www.nsf.gov/home/crssprgm/nano/nni01_03_env.htm

Environmental Protection Agency (EPA)

http://www.epa.gov/

National Center For Environmental Research (from EPA)

http://es.epa.gov/ncer/rfa/current/2003_nano.html

North Carolina Department of Health and Human Services

http://www.dhhs.state.nc.us/

National Institute of Environmental Health Sciences (NIEHS)

http://www.niehs.nih.gov/

National Toxicology Programme (NTP from NIEHS)

http://ntp-server.niehs.nih.gov/

Center for Biological and Environmental Nanotechnology (CBEN) – Rice University

http://www.ruf.rice.edu/~cben/

University of South Carolina (USC)

http://www.sc.edu/

Environmental Molecular Science Institute - University of Notre Dame

http://www.nd.edu/~emsi/

Center for Environmental Science and Technology (CEST) – University of Notre Dame
http://www.nd.edu/~cest/

Canada:

**International Center for Bioethics, Culture and Disability**\(^{16}\) - mission statement is to examine the cultural aspects and impacts of bioethical issues and of science and technology, to foster debate and understanding between different societal groups.

International Center for Bioethics, Culture and Disability
http://www.bioethicsanddisability.org/start.html

The University of Toronto Joint Center for Bioethics (**JCB**)\(^ {17}\) - actively assessing the impact of nanotechnology on the global community. In their report “Mind the gap: science and ethics in nanotechnology” the authors analyse some of the issues of nanotechnology development and propose mechanisms by which ethical considerations can be put in place now through appropriate funding, interdisciplinary research (involving social scientists, nanotechnologists, civil society organizations and government bodies), involvement of developing countries and public engagement.\(^ {18}\)

Join Centre for BioEthics – University of Toronto
http://www.utoronto.ca/jcb/main.html

The National Institute for Nanotechnology – University of Alberta
http://www.nint.ca/

8.13 Action groups

**ETC** (action group on Erosion, Technology and Concentration)- an international civil society organization based in Winnipeg, Canada.\(^ {19}\) ETC published a report in 2003 entitled “The Big Down” in which they discuss nanotechnologies and offer an analysis of the effects on society and the environment.\(^ {20}\) ETC wants a moratorium on commercial production of new nanomaterials
and “a transparent global process for evaluating the socioeconomic, health and environmental implications of the technology.”

ETC Group
http://www.etcgroup.org/

Greenpeace\textsuperscript{21} commissioned a report entitled “Future Technologies, Today’s Choices” by Imperial College London to independently assess the status of new technologies in terms of trends, organizations involved, drivers and risks.\textsuperscript{22} Greenpeace have a publicised stance on technology: “New technologies feature prominently in Greenpeace campaigns. While we campaign against the technology we believe will have a profound negative impact on the environment (like genetically modified crops and nuclear power), we also campaign in favour of those which provide solutions (like renewable energy and waste treatment technologies).”

\textbf{Media and public figures}

The editor of The Ecologist\textsuperscript{23}, Zac Goldsmith, has stated that “No one in the industry doubts that nanotech is the most powerful tool we've ever had, but it's mad that we're charging ahead without any debate. People are nervous because scientists have made a lot of mistakes — DDT, CFCs, thalidomide. A mistake with nanotechnology could be very much more serious than anything we've seen before." Public figures including Prince Charles have echoed these concerns.\textsuperscript{24}

\textbf{8.14. Projects}


The NANO-PATHOLOGY project is part of the Life Quality programme of FP5. The goals are to develop diagnostic methods and tools for the detection of micro- and nanoparticles relevant for pathological processes of unknown etiology, to investigate patho-mechanisms of possible particle-induced disease and to determine the pathological significance of nanoparticles. Coordinator is the Italian Institute for the Physics of Matter, Laboratorio die Biomateriali at the University of Modena.

http://www.nanopathology.it/

The NANODERM project investigates nanoparticles currently used for body care and household products. The major question is how deep these particles penetrate the horny layer of the skin. Coordinator is the University of Leipzig, Germany.

http://www.uni-leipzig.de/~nanoderm/

The NANOSAFE project assesses risks involved in production, handling and treatment, and use of nanoparticles in industrial processes and products, as well as in consumer products. The objectives are to assemble available information on the possible hazards involving nanoparticles, to evaluate the risks to workers and consumers, and to recommend regulatory measures and codes of practice to obviate any danger.

Contact: Dr. Rüdiger Naß
Nanogate Technologies GmbH
Keramische Nanotechnologie
Gewerbepark Eschberger Weg
66121 Saarbrücken/Germany
nanosafe@nanogate.com
8.15. Ethics courses

Norway - ethics courses are part of the entry requirements for all Norwegian university students.
EU - Socrates student exchange programme has course content on ethics. [http://europa.eu.int/comm/education/programmes/socrates/socrates_en.html](http://europa.eu.int/comm/education/programmes/socrates/socrates_en.html)
Center for the Study of Ethics in the Professions [http://www.iit.edu/departments/csep/PublicWWW/codes/](http://www.iit.edu/departments/csep/PublicWWW/codes/)

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2. [http://europa.eu.int/comm/european_group_ethics/docs/issue2.pdf](http://europa.eu.int/comm/european_group_ethics/docs/issue2.pdf)
4. [http://www.cordis.lu/nmp/whatis.htm](http://www.cordis.lu/nmp/whatis.htm)
6. [www.nanotec.org.uk](http://www.nanotec.org.uk)
9. OECD 2001
• 14 http://www.foresight.org/
• 15 http://www.crnano.org/
• 16 http://www.bioethicsanddisability.org/start.html
• 17 http://www.utoronto.ca/jcb/
• 19 http://www.etcgroup.org/
• 21 http://www.greenpeace.org.uk/
• 23 http://www.theecologist.org/
• 24 http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2003/06/05/nano05.xml
4th Nanoforum Report:

Benefits, Risks, Ethical, Legal and Social Aspects of NANOTECHNOLOGY

Part 7: the need for and rise of new LEGISLATION AND REGULATION caused by the emergence of Nanotechnology

2nd Edition - October 2005
The need for and rise of new

LEGISLATION AND REGULATION

caused by the emergence of nanotechnology

Version 2, September 2005

www.nanoforum.org

Author: Mireille Oud (versions 1 and 2)
1 Introduction

New technologies come with new possibilities and this will inevitably ask for new or revised legislation and regulations. New possibilities come with new and possibly unforeseen applications, that may be beneficial and increase prosperity, but may also have unwanted consequences. Nanomaterials could have risks for human health or for the environment. Safety issues also come up when military use is considered.

It is not only risks which justify reviewing and revising legislation and regulation. Unequal division of prosperity, the so-called 'nano-divide' is also an issue of concern. More neutral are technical matters such as patenting nanotechnology that can pose new questions, just as patenting gene-technology did. Nanotechnology may also lead to a need for new international (trade or other) agreements.

Nanotechnology makes boundaries between technologies fuzzy, technologies that are currently covered by different laws. Within these technologies, products need to fulfil other criteria for testing before they can enter the market: e.g. cosmetics versus pharmaceuticals, and pharmaceuticals versus medical devices. As a consequence, nanotechnology leads to a need for new norms, standards and testing procedures (e.g. for nanometer length scales, calibration of SPMs and other instruments, health effects of nanoparticles, toxic effects of the nanometer size of particles rather than of their chemical composition).

The composition of this report is guided by the following questions:

- Which European directives are already covering the application of nanotechnology? Which authorities or European agencies are responsible? What positions are European policy makers taking?
- For which issues have which groups in society (in European countries, as well as in the USA) already suggested a need for new legislation? Which positions have already been taken on a need for new legislation, norms and standards for these issues?
- Is there already a global debate about regulation of nanotechnology emerging, and what global regulatory activities exist?
- How should standardisation and testing be adapted, which institutes are involved, and what standard have already been developed?
- What arrangements have been made to cover intellectual property (patenting) and what issues are important concerning patenting?
- What industrial initiatives are emerging concerning regulation of nanotechnology, with respect to the various above mentioned topics?

The discussion on how nanotechnology leads to a need for new legislation appears to have begun only recently, but rapid progress is seen. In this chapter, we give an overview of the groups and institutes involved and the status quo of their involvement in nanotechnology. This report will be regularly updated, and we expect that the question of the need for new legislation and regulation caused by the emergence of nanotechnology will be answered still more closely in the future.

2 European regulations and directives

2.1 European Union regulatory activities

The European Union as an overall player in European regulation will be considered separately from other European activities. Political activities, from within the European Parliament, will be discussed first. These are currently at the stage of becoming informed on what nanotechnology is, what potential economic benefits it will bring, and what side-effects one should be aware of:

In the EUROPEAN PARLIAMENT, a **hearing** was organised by the Group of the European Peoples Party (Christian Democrats) and European Democrats (EPP-ED, the largest European Parliament group, [www.epp-ed.org](http://www.epp-ed.org)) and the Institute of Physics ([www.iop.org](http://www.iop.org)), on 3 March 2004. Alongside surveying industry, the European NanoBusiness Association (a Brussels based non profit organization dedicated to promoting a strong and competitive European nanotechnology based industry, [www.nanoeurope.org](http://www.nanoeurope.org)) was also giving evidence. Explaining the science and identifying the issues necessary for political action were the aims of this public hearing chaired by Giles Chichester MEP (Member of the European Parliament for South West
United Kingdom, [www.gileschichestermep.org.uk](http://www.gileschichestermep.org.uk). Several leading European experts were invited to contribute their expertise to the seminar. Professor Mark Welland from the University of Cambridge gave an introduction to what nanotechnology is and why governments, industry and science alike feel it is so important. The societal implications of nanotechnology were reviewed by Dr. K. Eijkel, the commercial director of the Nanotechnology Institute Mesaplus, Technical University Twente (NL). As with all public high-technology debates, it is extremely important to separate fact from fiction: Prof. Wolfgang M. Heckl from the Ludwig-Maximilians University in Munich and Ms. Fiona Fox from the Science Media Centre at the Royal Institution (UK) discussed ways for responsible scientists to promote dialogue. Concluding the hearing, Dr Renzo Tomellini from the EC Nanotechnology Programme and Tim Harper from the European Nanotechnology Business Association (ES) investigated what other economic areas are doing, and how their strategy differs from that of European countries.¹

On 11 June 2003, an earlier seminar had been organised in the European Parliament by a coalition including the ETC group, Greenpeace and the Green party in the EP. At this hearing, risks and other societal consequences of nanotechnology had been stressed. The Member of the European Parliament Dr. Caroline Lucas (UK, Green Party) and other participants called for a moratorium on nano-products applied to the skin. Dr. Jürgen Altmann (BICC, Germany) called for a moratorium on non-medical implants, which could be used for military applications (cyber-soldiers). It was proposed that the US should slow down research on military applications of nanotechnology to give time for a global debate about legal limits to the technology.²

**Positions of European political parties** on regulation of nanotechnology are the following. The Greens/ European Free Alliance ([www.greens-efa.org](http://www.greens-efa.org)) in the European Parliament adopted a policy statement on the Johannesburg World Summit on Sustainable Development (24-04-02). This includes a call for “An International Convention for the Evaluation of New Technologies (ICENT) responsible for evaluating the sustainability of new deep-impact technologies such as genetics and nano-technology as well as validating their regulation and use.” So far, other parties have not published positions covering nanotechnology regulation. The European Parliament has asked for more funding of nanotechnology research, as part of EU innovation policy.

ITRE, the Committee on Industry, Research and Energy of the European Parliament organised a workshop on "Precautionary Principle and Nanotechnology" in 2004. An accompanying report
has its focus on nanotechnologies and especially on nano-particles. This report concludes the following. The adaptation of the existing regulations to the nano specifics is still lacking. The Precautionary Principle of the European Union (COM 2000) points out that scientific uncertainty is no reason for inaction if there might be immense adverse effects. Some elements of the Precautionary Principle exist in different regulation approaches. The regulation of Chemicals, especially the proposal of the REACH (see further down in this section) regulation, as well as the regulation of pharmaceuticals are examples of a precautionary approach. The existing regulations might be able to capture potential adverse effects of nanotechnologies, especially of nano-particles. Further possible developments of nanotechnologies might be captured by approaches of the regulation of genetic modified organisms.³

European Union funded research comprises little research as to the risks and need for economic uptake of nanotechnology, despite the fact that a substantial amount of money was allocated for nanotechnology in the sixth framework programme:

In the SIXTH FRAMEWORK PROGRAMME, the Third Thematic Priority of the Focusing and Integrating research part is called "Nanotechnology and Nanosciences, knowledge-based multifunctional materials and new production processes and devices (NMP)", and has a budget of EUR 1300 million for 2002-2006⁴. This priority is oriented to technical research and explicitly states as a cross cutting issue that "A particular effort will be carried out to take into consideration the ethical, social, legal, regulatory and wider cultural aspects of the research including socio-economic research, and innovation, resulting from the possible deployment, use and effects of the newly developed technologies or processes and scenarios covered by each of the thematic priorities. This effort will be complemented by socio-economic research carried out within the priority addressing ‘Citizens and governance in a knowledge based society’". The work programme has sections on "Hazard reduction in production plant and storage sites", "Human-friendly, safe and efficient construction", and "Impact on human health and environment" (about nanoparticles). The section "Industrially relevant production of nanoparticles" (about storage of the nanoparticles, i.e. powders and/or fibres) mentions that "Toxicological studies should also be included, where these are relevant". Under the application areas health, food, chemistry, energy, and the environment the general header of "Ethical, legal,
"social aspects of research in nanotechnology" is found, where it is stated that there should be promoted a "dialogue with civil society focussing in particular on the communication. The issues to be addressed are ethical, legal (including, as the case may be, regulatory issues, establishing priorities for standards and metrology needs, and specific Intellectual Property Rights (IPR) aspects) and/or social (including, where relevant, foresight activities and the possible impact of nanotechnology, as such or in combination with information technology, nano-biology and/or cognitive sciences)." 

For the seventh framework programme, the European Commission has prepared a communication that foresees such research:

The EUROPEAN COMMISSION (http://europa.eu.int) has published a Commission Communication on nanotechnology. Ezio Andreta, director for Industrial Technologies in DG research announced this at the EuroNanoforum 2003 in Trieste, Italy, December 2003. The main topic of this Communication is the need for investment in nanotechnology under the Seventh Framework programme (2006-2011), but risk assessment is also addressed to. The Commission Communication was sent to the European Parliament and the Council 12 May 2004. 

In the Communication, the EC proposes a "European Strategy for Nanotechnology". This sketch for a policy plan includes several proposals related to legislation covering nanotechnology, such as patenting, standardisation and risks. The EU member states should increase and coordinate their activities in the areas of metrology, standardisation and normalisation (see pages 20, 21, and 22 of the Communication). The European Commission promises to maintain ethical principles governing nanotechnology (page 24). Globally, the European Commission aims for an international Code of Conduct to ensure global agreement on basic principles for a responsible development of nanotechnology (page 26). The Commission has also published a Communication on the future of research.

The long awaited Action Plan on Nanotechnology was adopted by the European Commission on 7 June 2005. It foresees to intensify dialogue at international level with a view to adopting a declaration or a ‘code of conduct’ for the responsible development and use of nanotechnology. The action plan addresses issues of mutual benefit at global level e.g. on nomenclature, metrology, common approaches to risk assessment and the establishment of a dedicated database.
to share toxicological and ecotoxicological as well as epidemiological data. In this Action Plan, the Commission calls upon the EU Member States to increase their support for nanotechnology research and capacity building in less developed countries. It highlights the potential of nanotechnology to contribute towards the Millennium Development Goals and sustainable development e.g. as regards water purification, providing high quality and safe nutrition, more effective delivery of vaccines, lower cost health screening, more efficient conservation and use of energy.9

The Directorate General for Health and Consumer Protection (DG SANCO) of the European Commission is concerned with health risks of nanotechnology. They have completed a preliminary risk analysis at a workshop held by DG SANCO on the 1-2nd March 2004.10

The Directorate General for Research also had a small workshop entitled "European Workshop on the Social and Economic Impact of Research on Nanotechnologies and Nanosciences" held on the 14-15th April 2004 in Brussels.11

As a sequel to the Communication on a European strategy for nanotechnology, the European Commission held a workshop 'Research Needs on Nanoparticles'.12 This workshop addressed the need for research as to the risks of nanoparticles for health and environment. Currently the regulation of the medical device industry in Europe is based on three European Commission Directives. These are the Medical Devices Directive (MDD), the Active Implantable Medical Devices Directive (AIMDD) and the In Vitro Diagnostic Directive (IVDD). Separate EU Directives relate to medicinal products for human use and clinical trials of medicinal products. Within the scope of the present regulations no distinction is made between medical devices and pharmaceuticals based on conventional technology and those based on nanotechnology. The Commission (Unit G.4 — Nanosciences and Nanotechnologies) found that, at present, no specific regulations exist in Europe which refer specifically to the production and use of nanoparticles either for workers or consumers’ safety or for environmental protection. They also concluded that there is no evidence of the need for such regulation. They concluded that "neither any nano-'euphoria' nor nano-'demonization' will be beneficial. "Appropriate beforehand
assessment should be carried out before starting with mass production of engineered nanoparticles, and guidelines should be issued for new possible production processes, on the basis of scientific evidence and need. Such guidelines should address the production phases and the full life-cycle of the nanoparticles. Cells, organs, organisms and the environment should be considered." They recommend international cooperation and see a coordinated or joint call in 2006 between the European Commission and concerned agencies of the USA such as EPA, NIH and NIOH as a promising action.

Technical research matters concern the development of methods to warrant safety and quality of products. Technical research is the scope of the Joint Research Centre. Health issues appear to be the main concern. No research specifically addressed to products involving nanotechnology exists yet. However, discussions as to this topic are currently taking shape:

The JOINT RESEARCH CENTRE (www.jrc.es) is the European Union's scientific and technical research laboratory and a part of the European Commission. It is a Directorate General, providing the scientific advice and technical know-how to support EU policies. The status as a Commission service, which guarantees independence from private or national interests, is crucial for pursuing the mission.

The Joint Research Centre has organized a workshop on the applications of nanotechnologies in the medical domain. "The workshop we are preparing aims at discussing the need for adapted/new European regulation in the context of nanotechnological applications in the health area with a small group of experts. This will probably be followed up by a study investigating the issue more in depth. For the time being, I am not aware of any regulatory initiative on a European level in this area. Our study is supposed to provide the necessary background information to support the decision-making process whether any initiative should be started." This European Workshop on Nanotechnology, Health and the Environment was held at the JRC Ispra, 17-19 May 2004.

General environmental protection issues are taken care of by the European environment agency. Nanotechnology is not yet a separate point of attention, but is attracting attention together with other emerging technologies:
EUROPEAN ENVIRONMENT AGENCY (EEA) aims to support sustainable development and to help achieve significant and measurable improvement in Europe's environment through the provision of timely, targeted, relevant and reliable information to policy-making agents and the public (http://org.eea.eu.int). In their annual management plan for 2004, EEA intended to focus 72 weeks of time and 130 thousand euros on emerging issues. EEA aims to "Identify and select for analysis and outreach a few emerging issues, that are arising from scientific research, monitoring, public concerns and from policy analyses. Focus on developing further the idea of long term environment and health monitoring, understanding better how to move from information to action, the application of the precautionary principle with case studies on for example nanotechnologies, and the treatment of uncertainty."  

In the specific area of chemistry, a longer history of safety awareness exists. This concerns the risks of fine dust; a topic instigated by e.g. the asbestos problem. As no distinction of particle sizes was made so far, logically no particles were labelled as nanoparticles. The issue of fine dust is covered by the EU regulatory framework REACH:

A safety issue especially related to nanotechnology is that of fine dust, nowadays called nanoparticles. This is an issue within the scope of chemistry. However, up to now nanoparticles have not been a specific subject of the current considerations of the European Parliament or Council on the Commission's proposal, says Geert Dancet, Head of the Unit Environmental aspects of enterprise policy, resource-based & specific industries that deals with the regulations of REACH. This is the acronym of Registration, Evaluation and Authorisation of Chemicals, a EU regulatory framework that was adopted on 29 October 2003. On 26 April 2005, the organisation European Voice held a conference "Within REACH, a major one-day conference on EU chemicals policy". In his introductory speech, Stavros Dimas, Member of the European Commission, responsible for Environment, said: "..., our well-being as a society is substantially based on chemicals. Chemicals are everywhere, and are an essential component of our daily lives. ... There is a worrying increase in health problems that can be partially explained by the use of chemicals. ... The cause of these problems is the same: there is, at the moment, a huge knowledge gap in relation to chemicals. ... With REACH, chemical safety will go hand in hand
with chemical innovation." European Voice is a weekly newspaper with an independent view of the EU, published by The Economist Group since 1995.

On 13th February 2001, the European Commission adopted a white paper setting out the strategy for a future Community Policy for Chemicals. The main objective of the new Chemical Strategy is to ensure a high level of protection for human health and the environment, while ensuring the efficient functioning of the internal market and stimulating innovation and competitiveness in the chemical industry (COM(2001)88). Art. 1 states that this Regulation "lays down provisions on substances within the meaning of Article 3(1)", in which substance roughly means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive but excluding any solvent. These provisions shall apply to the manufacture, import, placing on the market or use of such substances on their own, in preparations or in articles. "So this Regulation aims at ensuring safe manufacture and use of a substance. It does not specifically address the issue of particle size. However, the obligation is on the manufacturer to assess the properties and the potential exposure resulting from the manufacture and use of this substance. Article 13 requires that a chemical safety assessment that addresses human health, physicochemical and environmental hazards shall be performed according to Annex I of the proposal. So it would be in this assessment to take into account any specifics of the particle size of a substance." Further research into nanoparticles toxicity is also carried out by the EC-funded project Impart-Nanotox.

A Briefing Note of the European Parliament more specifically addresses the issue of nanotechnology, and points out that the above mentioned White Paper faces the challenge of introducing a system that is capable of dealing with the large number of already existing substances. These substances account for 99% of total sales, and among these are the fine particles that are now labelled as nanoparticles.

The EU Scientific Committee for Cosmetic Products and Non-Food Products (SCCNFP) issued an opinion, that titanium dioxide particles are a safe component in sunscreen whether or not subjected to various treatments (coating, doping, etc.), irrespective of particle size. However, in the case of nanoparticulate ZnO also used in sunscreen formulations the SCCNFP concluded that for a proper safety evaluation an appropriate safety dossier on micronised ZnO itself, including possible pathways of cutaneous penetration and systemic exposure, is required.
In March 2005, a European Commissioned-funded project NANOLOGUE was launched, bringing together leading researchers from across Europe to facilitate an international dialogue on the social, ethical and legal benefits and potential impacts of nanoscience and nanotechnologies. This 6th Framework Programme project is led by Wuppertal Institute in Germany and features 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 will last 18 months.

2.2 Other European regulatory activities

Initiatives not coming from the European Union are those from business associations and from technology assessment (TA) organisations and NGOs. Two major business associations are the European Nanobusiness Association (ENA), for emerging nanotechnological industry, and Eucomed, for medical technology. A European Technology Assessment network under formation is TANTE, which is currently centred in The Netherlands. ENA and TANTE are organisations that are specifically occupied with nanotechnology. Eucomed has a wider scope, but is aware of the regulation issues that nanotechnology presents.

The EUROPEAN NANOBUSINESS ASSOCIATION (www.nanoeurope.org) is an industrial and trade organisation founded to promote the professional development of the emerging business of nanotechnology at the European level. Among its activities are: providing education for the public; writing of position papers; analysis of legislation; drafting of standards; and providing expert testimony to political leaders and decision makers. In their 2004 Survey, they found that the majority of the participants in the survey felt that regulation would moderately-to-a-lot influence their business, and that regulation should come from the European Union. 27

EUCOMED (www.eucomed.be), The European Medical Technology Industry Association, is a European association of medical device manufacturers. This association represents the interests of a large number of non-pharmaceutical European medical technology industry. However, the borders between the fields of pharmaceutics and medical devices become less and less clear.
(think of, for example, drug delivery by means of nano-carriers), and Eucomed called upon all European health authorities to develop a new approach for the growing variety of emerging medical technologies, which elude the traditional drugs-devices, divide. In the UK, such new approach has already been put into practice by merging two agencies for medicines and devices control.28

The other side of the coin becomes apparent in the proposed European directive 2001/83/EC, in which no exception is made for borderline products: if medical devices were regulated as pharmaceuticals, the registration process would last a number of additional years. Many medical devices have a much shorter lifecycle than drugs and consequently only a relatively small number of units are sold per model; treating these as drugs would give needless delay and highly increased costs and possibly a downturn on their investment in Europe would take place.29

Richard Moore, Director of Scientific Affairs at Eucomed, foresees potential benefits for patients of the innovation arising from “integration of several different advanced technologies into a single product, e.g. electronic miniaturisation, advanced materials science and telematics”, but also expects a need for new EU legislation to ensure patient safety and a good investment environment. A “potential area of concern from the regulatory viewpoint is emerging medical technologies such as nanotechnology and where within the regulatory framework these may fit. …work at the atomic, molecular and nano-levels has the potential to profoundly challenge ‘traditional’ regulatory demarcation boundaries.” 30

TANTE will be a network for TECHNOLOGY ASSESSMENT OF NANOTECHNOLOGY IN EUROPE. It is led by Arie Rip of the University of Twente, and aims aim to have a worldwide span. Members from Nano-Impulse and NanoNed will form this network. As for now, members of the Universities of Twente, Utrecht, Amsterdam, Delft, Eindhoven are involved, as well as from Nanoforum, TNO (Dutch organisation for Applied Science Research, for companies, governments and societal organisations, www.tno.nl), STT (Netherlands Study Centre for Technology Trends, www.stt.nl), WUR (Agricultural University Wageningen) and the Rathenau Institute. NanoNed is an initiative of the Dutch Department of Economic Affairs, as a result of a 2002 marketing research project to explore the chances for microsystems technology in The Netherlands. Part of NanoNed is financed under the name "Nano Impuls". An amount of 22.7 million euro is allocated to this programme.31
3 National regulatory institutions and discussion groups

The amount and type of attention that is paid to the prospected impact of nanotechnology differs between countries. Most attention is given to issues concerning health, safety and environmental risks. Germany produced a TA study with the widest scope that also included labour legislation. A Swiss TA institute presented a study in the area of medicine. In the United Kingdom an extensive study is currently being carried out on nanotechnology, part of which will be devoted to investigating the need for legislative action for nanotechnology. In the Netherlands, a TA institute is involved in stimulating the national public debate and has nanotechnology as one of its working fields. Outside Europe, the USA is leading the discussion about nanotechnology, with their recent Nanotechnology Initiative having attracted worldwide attention.

3.1 Germany

In 1990 the German government created the Office of Technology Assessment (TAB)\(^{32}\) whose remit is to design and implement technology assessment exercises that aid the German government’s decision-making processes on research and technology developments. As part of this TAB produced a report (number 92) on nanotechnology in July 2003.\(^{33}\)

In summary, their findings and conclusions were as follows. No regulations especially devised for nanotechnology exist in Germany, and were not found in other countries either. First, a systematic and extensive analysis of existing relevant legislation has to be done. In first instance, the following law systems are relevant for nanotechnology:

- (German) air pollution legislation
- Chemistry legislation
- Labour legislation
- Pharmacy legislation
- Medical products legislation
- Food and preservative legislation
- "Novel Food" regulation (EU)

From these, the following regulation instruments can be built:
<table>
<thead>
<tr>
<th><strong>Nano product</strong></th>
<th><strong>Safety check by means of</strong></th>
</tr>
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<tbody>
<tr>
<td>Pharmaceutics</td>
<td>Admittance policy</td>
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</table>
| Medical products| - No governmental admission policy  
|                 |   - Conformity procedures (CE-Marking)  
|                 |   - Self-certification (low risk products)  |
| Food            | - Production requirements  
|                 |   - Licence and registration obligations  
|                 |   - Caution and safety labels  
|                 |   - Bans  |
| "Novel Food"    | - Admission policy  
|                 |   - Notification of available equivalents  |
| Cosmetics       | - Policies on micro-biological state  
|                 |   - Licence and registration obligations  
|                 |   - Proof of competence as requirement for practising in cosmetics  |
| Air pollution   | - Limiting values according to BImschG/BImsch V 22  |
| Risk at the workplace | - Safety measures  |
| Dangerous substances | - Registration of substances  
|                 |   - Rules for handling dangerous substances  |

In addition to providing an analysis of trends in nanotechnologies and nanosciences, this report examines the social and ethical implications and recommends that: “Research into societal and ethical aspects of the development and widespread use of nanotechnology should be initiated now.”

- Data protection and privacy arrangements are investigated regularly and publicly debated.
- There is a central information point for public access.
- “Sociological and liberal arts” training be incorporated into the education of future nanotechnologists.
- An improved database on the environmental and human health impacts of nanotechnology be established to allow informed political decisions to be taken.

- A “systematic and comprehensive” review of current legislation as pertaining to nanotechnology is performed.

- A monitoring programme is established to track future applications of nanotechnology. This Monitoring-Programme should e.g. point at and evaluate biomedical, ecological, social and economical consequences, and stimulate research projects to solve open questions, and possibly gives directions for modifications of relevant legislation.

The German government has engaged the public and scientists in debate by staging a series of events around the country as part of the “Year of Technology 2004”. As part of the “Agenda 2010” reform programme there is recognition that the public must have input into ethics in science and that this will be a continuing relationship. The German government also established the National Ethics Council in 2001 that advises on ethical issues in life sciences (and therefore could advise on future implications of nanotechnology in health and medicine).

The parties of the German parliament support Nanotechnology in an unusual uniformity. Most parties want an increase in the concomitant research about ethical aspects and the benefits and risks of nanotechnology, and they support the financial funding by the government. Some want a further increasing in the level of funding.

The German Green Party held a hearing to discuss nanotechnology on March 1st, 2004. The conclusion from this was, that nanotechnology shows enormous potential but it also warned against optimistic expectations. As a result, the party wants to improve the interdisciplinarity of and networking in research, and states that it is indispensable to include ecological, ethical and social concomitant research from the beginning. It also recommends that effects on the environment and health should be analysed.

The German parliament held a plenary debate about nanotechnology on May 6th, 2004. The debate was requested by the coalition of Social Democratic Party (SPD) and Green Party and an initiative of the Free Democratic Party (FDP). The FDP has asked for a department spanning
strategy and a strengthening of basic research, a further development of application oriented research in close cooperation with companies and a strengthening of the centres of competence. They support improved research of ethical aspects and the impact on environment and health. The SPD and Green Party support the recently published German framework programme and also an improved networking between basic research and companies along the whole value chain. They request an intensifying of the public discussion about the benefits and risks of nanotechnology.

The Christian Democratic Union (CDU) has also a positive standpoint on nanotechnology. They support further increases in funding by the German government.\textsuperscript{39}

RESEARCH CENTER KARLSRUHE organised a workshop for material scientists, toxicologists and technology researchers on 8 December 2003, to discuss the relationship between nanomaterials, toxicology and technology assessment. Companies and institutes contributing to the panel were the Research Centre Karlsruhe, Fraunhofer-Institute INT Euskirchen, VDI Düsseldorf, University of Bern, Degussa Hanau, and BASF Ludwigshafen. The outcome was a set of lists of research questions from Toxicologists, Nanomaterials experts and Technology Assessment experts to each other.\textsuperscript{40}

3.2 Switzerland

TA-SWISS is the national Technology Assessment organisation in Switzerland (www.ta-swiss.ch). A recent TA-Swiss study on Medical nanotechnology\textsuperscript{41} recommended some legislative activities to control nanotechnology. In particular, they recommended the installation of an international Competent Body, which should monitor the development of nanotechnology and identify and limit potential dangers caused by it early on. This body should also stimulate communication about nanotechnology between scientists and the public and launch awareness-raising campaigns to enable consumers to evaluate the usefulness of nanotechnology for their health planning. A special report was dedicated to nanotechnology in medicine. The report points at the risks of abuse and at the risk of the "transparent" citizen (due to improvements in gene and other analyses). Due to the latter, the right of ignorance will be a matter of debate. The report
recommends the institutionalisation of a permanent process of observation, reflection and critical analysis. Actors in this process should be research, business, society and government. In this way, they hope to avoid mistakes that occurred previously with the introduction of novel technologies like gene technology.42

On 15 September, 2005, The Innovation Society (Innovationsgesellschaft) launched an international “Nano-Regulation” platform43, during the NanoEurope 2005 conference in St Gallen, Switzerland. This platform is currently supported by 16 private and public partners interested in nanotechnology regulation from Switzerland. They are open to partners from other countries as well. They intend to discuss a first progress report at NanoEurope 2006, on 13 September 2005 in St. Gallen.

3.3 United Kingdom

The Economic and Social Research Council (ESRC) published a report in 2003 entitled “the social and economic challenges of nanotechnology”.44 This report identified three important themes for the social sciences: the governance of technological change; social learning and the evaluation of risk and opportunity under uncertainty, and the role of new technology in ameliorating or accentuating inequity and economic divides.

In June 2003 the UK government commissioned the Royal Society and the Royal Academy of Engineering to carry out an independent study of likely developments in nanotechnology and to examine whether nanotechnology raises, or is likely to raise, new health and safety, environmental, social or ethical issues which are not covered by current regulation.45 The study consisted of a number of workshops variously involving scientists and engineers, civil society groups and a cross-section of the general public. A final report was published in summer 2004.

Findings and discussions of this report included:

- Lack of public perception (only 29% had heard of nanotechnology and only 19% could give a definition). However of those that had heard of nanotechnology the majority (68%) were positive about it listing benefits in health and material science.

- Necessity for the scientific community to engage with the media, as media coverage of nanotechnology developments will have a major impact on public perception. In this
context it is important that balanced, realistic views that use unambiguous language are presented to remove the image of nanotechnologies being “science-fiction” or “too dramatic and radical, and therefore risky” e.g. clean rooms are often perceived as being associated with infectious diseases and radiation, while the terms “self-replication” or “self-assembly” conjure up images of “grey goo”.

- Observation that the pace of technological advances should be linked to public understanding and decision-making, and that nanotechnology should not be imposed on the public (e.g. eradication of disability). If the public are not engaged early on this could have a major negative impact on development.

As to regulation, the report concludes that present regulatory frameworks at EU and UK level are sufficiently broad and flexible to handle nanotechnologies at their current stage of development. For the near future, the report mentions several examples of areas where modification of regulation on a precautionary basis is recommended:

**Nanoparticles and nanotubes**: it is recommended that the Health and Safety Executive carry out a review of the adequacy of existing regulation to assess and control workplace exposure to these particles.

**Chemicals produced in the form of nanoparticles**: are recommended to be treated as new chemicals under the existing regulatory frameworks of UK chemical regulation (Notification of New Substances) and its proposed replacement being negotiated at European Level (Registration, Evaluation and Authorisation of Chemicals).

**Cosmetics**: it is recommended that the use of nanoparticles in such products be dependent on a favourable opinion by the relevant European Commission scientific safety advisory committee. It is also recommended that the European Commission, with the support of the UK, review the adequacy of the current regulatory regime with respect to the introduction of nanoparticles into any consumer products.

**Disposal, destruction or recycling** of products that contain nanoparticles or nanotubes: it is recommended that procedures be published that outline how these materials will be managed to minimise possible human and environmental exposure.

Future applications of nanotechnologies may have an impact on other areas of regulation as, for example, developments in sensor technology may have implications for legislation relating to
privacy. In the report, it is concluded that there is no case for the moratorium which some have advocated on the laboratory or commercial production of manufactured nanomaterials. 

The UK government has responded to this report with promises of tighter regulation and further research to fill knowledge gaps. The government's response pledges an assessment of current regulatory mechanisms intended to control the release of nanoparticles and nanotubes in the environment, and to ensure that safeguards to public health are robust. The government will also work with its EU partners in order to gauge the need for specific European guidance on the assessment of risks associated with medicines and medical devices.46

As the borders between the categories of pharmaceutics and medical devices are less and less clear, the Medical Devices Agency (MDA) has been merged with the Medicines Control Agency (MCA) as of 1st April 2003, to form the MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY.47

3.4 The Netherlands

The RATHENAU INSTITUTE is an independent institute raised by the Ministry of Education, Culture and Science, which stimulates research and discussion in order to help politicians and citizens to form an opinion about scientific and technological developments. In a workshop on the risks of nanoparticles, representatives from government, industry, science and pressure groups discussed how such risks could be handled.48

The Rathenau Institute organised a hearing with the Dutch Parliament and the Parliamentary Theme Committee Technology Management on 13 October 2004. As a guide to this hearing, the Rathenau Institute published the document "To appreciate the small..." 49. With this concise booklet, a very readable document for the Dutch-speaking regions appeared. An ample overview is given without elaborating on details. The interested reader is shown the way to more information in the ten pages of notes supplemented. The text of this document is well accessible for both experts and non-experts. For non-Dutch readers, a summary can be found at www.nanoforum.org (article of 5 May 2004). An account of the hearing can be found in the report "Small technologies - large consequences" 50.
During 2005, the Rathenau Institute is organising several public debates on nanotechnology, including a Tumult Debate in June 2005 in Utrecht and a future workshop on biosensors with Studium Generale in Eindhoven, in September 2005. They are also working on Nanotechnology in Focus, which aims to select the five applications of nanotechnology which lead to most pressing societal issues at the moment. The list of candidate applications will be published in Autumn 2005.  

The ROYAL NETHERLANDS ACADEMY OF ARTS AND SCIENCES (KNAW) prepared a report on nanotechnology after a request of the Ministry of Education, Culture and Science, entitled "How big can small be?". One of the recommendations in the report was: "The government has a task in initiating a well structured discussion on the use and risk of nanoscience and nanotechnology." End December 2004, the minister of Education sent the report by the expert committee on nanotechnology of the Royal Dutch Academy of Sciences to the Parliament. Minister Maria van der Hoeven believes that nanotechnology is important for economy and society. The report also points out potential risks for health and environment. Both aspects will receive attention from the Dutch government.

FOUNDATION NATURE AND ENVIRONMENT (Stichting Natuur en Milieu, www.natuurenmilieu.nl) through prof. dr Lucas Reijnders, professor in environmentology at the University of Amsterdam (www.science.uva.nl/ibed) and the Open University, warns against the risks of nanoparticles for health. Reijnders advises that government and industry reserve about ten percent of their expenditures for the study of risks and risk restrictions. In an article in the Financial Newspaper (Financieële Dagblad), he tries to stimulate the public debate on the risks of nanotechnology by giving examples of animal experiments in which nanoparticles have proven to be harmful. Buckyballs, fibres in textile, titanium and zinc oxide in suntan oil and Teflon layers in frying pans are mentioned as examples. He wrote his article in reaction to the Science Budget 2004 of the present Dutch government in which nanotechnology was declared to be one of the three top priorities with a government budget of about 150 million euros.

In response, Reijnders' article, the editor of CHEMICAL WEEKLY (Chemisch2Weekblad), Alexander Duyndam, has published an editorial that supports Reijnders' view. Alexander
Duyndam emphasises that the questions raised are not of the 'grey goo' type, but of questions that are already relevant such as small particles, like fine dust, cigarette smoke and viruses. At the HOGESCHOOL ZUYD / UNIVERSITY DÜSSELDORF (Germany), prof. Paul Borm says in a reaction to Reijnders' article, that the Dutch interest in possible risks is not as low as Reijnders suggests. He refers to a meeting of the Rathenau Institute and the pan-European attention via the sixth Framework Programme, and the fact that other countries such as Germany have already performed pioneering work.

RIVM, the Laboratory for Toxicology, Pathology and Genetics at the National Institute for Public Health and the Environment is currently performing an investigation into the presence of fine dust concentrations as air pollution in The Netherlands. In a draft report (nr 609026003) they observed that concentrations often cross the specified thresholds. In a relatively small country such as The Netherlands, there is a relatively large contribution of foreign countries to its air pollution. This necessitates European legislation, in addition to the responsibility of the ministries of VROM (housing, land-use planning and environmental management), of Economic Affairs, of Transport, Public Works and Water Management, and of Agriculture, Nature and Food Quality for intervening measures. RIVM is currently working on studies to look at chances and risks of nanotechnology for health.

FRIENDS OF THE EARTH NETHERLANDS (Milieudefensie) and the regional action group ZUID-HOLLANDSE MILIEUFEDERATIE also picked up on the issue of aerosol pollution. Their study was specifically focussed on exhaust fume pollution near motorways. During a city debate on 20 March 2003, prof. Sjaak Slanina of the Universities of Wageningen, Beijing and San Salvador, presented a survey of the alarming situation in The Netherlands. In order to regulate the problem, the advice was given to limit the maximum allowed speed to 80 km/h. Later the same year, Milieudefensie proposed this solution in a letter to the Lower Chamber committees for Transport, Public Works and Water Management and VROM.

The HEALTH COUNCIL Gezondheidsraad has installed a committee on Nanotechnology and Health in December 2004. This committee will publish an advice to the Dutch government on this in Autumn 2005. Members are professors Wiebe Bijker (Univ. Maastricht), Inez de Beaufort
The MINISTRY OF JUSTICE has organised a conference on Ethical, Legal and Social Implications of New Technologies with a strong focus on nanotechnology on 6 April 2005. The aim of this conference was to start an internal debate in this and other government departments about legislative aspects of the emergence of these technologies which may occur in the next 25 years.59

The MINISTRY OF ENVIRONMENT VROM will publish a survey of chances and risks of nanotechnology for the environment in November 2005. They have asked the Health Council (Gezondheidsraad) and RIVM for reports on health effects on nanotechnology, which will be published beforehand.1

3.5 France

CCNE (Comité Consultatif National d'Ethique) is a national ethics consultation committee that has a working group Nanotechnologies with six members. This working group will make proposals to the United Nations for establishing, on an international level, regulations on the safe use of nanotechnology. In this scope, PACTE (Prospectives et Actions Communautaires pour les Technologies et l'Ethique), an association concerned with prospectives and social actions on ethics and technology, held a debate on ethics and nanotechnology on 4 May 2004.60

In a French Senate report on nanotechnology and medical progress, also international regulations for manufacturing are said to be desired.

3.6 Belgium

The Flemish Institute on Science and Technology Assessment viWTA has organised a discussion in the Flemish Parliament on Nanotechnology in June 2005. Participants were natural and social scientists working on nanotechnology, politicians and the public. At this meeting they presented a

1 Source Rathenau Institute: http://www.rathenau.nl/showpage.asp?steID=1&item=1162#project
dossier on nanotechnology summarising the state of the art of research and industrial interest in Belgium and an overview of policy issues. The natural scientists were concerned that too much public debate at this early stage on nanotechnology would slow down technology development in Belgium (or Europe in general).\textsuperscript{61}

The Flemish Green party Groen! organised a workshop on nanotechnology, health and environment at their summer weekend in August 2005. Over 20 politicians and other members discussed policy issues of nanotechnology together with Dr Lieve Goorden of University of Antwerp and Ineke Malsch on behalf of Nanoforum.\textsuperscript{62}

3.7 The United States

The US funding of hundreds of millions of dollars a year is shared by a broad range of federal agencies that are presently investing in nanotech research and development: the Department of Defense, Department of Energy, Department of Justice, Department of Transportation, Environmental Protection Agency, NASA, National Institutes of Health, National Institute of Standards and Technology, National Science Foundation, and the Department of Agriculture (Gutierrez 2004). Although there are a number of governmental agencies involved in nanotechnology research, this work is facilitated and directed by the NATIONAL NANOTECHNOLOGY INITIATIVE (NNI, \url{www.nano.gov}). The recently passed bill puts the President's National Nanotechnology Initiative into law and authorizes $3.7 billion over the next four years for the creation of the Nanotechnology Coordination Office and the funding of federal government nanotechnology programs. Part of this program is reserved for research on economic, social and ethics aspects of nanotechnology. For this part of the research the American Nanotechnology Preparedness Center was established.

The ELECTRONIC PRIVACY INFORMATION CENTRE warns that nanotechnology has the potential to revolutionize our concept of individual privacy. As computing capabilities become increasingly smaller and more efficient, collecting, storing, sharing and processing large amounts of information will become easier and cheaper. With that, nanotechnology has the capability of dramatically improving surveillance devices. They advise that it would be wise for Congress to enact legislation in advance of the adoption of nanotechnology innovations to guard not only
against threats posed to the environment, health, safety, public welfare, but also to threats posed to privacy\textsuperscript{63}.

At RICE UNIVERSITY’S CARBON NANOTECHNOLOGY LAB, Emmanuelle Schuler focuses attention on the consequences of the public perception of risks and nanotechnology. She points at the discrepancy between the perceived risks and the proven risks. Although there is no scientific evidence to support the notion that nanoparticles and nanotubes pose risks on human health and the environment, there have already been considerable discussions in the mass media and at the US Senate about the potential hazards of these small particles. Schuler warns against the temptation to consider public "fears" as merely irrational and due only to a lack of literacy and understanding. Doing so can have serious consequences to the market acceptance of a new technology, as was seen with e.g. genetically modified crops: where Monsanto, a large corn producer, experienced important financial losses in Europe\textsuperscript{64}.

NATIONAL SCIENCE FOUNDATION performed an internet survey on public attitudes towards nanotechnology. From the data of almost 4000 respondents, they conclude that the respondents do not associate nanotechnology with pseudoscience, despite its imaginative exploitation by science fiction writers. The analysis revealed that high levels of enthusiasm for the potential benefits of nanotechnology exist with little concern about possible dangers\textsuperscript{65}.

The CENTRE FOR RESPONSIBLE NANOTECHNOLOGY (CRN, \url{http://www.crnano.org}) started in December 2002 and has the mission to raise awareness of the issues of advanced nanotechnology. CRN is looking into effects of military nanotechnology development on arms control and proliferation.\textsuperscript{66}

The FORESIGHT INSTITUTE (\url{http://www.foresight.org}) is a non-profit organization with the goal to guide emerging technologies to improve the human condition. Foresight focuses its efforts upon nanotechnology, the coming ability to build materials and products with atomic precision, and upon systems that will enhance knowledge exchange and critical discussion, thus improving public and private policy decisions. In a report, they propose a regulatory framework that has four phases:
Phase 1—Pre-assembler: Safety standards are developed in parallel with the technology; regulatory controls are phased-in; security is increased to protect key aspects of assembler technology and key personnel.

Phase 2—Post-assembler, Pre-assembler lab: Close monitoring of key developers by a regulatory agency to assure compliance with safety standards; heavy security of facilities with "open" assemblers; efforts are directed to develop sealed assembler labs; commercial products can be made available after review by a regulatory agency.

Phase 3—Post assembler lab, Pre-active shield: Most research can be done safely in sealed assembler labs, so most close monitoring of Phase 2 is no longer necessary; still need heavy security of facilities with "open" assemblers; commercial products can be developed by anyone and submitted for review prior to manufacture by a secure facility; other efforts are devoted toward developing an active shield.

Phase 4—Post active shield: Environment is safe from assemblers, secure facilities are no longer needed; regulatory controls exist as necessary.\

In 1999, during a workshop on Molecular Nanotechnology, the Foresight Institute developed a guideline for work with Molecular Nanotechnology. The guidelines include assumptions, principles, and some specific recommendations intended to provide a basis for responsible development of molecular nanotechnology. In a more recent case study using the Toxic Substance Control Act, they reviewed the present status quo in collaboration with the WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS and the School of Engineering and Applied Science of the UNIVERSITY OF VIRGINIA. It was concluded that today, there is still no real regulatory policy formulated to deal with nanotechnology. They found three papers that explored regulatory opinions. Reynolds makes three conclusions. The first is that a ban on nanotechnology is impossible and harmful. The second conclusion is that strict government regulation is probably not completely possible. The third conclusion is that nanotechnology regulation is a process, not an event.

In CALIFORNIA, a hearing took place with the nanotechnology community on 20 January 2004 in Sacramento, about the impact of nanotechnology developments on the state of California. The hearing is part of the larger programme ‘Preparing California for the 21st Century’, in which the Californian government seeks advice about rising technologies and their economic, social, ethical and legal consequences. It was concluded that there does not exist a central, coordinated
policy for nanotechnology research, and that the policy makers do not have a vision on the economic and other consequences of nanotechnology.\textsuperscript{71}

EPA, the Environmental Protection Agency (www.epa.gov), is also discussing the need of regulating new technologies.\textsuperscript{72}

The US FOOD AND DRUG ADMINISTRATION (FDA, www.fda.gov) regulates a wide range of products, including foods, cosmetics, drugs, devices, and veterinary products, some of which may utilize nanotechnology or contain nanomaterials. The FDA defines nanotechnology in a similar way as the patenting agency USPTO does (see section 7). FDA expects many nanotechnology products that they regulate to span the regulatory boundaries between pharmaceuticals, medical devices and biologicals. These will be regulated as "Combination Products" for which the regulatory pathway has been established by statute. In such cases, FDA will determine the "primary" mode of action of the product. This decision will determine the regulatory framework for the product, i.e. a drug, medical device or biological product. FDA has only limited authority over some potentially high-risk products, e.g. cosmetics.\textsuperscript{73}

The MERIDIAN INSTITUTE (www.merid.org) is a non-profit organization whose mission is to help people solve problems and make informed decisions about complex and controversial issues. Their work focuses on a wide range of issues related to environment and sustainability, science and technology, agriculture, homeland security, and health care. This institute is convening a 'Global Dialogue on Nanotechnology and the Poor: Opportunities and Risks'. They developed a Paper to raise awareness about the implications of nanotechnology for poor people, both the potential opportunities and risks. Between 24 January 24 and 1 March 2005, they sponsored an on-line consultation process, and from more than 280 people they received responses to a set of questions related to the Paper. On 17-18 June 2004, the Meridian Institute and the National Science Foundation (NSF) convened an informal dialogue among representatives from 25 countries and the European Union. Together with the Woodrow Wilson International Center for Scholars (WWICS), they co-convened a series of dialogue sessions in Washington, DC, focused on the relationship between nanotechnology and federal regulations in the United States. They also organized informational sessions on nanotechnology for the
Rockefeller Foundation and facilitated the first meeting of the International Council on Nanotechnology.\textsuperscript{74}

4 International regulatory activities and international action groups

Global activities are mainly related to the international economic market, to worries about military misuse, and to speculative disastrous impacts of nanotechnology.

At the EU-US summit of 20 June 2005, both parties agreed on:
“\textbf{The United States and the European Union Initiative to Enhance Transatlantic Economic Integration and Growth}

At the 2004 Dromoland Summit, we committed to finding ways to:

- further transatlantic economic integration,
- spur innovation and job creation, and
- realize the competitive potential of our economies.

…

The U.S. and EU will increasingly rely on innovation and advanced technologies to stimulate economic growth and prosperity. Our aim is to increase synergies across the Atlantic as we become more knowledge-based economies.

To achieve this, we will work to:

…

- support an international dialogue and cooperative activities for the responsible development and use of the emerging field of nanotechnology;

…”\textsuperscript{75}

UNIDO has also discussed global cooperation on nanotechnology, at a meeting in Trieste, Italy, 10-12 February 2005. They concluded that Researchers from developing countries should join nanotechnology development now, to avoid widening the knowledge gap.\textsuperscript{76}

On 14-15 July 2005, an exploratory meeting for "responsible" research and development in nanotechnology was organised under the chairmanship of the European Commission. The meeting took place in Brussels and marked a step forward with respect to the international dialogue initiated in Alexandria (VA, USA). However, all participants acted in a personal capacity and the discussions were informal. The next meeting will be in Japan.\textsuperscript{77}
The OECD is beginning to look into health and safety aspects of nanotechnology. The Reinsurance company Allianz has published a report on Opportunities and Risks of Nanotechnologies which they developed in close collaboration with the OECD International Futures Programme. However, the opinions expressed in the report are only those of Allianz.

On 7 June 2005, the OECD Chemicals Committee held a special session on "the implications of manufactured nanomaterials for human health and environmental safety". The main aim was is to identify those issues related to the safety of nanomaterials which (potentially) need to be addressed in the future, both at the national and international level. A number of issues were identified for a more detailed discussion. There will be a follow-up Workshop, to be hosted by the United States, which will be held in Washington DC in December 2005. Information on these discussions is being published on the OECD Environment Safety webpages.

The OECD's Chemicals Committee comprises delegates from the 30 OECD member countries (as well as some non-member countries) from those ministries and regulatory agencies with a responsibility for the safety of chemicals - both in terms of both human health - and environmental safety. Many of the activities of the Chemicals Committee address issues in chemicals risk assessment and risk management.

COLIPA (www.colipa.com) is the European Trade Association representing the interests of the cosmetic, toiletry and perfumery industry. Colipa wants safe products and serves as the particles bureau to assure safe usage of nanoparticles in cosmetic products. Colipa was set up in 1962 to act as a voice for a €51.6 billion industry. Globally, the industry's turnover amounts to €190 billion.

The mass media have covered issues that are related to the question of new or other legislation as far as the risks of nanotechnology are concerned. The public debate has been mainly initiated by two large organisations, ETC and Greenpeace:

The ETC GROUP, an action group on Erosion, Technology and Concentration (www.etc.org), is concerned with what they call the 'corporate concentration of material building blocks and processes that make everything from dams to DNA'. ETC is the main force for pushing a moratorium on the manufacture of nanomaterials. They have asked for a moratorium until such a
time when the interactions of nanomaterials with living systems are more fully understood. The ETC group has asked for a UN International Convention on the Evaluation of New Technologies to regulate new technologies including nanotechnology. GREENPEACE is pushing more for a public consultation on this question. In their recent report, they discuss the existing socio-political concerns and the regulation debate. They focus on: medical issues, such as the possibility of genetic discrimination due to highly specific drug therapies; the nano-divide, the inequality in the distribution of wealth; and destructive misuse for military aggression. As to the regulation debate, they show the spectrum from the curbing approach of the ETC group to the more modest regulation structures advocated by nano-enthusiasts, such as the consensus standards proposed by the Foresight Institute.

Currently, the issue of military applications of nanotechnology has not been picked up by peace movements. However, the German centre BICC and the Acronym institute in the United Kingdom solidly fill this gap:

Dr Jürgen Altmann of the BONN INTERNATIONAL CENTRE FOR CONVERSION (BICC) and the University of Dortmund; and Dr. Mark Gubrud, University of Maryland, USA have published on the military applications of nanotechnology and are requesting a moratorium on non-medical implants. Since the USA is way ahead in research, and invest by far the most money in military nanotechnology, this moratorium should be unilaterally decided on by the US government. The moratorium should enable time for the international community to develop preventive arms control limits, as well as verification plans. “Long term security thus calls for strengthening of law and political institutions on the international level, including international criminal law, reducing the dependence on national military forces.”

In Disarmament Diplomacy, an online publication from the ACRONYM INSTITUTE, UK www.acronym.org.uk/dd in 2002, two articles were published discussing the need for an arms treaty to prevent the use of nanotechnology for weapons of mass destruction. Sean Howard (July-August 2002) based his argument on the contents of the defence part of the US National Nanotechnology Initiative, the replicator scenario of Eric Drexler and on the article of Bill Joy in which he warned that nanotechnology may enhance the capacity for mass destruction of
chemical and biological weapons. Sean Howard expects the US to want to develop such military nanotechnology for fear that terrorists otherwise may get a hold of such weapons first. But terrorists can only steal the weapons if national research programmes develop the technology and the knowledge. Therefore, Sean Howard proposes the disarmament community to develop an “Inner Space Treaty” to regulate military uses of nanotechnology. This treaty may either “ensure peaceful exploitation of the nano-sphere”, or ban the further development of nanotechnology completely. He proposes to start debating such a treaty in the UN Conference on Disarmament, under the already existing heading of “New Types of Weapons of Mass Destruction and New Systems of Such Weapons”.

A few months later, André Gsponer (October-November 2002) argued that nanotechnology was already applied in Fourth Generation Nuclear Weapons (also known as mini-nukes) and other new types of precision bombs, which are being developed around the globe in military research labs. The development of these nuclear weapons is not prohibited by the existing Comprehensive Test Ban Treaty (CTBT), because the explosive charge of one such mini-nuke is not large enough to make it a weapon of mass destruction. Also, the radioactive fall-out will be limited. The military want these warheads to enable them to penetrate the ground and want them to explode in caves and bunkers. Gsponer supported Howard’s call for an “Inner Space Treaty”.

5 Miscellaneous action groups

Here and there more or less obscure action groups arise, who often have in common the use of agitated language and unusual concepts:

**Angels Against Nanotech**, "Nanotech industry front group use Indymedia to talk to angels". The concept of angels is borrowed from the 19th century artist Edward Burne Jones. They also call themselves THRONG (The Heavenly Righteous Opposed to Nanotech Greed).

**The Globalism Institute**, an institute of the RMIT University in Melbourne, Australia, a university founded under the Royal Melbourne Institute of Technology Act 1992. The Globalism Institute was founded in 2002 and undertakes engaged research into globalisation, transnationalism, nationalism and cultural diversity. At this institute, Dr Gyorgy Scrinis, a research associate of the School of Architecture and Design acts as the expert regarding
nanotechnology. In a newspaper article on nanotechnology revolution, he suggested to pencil the term "nanopollution" into our ecological lexicons, compared the nano debate with the GE food debate and thought the question of who controls nanotechnology, who benefits from it, how it will be regulated and applied, and who takes the risks to have already been decided.\textsuperscript{89}

Even at a popular literature festival, the Hay Festival\textsuperscript{90}, a nanotechnology lecture by physicist Richard Jones is one of the highlights. Jones' opinion can, for example, be found in a PhysicsWorld article (http://physicsweb.org/articles/world/17/8/7).

6 Standardisation and testing

In general, in trade, standards and norms are of vital importance in order to ensure the quality and safety of a product. The buyers (industrial parties) want to know what they are buying and for this, uniform systems have been developed to describe the features of products and how to measure and test these features in advance. As nanotechnology is an overlap between existing technologies, new norms, standards and testing procedures may have to be developed. For example, the size of nanoparticles in addition to their chemical composition may determine their possible toxic effect, as mentioned earlier. In nanotechnology, there is also the complication that measurement techniques are still under development. For surfaces, this development started with the invention of the scanning tunneling microscope (STM) in 1981, followed by the scanning near-field optical microscope in 1984, the atomic force microscope (AFM) in 1986 and, currently being developed, the friction force microscope, the magnetic force microscope and an in vivo STM for producing moving images. Although each of the 'older' techniques are much further developed nowadays, an interlaboratory comparison of the step-height determination of AFMs showed a wide spread in measurement results. As a consequence, a standardisation organisation like CEN/STAR is concerned that insufficient standardisation will hamper the greater use of SPMs by industry.\textsuperscript{91}

In this section, we explore who the main players in metrology are and to what extent nanotechnology has already been discovered by them as a separate issue for attention. The EU policy with respect to metrology will be discussed separately from other European metrology institutes. Next, global institutes in metrology are discussed and two national institutes.
6.1 European Union metrology advices

Under the FIFTH FRAMEWORK PROGRAMME for Research and Development, the European Commission formed a HIGH LEVEL EXPERT GROUP (HLEG) to advise on activities within the generic technology “Measurement and Testing” with the aim of identifying new needs for research and development in metrology (including both measurement and testing) to support the demands from nanotechnology. It is argued that "To demonstrate that any product or manufacturing process meets a specified functional demand requires quantitative measurements traceable to an agreed metrology scale. Hence, to bring nanotechnology into a successful business, calls for access to the relevant metrology tools that give ability to measure in three dimensions with atomic resolution over large areas. Measurements are required of all important physical, chemical and biological quantities at various stages in the development of nanosystems, from design, prototype evaluation, and implementation. Therefore, nanometrology should be seen as an indispensable part of nanotechnology."

The HLEG recommended to the Commission "that a substantial fraction of the funding for nanotechnology should be particularly addressing the related measurement and testing needs based on open calls for proposals. Simultaneously, the nanometrology within the ERA should be explored by building upon existing European networks and centres of excellence. Also, systematic dissemination of knowledge is desirable. Specific actions should be supported by studies so they fall within areas where European impact may be expected to be greatest. Those identifications should also take into account and reflect global aspects, such as what are the situations and the trends in other regions, as in the Americas and East Asia. The situation in the U.S. should be taken to be particularly interesting. But also, the state of science and technology in Russia and the Middle and East European States should be treated. European organisations such as EUROMET, Eurachem, Eurolab, and euspen should be engaged. Other regional or national organisations such as NIST (National Institute for Standards and Technology) of the US will be involved. Contacts should be established with the Bureau International des Poids et Mesures BIPM who have set up two initiatives within nanometrology."

In the nanomaterials and production processes part of the third priority of the SIXTH FRAMEWORK PROGRAMME, it is stated in general that "Whenever appropriate, ethical, societal, communication, health, environmental and regulatory issues, in particular metrology and
measurement traceability aspects, should be addressed." This advice is repeated under the specific section of research areas.

6.2 European metrology institutes

EUROPEAN COMMITTEE FOR STANDARDISATION (CEN) is contributing to the objectives of the European Union and European Economic Area with voluntary technical standards which promote free trade, the safety of workers and consumers, interoperability of networks, environmental protection, exploitation of research and development programmes, and public procurement (www.cenorm.be). CEN proposed to their Members to set up a Working Group on Nanotechnologies, from which specific standardisation activities could be launched more easily. "Such an approach has worked in the past for challenging domains."93

A possible scenario for the Working Group would be the establishment of a new Technical Committee (TC) that overarches existing Working Groups. This would prevent fragmentation and duplication of effort. "Failure to act swiftly in this area could have significant repercussions for standards development and adaptation worldwide." 94 In March 2004, the CEN Technical Board (BT) created CEN/BT/WG 166 'Nanotechnologies'. The Working Group reports to the CEN/BT and its secretariat is with the BSI (British Standards Institution). Its major task is to analyse the need for standardization activities in this new area and to initiate relevant activities. The first step is the drafting of a Business Plan for a new CEN/TC. The first two meetings took place in July 2004 and October 2004,95 The scope of the Working Group encompasses three elements:

1. Developing a strategy for standardization in the field of nanotechnologies for Europe (a roadmap).
2. Monitoring and coordinating work in the area.
3. Liaising with other European initiatives in relation to nanotechnologies.

Hence the working group does not have a programme of work in standards development per se. In February 2005 the Working Group had carried out a survey of four different categories of stakeholders - industrial and nonindustrial (national) organizations, relevant CEN Technical Committees and 'pan-European' organizations and groups, e.g. European trade associations and European networks in nanotechnologies. The analysis of the results of this consultation will form
the basis of a strategy proposal, a draft of which was considered at the meeting on 15 April 2005, with the final version due for delivery to CEN Technical Board towards the end of June 2005. A new Technical Committee has not yet been established. During the meeting of 15 April, it was discussed that the title for the Committee should be 'Standardization and coordination in the field of nanotechnologies', and that this committee should get a status of its own and be known by other Technical Committee as nanotechnology has much in common with other disciplines. Of these other disciplines, several relevant ones (on textiles, and on biocompatibility of medical materials and devices) had not yet reacted to the nanotechnologies committee. (Source: internal report of the April meeting; Delft, 15 April 2005.)

The Netherlands is of the opinion that standards for Nanotechnology should be developed worldwide in the international organisation ISO (see section 6.5), not within CEN. (Source: internal document with comments on CEN draft proposal, 14 April 2005.)

In the Netherlands, the CEN draft proposal was discussed by a group of industrial (Shell, DSM, Philips, governmental (Ministries of Economics affairs and of Environment) and non-governmental (Foundation Technical Sciences (for NanoNed), University Leiden, NEN, NMi, MinacNed) partners involved in nanotechnology. (Source: internal report of their meeting of 11 April 2005).

In a proposal of June 2005, the working group CEN/BT/WG 166 recommends that CEN/BT establishes forthwith a new Technical Committee in the area of Nanotechnologies. This new Committee will be occupied with standardization in the field of nanotechnologies, with specific tasks being classification, terminology and nomenclature, basic metrology, characterization (including procedures for calibration), health, safety and environmental issues; and will also act as a liaison with relevant National, Regional and International standardization bodies and organisations, and with other relevant bodies, organisations and groupings world-wide.96

The United Kingdom commissioned a Publicly Available Specification (PAS) - a national form of a CEN Workshop Agreement - for a vocabulary in nanoparticles. This PAS is due for delivery by the middle of 2005 and could form the basis for an international, collaborative terminology document.97 England initiated the formation of a European group that will set up a strategy for normalisation in nanotechnology. This group started in July 2004. A survey among European
stakeholders was carried out end 2004, which attracted 140 reactions. (Source: internal document of Dutch stakeholders meeting on 11 April 2005).

Other large European standardisation institutes are CENELEC and ETSI, but these institutes have not yet addressed nanotechnology. For details, see chapter 7, "who's who".

EN - The EUROPEAN STANDARD. European Standards (EN) are documents that have been ratified by one of the three above described European Standards Organizations, CEN, CENELEC or ETSI. They are designed and created by all interested parties through a transparent, consensual process. European Standards are a key component of the Single European Market. Though rather technical and unknown to the general public and media, they represent one of the most important issues for business. Although often perceived as boring and not particularly relevant to some organizations, managers or users, they are actually crucial in facilitating trade and hence have high visibility among manufacturers inside and outside the European territory. A standard represents a model specification, a technical solution against which a market can trade. It codifies best practice and is usually state of the art. A standard relevant to nanotechnologies is EN 725-6: determination of specific surface area of ceramic powders. This standard, however, tends to be test-method based rather than metrology or product based.

CE MARKING (Conformité Européenne / European Conformity) is an obligatory European product marking indicating a successful completion of the products' compliance 'certification' according European 'CE Marking' Directives. It applies to products regulated by certain European health, safety and environmental protection legislation (www.cemarking.net). Currently, there is no information on nanotechnology. President of CEMarking.net Han Zuyderwijk thinks that the European legislator did not foresee nanotechnology when the issue of CE-marking was written. "In theory, nanotechnology would fall under several directives, such as the General Product Safety directive 2001/95/EC, the directive about product liability, the machinery directive 98/37/EC (if moving parts are involved), and the EMC directive (electronics). The General Product Safety Directive and the directive on product liability apply to all moveable properties. Apart from these directives, it seems to me that the risks of nanotechnology are of a totally different nature than those intended to be regulated in the CE-
directives. In case of specific use for medical devices, the Medical Devices Directive 93/42/EEC and the Active Implantable Medical Devices Directive 90/385/EEC may apply. 99 The regulative framework of the latter two Directives is discussed in Thumm et al. 2000 100. Important factors were shown to be: a) The directives are limited to essential requirements. To protect the safety and health of patients and users; they contain no specific technical rules. This means that regulation offers technological flexibility for innovation. b) The use of harmonised standards is a possible instrument for assessing conformity with the Directives in an efficient way. c) The directives offer different conformity assessment procedures. The manufacturer is therefore offered a modular and flexible organisational framework for conformity assessment. He can choose the best procedure for the firm and the product. 101

The General Product Safety Directive states in very general terms when safety is assured, and takes national and European legislation as point of departure: "… A product shall be deemed safe, as far as the aspects covered by the relevant national legislation are concerned, when, in the absence of specific Community provisions governing the safety of the product in question, it conforms to the specific rules of national law of the Member State in whose territory the product is marketed, … A product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, …" When suitable legislation is not available, the Directive gives quite broad statements to assess product safety, like: "…product safety codes of good practice in force in the sector concerned; the state of the art and technology; reasonable consumer expectations concerning safety."

European organizations EUROMET (European collaboration on measurement standards), EURACHEM (A focus for analytical chemistry in Europe), EUROLAB (European Federation of National Association of Measurement, Testing, and Analytical laboratories), and Euspen (European Society for Precision engineering and nanotechnology) have been addressing various aspects of nano-measurement and testing. Euromet investigated in detail the available measurement capabilities and forecasting the needs, planned a global workshop. Euspen set up an educational program that included nano metrology, funded by the fifth framework program 102.
The Taskforce Business Development of the Netherlands Normalisation institute NEN (www.nen.nl) is investigating the possibilities to deploy normalisation in new fields. NEN is one of the partners of a EUROPEAN COLLABORATION ON NORMALISATION coordinated by CEN. Their aim is to prevent different norms and standards from being developed for the field of nanotechnology. Aspects thought of specifically on the nanoscale are: definitions, basic metrology, determining physical characteristics, chemical composition and properties, biological properties (Projectmanager NEN - Business Development, by email 28/04/04). For the Dutch audience, NEN published a web special on "Nanotechnology: the next industrial revolution?" 103.

6.3 Other European standardisation activities

The European Nanobusiness Association (ENA, see section 2.2) launched its first workshop on Nanotube Standardization in October 2004. At this workshop it was concluded that the three “critical” test method requirements: length, diameter and absolute fibre fraction, should form the basis of a collaboration between those present with a view to preparing the basis/working drafts for standards projects that can be proposed to the relevant TC in CEN or ISO. Furthermore, one thought that the industry should consider adopting a standard data sheet containing data for bulk density, bulk moisture, bulk resistivity (optional), chemical composition, specific surface area measured using standardized test methods.104 The 2nd Workshop organised by ENA was hold in April 2005. At this workshop recommendations were made for quality assurance and characterisation techniques, and for risks prevention policies and recommendations for safe handling of materials.105 The 3rd Workshop on Standardization for Carbon Nanotubes will be hold on the 27-28 October 2005.

6.4 National metrology institutes

6.4.1 Germany

The German federal institute for materials research and testing BUNDESANSTALT FÜR MATERIALFORSCHUNG UND -PRÜFUNG (BAM, www.bam.de) and the German national metrology institute PHYSIKALISCH-TECHNISCHE BUNDESANSTALT (PTB, www.ptb.de)
are leading a consortium dealing with standard materials for lengths on the nanoscale and for thin film thicknesses (a governmental BMBF project).\textsuperscript{106}

The DEUTSCHES INSTITUT FÜR NORMUNG E. V. (DIN, www.din.de) also made a start of standardization activities in nanotechnology. At 23 June 2005 they organised a workshop on standardization in the field of nanotechnology, from without their department Deutsche Kommission Elektrotechnik Elektronik Informationstechnik (DKE, www.dke.de), a department that is supported by VDE, the Association for Electrical, Electronic & Information Technologies. Six areas will be represented: health technology, automobile, (opto-)electronics, chemicals, sensors, and measuring devices. The topics seen as high importance are: general terminology for nanoscience, nanotechnology and for materials composition and materials properties, environmental and health risks, measurement and testing methods.

\subsection*{6.4.2 United Kingdom}

Within the United Kingdom's national measurement laboratory NATIONAL PHYSICAL LABORATORY NPL, the Surface and Nano-Analys is Team is a national focus for the main Surface and Nanoanalysis techniques used by industry.\textsuperscript{107}

BRITISH STANDARDS INSTITUTION (BSI) was founded in 1901 and is the National Standards Body of the UK. They work with government, businesses and consumers to represent UK interests and facilitate the production of British, European and international standards. The CEN Working Group 166 'Nanotechnologies' (see section 2.2) was created under the leadership of BSI and the UK. BSI has established a national committee to provide the UK input into this review of current activities that is carried out by the CEN Working Group.\textsuperscript{108}

\subsection*{6.4.3 China}

China has created a body to draw up standards for nanotechnology. The National Technical Committee on Nanotechnology of Standardization Administration of China (SAC/TC279) was set up on 20 June 2005 in Beijing and is headed by Bai Chunli, director of the National Center for
Nanoscience and Technology. China has released seven nanotech standards since 2001. The new panel will coordinate between government bodies and research institutes to speed up determination of terminology, measurement and manufacturing norms.  

6.4.4 USA

In the USA, the NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST) planned in 2003 to spend around 4 million dollars on supporting "the development of nanotechnologies in fields such as health care, semiconductors, information technology, national security, biotechnology, and magnetic data storage. NIST will develop new standard reference materials, data, and measurement systems for the nanoworld to enable the private sector to develop and commercialize innovative products." "The technical risks in this field are high because even an individual molecule out of place may cause a device to fail."  

SEMATECH (www.sematech.org) is a company that assist in the commercialisation of technology innovations into manufacturing solutions, in the areas of semiconductors. Together with NIST, they published an improved method for determining nanoscale "linewidth roughness", an important quality control factor in semiconductor fabrication. As circuit features shrink in size to below 50 nanometers, wavy or rough edges within semiconductor transistors may cause circuit current losses or may prevent the devices from reliably turning on and off with the same amount of voltage.  

The AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI) is a private non-profit organization whose mission is to enhance global competitiveness and the quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. Composed of businesses, professional societies and trade associations, standards developers, government agencies, and consumer and labor organizations, the ANSI Federation represents the diverse interests of more than 120,000 entities and 3.2 million professionals worldwide. ANSI is the official U.S. representative to the International Accreditation Forum (IAF), the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC).
ANSI was approached by the Office of Science and Technology Policy (OSTP) in the Executive Office of the President to address this area of standardization in support of academics, various industries, the investment community and government agencies that utilize or regulate nanotechnology.

ANSI formed a *Nanotechnology Standards Panel* (ANSI-NSP), a new coordinating body for the development of standards in the area of nanotechnology. The panel first convened on 29-30 September 2004, at the National Institute of Standards and Technology (NIST) in Gaithersburg, MD, to focus its initial work on nomenclature and terminology. To guide the efforts of the ANSI-NSP, a Steering Committee is being formed and will be co-chaired by representatives of government, industry and the academic community. The co-chairs include: Dr. Clayton Teague, Director of the National Nanotechnology Coordination Office (NNCO); Dr. Vicki Colvin, Professor of Chemistry at Rice University and Director of the National Science Foundation-sponsored Center for Biological and Environmental Nanotechnology (CBEN); and Dr. David Bishop, Vice President of Nanotechnology Research, Lucent Technologies, and President of the New Jersey Nanotechnology Consortium. Action is underway for the ANSI ISO Council (AIC) to approve the ANSI Nanotechnology Standards Panel (ANSI-NSP) Steering Committee to act as an Interim Advisory Group to the AIC. The ANSI-NSP currently serves as the cross-sector coordinating body for standards in the area of nanotechnology and provides the forum within which stakeholders can work cooperatively to promote, accelerate, and coordinate the timely development of useful voluntary consensus standards.

The ANSI-NSP is open to all interested parties. ANSI has issued a call to organizations and individuals working or familiar with nanotechnology to consider the opportunity to participate on the panel and its Steering Committee\(^{112}\). To this call, the British Standards Institution (BSI) has submitted to ISO a proposal for a new field of ISO technical activity on nanotechnologies. The scope of the proposal identifies specific standardization tasks in the field of nanotechnologies such as classification, terminology and nomenclature, basic metrology, characterization, including calibration and certification, risk and environmental issues. Test methods include approaches for determining physical, chemical, structural and biological properties of materials or devices for which the performance, in the chosen application, is critically dependent on one or more dimension of <100nm. Test methods for applications, and product standards shall come within the scope of the Technical Committee.\(^{113}\)
In November 2004, ANSI-NSP released their first priority recommendations related to nanotechnology standardisation needs. The recommendations identify four broad standardization topics to be most urgent in a 12-month-or-less time frame:
- General terminology for nanoscience and technology, including definition of the term “nano,” consideration of impact on intellectual property/other issues, sensitivity to existing conventions.
- Systematic terminology for materials composition and features, including composition, morphology and size.
- Toxicity effects/environmental impact/risk assessment, including environmental health and safety, reference standards for testing, controls, and testing methods for toxicity.
- Metrology/methods of analysis/standards test methods, including particle size and shape, and particle number and distribution.

The AMERICAN SOCIETY FOR TESTING AND MATERIALS (ASTM) installed a Committee E56 for Nanotechnology in January 2005. This Committee addresses issues related to standards and guidance materials for nanotechnology & nanomaterials, as well as the coordination of existing ASTM standardization related to nanotechnology needs.

At the Cornell University, a chemical substances inventory has been set up, the Toxic Substances Control Act (TSCA). As for today, this extract has been prepared for Cornell University user convenience only.

6.5 International metrology institutes

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO, www.iso.org) is a network of the national standards institutes of 148 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization. Many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. Other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations. Therefore, ISO is able to act as a bridging organization in which a consensus can be
reached on solutions that meet both the requirements of business and the broader needs of society, such as the needs of stakeholder groups like consumers and users (www.iso.ch).

So far, only one published standard, in the area of surface chemical analysis: ISO/TR 19319:2003 provides information for measuring (1) the lateral resolution, (2) the analysis area, and (3) the sample area viewed by the analyser in Auger electron spectroscopy and X-ray photoelectron spectroscopy. No standards under developments were found. However, in May 2005, ISO established a new field of technical activity on nanotechnologies, the technical committee ISO/TC 229\textsuperscript{117}, with international approval.

VAMAS-CEN/STAR Workshop on MEASUREMENT NEEDS FOR NANO-SCALE MATERIALS AND DEVICES, held in the UK in 2002, concluded that: “there is an overarching need for methods, standards, reference materials and guidelines in mechanical property determinations for the characterization of nano-scale materials and devices. The most immediate high priority needs were for tests for a range of properties, including adhesion, deformation, stiffness and fracture. For imaging at the nano-scale, the trend for real-time, in-vivo measurements was highlighted. Furthermore, the importance of scanning probe tip characterization, critical to reliable measurements, was heavily stressed.”\textsuperscript{118}

INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS (IEEE) has a NANOTECHNOLOGY STANDARDS WORKING GROUP P1650 that will develop standard methods for the electrical characterization of carbon nanotubes. The methods will be independent of processing routes used to fabricate the carbon nanotubes. "There is currently no defined standard for the electrical characterization of carbon nanotubes and the means of reporting performance and other data. Without openly defined standard test methods the acceptance and diffusion of carbon nanotube technology will be severely impeded."\textsuperscript{119}

7 Patenting

The issue of covering intellectual property is gradually coming into focus. It rises questions as to whether and when nanoproducts are patentable. When is a nano-object a natural object (and thus not patentable) and when is it a constructed object? Should separate patent classes be designed
for nanotechnology products or can they be covered under existing patent legislation? Many debates are hold, and as a result, first adaptations of intellectual property legislation arise.

A concern of the ETC group is the fact that the general doctrine in patent law, that products of nature cannot be patented, can be sidestepped because of the atomically engineered building techniques.\textsuperscript{120}

At the 11 June 2003 seminar organised in the European Parliament by a coalition including the ETC group, Greenpeace and the Green party in the European Parliament, Pat Mooney of the ETC group raised the issue about patenting nanotechnology. One fundamental nano-patent might dominate developments in many industrial sectors, and enable the ownership of nature.

In the 12 May 2004 \textit{EC Communication "Towards a European Strategy for Nanotechnology"}, the Commission says that the issue of what is or is not patentable (e.g. at the level of individual molecules) should lead to a European or global agreement on concepts and definitions. The Commission wants to prevent unfair competition due to different local applications of Intellectual Property Rights (IPR). Patenting organisations should collaborate to develop a global patenting system. For released nanoparticles, the EU member states should revise the current legislation in order to cover for specific properties of nanotechnology, and agree on a common European approach.

The EUROPEAN PATENT ORGANISATION (EPO) is the executive body of the European Patent Organisation. This organisation was established by the Convention on the Grant of European Patents (EPC), signed in Munich 1973, and is the outcome of the European countries' collective political determination to establish a uniform patent system in Europe. It's training centre, the EPO International Academy, organised an \textit{International Symposium on Nanotechnology and Patenting} on 9-10 November 2004.\textsuperscript{121}

The UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO) has established a new cross-reference digest for nanotechnology designated Class 977/Dig.1, entitled Nanotechnology. Establishing this nanotechnology cross-reference digest is the first step in a
multi-phase nanotechnology classification project. The agency is continuing to identify and add
relevant documents to the new digest, and is developing a comprehensive nanotechnology cross-
reference art collection (Class 977, Nanotechnology classifier122) classification schedule that will replace
this digest. The ultimate nanotechnology cross-reference art collection schedule for Class 977
will include definitions, subclasses and search notes related to classifications in other U.S.
classes. The USPTO defines nanotechnology as: a) related to research and technology
development at the atomic, molecular or macromolecular levels, in the length of scale of
approximately 1-100 nanometer range in at least one dimension, and b) providing a fundamental
understanding of phenomena and materials at the nanoscale and creating and using structures,
devices and systems that have novel properties and functions because of their small and/or
intermediate size.123

As entrepreneurs are striving to claim patents over as many key nanotechnologies as possible,
nano patents may come in conflict. To analyze the nanotechnology landscape, Lux Research and
the law firm Foley & Lardner LLP reviewed 1,084 U.S. patents relating to five key
nanomaterials: dendrimers, quantum dots, carbon nanotubes, fullerenes and nanowires, patents
that were foundational to many other inventions. Of the 319 quantum dot patents, there were a lot
that overlapped. Part of the reason behind this confusion is nanotech patents often use different
language to describe quantum dots: "quantum dots", "semiconductor nanocrystals" or "silicon or
germanium nanoparticles". This, again, shows the need for standardized terminology.124

With respect to the already mentioned quantum dots, a legal battle is expected to be inevitable.
As the nanotech devices known as quantum dots grow ever more popular with the electronics and
life-sciences industries, analysts fear the complicated patents underlying the field will trigger an
expensive set of legal battles that benefit no one. Quantum dots are semiconductor crystals only
billionths of a meter wide and made up of as few as 10 atoms. They fluoresce brightly when they
absorb even tiny amounts of light. Quantum dots could help scientists image the behavior of cells
and organs to a level of detail never seen before in the $500 million worldwide market for
biological detection agents. Of the 319 quantum dot patents, many overlap.125
8 Industrial initiatives

Parallel to the detection of nanoscale particles comes the detection of chemical elements when occurring in very low densities (sub-ppm). PANALYTICAL (formerly Philips Analytical) and DSM RESOLVE have launched the first set of standards for the analysis of toxic elements in polyethylene, such as cadmium. Available under the name of TOXEL, the set of standards will provide the plastics industry with an essential tool for compliance with new international legislation governing the manufacture of plastics. This set of standards has been developed in response to the European Union’s RoHS and WEEE directives. RoHS = Restriction of Certain Hazardous Substances (2002/95/EC). WEEE = the Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC) was published on 13 February 2003. TOXEL has been developed for the use with XRF (X-Ray Fluorescence) analysis – a very effective method of measuring sub-ppm levels of toxic elements.126

CIENTIFICA (www.cientifica.com) is a consulting firm, providing global nanotechnology business intelligence and consulting services to industry, investors and governments. They issued a white paper on risks and regulation in nanotechnology. In this paper, they do not only describe the need for regulation, but also warn for the risks of regulation. For example, a major risk to business is that of hasty or poorly thought out legislation evoked by a single industrial accident.127 Another consequence of regulation are the high costs emerging from it. For example, the European Commissions REACH proposals (see section 2.1) may cost European industry some 1.4-12.8 billion euros.128

9 Conclusions

A considerable amount of attention is devoted to the issues of regulation and legislation. However, practical set-up of new legislation or adaptation of existing legislation is still in its infancy. It can be said that most countries are still in the phase of raising awareness and investigating what the regulated topics should be.
Most attention is focussed on health risks and environment protection. This is followed by military abuse. Science fiction scenarios like the run-away replicator are not taken entirely serious, but are not entirely neglected either. For practical implementation of regulation and legislation, however, health and environment protection have priority.

At the level of the European Union, activities are in the phase of organising hearings and setting up communications. At world level, Greenpeace and ETC are leading the public debate.

In many countries, specialised networks are booming and explorative studies are being performed. A very thorough study on nanotechnology in general was performed in Germany, a study that was directed to the German situation but can easily be generalised to other countries. The Swiss also provided a thorough study, restricted to the area of medicine.

Many standardisation institutes appear to be aware of the need of looking at and devising nanotechnology-oriented standards, but hardly any standards existed while writing the first version of this report, in June 2004. Mid 2005, several technical committees have been established worldwide and as a result several standards have been developed and adopted in various parts of the world, such as the USA, Europe, and China.

As to military issues, scientists in Germany, the UK and the USA act as spokesmen on the fears of abuse of nanotechnology.

The issue of covering intellectual property is gradually coming into focus. First careful questioning on the necessity of special patenting legislation for nanotechnology were heard around 2003, and in subsequent years several international conferences and symposia were organised.


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13. Dr. Anne-Katrin Bock, IPTS Institute for Prospective Technological Studies, Sevilla, Spain, by email 19 March 2004.

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