Nano in the Netherlands

Policy paper for the Nanotechnology Round Table Talks of the Permanent Committee for the Ministry of Economic Affairs on 3 June 2009

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Website: www.rathenau.nl
Publisher: Rathenau Instituut

Cover design: Smidswater, The Hague
Layout: Rathenau Instituut, The Hague
Translation: Taalcentrum, VU University Amsterdam
Print: Drukkerij Rob Stolk, Amsterdam

Preferred citation:
Bart Walhout, Ira van Keulen, Rinie van Est, Frans Brom (Rathenau Instituut)
Ineke Malsch (Malsch Techno Valuation). Nederland Nanoland - Notitie voor de rondetafel Nanotechnologie van de Vaste Kamercommissie voor Economische Zaken op 3 juni 2009. Den Haag, Rathenau Instituut TA

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Preface

This summer, the Dutch House of Representatives held a debate on nanotechnology. The members had a barrage of questions for the ministers. “Can the Cabinet say how the Netherlands intends to maintain its competitive edge? What choices will this involve and who will make them? What needs to be done to get the commercialization of scientific nano research off the ground? Does the Cabinet see any opportunities to turn the risk analysis into a market spearhead? Is the Cabinet’s sense of urgency strong enough to tackle potential risks? Shouldn’t the government invest more in adequate testing and assessment procedures?”

Many of these questions stemmed from the round table meeting on 3 July 2009, organized by the Permanent Committee for Economic Affairs in collaboration with the Rathenau Institute, where seven speakers from public organizations, academia and industrial and consultancy sectors presented their views on the opportunities and risks of this key technology. In preparation for the round table meeting, the Rathenau Institute wrote a paper entitled *Nano in the Netherlands*, which asked four key questions: What is the economic significance of nanotechnology? What is the global position of the Netherlands? Is the Netherlands seizing its chances? What should it concentrate on in terms of risks?

The nano debate is not expected to get into gear until this autumn. On 29 September 2009 a broad public dialogue on nanotechnology has started under the leadership of the Nijkamp Commission. This dialogue will continue for eighteen months and give everyone an opportunity *and* the necessary funding to formulate and express an opinion. This summer, the House of Representatives adopted three motions: The government must introduce reference values for the most frequently applied nano particles with a view to exposure on the work floor, a mandatory public risk analysis, and a report obligation for the use of nano particles in products in the Netherlands. And we have not yet heard the last of the government’s upcoming investment in infrastructure and areas of application for nanotechnology. The Committee of Wise Men has not yet approved the FES proposal *High-Tech Systems & Materials*. The consortium has been given a second chance.

So the future of nanotechnology is still in the balance. And not only in the Netherlands. Worldwide investments are being legitimized on the basis of publication scores, patent lists and market analyses. But the OECD concluded recently that the underlying figures are certainly inconsistent and sometimes even incomplete. Other

uncertain factors are the potential risks and whether international agreement will be achieved on research and regulation in the foreseeable future.

Governments and politicians will have to make choices at national and international level. This paper provides an account of the current political issues for the Netherlands.

Jan Staman
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Summary

Nano in the Netherlands - points of political focus

The Second Chamber held a debate on nanotechnology on 11 June 2009. This is a significant point in time, for while the Netherlands prepares for a new investment programme, the European Parliament is seeking to set clear boundaries on the use of nanomaterials and the introduction of nanotech products on the market. Why is nanotechnology so important? And what needs to be done to avoid potential risks? In the run-up to the political discussion, the Rathenau Institute wrote the background memorandum, *Nano in the Netherlands*. In this summary, we set out the most significant political points of focus.

Nanotechnology: opportunities and risks

Nanotechnology makes all kinds of developments possible: from lighter, stronger materials and cosmetic products to smaller computers and molecular medicine. Such developments give rise to numerous and widely varying social concerns relating to the safety of humans and the environment, privacy and patients' interests, ideal and worst scenarios. These are issues that deserve to be debated openly. In the coming year, the Social Dialogue on Nanotechnology – recently set up by the cabinet - will move the debate on the social impact of nanotechnology forward. At the same time, important decisions are already being taken with a view to realizing the Dutch aspirations for establishing nanotechnology as a significant aspect of our knowledge economy in a responsible manner. Our approach to the most urgent issue – uncertainty concerning the safety of nanomaterials for humans and the environment – is a necessary part of this. Consequently, important (political) decisions must be made in respect of opportunities and risks alike.

What is it about?

- Global investment in 2008: $ 8.4 m (state), $ 8.6 m (industry)
- Dutch investment in 2006: € 155 m (state), € 240 m (industry)
- Market of $147 m in 2007 and predicted at $3100 m in 2015

Figures: Lux Research and Economic Affairs

Political points of focus

Will the Netherlands grasp its opportunities?

Research and innovation

The powers of innovation within Europe and the Netherlands are generally not strong. Despite sound infrastructure, the Netherlands and other European countries such as France and the United Kingdom underperform as regards numbers of knowledge workers, R&D investments and 'brain drain'. The cooperation between science and industry is therefore an important point of focus, and so both knowledge institutes and industry have worked on the strategic research agenda (SRA) of the Netherlands Nanotechnology Initiative (NNI). Decisions have been taken in respect of four knowledge areas and four application areas: a small country like the Netherlands cannot excel in everything, after all. The Committee of Wise Men is currently evaluating the FES High Tech Systems & Materials proposal, which is to lend the first fulfilment of the SRA. But other aims are also formulated in the FES proposal, at the request of the Ministry of Economic Affairs, such as the study by the Holst Center and MicroNed. This raises the following questions:

– Is there sufficient focus in the research and innovation agenda on nanotechnology in the Netherlands?
– Is the step from research to innovation being taken effectively, and has the cooperation between science and industry improved?

Social interests

Focus implies a goal, and that requires embedding in society. In the SRA, the subjects of energy, clean water and nanomedicine are three areas of application that meet a clear social demand. These areas are also structured in such a way that social involvement can take shape as the new technology develops. In the area of nanoelectronics, social issues do not form any direct impetus for innovation, but innovation is being encouraged from a mainly economic perspective. In the long term, nanoelectronics will contribute to the development of all kinds of intelligent products. A sound social embedding of these applications will not come about automatically, however. In today's NanoNed there is therefore a separate 'flagship' of Technology Assessment (TA). The purpose of this research is to understand and improve the interaction between science, technology and society. Internationally, the Netherlands stands as an example in this. But within the FES proposal, TA has not been given a place, which raises the following questions:

– Is there sufficient balance between social interests and industrial interests?
– Is there sufficient attention being paid to the impact of nanotechnology on society?

The European Parliament (EP) In March this year, the EP established two legislative resolutions with explicit rules in respect of nanomaterials: realignment of the cosmetics regulation and regulation in the area of new food products. In April this year, the EP adopted a resolution on the legislative aspects of nanotechnology with a large majority. With these three resolutions, the EP is giving a strong political signal based on a strict interpretation of the 'no data, no market' principle.

Is there sufficient focus on risks?

Science is uncertain as regards the safety of nanomaterials. Now that nanotech products are appearing on the market and around 400 people are working with nanomaterials in the Netherlands alone, the issue acquires a social urgency: requirements relating to health, safety and environment risk assessment need to be reviewed, but the knowledge and expertise necessary to perform this is still largely lacking. Since it is expected to take years for that knowledge to be available, the existing knowledge should be shared as much as possible to allow the best choices to be made. The European Parliament has brought the discussion on the approach to the risks of nanotechnology into sharp focus with a package of requirements that must be realized within two years (see box). For each of the three solution areas (research, regulation and information) we therefore cite an important political point of focus and our recommendation as to how the Dutch government should approach the negotiations concerning the requirements of the European Parliament.

Research

Risk research should be largely financed from innovation funds, with associated funding criteria. The European Parliament desires adjustment of the evaluation criteria for the funding of risk research and an independent European network to coordinate the research.

– Does the Dutch funding of risk research deliver adequate results, and how is this research to be coordinated with the requirements of the risk assessors?
– What needs to be regulated at European level, and what are the requirements of this, both nationally and globally?

Regulation

The adjustment of European guidelines such as for working conditions, chemical substances (REACH), nutrition (novel food) and cosmetics, will take time. The European Parliament desires adequate admission procedures for nanomaterials and nanotech products within two years.

– What can the Dutch government do to accelerate the necessary adjustments in the execution of REACH?
– Are temporary measures required, or is the term set by the European Parliament sufficient?

Information

A priority in the closing of knowledge gaps is to gain insight into the scale of the problem. Which products have which nanomaterials processed within them, and how are these processed? The European Parliament also wants all consumer products containing nanomaterials to state 'Nano' on the label, so that the consumer can make a choice.

– Can short-term adjustment to the European guidelines provide sufficient information on the use of nanomaterials, or are other registration systems required? What is the best means of getting companies to cooperate on registration?
– Is labelling a solution that should be applied at the present time? If so, what is needed for this?

Policy and debate in the Netherlands

2004:
- Founding of NanoNed (FES round 1)
- Public meeting on Nanotechnology (Second Chamber theme committee on Technology Policy)

2005:
- Cabinet response to KNAW (Royal Netherlands Academy of Arts and Sciences) recommendation 'How big can small get'; statement of Cabinet position

2006:
- Cabinet position on Nanotechnologies 'From small to Great', and response to Health Council report 'Significance of nanotechnologies to health'

2008:
- Strategy document 'Dealing with risks of nanoparticles' (VROM)
- Nanotechnology Action Plan
- Response to Parliament questions on risks of nanoparticles (VROM, Economic Affairs)
- AO Innovation, Action Plan Nanotechnology on the agenda

2009:
- AO Nanotechnology

1 Nano in the Netherlands

The Dutch House of Representatives was due to hold a debate on nanotechnology on 11 June 2009. This would mark an important occasion for, whilst the government gears up for a new round of investments, the European Parliament wants to set clear limits for the use of nanomaterials and the marketing of nanotech products.[1] Why? What is the problem? What needs to happen? And why is nanotechnology so important? To ensure that the participants in this political debate are optimally informed and prepared, the Rathenau Instituut, in association with the Permanent Committee for Economic Affairs, was holding round table talks on nanotechnology on 3 June. The main issues are explained in this paper.

Nanotechnology and political choices: rising to the societal challenge

Amongst other things, nanotechnology enables us to process materials on the minutest scale. It opens up opportunities for a whole array of innovations, everything from new materials and cosmetic products to smaller computers and molecular medicine (see Section 2.1). However, these innovations raise many different questions concerning human and environmental safety, privacy and patient interests, desirability, and dream and nightmare scenarios. The impact of nanotechnology extends across such diverse areas that it will not only raise new questions but rekindle existing ones as well.

The Cabinet is eager to meet the challenge. The Dutch government sees nanotechnology as an important pillar in the national knowledge economy and has invested heavily in it so far. To address the various issues, the Ministry of Economic Affairs presented the Cabinet's Vision of Nanotechnology in 2006 and the Nanotechnology Action Plan in 2008. Meantime, developments in nanotechnology have been attracting more and more interest; first, because of the potentially highly promising applications, and second, because of the growing uncertainty regarding the safety of nanomaterials. It is important to determine – with a view to the political

[1] The European Parliament understands nanomaterials both as nano-objects (i.e. nanoparticles or "separate objects with one, two or three outer dimensions on nanoscale") and as nanostructured materials (i.e. materials "with an inner or surface structure on nanoscale"). More defintions in Paragraph 2.1.

decision-making – whether the Netherlands can tackle the challenges posed by nanotechnology within the framework of current government policy.

Focus: what needs to happen *now*?

Nanotechnology touches on so many areas of development that it is virtually impossible to deal effectively with all the issues in one debate. However, we can still define the topics at this moment in time. A wide-ranging public debate is required so that we can position ourselves strategically with a view to the future. What can we expect? Where do we want to go? The recently appointed Committee for Public Dialogue on Nanotechnology will be exploring these questions in the coming year. At the same time, important choices – political and otherwise – need to be made about the opportunities for the Netherlands. Hence, we need to answer the most pressing question: Is the uncertainty regarding the human and environmental safety of nanomaterials being adequately addressed? Serious steps need to be taken now in relation to both risks and opportunities. The aim of the round table talks is to gain a clear picture of the current debate at national, European and international level.

What is it all about?

In Section 2 we look at the area covered by nanotechnology – an extensive area because it concerns research and technological development on a specific scale, rather than within a specific domain. Like ICT and biotechnology, nanotechnology is a key technology and, as such, is relevant in many different fields of application. Much of the current research and many of the new applications are even based on a combination of these three key technologies (plus technologies from neuro and cognitive sciences). In this section we look at these converging technologies and the important role played by nanotechnology within them. The participants in the round table talks need to gain an impression of the significance of nanotechnology in society. At the same time, it would be useful to form an idea of the significance of nanotechnology for the Netherlands. What investments has the Dutch government made in recent years and what have they returned so far? We shall also consider whether the Netherlands can keep pace with the global developments in and around nanotechnology.

Are we seizing our opportunities?

In Section 3 we review the new research and innovation agendas in the Netherlands. New rounds of investment have begun. The national NanoNed Programme expires in

2010, so a new strategic research agenda has been compiled which has been partially translated into an application for the Fund for Strengthening the Economic Structure (*Fonds Economische Structuurverstrekking / FES*). This is a crucial moment for the politicians, who need to ascertain whether the Netherlands can effectively speed up its efforts to retain its position among the top nanotechnology countries. In this section we identify some key issues. Is enough attention being paid to societally desirable goals? Is the taxpayers' money being invested to maximum effect? We explain the background to these questions in Section 3.

Is enough attention being paid to the hazards?

In Section 4 we discuss the response to the potential hazards of nanomaterials. The health and environmental risks need to be properly addressed before we can determine the innovation opportunities for nanotechnology. The European Parliament recently sent out a powerful political signal with its stringent interpretation of the 'no data, no market' principle for nanomaterials in food and cosmetics (see also Appendix C). What does the Dutch government have to do to speed things up so that the European directives for chemical substances, cosmetics and food can also be applied to nanomaterials and nano products? And what needs to happen in the meantime to combat potential risks? There are divergent opinions on these questions. In recent years scientists, businesses and public organizations have adopted a fair number of standpoints and offered copious recommendations. In this section we present the main similarities and differences and identify issues that need political attention.

Contribution of experts

During the nanotechnology round table talks on 3 June the members of the Permanent Committee for Economic Affairs (EZ) will be afforded an opportunity to put questions to representatives from the scientific community, the business sector, public organizations and regulating bodies. A draft version of this paper has already been forwarded to these experts. The Rathenau Instituut wishes to thank the following people for their input: Dirk van Aken (VWA,) Dave Blank (Dutch Nano Initiative), Hans Jager (Netherlands Society for Nature and Environment), Adriënne Sips (National Institute for Public Health and the Environment), Willem-Henk Streekstra (Confederation of Netherlands Industry and Employers), Wim van Veelen (Dutch Trade Union Federation) and Ronald van Welie (The Dutch Cosmetics Association).

2 Nanotechnology in the Netherlands

What exactly are we saying when we talk about nanotechnology and what does nanotechnology mean in the Netherlands? We aim to answer these questions in this section. In Section 2.1 we take a brief look at the terrain covered by nanotechnology. In Section 2.2 we explain the relevance of nanotechnology for the Netherlands and answer the question whether the Netherlands can keep pace with worldwide developments in and around nanotechnology.

2.1 What is nanotechnology?

Nanotechnology (including nanoscience) is an amorphous, interdisciplinary field. Nanotechnology is not a self-contained, clearly defined concept, but a blanket term for different domains of theory and practice. In simplest terms, nanotechnology means working on the minutest possible manipulable scale. This is conveyed in the definition of nanotechnology in the Strategic Research Agenda: *"the design, characterization, production, manipulation and application of structures on nanoscale, with one or more dimensions which are typically (but not absolutely) below the 100 nanometre scale."* (SRA Nanotechnology 2008, p. 8).

One nanometre is a billionth part of a metre. It is extremely difficult – if not impossible – to imagine a concept on such an infinitesimally small scale. One commonly used illustration is the fingernail, which grows by between five and ten nanometres a minute. Nanotechnology enables us to study and manipulate our environment on nanoscale – the scale of molecules and atoms. It deepens our understanding of the rudimentary building blocks of biology, chemistry, electronics and physics. This is why nanotechnology is often referred to as a 'key' technology.

Convergence of technologies

Nanotechnology stems from the science of materials. It was material scientists who performed the first experiments on controlling substances on nanoscale and thus created materials with new properties. The resultant nanoparticles often have different properties and behave differently from larger particles. Carbon nanotubes,

for example, are very light, strong and conductive compared with normal carbon. So, it looks as if a whole world is waiting to be explored on this minute scale.

The Netherlands has always been strong in materials science. We have been investing in it since the 1970's. Interestingly, nanotechnology is bringing huge momentum not only to materials science but to two other key technologies as well – biotechnology and information technology – where we have also been making our mark for many years. The combination of these three technologies has even led to a totally new field of science: synthetic biology. This development is known as NBIC convergence (nano, bio, info and cogno). Nanotechnology is, in effect, the driver of this convergence because important biological processes take place on nano scale whereby genes, bits and neural reactions can come together. This is how the subcellular electrical information processor in neurons plays a crucial role in learning and memory. Scientists are now able to measure this electronic activity with nanothreads and even exchange information with the same neurons.

The convergence of all these disciplines at nano level is opening up new scientific horizons. Or, in the words of the European Commission: NBIC convergence is leading to a new wave of technology with relevance for many fields of application.[2] It is not within the scope of this paper to explain the extent of these applications. In the next section we do, however, offer an idea of the types of application that are specifically based on nanotechnology. It goes without saying that these applications have implications for other areas of science and technology.

Applications and products

– There are three main types of application or end product in nanotechnology:
– Nanotechnology instruments that make it possible to conduct research on nanoscale and to produce nanomaterials and structures, such as optical tweezers and atomic force microscopes;
– Products with parts that are structured on nanometre scale, such as chips that are tested on nanoscale and nanosieves for water filtration;
– Products that contain synthetic nanoparticles with specific (new) properties, such as:

[2] In 2004 the European Commission set up an expert group to provide insight into the nature and extent of the concept of converging technologies for Europe. The official name of this group is the *High Level Expert Group Foresighting the New Technology Wave.*

- Silver nanoparticles with antibacterial and anti-fungal properties. Applied in textiles, toothbrushes, plastic packaging for food, and paint for hospital walls;
- Carbon nanotubes, strong, light spheres and fibres that can conduct electricity. Applied in sensors, batteries and various materials for motor vehicles, aircraft, etc.;
- Silicon nanoparticles in medical applications to strengthen silicon rubber and in cosmetics (*inter alia* for anti-ageing)[3];
- Titaniumdioxide nanoparticles absorb UV rays in cosmetics. This catalytic effect is also used to neutralize air pollution in paint and coatings[4];
- Silicon dioxide nanoparticles to improve emulsifiers in food[5];
- Nanocontainers, spheres containing medication that sensitize surfaces and release medication at the right place. Can be used to treat carcinoma;

– Structures that acquire specific properties because they have been made with nano dimensions, such as 'single-electron devices' which transfer electrons and will lead to supercomputers, or materials that switch with light (photonics) or magnetism (spintronics).

So, nanomaterials are not always about nanoparticles. There are also nanothreads, nanofibres, nanotubes, 'quantum dots' (nano-dimensional crystals made of semi-conductive material), constructed biomolecules (such as peptide, proteins, adapted viruses) and nanospheres containing, for example, medication or vitamins.

In Section 4 – potential risks to the environment and human health – we concentrate on products in the third category, i.e. products containing nanoparticles.

[3] See http://www.siriusinternational.nl/pdf/nieuwsbrief_december_2007-Silibrite.pdf
[4] Source: http://www.scientificamerican.com/article.cfm?id=paving-out-pollution
[5] Source: http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier004.pdf

The Woodrow Wilson nanoproduct database

The main source worldwide on nanoproducts for the consumer market is the database of the Woodrow Wilson Center in the USA.[6] This database contains 803 products (end 2008) and is based on marketing information and other data that businesses supply with the products. In other words, these are 'manufacturer-identified nanotechnology-based consumer products'.

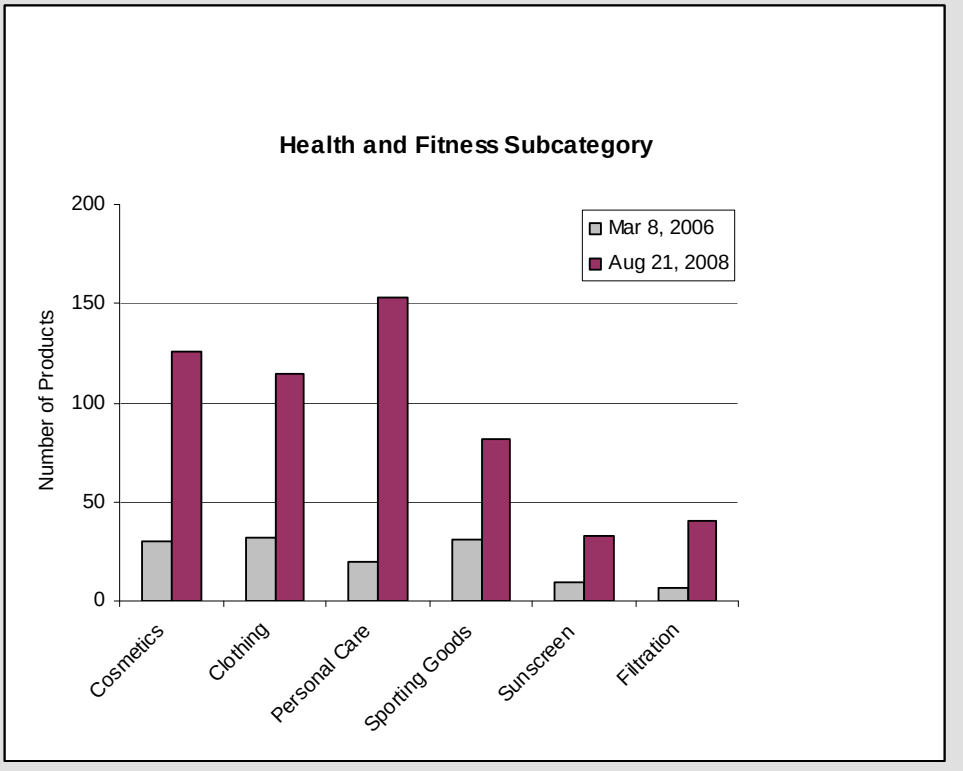
We have two serious reservations about this database. First, it contains no products or materials based on nanotechnology from the B2B chain. Secondly, it may also list products which the producers say are based on nanotechnology because they hope this will push up sales. The 'Tata Nano' car, for example, has nothing to do with nanotechnology.
That said, this is still a useful database. It is, after all, the only one of its kind and it does at least give an impression of the type of nanoproducts that are currently on the market. It is unclear at present if this database is regularly updated.

Additionally, most of the products in the database fall into the category of health & fitness (502). This is followed by home & garden (91), food & drink (80), electronics & computers (56), product coatings (52), motor vehicles (43), domestic appliances and batteries (31) and children's products (18). The largest category, health & fitness, is split into subcategories in the graph below.

The National Institute for Public Health and the Environment (RIVM) and the RIKILT Institute for Food Safety used the Wilson Center database for estimates that they published in mid-2007 on the number of products on the Dutch market. Around two hundred products that probably contain nano materials are available on the Dutch market. The RIVM announced in September 2008 that the nanomaterials in these products consist mainly of nano forms of silver (antimicrobial effect), titanium dioxide (absorption of UV rays in sunscreens), cerium dioxide (added to diesel to reduce soot emissions and to save energy) and carbon tubes (light, strong, conduct electricity)

[6] See www.nanotechproject.org/inventories/consumer/

Graph 1: Consumer products in the health & fitness category



Source: Woodrow Wilson Center (2008)

Growth market

It appears therefore that only a limited number of products containing specific nanoparticles are being marketed at present. Some research agencies are nonetheless predicting that the market for these products will burgeon. Lux Research (2009) says that the market will be worldwide and will be worth more than 3100 billion dollars in 2015 (compared with 147 billion dollars in 2007). It should be noted that these figures relate to the total sales of end products, and not only to the contribution of nanotechnology. In many cases, nanotechnology accounts for only a fraction of the end product. Take, for example LCD screens, which contain nano crystals.

According to Lux Research, at least 86 percent of these sales between 2007 and 2015 will consist of end products in which nanotechnology is applied, such as cars, mobile phones and buildings. Moreover, 6 - 14 percent will consist of intermediary products such as composites, displays and coatings, and only 0.5 percent of nanomaterials such as carbon tubes and silver nanoparticles.

Further predictions say that nanotechnology will be internationally applied primarily in the following four sectors:

– materials and manufacturing, e.g. the motor industry, construction and chemicals;
– electronics and IT;
– health and life sciences;
– energy and the environment.

Lux Research says that the greatest profits are to be made between 2007 and 2015 in the materials and manufacturing industry (58 – 65 percent). Health and life sciences (10 percent) and energy and the environment (less than 2 percent) are at the bottom of the list. The fastest growth will, however, take place in energy and the environment.

2.2 What is the position of the Netherlands in nanotechnology?

Despite its diminutive size, the Netherlands is performing well in nanotechnology. According to the Nanotechology Action Plan, we even rank among the global sub top. In this section we provide a summary of the nano activities in the Netherlands. We then present the available figures for public and private investments, followed by a review of various businesses, knowledge institutes and start-ups, patent applications and academic publications. To facilitate comparison we present, where possible, figures from other countries and other fields of technology.

Public and private investments

In 2008, as in previous years, total investment in nanotechnology rose worldwide by 15 percent compared with 2007 (total 15.8 billion dollars).

The Dutch government has been investing heavily in materials science since the 1970's and is now investing in nanotechnology as well. If we look at public investments in key domains between 2004 and 2010 based only on subsidies under the BSIK programme (government resolution on investment subsidies for knowledge infrastructure), Hightech Systems & Materials is in second place at 444 million Euros (Committee of Wise Men 2008). Nanotechnology forms a very important part of this field. Hightech Systems & Materials comes after Life Sciences & Health (1092 million) and before ICT (229 million). In the international figures for public investment in

nanotechnology, the Netherlands, with 242 million dollars in 2008, occupies ninth place in the world and fourth place in Europe (Lux Research 2008). Together with Germany (700 million dollars), France (538 million dollars) and the UK (318 million dollars) the Netherlands is the greatest investor in nanotechnology in Europe.[7]

TABLE 1: (Inter)national investments in nanotechnology in 2008 (Lux Research 2009)

	World	**Europe**	**The Netherlands**
Public investments	$8.4 billion	$2.6 billion	$242 million
Large corporations	$8.6 billion (all businesses)	$1.7 billion (all businesses)[8]	-
Venture Capitalists	$1.2 billion	-	-
Total	$ 18.2 billion	-	-

In 2008 international investments from industry amounted to a total of 8.6 billion dollars, an increase of 11 percent compared with 2007 (7.8 billion dollars). Interestingly, the bulk of the private investment in nanotechnology was for electronics and ICT (49 percent). This was followed by materials and manufacturing (31 percent), energy and the environment (13 percent) and finally healthcare and fitness (7 percent).

Internationally, public and private investments were fairly evenly balanced. Private investment even exceeded public investment for the second year in a row. In Europe public investment still exceeded investment by large corporations. It is unclear whether this also applied to the Netherlands in 2008 as the figures on corporate investment are still to be published. According to the Cabinet, corporate investment across the board (large corporations and SME) in the Netherlands in 2005 and 2006 exceeded the public investment (240 compared with 155 million Euros, Nanotechnology Action Plan 2008).

Plainly, the commercialization of research & development in nanotechnology intended for marketable products and processes is not yet generating enough cash flow to

[7] These four countries also account collectively for 69 percent of the total public investment in Europe (2.6 billion dollars).

[8] Much of the European corporate investment comes from large chemical and materials companies, such as Evonik in Germany and Akzo Nobel in the Netherlands.

support itself financially. Public money will continue to be needed for the time being at least. Public investment has always been important in fundamental research, but in the case of nanotechnology, governments throughout the world are increasingly shifting the focus to commercialization (Lux Research 2009). Section 3 will show that the situation in the Netherlands is no different. This can be inferred from the fact that many more businesses are participating in the FES proposal for nanotechnology than in the current (soon to expire) NanoNed programme.

Businesses and knowledge institutes

There is no official list of the businesses and organizations in the Netherlands that are working with nanotechnology. The Action Plan of the Dutch Cabinet (2008) and the Strategic Research Agenda (SRA) of the Netherlands Nanotechnology Initiative (NNI 2008) reckon that 270 industrial players were active in nanotechnology in 2006.[9] Most of these were existing companies. It is thought that ten or eleven start-ups are added every year. Thirteen of the twenty most R&D-intensive businesses in the Netherlands are investing in nanotechnology. These include some heavyweight players: Philips, NXP, ASML and FEI, followed by DSM and AKZO NOBEL.

At present,117 large, medium and small-sized enterprises are participating in the Netherlands Nanotechnology Initiative (the successor to NanoNed) as well as thirteen universities, six teaching hospitals and nine large technological institutes (Onderzoek Nederland 2009).

According to SenterNovem (2005 and 2006), nanotechnology businesses in the Netherlands are active in nanomaterials (approximately 75), instrumentation (approximately 40), devices and system integration (approximately 25), bionanotechnology (approximately 20) and precision manufacturing (approximately 10).

It is not easy to convert the above figures into employment statistics. Statistics Netherlands is still having difficulty allocating relatively new sectors like nanotechnology to existing business categories.[10] Borm *et al.* studied 37 businesses

[9] At present the Netherlandsse Chemical Industry Association (VNCI) is checking this list in order to distinguish between businesses that engage in research and businesses that produce products based on nanotechnology .

[10] Statistics Netherlands has recently started collecting better figures on the relevance of biotechnology and nanotechnology in Dutch business (CBS Annual Plan, 2009). It is unclear whether this extends to employment figures.

and organizations that work with nanomaterials. They estimate that several hundred employees and researchers in the Netherlands work directly with nanotechnology or nanomaterials (important in relation to health and safety regulations) and that the total number of employees at the above-mentioned businesses numbers 41 thousand (Borm *et al*., 2008). This figure includes the people who are directly and indirectly dependent on nanotechnology.

Patents

The Netherlands scores well in all lists for nanotechnology patents. This is a key piece of information as patent lists shed light on the current technological activities in a country. People apply for patents in order to protect new knowledge or applications.[11] One should be aware, however, that an application for a patent does not always lead to the launch of a product.
The data on Dutch nanotechnology patents as a percentage of the total number of patents in the world tend to fluctuate.[12] One aspect which all the figures have in common is that the Netherlands holds fourth place in Europe.

The most recent figures are taken from the 2008 Compendium of Patent Statistics (OECD 2008). They indicate that the Netherlands owned 2.1 percent of the nanotechnology patents in 2005. The Netherlands holds seventh place in the world,[13] and fourth place in the EU.[14] The Dutch region of North Brabant, with 72 patents, was eighth for nanotechnology patents in the top thirty regions in the world between 2003 and 2005 (1.7 percent of the total). This is the only Dutch region in the world top 30 and is also the highest ranked European region. The OECD report also draws comparisons in other key domains such as ICT and biotechnology. The Netherlands scores more or less equally in both domains: eighth place in the world and fourth in the EU for ICT and seventh in the world and fourth in the EU for biotechnology. The score for North Brabant is much higher – fifth place – when it comes to ICT. There are no Dutch regions in the top forty regions with biotechnology patents.

[11] Knowledge can also be protected by observing secrecy or by a fast market launch. The strategy differs according to the preferred practices of the business and the sector in question. Seventy percent of businesses in the electronics sector opt for patenting, compared with only 25 percent in the biotechnology sector (CBP, 2008). The situation regarding nanotechnology in the Netherlands is unknown.

[12] The figures vary between an average of 1.4 percent in 1978-2005, to 1.7 percent in 1994-2000 (Igami & Okazaki 2007) to 2.1 percent in 2005 (OECD 2008) and to 3.1 percent in an unspecified period (Patent Office).

[13] For purposes of comparison: 41.8 percent in the USA, 25.4 percent in the EU, 16.7 percent in Japan and 2.6 percent in the BRIICS countries (Brazil, Russia, India, Indonesia, China and South Africa).

[14] After Germany (8.8 percent), France (4.7 percent) and the UK (4.0 percent).

The Patent Centre of the Ministry of Economic Affairs reports that patent applications in nanotechnology are growing fastest in the Netherlands (Appendix 1 Nanotechnology Action Plan) and that most of the Dutch nanotechnology patents are in the ICT sector (nano-electronics). The number of patents for nanomaterials is rising fastest in the Netherlands. In the next four years the FES proposal for High-Tech Systems and Materials (2010-2014) should generate 280 patent applications (Onderzoek Nederland 2009).

Academic publications

Our knowledge position in nanotechnology is excellent according to the Cabinet (Nanotechnology Action Plan 2008). Indeed, the standard of Dutch research is, relatively speaking, very high when we look at the citation cores. A recent study by researchers from MERIT in connection with the European Observatory Nanoproject revealed that, in 2006, the Netherlands had the highest citation score worldwide (2,589), ahead of Switzerland (2,369) and the United States (2,265) (Newman *et al*., 2009). We held fourth place in 2002 and third place in 1998.

The Netherlands, with over two thousand nano publications, shared eighth place with Switzerland in the EU between 1998 and 2007 (after Germany, France, the UK, Italy, Spain and Poland). Europe leads the world in the number of publications in nano science. Between 1998 and 2007 one third of all nanotechnology publications in the world came from the EU.

If we look at the performance of the universities of technology we see that TU Delft and TU Eindhoven ranked among the forty best institutes in 2006.[15] In the same year TU Delft came eleventh in the world for citations with a score of 3,057 and 126th for publications; TU Eindhoven came nineteenth in the world for citations with a score of 2,668 and 120th for publications.

Between 1998 and 2007 three Dutch companies were among the eight companies in the world that produced scientific publications on nanotechnology: Philips (7th with 449 publications), Unilever (29th with 168 publications) and Shell (53rd with 75 publications).[16]

[15] The citation score applies only to Web of Science, April 2008. Both universities score higher in other databases.
[16] IBM (USA) came first with 1,375, followed by NTT (Japan, 1,191), Samsung (Korea, 1,000), Hitachi, NEC and Toyota (all Japan).

Position of the Netherlands compared with other countries

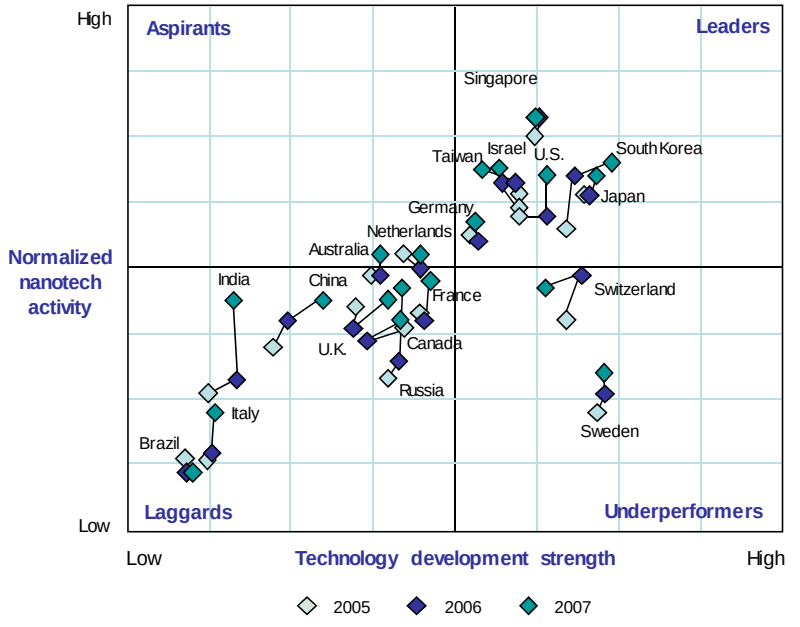
The Lux Research benchmark which compares the leading countries in nanotechnology every year is widely quoted (see, for example, the Nanotechnology Action Plan and the Strategic Research Agenda of the NNI). In this paper we also rely on the methodology analyses of Lux Research to gauge the knowledge and innovation position of the Netherlands in nanotechnology compared with other countries.[17]

One needs to clearly understand the meaning of the axes in order to get to grips with the graphs. The scores for the general developmental strength of technology (the x-axis) are based on the relative figures for R&D expenditure, the number of knowledge workers, the number of PhDs in physics and engineering, the emigration of knowledge workers, the infrastructure and the investments in high-tech manufacturing. The score on this axis is fairly crude as it relates to the general innovative strength of a country and not specifically to nanotechnology.
The assessment of the nanotechnology activities in a country (the y-axis) is based on the number of nanotechnology initiatives and nanotechnology centres, the public and private investments in nanotechnology, the availability of venture capital, the number of academic publications and patent applications and the number of businesses that engage in nanotechnology.

Normally, Lux Research uses the *absolute* figures for nanotechnology activities (as in Figure 3), because these figures, expressed as e.g. numbers of publications and levels of investment, also have an absolute impact. As a result, large countries tend to score better than small countries on the y-axis.
However, when the nanotechnology activities are considered in a relative context (i.e. normalized to GNP), the Netherlands scores higher. Figure 2 shows that investments and activities in nanotechnology are doing well compared with general technological innovation. The Netherlands may not rank among the actual world leaders, but it certainly ranks among the aspiring world leaders.

[17] Raymond Creemers of Lux Research will be present at the round table talks of 3 June to explain the graphs and the figures.

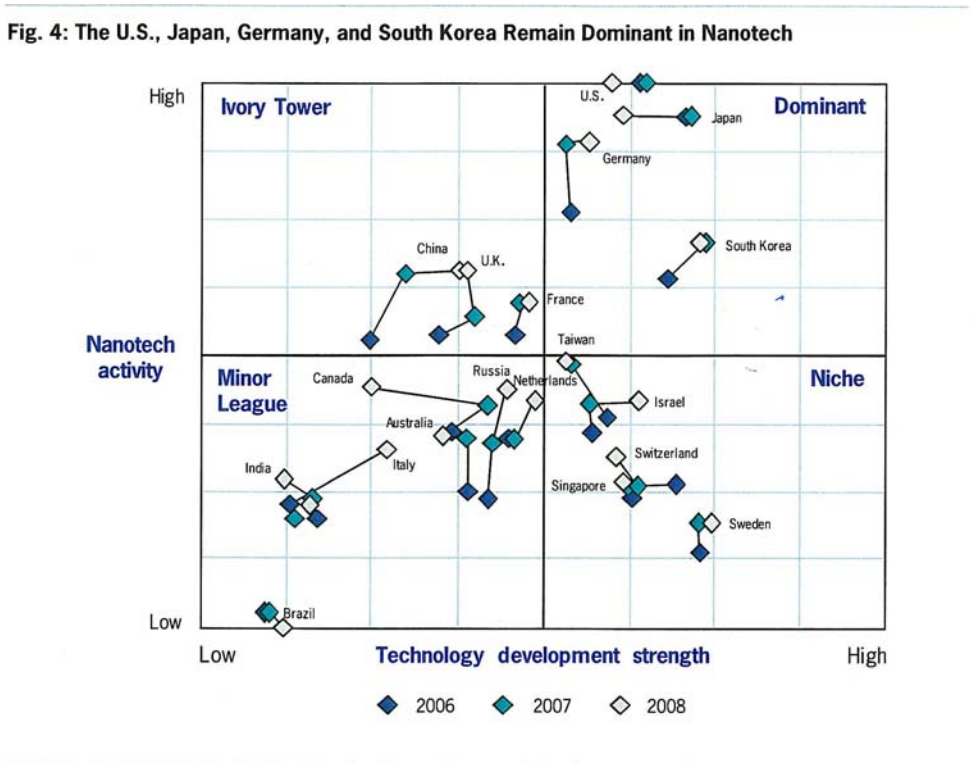
Figure 2: Relative nanotechnology activity in the top nanotechnology countries 2005-2007



Source: Mail exchange with Raymond Creemers, Lux Research

Figure 3 is based on more recent figures from 2008. It shows the nanotechnology activities in absolute figures. We can generally conclude from the figure that the USA, Japan, Germany and South Korea will continue as the world leaders in nanotechnology in 2008. The Netherlands has definitely improved its position since 2007, but, as a small country, is seems to be lagging behind in this graph. Even so, the graph shows that the Netherlands scores well for nanotechnology activities compared with other small countries in Europe. The report also reveals that the Netherlands scored fairly high in 2008 for investment in high-tech manufacturing, for infrastructure and for emigration of knowledge workers. The average scores for development strength are attributable to low expenditure on R&D and the shortage of knowledge workers

Figuur 3: Absolute nanotechnology activities for the top nanotechnology countries in 2008



Source: Nanomaterials State of the Market Q1 2009, Lux Research, p. 6.

3 Opportunities for the Netherlands

The Netherlands has clear ambitions for nanotechnology. The aim, as worded in the Dutch Cabinet's Vision on Nanotechnologies, is *'to keep pace with the global developments in and around nanotechnology and to retain a place in the world top'* (Nanotechnology Action Plan, p.3). As shown in Section 2, the Netherlands is well placed to profit from the anticipated growth of the market in products based on nanotechnology. The Cabinet believes that, in order to capitalize on these opportunities, it is just as important to *'find ways of controlling potential risks to human health and the environment'* (Nanotechnology Action Plan, p.3). The potential risks of nanotechnology are discussed in detail in Section 4.

3.1 Nanotechnology Strategic Research Agenda (SRA)

To give shape and substance to the Dutch ambitions the Cabinet instructed the Netherlands Nanotechnology Initiative (NNI 2008) to draw up a Strategic Research Agenda (SRA) for Nanotechnology. The large-scale nationwide NanoNed research and innovation programme (2004-2010) is nearing an end and the country is gearing up for new rounds of public investment. The NNI is a partnership between NanoNed, the STW technology foundation and the Foundation for Fundamental Research on Matter (FOM).

Themes and areas of application

The SRA is building on the NanoNed programme, but with a clear reprioritization from nano electronics to other themes. For example, the NNI has selected four generic themes for the Nanotechnology SRA with the purpose of generating new knowledge:

– Beyond Moore (nano electronics, and chip technology in particular);
– Nanomaterials (materials with new functional properties);
– Bio-nano (nano in medicine);
– Nanofabrication (instruments for research and manipulation on nanoscale).

The Netherlands Organization for Scientific Research (*Nederlandse Organisatie voor Wetenschappelijk Onderzoek* / NWO) published a strategic memorandum in 2005 in which it stated that the Netherlands excels in these areas.

The SRA addresses the Cabinet's vision (Kabinet 2006) in another four strategically important areas of application: nanomedicine, food, energy and clean water. The Nanotechnology SRA stresses that there is a clear demand in the industrial sector for nanotechnology research in relation to health and nutrition (e.g. MinacNed 2006).

No less important is the theme of 'impact on society and risk analysis'. This is another area in which the Netherlands enjoys a good international reputation. According to the Cabinet, the National Institute for Public Health and the Environment (specifically the KIC expertise centre on nano risks) even has the *'potential to grow into an international centre for monitoring and detecting risks of synthetic nanoparticles'* (Nanotechnology Action Plan 2008). Research on technology assessment is also farther advanced in the Netherlands (NNI 2008).

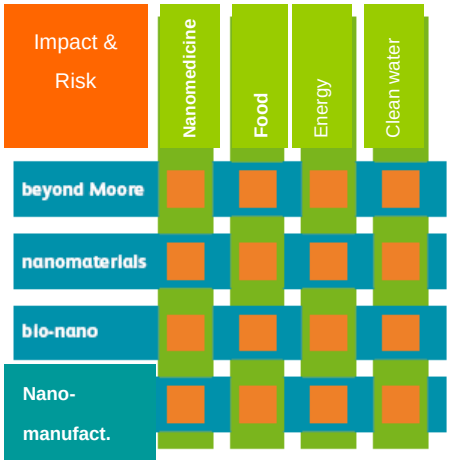


Figure 6: Schematic presentation of the generic themes and areas of application with the theme 'impact on society and risk analysis' at the intersections

Source: NNI, Nanotechnology Strategic Research Agenda, 2008, p. 33

Allocation of the investment

The NNI recommends that the Netherlands continue to invest heavily in nanotechnology in the next ten years. One hundred million Euros is needed annually to realize the aims of the Nanotechnology SRA. Half of this sum must be raised from public money. The other half must be raised by industry (20 percent), knowledge institutes (15 percent) and nano initiatives by the Netherlands Organization for Scientific Research and the European Union (15 percent). The investment is allocated as follows:

– application research (25 percent);
– generic research (20 percent);

– infrastructure and open innovation (20 percent);
– research on the risks and implications for society (15 percent);
– human capital (10 percent).

Basis for thrashing out the Dutch ambitions
The Nanotechnology SRA forms a good basis for thrashing out the ambitions of the Dutch government. The reasons are twofold: first, the NNI has made some clear choices in theoretical and applied domains. The preface to the SRA states: 'Nanotechnology covers a broad and varied field which is expanding and developing all the time. The Netherlands therefore needs to make choices.' In contrast with NanoNed, which placed a strong emphasis on nano electronics, the urgently needed expansion has been realized.

Second, the NNI has clearly tried to improve the connection between research and innovation. The NNI says itself that *'there is room for improvement in the collaboration between scientists and industry'* (p. 70). So far, it is mainly the academics who have benefited from public investment. This led to, amongst other things, the highest citation score worldwide for the Netherlands in 2006. But crucial opportunities await in the future, particularly in *'linking academic findings to utilization and open innovation'* (p. 14). NanoNed and the Nanotechnology SRA are now finding practical applications for academic research. Accordingly, the NNI now consists of 117 large, small and medium-sized enterprises, 13 universities, 6 teaching hospitals and 9 major institutes of technology (Onderzoek Nederland 2009). NanoNed, in contrast, was a consortium of 7 universities, TNO and Philips.

Partnership between scientists and industry is still fragile

Research by the Rathenau Instituut (2007) on innovation dynamics in areas where nanotechnology is applied indicated that the partnership between scientific research and industrial operations in the Netherlands is still a little fragile on occasion. There are, for instance, two serious problems in the application of solar cells.[18] The solar cell industry in the Netherlands is very limited and cooperation between industry and science is pretty low-key in the Netherlands and Europe as a whole. The knowledge base on water treatment is still very fragmented in the Netherlands and, again, there is very little cooperation. Moreover the intensity of R&D is modest. On the other hand, the Dutch nano-electronics industry and Dutch expertise in the application of nano-

[18] Nanomaterials can be used in new or improved types of photovoltaic solar cells with higher efficiency or at lower cost prices.

electronics are among the best in the world. Cooperation between the two is excellent. Industry and science are also working closely together In nanomedicine, though there is still hardly any drug-delivery industry in the Netherlands (still run mainly by start-ups and SMEs) (Rathenau 2007).

3.2 FES proposal for High Tech Systems and Materials

As a follow-up to the Nanotechnology SRA, the NNI is working on a business plan to pull off the proposed (public) investment. Part of the plan involves the submission of a FES proposal. Initially, this proposal was based only on the SRA, but at the request of the Ministry of Economic Affairs (i.e. SenterNovem), it was combined with FES proposals based on the research agenda of MicroNed and the Holst Centre. The proposal was renamed 'High Tech Systems and Materials' (2010-2014) and it no longer relates only to nanotechnology, but also to microsystems (MicroNed), wireless sensors and polymer electronics (Holst). The FES proposal includes two other themes besides the nine mentioned at this start of this section, namely: sensors and actuators and autonomy and flexible devices.

The chairperson of the FES proposal, Dave Blank (Onderzoek Nederland 2009), says that fundamental and societal research (e.g. Technology Assessment, TA) should form no part of the FES proposal. Nanoned, in the BSIK programme, had an explicit TA component (TA NanoNed).[19] Research on potential environmental and health risks does, however, account for 15 percent of the part of the proposal that concerns nanomaterials. The Committee of Wise Men and the Netherlands Bureau for Economic Policy Analysis are expected to put forward recommendations on the FES proposal for HTS&M in the very near future.[20]

Allocation of the FES proposal

The FES proposal entails a total sum of 434 million Euros (300 million in public investment and 134 million in private investment). Out of the 300 million in public investment money 85 million will come from the universities and 215 million from FES. Interestingly, 148 million Euros are earmarked for generic technological development, 67 million for societal applications and 15.2 million for risk analyses

[19] TA NanoNed was even added to the BSIK application upon the recommendation of the Committee of Wise Men.

[20] These recommendations go to the CEKI which prepares the papers for the Cabinet, which will make a statement before the summer recess onthe FES proposals to be funded.

(around 15 percent of the part of the proposal that concerns nanomaterials) (Onderzoek Nederland 2009). It should also be noted that the FES proposal embraces less than half the Nanotechnology SRA: between 15 and 20 million Euros a year of the 50 million Euros invested by the government. The NNI intends to ask the Netherlands Organization for Scientific Research and various ministries to invest in the parts of the SRA which are now missing from the FES proposal.

How great is the difference between the annual public investment available for the old BSIK programme and the annual public investment available for the new FES programme as a whole and for nanotechnology in particular? That is an intriguing question. Table 2 shows that, at present, they are more or less equal. If the FES proposal is approved, a slight rise may be expected. But, of course, the table tells us nothing about extra investments outside BSIK/FES that the government has made and may make in the future via the Netherlands Organization for Scientific Research or the ministries. For example, the Ministry of Economic Affairs is investing a separate €343 million (till 2012) in Point-One, an association of large and small and medium-sized businesses and knowledge institutes that specialize in nano-electronics, embedded systems and mechatronics. The industry is investing €734 million in the same period.[21]

TABLE 2: Dutch investments on the basis of the BSIK/FES programmes

The Netherlands	Total investments from BSIK and other sources in 2004-2010 in Hightech Systems and Materials (Committee of Wise Men, 2008[22])	FES proposal Hightech Systems and Materials, (NanoNed, MicroNed, Holst Centre etc.) in 2010-2014[23]	Total BSIK grant for NanoNed in 2004-2010 (NOWT Observatory of Science & Technology, 2008)	Total FES grant for Hightech Systems and Materials relating to nanotechnology in 2010-2014 (Onderzoek Nederland, 2009)
Public investments	€ 444 m.	€ 300 m. (69%)	€ 95 m. (93%)	€ 60-80 m.

[21] See press release on Point-One, 15-07-08, http://www.point-one.nl/Press/Pressroom/Press_releases?session=09r4kfu18885d6qgdoosrkmqp7

[22] BSIK programmes MicroNed, NanoNed and NanoImpuls, and ESI. Other programmes: Holst, Point One, High Tech Automotive Systems, Innovatieprogramma Materialen (M2I), IOP's PT, EMVT, IPCR, SHM and PD; MEMPHIS (Photonics), SMARTPIE (Piëzo), NIMIC (Microscopie). Source: Committee of Wise Men ICES/KIS, 29 April 2008: Advice from the Committee in response to the midterm evaluation of the BSIK projects.

[23] Source: Onderzoek Nederland, March 2009.

Public investments per year	€ 74 m.	€ 75 m.	€ 16 m.	€ 15-20 m.
Businesses	-	€ 134 m. (31%)	€ 7 m. (7%)	-
Businesses per year	-	€ 33.5 m.	€ 1.2 m.	-
Total	-	€ 434 m.	€ 102 m.	-

3.3 Focal points for the politicians

On the basis of the data and the above analysis we have formulated some questions relating to the ability of the Netherlands to extend its good starting position in nanotechnology in the near future:

– Is the transition being made from research to innovation and has the cooperation between science and industry improved?

Innovative capacity has never been strong in Europe or the Netherlands. Despite a good infrastructure, the Netherlands and other European countries, including France and the UK, achieve only mediocre scores for numbers of knowledge workers, R&D investment and 'brain drain' (Lux Research 2007). Attention therefore needs to be paid to the – fragile – collaboration between science and industry if nanotechnology activities are to get a realistic chance of development in the Netherlands. This applies particularly to solar cells (SRA energy theme) and water treatment (SRA clean water theme). It does not, incidentally, apply to nanoelectronics (SRA beyond Moore theme) or drug delivery (SRA nanomedicine theme), where the collaboration is already strong (Rathenau 2007).

– Is there enough focus in the research and innovation agenda?

The NNI has clearly opted for four fields of knowledge and four fields of application in its nanotechnology SRA. These choices are important given that a small country like the Netherlands cannot excel in everything. In the FES proposal for HTS&M the NNI has, however, added two themes as a result of the partnership with MicroNed and the Holst Centre. In the process, it diverges from the general line of intent, which is to introduce more focus in the Dutch research and innovation agenda, and creates a risk that the public investment will not be deployed effectively.

– Are the public interests and industrial interests properly balanced?

Energy, clean water and nanomedicine are three fields of application that clearly respond to societal needs. They are also structured in a way that enables society to play a meaningful role in the further development of new technology. In nanoelectronics innovation is driven more by economic benefits than by societal issues. Industry clearly controls the innovation agenda for nanoelectronics and chip technology (in contrast with energy and water, where the government is in control). However, the public does need to become effectively involved in this area. In the longer term nanoelectronics will contribute to the development of all sorts of intelligent products, which will not become embedded of their own accord (Rathenau 2007).

– Is enough attention being paid to the impact of nanotechnology on society?

There is a separate flagship in NanoNed that is dedicated to research on Technology Assessment (TA) for nanotechnology. The aim of TA is to understand and improve the interaction between science, technology and society. TA research has no place in the FES proposal even though the Netherlands is one of the world leaders in this field. In the battle for public funding this kind of social science research must not disappear to make space for ‘harder’ nanotechnological research and innovation. As consumers do not automatically accept new technologies, particularly when it comes to food, social science research can provide insight into preferences and concerns.

4 Tackling the risks

In this section we search for solutions to the complex policy problem of ‘tackling the risks of nanomaterials’. We begin with a brief outline of the problem in 4.1. We then show that the problem involves social and political urgency as well as scientific uncertainty. In plain terms, the best way forward is to reduce scientific uncertainty by carrying out research that generates knowledge. This theme is further explored Section 4.2. The societal problem must be assuaged by reviewing the regulations. We discuss this aspect in Section 4.3. However, before we can make the necessary changes we need the knowledge generated by research. Knowledge-sharing is therefore the third key source of solutions. We need knowledge not only to ensure that the right amendments are made to the regulations but also to coordinate research and to take interim decisions. We address this question in Section 4.4, where we compare the main similarities and differences in current standpoints and recommendations in all three areas (research, regulation and information). The section concludes with a list of areas that politicians need to address.

4.1 What’s the problem?

What makes nanomaterials so interesting is the fact that they possess all sorts of new or improved properties. They are stronger, lighter or can conduct electricity. But many of the potential risks to health and environment that are posed by these new materials are still uncharted territory. Most of the concerns relate to the dispersal of free, non-degradable synthetic nanoparticles.

Scientific uncertainty

Warnings have been circulating about the potential risks of nanomaterials since the late 1990’s. But the urgency only became really clear in 2004, when two reports, one published by the Swiss insurance organization Swiss Re and the other by the British Royal Society of Science and the Royal Society of Engineering, made a deep impact worldwide. The reports both reached the conclusion that more intensive research was needed on the potential risks of synthetic nanoparticles. This conclusion has since been confirmed and repeated many times, but the research is nowhere near up and Running.

Societal problems

At present some four hundred people work with nanomaterials in the Netherlands alone. The number of nanoproducts on the consumer market is constantly growing, and still very little is known about their effects on the environment. The lack of knowledge about potential risks is a problem which does not stop with the scientists but spills over into society. Secondly, it is not entirely clear which nanomaterials are being used in which products. So far, researchers and regulators have had to take recourse to databases like the ones at the Woodrow Wilson Center, which only list products with the word ‘nano’ in the manufacturer’s description.

Slowly but surely, public organizations are joining the debate on the possible risks and expressing concern about the way in which the government is tackling the issue. One lesson that can be drawn from the past experience of many organizations is that uncertainties regarding health and the environment (with asbestos and particulates as cases in point) can lead to very protracted policy processes. Often the rules come later, at the end of a long campaign to raise awareness. The current guidelines are stringent ; for example, the industry itself is responsible for supplying data on the environmental and health risks of the substances its uses. Even so, many organizations maintain that, despite their stringency, these guidelines still fail to adequately address the potential risks of nanomaterials.

Political urgency

This spring, the European Parliament sent out a clear message when it announced radical changes to the European directives on chemical substances (**R**egistration **E**valuation **A**uthorization and Restriction of **Ch**emical substances/REACH), food (nanofood is ‘novel food’) and cosmetics. The changes to the cosmetics directive come into effect this summer. The European Parliament also concluded that the member states and the European Commission must regulate matters forthwith as the situation has become so urgent that it is necessitating the appointment of a permanent, independent and decision-making European body that will supervise nanotechnologies and nanomaterials and draw up a programme of fundamental and applied research on the methods used in nanotechnologies and nanomaterials (EP-ENVI 24-04-09).

European Parliament draws up nano-regulations

On 23-26 March 2009 the European Parliament approved two legislative resolutions setting out explicit rules for nanomaterials: the realignment of the directives on cosmetics and novel food. Both resolutions were approved in the first reading. The European Commission must re-submit them to the European Parliament if substantial amendments are made. The European Council and the European Parliament will decide on the resolutions together.

In both regulations the European Community will contribute to the formulation of a uniform international definition of the term “nanomaterial”. This will be followed by a change to the provisional definition in the regulations. The provisional definition in the cosmetics regulation reads: “*An insoluble or bio-resistant and intentionally manufactured material with one or more external dimensions or an internal structure on a scale from 1 to 100 nm*”. The definition in the directive for novel food is more detailed.

Guidelines are needed for testing methods to assess the safety of nanomaterials. New testing methods must be developed for the safe use of nanomaterials in novel food, without involving animal experimentation. Foodstuffs produced with nanotechnology will be sanctioned only after being tested with approved methods.

Businesses are required to inform the European Commission of the presence of substances in the form of nanomaterials in cosmetics. The European Commission will publish a list of nanomaterials that are approved for cosmetics and food packaging. The labels must state clearly whether cosmetic products or novel food contain nanomaterials.

The European Parliament has also approved a resolution on regulatory aspects of nanomaterials. The text can be found in Appendix C.

The demands of the European Parliament mark a new phase in the political debate on the safety of nanomaterials. In recent years toxicologists and policymakers have worked nationally and internationally on risk strategies. Now that the policy goals are known and there are enough concrete applications to define classifications, it looks as if the time has come for action. However, there is still no clear conception of the nature and extent of the problem. This uncertainty is standing in the way of cut-and-

dried solutions. But uncertainty itself demands action. In this section we paint a picture of what can and must be regulated in the current climate of uncertainty.

Precautions: dealing with uncertainty

In effect, the debate on the safety of nanomaterials hinges on the way in which the precautionary principle is interpreted. In 2007 the European Commission issued a code of conduct which called on the member states to apply the precautionary principle when engaging in research. The precautionary principle states that all cost-effective measures should be taken to avoid potential risks that have been scientifically indicated. This is a clear starting point, but it is cannot be easily applied to nanomaterials. Nanotitaniumdioxide in sunscreens, for example, could pose a health risk, but it may be an acceptable risk if the probability that these particles will actually enter the body is very small. And, if these particles are released into the environment, they may constitute a threat to health but not necessarily to the environment itself. On the other hand, though we have been using the antibacterial properties of silver for many years, the increased use of nanosilver could present a problem for the drinking water supply.

In short, no two particles are the same, so it is not immediately obvious which measures need to be adopted. Identifying every possible risk and formulating measures is a mega-chore that will take many years to complete. We are still waiting even now for internationally harmonized definitions of nanoparticles and nanomaterials. Without these the legislative procedures in REACH cannot be amended.

Obviously, a lot needs to happen to ease the uncertainty about the safety of nanomaterials and to retain public confidence in nanotechnology. Less obvious is who should do what. The scientific problem, the societal problem and the growing disquiet, though closely intertwined, each require a different approach. Who should set the research agenda? What is the extent of the producers' responsibility? What can be expected from the government? And above all: what should be first steps?

In situations of uncertainty the answers to such questions are determined in the discussions between the players. In the following section we set out the main similarities and differences in the standpoints and recommendations. Appendix B provides a summary of the reports most relevant to the current debate in the Netherlands.

4.2 Investigating the risks: a force majeure

The first, most logical step is to tackle the problem at the source by undertaking extensive research to ease the scientific uncertainty. In the past few years the Dutch government has invested some 155 million Euros a year in nanotechnology research. In 2008, 2.5 million of this – around 1.6 percent of the research budget for nanotechnology – was spent on investigating the risks of nanoparticles (VROM 04-09-08). An estimated 7 percent of the EU-funded research is spent on risk investigation (spokesperson European Commission at STOA/NanoCap Congress in Brussels, 02-04-09).

Both the government and the environment movements say that this percentage too low, but opinions are divided on the size of the increase. The Cabinet has proposed that the funding for the nanotechnology research agenda should go ahead only on the condition that at least 15 percent is reserved for at least five years for investigating the risks (Cabinet 2008). The Health and Environment Platform (06-10-08), an umbrella for public organizations, has asked the House of Representatives to try to win 25 percent of the nanotechnology budget for risk investigation. The Netherlands Society for Nature and the Environment (03-11-08) argues that 30 percent of the budget should be reserved for investigating risks and toxicology. Its sister organization, the European Environment Bureau, even goes as far as to claim that 80 percent of the budget should be spent on risk investigation at first and gradually wound down to 15 percent in the longer term.

How is research funding to be released?

Behind the differences of opinion on the percentage lurks a much thornier question. Where is the research funding to come from and how is it to be released? The European Parliament (EP 24-04-09) makes no mention of percentages but it does believe that the budget needs to be substantially increased and, in the process, turns the spotlight on a major hurdle in the current European funding for risk investigation. The 7th Framework Programme (FP7) states the research budget that the European Commission makes available for research applications. The conditions of FP7 are geared to innovative research, often to the disadvantage of risk investigation. The European Parliament therefore wants to revise the evaluation criteria in FP7 and finance risk research with the intention of improving the current risk assessment, if necessary from a separately reserved fund.

International agreement

The comments by the European Parliament on the criteria for risk investigation raise a crucial question. How do you arrive at a good research strategy? International agreement is essential in order to prevent everyone from researching the same topic. But international agreement will never be reached without an international research strategy. And that is a time-consuming task, which is currently being executed by an OECD working party. Eventually, these efforts will lead to internationally harmonized characterizations of the properties of nanomaterials. The same holds for the standardization that is underway in the International Organization for Standardization (ISO).

Major strides needed to build specific knowledge
It will probably take years for these international efforts to bear enough fruit. The latest survey of worldwide research into the risks of nanomaterials (EMERGNANO 2009) indicates that, so far, not a single study has produced new guidelines for characterizing the properties of nanomaterials. This is party due to the absence of a systematic research strategy like the one being devised by the OECD working party. Another important factor is that the current research is making only gradual progress, whereas major strides are needed in order to find answers to the most pressing questions. It is doubtful whether the OECD programme can solve this problem. What is more, the OECD programme is focusing on the basic properties of nanomaterials; but these can be added in different ways to the products that are eventually marketed.

From knowledge of the dangers to assessing the risks
Just how long can risk assessors wait for the findings that the international research programme needs to deliver? The European Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2009) and the European Food Safety Authority (EFSA,2009) have both produced a list of urgent research priorities – an action which implies not only that there is a huge dearth of knowledge about the toxic effects of nanomaterials, but also – and more importantly – of exposure data. In what ways exactly are humans and the environment exposed to nanomaterials? This information is not yet available because the European regulatory framework (such as REACH) still has to be worked out for nanomaterials. And that could take a very long time.

Choices and priorities
At the end of the day choices will have to be made. The National Institute for Public Health and the Environment is pushing for a shift in emphasis from reactive to anticipatory risk investigation. Toxicological research is trailing years behind the

development of new nanomaterials, so the best option would be to start the risk investigation in good time when the next generation of nanomaterials are being developed[24] But it will take a long time to catch up. A recent review by the British Institute of Occupational Medicine (EMERGNANO 2009) says, on the one hand, that very little research is being conducted worldwide on the environmental impact and, on the other, that nanosilver and nano-titaniumdioxide are among the top three nanomaterials that must be treated with extreme caution.

Given these dilemmas, strenuous efforts are needed in all fields. Otherwise, we need to make clear choices. If we do not, there is a risk that any advances which are actually made will be too small to make any difference. In Section 4.5 we discuss the main political choices that can point a way forward .

4.3 Regulations: supervision waiting for insight

Research is certainly useful, but in the long run we must be able to avoid the risks through mutual agreement and regulation. This is important in order to protect employees, consumers and the environment. But do we need new legislation for this? Perhaps even in the form of a separate nanotechnology act? Or does the current legislation afford enough scope for characterization of the properties of nanomaterials? At present everyone seems to agree that the principles in the current legislation will suffice, but the technical details will need to be altered. To enforce the regulations the government will have to reach agreement with the business community on how to deal with the potentially hazardous properties of nanomaterials.

How long will it take to push through the changes?

The most pressing issue that needs to be settled is how soon the changes can be pushed through. The Cabinet (2008) wants to retain the current regulations during the first five years and embed the changes in EU regulations in the meantime. The European dimension is important as all legislation on working conditions, product safety and the environment must comply with the European directives. The European Parliament therefore wants to adapt all directives in the relevant legislation within two years in order to gain an adequate assessment of nanomaterials, particularly in the

[24] Nanolab NL – the national consortium for infrastructure for nanotechnology research and innovation – has since announced that it wishes to invest in the development of instruments to measure the effects of nanoparticles amongst other things. Nanolab will work with the National Institute for Public Health and the Environment and TNO.

case of chemical substances (REACH and biocides), cosmetics, food (including additives), worker protection, the quality of air and water, and waste (EP 24-03-09). The Society for Nature and Environment (3-11-08) wants the regulations amended in the Netherlands within two years, if possible within REACH, but certainly nationwide.

The greatest drawback that might prevent this demand from being realized is that, at the end of two years, there may not be enough research findings to precisely define the amendments. The Cabinet has announced that adequate assessment methods must be in place before the regulations can be tightened (Ministry of Economic Affairs 01-10-08). In any case, if new assessment methods were to be devised within two years, they would still need to be internationally approved (see 4.2). Still more time would be consumed if amendments had to be made to the EU directives themselves regarding, for example, the threshold for separate registration of chemical substances within REACH. The FNV trade union federation has called on the Dutch government to ask the European Commission to lower the threshold for nanomaterials (FNV 28-10-08). In view of the long procedures, a ‘case-by-case’ approach and temporary measures seem necessary. These are addressed below. In Section 4.5 we discuss an important question: What position should the Dutch government adopt in the negotiations on the requirements and deadlines which have been set by the European Parliament?

Temporary precautionary measures

The Cabinet (2008) sees no need to restrict the application of nanomaterials at present, but this position could easily change as more knowledge becomes available. The Cabinet therefore wants transparent political decision-making and clearly allocated responsibility among the stakeholders. The Cabinet also wants to involve the public in the decision-making. The allocation of responsibility and the binding effect thereof are important. After all, the Cabinet can, under the law, hold the business community responsible for the safety of human beings and the environment (as in the case of working conditions, see VROM 04-09-08). The government, the business community and the academics must work together to formulate effective measures. But this is easier said than done. Experience from other countries has shown that voluntary registration does not work unless clear agreement is reached beforehand on, amongst others, the protection of industrial secrets. The proposals for working conditions, product safety and environmental requirements are discussed below.

Working conditions

The debate on nanomaterials in the Netherlands is most advanced in the context of working conditions. ZUYD University was commissioned by the Ministry for Social Affairs and Employment to carry out a study on how people deal with nanoparticles in the workplace (Borm *et al.* 2008). According to the results, sixty Dutch businesses and knowledge institutes use synthetic nanoparticles. Thirty-seven of these organizations cooperated in the research (15 large corporations, 11 SMEs and 11 knowledge institutes). Around four hundred people in the employment of these organizations (approximately 1 percent) work regularly with nanoparticles. This number is expected to rise quickly in the next five years. Almost all the organizations have performed a risk analysis, but there is a shortage of reliable measuring instruments. Only 8 percent have measured exposure. There is an urgent need for knowledge-sharing, not least because of the wide discrepancies in safety policy.

Limit values needed

On the basis of this research the Minister of Social Affairs and Employment asked the Social and Economic Council for advice regarding, amongst other things, the application of the precautionary principle. The Council submitted its advice on 20 March 2009 (supported by employers and employees alike). It consists of a series of recommendations for the government, employers and employees and is based on the minimalization principle. In other words, exposure should continue to be limited as far as possible. The Council has asked the government to commission the Health Council of the Netherlands to draw up the necessary norms. If this proves infeasible, the Social and Economic Council asks the Health Council to look into the application of reference values. The SEC has also asked the government to speed up the embedment in REACH. The FNV trade union federation had already asked for the appointment of a scientific committee to formulate temporary limit values for extensively used nanomaterials (FNV 28-10-08).

Role of the government in temporary measures

The current Arbo (health and safety) legislation remains the starting point for worker protection, but as there are no limit values or accepted regulations, the Social and Economic Council is drawing attention to the need for temporary measures. The Council has asked the government to ascertain whether a temporary registration obligation and exposure registration system would serve a useful purpose. The Council expects employers and employees to pay specific attention to nanomaterials in the obligatory risk inventory and assessments. But the most important instrument for worker protection in the short term would be a ‘best-practices’ guideline. The Council has asked the government to provide proper and adequate support for this initiative.

Product safety

In contrast with worker protection, there are, according to the National Institute for Public Health and the Environment (23-09-08), scarcely any openings for consumer protection. According to estimates from the National Institute for Public Health and the Environment and the Institute of Food Safety, in 2007, there were around two hundred products on the market that contained nanomaterials. The Food and Consumer Product Safety Authority then advised the government to give priority to filling the gaps in the knowledge of insoluble nanoparticles. The Authority said that food products containing nanomaterials must be regarded as ‘novel food’ and assessed according to the proper procedures (VWA 30-01-08). The Netherlands Society for Nature and the Environment (03-11-08) is urging the government to implement the recommendations of the Food and Consumer Product Safety Authority.

The Dutch Platform for Health and Environment (06-10-08) wants the government to clamp down on the use of nanomaterials in consumer products and food. The Department of the Environment (VROM) wants to implement the current regulations. Acceptance criteria for new foodstuffs, pesticides and cosmetics also apply to products containing nanoparticles. The Department of the Environment (VROM) reports that the government is closely monitoring the market and consulting the producers. Consumer products containing nanomaterials may therefore be traded freely – like any other products – provided it can be proven that they do not pose a threat to human health or safety (VROM 04-09-08).

Food

In contrast with the Department of the Environment, the European Parliament maintains that the acceptance criteria must be changed. This spring, the European Parliament put forward a proposal to change the directives on cosmetics and food. Food products that contain nanomaterials must be regarded as ‘novel food’ and should be assessed accordingly (EP 25-03-09). That was also the advice of the Food and Consumer Product Safety Authority (30-01-08), but the European Parliament went a step farther: ’*In the event of doubt, due to, for example, insufficient scientific certainty or a shortage of data, the precautionary principle must be applied and the food in question must not be added to the community list.’* (EP 25-03-09, Article 6.1). The European Parliament also sets this condition for all food that is prepared in a process *’that uses nanotechnology’* (Article 6.1).

Cosmetics

The EU directive on cosmetics is also being reviewed at present. The amendments proposed by the European Parliament will probably come into effect this summer. In 2007 the Scientific Committee on Consumer Safety (SCCS) advised that the existing risk-assessment methods for soluble nanoparticles may be adequate but that additional data on, for example, quantities, surface size and distribution need to be taken into account for insoluble nanoparticles (SCCS 18-12-07). The cosmetic industry, for example, has provided information on the safety of titanium-dioxide nanoparticles which are used extensively in sunscreens. This information is currently awaiting assessment by the SCCS. The process might be complicated by the prohibition on animal testing for acute toxicity in cosmetic products that went into effect on 11 March 2009 and the absence of in-vitro testing methods for nanomaterials (SCCS 18-12-07). To prevent confusion and to allow the regulatory bodies enough time to assess cosmetic products that contain nanomaterials, the Dutch Cosmetics Association (NCV) suggests that these products should be reported to a government body before being introduced to the market (website NCV).

Environmental regulations

The environmental regulations for chemical substances are set out in REACH, but there has been scarcely any research on the potential environmental risks of nanomaterials (EMERGNANO 2009). Very few Life Cycle Analyses (LCA) have been produced and very little is known about exposure. Lack of knowledge on the natural presence of nanomaterials is also complicating assessment. Recently, Wageningen University calculated that the environmental damage from nanocarbon particles pales into insignificance compared with the presence of natural nanoparticles[25]. On the other hand, the emission of nanoparticles from office printers can constitute a health risk. This sort of knowledge adds to the picture but it still fails to tell us whether problems can be expected from other types of nanomaterials. The National Institute for Public Health and the Environment says on its website that the conclusions of Wageningen University are premature. The Institute ascertained earlier that there are scarcely any pointers at present for environmentally protective measures. Hence, the restriction of emissions from nanomaterials is the most obvious course of action (RIVM 23-09-08).

[25] See: http://www.wur.nl/NL/nieuwsagenda/nieuws/nano090318.htm.

4.4 Information: knowledge-sharing calls for organization

Like the need for research, the importance of knowledge-sharing is broadly recognized. But knowledge-sharing will not happen of its own accord. It will have to be organized – all the more so in the current climate of uncertainty. The Cabinet has therefore created a Knowledge and Information Centre for the Risks of Nanomaterials (Nano KIC) at the National Institute for Public Health and the Environment. At the same time, the Department of the Environment has organized a sounding board group in which public organizations, the scientific community and businesses can respond to government policy on the risks of nanomaterials. The government maintains, however, that businesses and research institutes are primarily responsible for providing information on the risks of nanotechnology. The government provides information on it own policy on nanotechnology. The Committee for Public Dialogue on Nanotechnology will be asked to organize a transparent public debate on the ethical and societal implications of nanotechnology (VROM 04-09-08).

Nano KIC as the main knowledge centre

Nationally, the Nano KIC plays a pivotal role in harmonizing the research and regulations. The Minister of Social Affairs and Employment has already designated Nano KIC as a knowledge centre by facilitating the establishment of an expert platform there to safeguard working conditions. The minister maintains that the business community has its own responsibility to ensure that the workers are provided with information on risks and adopted measures (SZW 05-09-08). The Social Economic Council has asked employers to pass on information on nanoparticles in the chain and to contribute to knowledge-sharing and public information (SER 20-03-09).

Control in the use of nanomaterials

A clear picture is needed of the use of nanomaterials in order to devise an effective strategy and organize supervision. Which nanomaterials are in circulation? In what quantities? And what is known about the potential risks? At the start of 2008 the FNV trade union federation called on the business community to be more open about the risks of nanotechnology (FNV 01-08). The businesses and the researchers replied that they valued transparency and had nothing to hide (VNO-NCW 14-02-08). These announcements indicate that uncertainty about potential risks will continue to fuel

mutual distrust as long as there is no clarity about the organizations and the materials involved.

The best way to achieve clarity is to implement registration obligations for nanomaterials in REACH. This promises to be a lengthy process, which is further complicated by the fact that the discussion on the threshold value for mandatory registration has not yet reached a conclusion (see 2.2). Some countries have launched initiatives for voluntary registration, but with little success so far. For example, one such project in England cost millions of Euros and delivered only nine registrations. The French government was then prompted to introduce mandatory registration for nanomaterials. The FNV (28-10-08) is urging the Dutch government to follow suit and introduce centralized mandatory registration of manufactured or imported products containing nanoparticles.

The greatest problem raised by these initiatives is how to protect sensitive industrial information. This not only explains the failure of the voluntary initiatives, it raises doubts as to whether mandatory systems are even feasible. The business community can field good arguments for a transparent, safe and preferably European system. These signals are picked up by the European Parliament in its request to the European Commission to *'draw up before June 2011 an inventory of the different types and applications of nanomaterials on the European market, and to retain legitimate trade secrets, such as recipes, to make this inventory publicly available and to report on the safety of these nanomaterials.'* (EP 24-04-09)

Consumer information

The National Institute for Public Health and the Environment (23-09-08) and the Food and Consumer Product Safety Authority (30-01-08) are both of the opinion that information is the most important means of consumer protection at this moment. The Cabinet writes that the government, knowledge institutes, businesses and public organizations share responsibility for informing the public. The Nano KIC provides scientific information on the risk of nanotechnology on its website www.stoffen-risico.nl (Cabinet 04-07-2008). However, the Minister of Economic Affairs says that, as not enough is yet known about the risks to consumers, it is impossible to provide reliable information. The Food and Consumer Product Safety Authority should identify the risks and, if possible, inform the consumers (EZ 01-10-08).

Labelling?
But a website alone will not be enough to reach the consumers. Discussions have been held on whether the use of nanomaterials should be stated on the labels of food and consumer products. The Netherlands Society for Nature and the Environment wants to see labels on approved products containing nanoparticles, so that members of the public can make an informed choice (SNM 3-11-08). The Health & Environment Platform (06-10-08) has asked the government to compel producers to state ingredients on the labels. The Minister of Housing, Spatial Planning and the Environment (04-09-08) says: *'In the substance policy, with the effectuation of REACH, the information obligation regarding the risks of substances and products was placed with the producer.'* It is open to question whether, at this moment in time, REACH offers enough scope for this (see 2.2), but it seems only logical to organize labelling in a European context. This is also the position of the Dutch Cabinet (VROM 04-09-08).

Both the Dutch government and the environmental movement seem to be on the same wavelength as the European Parliament when it comes to cosmetics and novel food. The European Parliament is stressing that manufacturers should inform consumers of the use of (synthetic) nanomaterials in consumer goods by, for example, placing 'nano' between brackets behind the name of the respective ingredients (EP 24-04-09). The European Parliament specifically submitted this proposal in Article 19 (Consumer Information) of the proposed realignment of the Cosmetics Directive (EP 24-03-09), and in Article 7.2 of the amended directive on novel food (EP 25-03-09). The European Parliament further requested that Directive 2006/114/EC be executed in full to prevent misleading advertisements on nanomaterials (EP 24-04-09). The European Parliament has called on the European Commission and the member states to organize an EU-wide public debate on nanotechnologies, nanomaterials and the regulatory aspects of nanomaterials (EP 24-04-09).

4.5 Topics for political debate

What can be inferred from the summary of standpoints and recommendations in the previous section? Obviously, a lot needs to be done, but the need to reach agreement first is standing in the way of meaningful progress. The tension between the desire to act nationally and the need to reach agreement internationally has created some awkward dilemmas for the government. However, we can still list a number of questions which should prevent the discussion from going round in circles.

Research:

– Investigating the risks must be financed largely by the innovation funding. Will a fixed percentage for risk investigation deliver enough results and how should the risk investigation be aligned with the requirements of the risk assessors?
– What are the catch-up priorities: environment protection, employees or specific substances?
– How can we avert problems in the future? By making risk investigation mandatory in the development of nanomaterials, even below the REACH threshold?

Regulations

– How can we speed up embedment in REACH? What would the Dutch government have to do to achieve this? What position should the Dutch government adopt in the discussion on the feasibility of the timeframe (two years) set by the European Parliament?
– In which areas do we need legally enforceable interim regulations? (Registration of nanomaterials? Best practices for protecting working conditions? Definitions of nanomaterials?). What can we do on the basis of current knowledge?
– The European Parliament wants to set up a European network to supervise the use of nanomaterials and to coordinate research. Is that a good idea or should existing arrangements be used for this purpose?

Information:

– Should consumer products be labelled? How should the Dutch government respond to the European Parliament's demands for labels on food, cosmetics and other consumer goods?
– Is a temporary notification obligation desirable? Can this be organized at national level to save time or does it have to happen at European level? Are there already definitions on hand to enable the enforcement of any such obligation?
– The Nano KIC-wants to set up a platform for medical applications and the environment in addition to a platform for working conditions and food and consumer goods. The Nano KIC could also serve as an information point. Does the Nano KIC have the means and resources to fulfil these tasks?

Appendix A: reports and recommendations for an inventory of the position of the Netherlands

Organization	Title	Weblink
The Netherlands		
NanoNed, STW, FOM	*SRA Nanotechnology (FES proposal High Tech Systems & Materials?).*	http://www.fom.nl/live/nieuws/archief_persberichten/Persberichten_2008/artikel.pag?objectnumber=81383
Cabinet	*Actieplan Nanotechnologie; Nederland in international verband* [Nanotechnology Action Plan, the Netherlands in an International Context], 2008, Cabinet Vision of Nanotechnologies 2006.	http://ez.nl/nanotechnology
Committee of Wise Men ICES/KIS	*Midterm Evaluation Report*, 2008.	Appendix bij kamerstuk 25017 nr. 63, http://parlando.sdu.nl/cgi/login/anonymous
Netherlands Observatory of Science & Technology	*Wetenschaps- en Technologie-indicatoren, 2008* [Science and Technology Indicators for 2008].	Appendix bij kamerstuk 31288, nr. 25, http://parlando.sdu.nl/cgi/login/anonymous
Netherlands Patent Office	Knecht, 2004. *Nanotechnologie; informatie uit octrooien* [Nanotechnology, information from patents].	http://www.octrooicentrum.nl/images/stories/download/kob/rapporten/Rapport_Nanotechnology.pdf
Opportunities		
TA NanoNed	Publications.	http://www.nanoned.nl/TA/Documents+and+publications.htm
TNO	*Nanotechnology for Defence*, 2008.	http://www.isoconnectors.com/defensie/
Rathenau	*Om het kleine te waarderen*, 2004. [Appreciating the Small Things] *Nanotechnology van agendering tot innovatie* 2007 [Nanotechnology from planning to innovation].	www.rathenau.nl
Point One SRA	*Multi-year roadmap* 11-2008.	www.point-one.nl

TWA Network	*Nano & micro-system technology*.	www.twanetwerk.nl
MERIT/ Observatory Nano, Nils Newman, Can Huang, Ad Notten, Lili Wang	*Report on Benchmarking Global Nanotechnology Scientific Research,* 2009. Working Paper 2008-058.	*www.observatorynano.org* http://www.merit.unu.edu/publications/wppdf/2008/wp2008-058.pdf
MinacNed	*Roadmap Micro-nano in food*, 2006.	www.minacned.nl
NWO	*Strategienota nanotechnologie*; Strategienota 2007-10 [Strategic Paper on Nanotechnology].	http://www.minacned.nl/download/strategienota_nwo.pdf http://www.nwo.nl/nwohome.nsf/pages/NOP_5SME25
Malsch	*Nanotechnology for Developing Countries*.	www.thebrokeronline.eu
WODC Min Justitie	*Security Applications of Converging Technologies*, 2008.	http://www.wodc.nl/onderzoeksdatabase/converging-technologys.aspx?cp=44&cs=6798
Cie Grootschalige onderzoeks-faciliteiten	*Nederlandse Roadmap Grootschalige Onderzoeksfaciliteiten* [The Dutch Roadmap, large-scale research facilities] 2008.	Appendix bij kamerstuk 27406, nr. 124, http://parlando.sdu.nl/cgi/login/anonymous
EU		
EC	*Nanotechnology Action Plan* 2005-2009. EC press release, March 2008.	http://cordis.europe.eu/nanotechnology ftp://ftp.cordis.europe.eu/pub/nanotechnology/docs/press_release_2008_march.doc
ETP Nano-medicine	*SRA and Vision document*.	http://www.etp-nanomedicine.eu/public/press-documents/publications
ENIAC	*SRA*.	http://www.eniac.eu/web/SRA/local_index.php
Observatory-Nano	*Technical and economic trend reports, May 2009?*	*www.observatorynano.org*
Abroad		
OECD	WPN OECD 2008 *Compendium of Patent Statistics* Igami & Okazaki, 2007:Capturing Nanotechnology's Current State of Analysis via Analysis of Patents, STI Working Paper 2007/4.	www.oecd.org/sti/nano http://www.oecd.org/searchResult/0,3400,en_2649_201185_1_1_1_1_1,00.html

Appendix B: reports and recommendations for an inventory of the standpoints on tackling risks

An inventory of the visions and standpoints on risks to health and the environment has been compiled on the basis of the following reports:

Organization	Title	**Weblink**
The Netherlands		
Cabinet	*Actieplan Nanotechnologie* 2008, Kabinetsvisie Nanotechnologiën 2006 [Nanotechnology Action Plan 2008'.Cabinet Vision on Nanotechnologies 2006]	http://ez.nl/nanotechnology
Ministry of Housing, Spatial Planning & the Environment	*Omgaan met risico's nanodeeltjes*, 14-02-2008-1, *Beantwoording vragen risico's nanodeeltjes in consumentenproducts* 3463 2008, Gezondheid en milieu (brief over WRR en GR adviezen omgaan met risico's) 28093, nr. 23, 2009 (VROM 2009) [Dealing with the risks of nanoparticles, 2006-1, Answers to questions on the risks of nanoparticles in consumer goods 3463 2008, Health and the environment] 28093, no. 23, 2009]	http://ez.nl/dsresource?objectid=159533&type=PDF http://overheid-op.sdu.nl/
Ministry of Economic Affairs	*Beantwoording vragen over koolstof nanobuisjes*, 2008 [Answers to questions on carbon nanotubes, 2008].	http://ez.nl/dsresource?objectid=160213&type=PDF
Ministry of Social Affairs & Employment	*Adviesvraag omgaan met nanodeeltjes* 2008 [Request for recommendations on how to deal with nanoparticles].	http://home.szw.nl/index.cfm?menu_item_id=14188&hoofdmenu_item_id=13826&rubriek_id=391818&doctype_id=34&link_id=150521
Health Council of the Netherlands	*Betekenis van Nanotechnologie voor de gezondheid*, 2006 Voorzorg met rede, 2008 [The health implications of nanotechnology, 2006 Reasonable precautions, 2008].	http://ez.nl/dsresource?objectid=159532&type=PDF

Social and Economic Council	*Veilig omgaan met nanodeeltjes op de werkplek* 2009 [Safety and nanoparticles in the workplace 2009] .	http://www.ser.nl/nl/publications/adviezen/2000-2007/2009/b27741.aspx
Paul Borm *et al*.	*Omgaan met nanodeeltjes op de werkvloer*, 2008 [Dealing with nanoparticles in the workplace, 2008].	http://docs.minszw.nl/pdf/35/2008/35_2008_3_12183.pdf
National Institute for Public Health and the Environment	*KIR-nano: Nanotechnologie in Perspectief*, 2008 [Nano KIC: nanotechnology in perspective, 2008].	http://www.rivm.nl/rvs/075_nanotechnology/KIR_nano/
Food and Consumer Product Safety Authority	*Adviezen nanodeeltjes in voeding en consumentenproducten* 2008 [Recommendations on nano particles in food and consumer goods 2008].	http://www.vwa.nl/portal/page?_pageid=119,1639824&_dad=portal&_schema=PORTAL&p_news_item_id=23054
Scientific Council for Government Policy	*Onzekere veiligheid*, 2008 [Uncertain safety, 2008].	http://www.wrr.nl/content.jsp?objectid=4935
Confederation of Netherlands Industry and Employers	*Nanotechnologie en risico's* [Nanotechnology and risks].	http://www.vno-ncw.nl/web/show/id=94618/dbcode=754/filetype=dossier
Netherlands Society for Nature and the Environment	*Actieplan nanotechnologie* 2008, SNM positie [Nanotechnology Action Plan 2008].	http://www.natuurenmilieu.nl/pdf/081103.001_brf_cie.vrom_inzake_nano.pdf http://www.nanocap.eu/Flex/Site/Download.aspx?ID=1569
FNV trade union federation	Letter to Minister Donner 2008, etc.	http://www.nanocap.eu/Flex/Site/Download.aspx?ID=3754
Confederation of Netherlands Industry and employers / MESA+	*Forum – Kleine deeltjes, groot gevaar?* 2008 weblog Dave Blank [Forum – tiny particles, huge risks?].	http://www.vno-ncw.nl/web/show/id=94744/articlecode=7295/articletype=forum http://sites.google.com/site/sciencecafeenschede/weblog-dave-blank-1

Health and Environment Platform	*Letter to the Permanent Committee for Economic Affairs*, Second Chamber, 2008.	http://www.gezondheidenmilieu.nl/index.php?option=com_content&view=article&id=23:nanotechnology&catid=2:actueel&Itemid=25
Dutch Cosmetics Association	*Nanotechnology in cosmetics factsheet*.	http://pwam.websites.xs4all.nl/pages/view.php?page_id=215
EU		
EP	*Amendment to Novel Foods Directive* 2009; *Amendment to Cosmetics Directive* 2009.	http://www.europerl.europe.eu:80/sides/getDoc.do?type=TA&reference=P6-TA-2009-0171&language=NL&ring=A6-2008-0512 http://www.europerl.europe.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0158&language=NL&ring=A6-2008-0484
EP ENVI	*Resolution on the Regulatory Aspects of Nanomaterials* (2009).	http://www.europerl.europe.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A6-2009-0255+0+DOC+XML+V0//NL&language=NL
EC	*Communication on the Regulatory Aspects of Nanomaterials* (2008).	http://ec.europe.eu/nanotechnology/index_en.html
SCCP	*Scientific Opinion on the Safety of Nanomaterials in Cosmetic Products* (2007).	http://ec.europe.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf
SCENIHR	*Scientific Opinion on Risk Assessment on Nanotechnology Products* (2009).	http://ec.europe.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm#nano
EFSA	*Opinion on Food and Feed Safety Risks* 2009.	http://www.efsa.europe.eu/EFSA/efsa_locale-1178620753812_1211902362054.htm
SAFENANO	EMERGNANO 2009.	http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=16006
EEB (European Environment Bureau)	EEB Position Paper on Nanotechnologies and Nanomaterials. *Small scale, big promises, divisive messages*, 2008; EEB & BEUC: *The path to sustainable use of chemicals in*	http://www.nanocap.eu/Flex/Site/Download.aspx?ID=3753 http://docshare.beuc.org/docs/2/LFNHCGLDHGJJAOCBHOHLDJALPDBG9

	products: the European ecolabel as a signpost (2008).	DBYBY9DW3571KM/BEUC/docs/DLS/2009-00102-01-E.pdf
ETUC (European Trade Union Confederation)	*ETUC resolution on nanotechnologies and nanomaterials*.	http://www.nanocap.eu/Flex/Site/Download.aspx?ID=2840
CEFIC	*Position on Nanotechnologies and Nanomaterials.*	http://www.cefic.org/en/Nanomaterials.html
HEAL	*Nanotechnology and Health Risks.*	http://www.env-health.org/a/2892
BEUC	*Work programme 2009.*	http://docshare.beuc.org/docs/3/LFNHCGLDHGJJAOCBHOHLDJALPDBG9DBDC19DW3571KM/BEUC/docs/DLS/2009-00085-01-E.pdf
International		
OECD	*Current developments / activities on the safety of manufactured nanomaterials* (2008) *Preliminary analysis of exposure measurement and exposure mitigation in occupational settings: manufactured nanomaterials* 2009.	www.oecd.org/env/nanosafety
ISO	ISO TR 12885: *Nanotechnologies - health and safety practices in occupational settings relevant to nanotechnologies* (2008).	http://www.iso.org/iso/catalogue_detail?csnumber=52093
FAO/WHO	*Expert meeting nanofood safety* 1-5 June 2009.	http://www.fao.org/ag/agn/agns/expert_consultations/Nanotech_EC_Call_for_Exp_and_Info.pdf
BEF (Baltic Environment Forum)	*Positioning on Nanotechnology Issue*.	http://www.nanocap.eu/Flex/Site/Download.aspx?ID=3756
Nanoaction	*Principles for the Oversight of Nanotechnologies and Nanomaterials*, 2007.	http://www.nanoaction.org/nanoaction/index.cfm
Investor Environmental Health Network IEHN	*Many companies who use nanomaterials in their products do not communicate adequately about potential risks to their shareholders.*	http://www.iehn.org/publications.reports.toxicstock.php

Appendix C: European Parliament Resolution of 24 April 2009

European Parliament Resolution of 24 April 2009 on the regulatory aspects of nanomaterials (2008/2208(INI))

The European Parliament

– having regard to the Commission Communication of 17 June 2008 entitled “Regulatory aspects of nanomaterials” (**COM(2008)0366**) and the accompanying Commission staff working document (**SEC(2008)2036**),
– having regard to the Commission Communication of 12 May 2004 entitled "Towards a European strategy for nanotechnology" (**COM(2004)0338**),
– having regard to the Commission Communication of 7 June 2005 entitled "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009" (**COM(2005)0243**) ("the action plan") and to its resolution of 28 September 2006(1) on the action plan,
– having regard to the Commission Communication of 6 September 2007 entitled "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007" (**COM(2007)0505**),
– having regard to the opinions of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on definitions and risk assessment of nanomaterials(2),
– having regard to the opinion of the Scientific Committee on Consumer Products (SCCP) on the safety of nanomaterials in cosmetics (3),
– having regard to the Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research (**COM(2008)0424**) ("Code of Conduct"),
– having regard to the opinion from the European Group on Ethics in Science and New Technologies to the European Commission on the ethical aspects of nanomedicine (4) ,
– having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)(5),
– having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (6),

– having regard to Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (7) and its daughter directives,
– having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (8) as well as specific product legislation, in particular Council Directive 76/768/EEC of 27 July 1976 on approximation of laws of the Member States relating to cosmetic products (9),
– having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (10), Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives(11), Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (12), Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms (13), and Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (14),
– having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (15),
– having regard to Community environmental legislation, in particular Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (16), Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (17) and Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste (18),
– having regard to Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (19),
– having regard to Rule 45 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Employment and Social Affairs (**A6-0255/2009**),

1. whereas the use of nanomaterials and nanotechnologies (hereinafter referred to as "nanomaterials") promises important advances with multiple benefits in innumerable applications for consumers, patients and the environment, as nanomaterials can provide different or new properties compared to the same substance or material in normal form;

2. whereas the advances in nanomaterials are expected to have significant influence on policy decisions in the fields of public health, employment, occupational safety and health, information society, energy, transport, security and space,

3. whereas despite the introduction of a specific European strategy on nanotechnologies and the subsequent allocation of approximately EUR 3,500,000,000 for research in nanosciences for the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (FP7), the European Union is lagging behind its current main competitors – the USA, Japan and South Korea – who account for over half of the investment and two-thirds of the patents filed worldwide;

4. whereas nanomaterials on the other hand potentially present significant new risks due to their minute size, such as increased reactivity and mobility, possibly leading to increased toxicity in combination with unrestricted access to the human body, and possibly involving quite different mechanisms of interference with the physiology of human and environmental species,

5. whereas the safe development of nanomaterials can make an important contribution to the competitiveness of the European Union's economy and to the achievement of the Lisbon strategy,

6. whereas the current discussion about nanomaterials is characterized by a significant lack of knowledge and information, leading to disagreement starting at the level of definitions:
   a) concerning the size: approximate indications of the size (“in the order of 100 nm or less”) versus a specific size range (“between 1 and 100 nm”),

b) concerning different/new properties: different/new properties due to size effects, including particle number, surface structure and surface activity, as an independent criterion versus using such properties as an additional criterion for the definition of nanomaterials,
c) concerning problematic properties: limitation of the definition of nanomaterials to certain properties (e.g. insoluble or persistent) or not making such limitations,

7. whereas a fully developed set of harmonized definitions is not currently available although a number of international standards are either available or in progress, defining "nanoscale" as "having one or more dimensions of the order of 100 nm or less", and often distinguishing between:
– nano-objects defined as “discrete pieces of materials with one, two or three external dimensions at the nanoscale”, i.e. as materials constituted by isolated objects with very small dimensions,
– nano-structured materials, defined as materials “having an internal or surface structure at the nanoscale”, e.g. exhibiting cavities of small dimensions,

8. whereas there is no clear information about the actual use of nanomaterials in consumer products, for instance:
– while inventories by renowned institutions list more than 800 manufacturer-identified nano-technology-based consumer products currently on the market, trade associations of the same manufacturers question these figures, on the basis that they are overestimations, without providing any concrete figures themselves,
– while companies happily use “nano-claims”, as the term “nano” seems to have a positive marketing effect, they are strictly opposed to objective labelling requirements,

9. whereas clear notification requirements on the use of nanomaterials, information to consumers as well as full enforcement of Directive 2006/114/EC are necessary to provide reliable information on the use of nanomaterials,

10. whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials**,** but fail to provide reliable information about current uses,

11. whereas there is a major debate about the possibility of assessing the safety of nanomaterials; whereas the scientific committees and Agencies of the

European Union point to major deficiencies not only in key data, but even in methods of obtaining such data; whereas the European Union thus needs to invest more in adequate assessment of nanomaterials to close the knowledge gaps and to develop and implement as fast as possible, and in collaboration with its agencies and international partners, methods of evaluation and an appropriate and harmonized metrology and nomenclature,

12. whereas SCENIHR identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials; whereas SCENIHR furthermore found a general lack of high-quality exposure data both for humans and the environment, concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardized,

13. whereas current funding for research into the environmental, health and safety aspects of nanomaterials in FP7 is far too low; whereas moreover the evaluation criteria for granting research projects to assess the safety of nanomaterials under FP7 are too restrictive (i.e. they have a narrow innovation bias), and thus do not sufficiently promote the urgent development of scientific methods to assess nanomaterials; whereas it is essential to allocate sufficient resources for research on the safe development and use of nanomaterials,

14. whereas knowledge about potential health and environmental impacts of nanomaterials lags significantly behind the pace of market developments in light of the very rapid developments in the field of nanomaterials, thus raising fundamental questions about the ability of the current regulations to deal with emerging technologies such as nanomaterials in "real time",

15. whereas, in its resolution of 28 September 2006 on nanosciences and nanotechnologies Parliament had called for investigation of the effects of nanoparticles that are not readily soluble or biodegradable, in accordance with the precautionary principle, before such particles are put into production and placed on the market,

16. whereas the value of the above-mentioned Commission Communication entitled "Regulatory aspects of nanomaterials" is rather limited due to the absence of information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits, and thus no consideration of the legislative and policy challenges that result from the specific nature of

nanomaterials, resulting in only a general legal overview that shows that there are no nano-specific provisions in Community legislation for the time being**,**

17. whereas nanomaterials should be covered by a multi-faceted, differentiated and adaptive body of law based on the precautionary principle (20), the principle of producer responsibility and the polluter-pays principle to ensure the safe production, use and disposal of nanomaterials before the technology is put on the market, while avoiding systematic recourse to general moratoria or undifferentiated treatment of different applications of nanomaterials,

18. whereas the almost infinite application of nanotechnologies to such diverse sectors as electronics, textiles, biomedicals, personal care products, cleaning products, food or energy makes it impossible to introduce a single regulatory framework at Community level,

19. whereas, in the context of REACH, it has already been agreed that further guidance and advice on nanomaterials, in particular on substance identification, as well as an adaptation of risk assessment methods is needed; whereas a closer look at REACH reveals several further deficiencies to deal with nanomaterials,

20. whereas waste legislation in the absence of nano-specific provisions may not apply correctly,

21. whereas nanomaterials, throughout their whole life cycle, raise major challenges for occupational health and safety, as many workers along the production chain are exposed to those materials without knowing whether the safety procedures implemented and the protection measures taken are adequate and efficient; notes that the number and diversity of workers exposed to the effects of nanomaterials are expected to increase in the future,

22. whereas the significant amendments concerning nanomaterials adopted in a first reading agreement between the Council and the European Parliament in the context of the recast of the cosmetics directive (21), and the significant amendments adopted by the European Parliament in the first reading of the review of the regulation on novel food (22), respectively, highlight the need to amend relevant Community legislation to address nanomaterials adequately,

23. whereas the current debate about regulatory aspects of nanomaterials is largely limited to expert circles, even though nanomaterials have the potential

to bring about far-ranging societal change, which requires wide-ranging public consultation,

24. whereas a broad application of patents to nanomaterials, as well as the excessive cost of patenting and the absence of patent access facilities for very small businesses and small and medium-sized enterprises (SMEs), could stifle further innovation,

25. whereas the likely convergence of nanotechnology with biotechnology, biology, cognitive sciences and information technology raises serious questions relating to ethics, safety, security and respect for fundamental rights that need to be analyzed by a new opinion of the European Group on Ethics in Science and New Technologies,

26. whereas the Code of Conduct is an essential instrument for safe, integrated and responsible research in nanomaterials; whereas the Code of Conduct must be adopted and respected by all producers intending to manufacture or place goods on the market,

27. whereas the review of all relevant Community legislation should implement the principle "no data, no market" for nanomaterials,

1. Is convinced that the use of nanomaterials should respond to the real needs of citizens and that their benefits should be realized in a safe and responsible manner within a clear regulatory and policy framework (legislative and other provisions) that explicitly addresses existing and expected applications of nanomaterials as well as the very nature of potential health, environmental and safety problems;

2. Deplores the absence of a proper evaluation of the *de facto* application of the general provisions of Community law in the light of the actual nature of nanomaterials;

3. Does not agree, before an appropriate evaluation of current Community legislation, and in the absence of any nano-specific provisions therein, with the Commission's conclusions that a) current legislation covers in principle the relevant risks relating to nanomaterials, and b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation, when due to the lack of appropriate data and methods to

assess the risks relating to nanomaterials it is effectively unable to address their risks;

4. Considers that the concept of the "safe, responsible and integrated approach" to nanotechnologies advocated by the European Union is jeopardized by the lack of information on the use and on the safety of nanomaterials that are already on the market, particularly in sensitive applications with direct exposure of consumers;

5. Calls on the Commission to review all relevant legislation within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle, and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed;

6. Stresses that such review is not only necessary to adequately protect human health and the environment, but also to provide certainty and predictability to economic operators as well as public confidence;

7. Calls for the introduction of a comprehensive science-based definition of nanomaterials in Community legislation as part of nano-specific amendments to relevant horizontal and sectoral legislation;

8. Calls on the Commission to promote the adoption of a harmonized definition of nanomaterials at the international level and to adapt the relevant European legislative framework accordingly,

9. Considers it particularly important to address nanomaterials explicitly within the scope of at least legislation on chemicals (REACH, biocides), food (foodstuffs, food additives, food and feed products from genetically modified organisms), relevant legislation on worker protection, as well as legislation on air quality, water quality and waste;

10. Calls for the application of a "duty of care for manufacturers that wish to place nanomaterials onto the market; and calls on them to adhere to the European code of conduct for responsible nanosciences and nanotechnologies research;

11. Calls specifically on the Commission to evaluate the need to review REACH concerning *inter alia:*

– simplified registration for nanomaterials manufactured or imported below one tonne,
– consideration of all nanomaterials as new substances,
– a chemical safety report with exposure assessment for all registered nanomaterials,
– notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles

12. Calls specifically on the Commission to evaluate the need to review waste legislation concerning *inter alia*:
– a separate entry for nanomaterials in the list of waste established by Decision 2000/532/EC (23),
– a revision of the waste acceptance criteria in landfills in Decision 2003/33/EC (24)
– a revision of the relevant emission limit values for waste incineration to supplement the mass-based measurements by metrics based on particle number and/or surface;

13. Calls specifically on the Commission to evaluate the need to review emission limit values and environmental quality standards in air and water legislation to supplement the mass-based measurements by metrics based on particle number and/or surface to adequately address nanomaterials;

14. Underlines the importance for the Commission and/or Member States to ensure full compliance with, and enforcement of, the principles of Community legislation on the health and safety of workers when dealing with nanomaterials, including adequate training for health and safety specialists, to prevent potentially harmful exposure to nanomaterials;

15. Calls specifically on the Commission to evaluate the need to review worker protection legislation concerning *inter alia*:
– the use of nanomaterials only in closed systems or in other ways that exclude exposure of workers as long as it is not possible to reliably detect and control exposure,
– a clear assignment of liability to producers and employers arising from the use of nanomaterials
– whether all exposure routes (inhalation, dermal and other) are addressed;

16. Calls on the Commission to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market, while

respecting justified commercial secrets such as recipes, and to make this inventory publicly available; furthermore calls on the Commission to report on the safety of these nanomaterials at the same time;

17. Reiterates its call for the provision of information to consumers on the use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles should be clearly indicated in the labelling of the product (e.g. in the list of ingredients, the name of such ingredients should be followed by the word 'nano' in brackets);

18. Calls for full enforcement of Directive 2006/114/EC to ensure that that there is no misleading advertising with nanomaterials;

19. Calls for the urgent development of adequate testing protocols and metrology standards to assess the hazard of, and exposure of workers, consumers and the environment to, nanomaterials over their entire life cycle, including in the case of accidents, using a multi-disciplinary approach;

20. Calls for a major stepping up of the funding of research into the environmental, health and safety aspects of nanomaterials over their life cycle, e.g. via the establishment of a special European Fund within FP7; furthermore calls specifically on the Commission to revise the evaluation criteria under FP7 so that FP7 attracts and funds significantly more research to improve the scientific methodology to assess nanomaterials;

21. Calls on the Commission to promote coordination and exchange between Member States on research and development, risk assessment, guidance development and regulation of nanomaterials by using existing mechanisms (e.g. REACH Competent Authorities Subgroup on Nanomaterials) or by creating additional ones, if appropriate;

22. Calls on the Commission and Member States to propose, as soon as possible, the establishment of a permanent and independent European network responsible for monitoring nanotechnologies and nanomaterials, and a basic and applied research programme on the methodology for this monitoring (particularly metrology, detection, toxicity and epidemiology);

23. Asks the Commission and the Member States to launch an EU-wide public debate on nanotechnologies and nanomaterials and on the regulatory aspects of nanomaterials;

24. Recognizes that it is essential to remove the obstacles preventing very small businesses and SMEs in particular from accessing patents and calls at the same time for patent rights to be limited to specific applications or production methods of nanomaterials, and only to be extended to nanomaterials themselves on an exceptional basis, to avoid stifling innovation;

25. Considers that stringent ethical guidelines need to be developed in due time, particularly for nanomedicine, such guidelines being the right to privacy, free and informed consent, the limits set on non-therapeutic human enhancement, whilst offering encouragement to this promising interdisciplinary domain with breakthrough technologies such as molecular imaging and diagnostics, which can offer impressive benefits for the early diagnosis and smart and cost-effective treatment of many diseases; asks the European Group on Ethics in Science and New Technologies to draw up an opinion on this issue, building on its Opinion No 21 of 17 January 2007 on "Ethical aspects of nanomedicine" and drawing on the ethical opinion issued by EU national ethics bodies as well as the work undertaken by international organizations such as UNESCO;

26. Calls on the Commission and Member States to pay special attention to the social dimension of the development of nanotechnology; furthermore considers that the active participation of the social partners concerned has to be ensured from the earliest possible stage.

27. Calls on the Commission to evaluate the need to review legislation to address nanomaterials that are created as unintended by-products of combustion processes in a cost-effective manner;

28. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

Notes

(1) OJ C 306 E, 15.12.2006, p. 426.
(2) Opinion on “the scientific aspects of existing and proposed definitions relating to products of nanoscience and nanotechnologies; 29 November 2007”; http://ec.europe.eu/health/ph_risk/committees/04_het WCNG/docs/het WCNG_o_012.pdf And accompanying information by Commission services on the SCENIHR Opinion on ‘the scientific aspects of existing and proposed definitions relating to products of nanoscience and nanotechnologies; http://ec.europe.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_oc_012.pdf Opinion on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterials; 21-22 June 2007; http://ec.europe.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf Modified opinion (after public consultation) on the appropriateness of existing technologies to assess the potential risks associated with engineered and adventitious products of nanotechnology; 10 March 2006; http://ec.europe.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf Opinion on risk assessment of products of nanotechnologies; 19 January 2009; http://ec.europe.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf
(3) Opinion on safety of nanomaterials in cosmetic products; 18 December 2007; http://ec.europe.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf
(4) Advies nr. 21, 17 January 2007.
(5) OJ L 396, 30.12.2006, p. 1.
(6) OJ L 123, 24.4.1998, p. 1.
(7) OJ L 183, 29.6.1989, p. 1.
(8) OJ L 11, 15.1.2002, p. 4.
(9) OJ L 262, 27.9.1976, p. 169.
(10) OJ L 31, 1.2.2002, p. 1.
(11) OJ L 354, 31.12.2008, p. 16.
(12) OJ L 109, 6.5.2000, p. 29.
(13) OJ L 268, 18.10.2003, p. 24.
(14) OJ L 43, 14.2.1997, p. 1.
(15) OJ L 353, 31.12.2008, p. 1.
(16) OJ L 24, 29.1.2008, p. 8.
(17) OJ L 327, 22.12.2000, p. 1.
(18) OJ L 114, 27.4.2006, p. 9.
(19) OJ L 376, 27.12.2006, p. 21.

(20) Commission Communication of 2 February 2000 on the precautionary principle (COM(2000)0001).
(21) Position of the European Parliament of 24Marcht 2009, Texts adopted, P6_TA(2009)0158.
(22) Position of the European Parliament of 25 March 2009, Texts adopted, P6_TA(2009)0171.
(23) Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of waste pursuant to Article 1(a), of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1 (4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226 van 6.9.2000, p. 3).
(24) Council Decision of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 and Annex II to Directive 1999/31/EC, OJ L 11 van 16.1.2003, p. 27).

Appendix D: List of nanotechnology publications from the Rathenau Institute

2008

L. Hanssen, B. Walhout & R. van Est, *Tien lessen voor een nanodialoog*; red.: P. Messer, Den Haag: Rathenau Instituut, 2008. - 69 p. - ISBN 9789077364253

L. Hanssen, B. Walhout & R. van Est, Ten lessons for a nanodialogue; ed.: P. Messer, The Hague: Rathenau Institute, 2008. - 71 p. - ISBN 9789077364277

2007

S. Kern & A. Versleijen, *Nanotechnologie : van agendering tot innovatie : innovatiedynamiek op het gebied van drug-delivery, zonnecellen, waterzuivering en computertechnologie* [Nanotechnology: from agenda to innovation: Innovation dynamics in drug delivery, solar cells, water treatment and computer technology], Den Haag: Rathenau Instituut, 2007. - 53 p.

Malsch, R. van Est & B. Walhout, *Nanovoedselveiligheid* [Nano Food Safety], Den Haag: Rathenau Instituut, 2007. - 83 p.

/J. Staman, *Brief n.a.v. kabinetsvisie nanotechnologieën* [Letter in response to the Cabinet's vision of nanotechnology], 12March 2007, Den Haag : Rathenau Instituut, 2007. - 2 p.

R. van Est & B. Walhout, *Verslag workshop nanovoedselveiligheid* [Report of the workshop on food safety], ministerie van LNV, Den Haag, 13 June 2007. Den Haag: Rathenau Instituut, 2007. - 15 p.

R. van Est & B. Walhout, *Verslag ronde tafelbijeenkomst NGO's engaging nanotechnology* [Report of the round table talks NGOs engaging nanotechnology] : Rode Hoed, Amsterdam, 28 June 2007. Den Haag: Rathenau Instituut, 2007. - 36 p.

2006

C. Enzing & J. van Kasteren, *Nanotechnologie in focus : zoektocht naar maatschappelijk relevante toepassingen van nanotechnologie op middellange termijn*

[Nanotechnology in focus: quest for societally relevant applications of nanotechnology in the mid-long term] (till 2015), verslag eerste fase project. Den Haag: Rathenau Instituut, 2006. - 81 p.

I. Malsch, *Verslag expertmeeting milieu- en gezondheidsrisico's van nanodeeltjes : naar een prudent beleid* [Report of the expert meeting on the health and environmental risks of nanoparticles: towards a prudent policy], Parkhotel, Den Haag, 9 mei 2006. Den Haag: Rathenau Instituut, 2006. - 56 p.

J. Staman, *Brief aan de commissies voor EZ, OC&W, VROM en VWS en de Themacommissie Technologiebeleid over de risico's van nanodeeltjes* [Letter to the committees for Economic Affairs, Education, Culture & Science, Housing, Spatial Planning & the Environment, and Health, Welfare and Sport and the Theme Committee for Technology Policy on the risks of nanoparticles], 21 June 2006. Den Haag: Rathenau Instituut, 2006. - 2 p.

2005

Rathenau nano-enquête [Ratehnau nano questionnaire]. - Den Haag: Rathenau Instituut, 2005. - 27 p.

Verslag bijeenkomst nanotechnologie en de toekomst [Report of the meeting on nanotechnology and the future], Studium Generale, Eindhoven: 14 September 2005. - Den Haag: Rathenau Instituut, 2005. - 2 p.

E. Houtsma, *Verslag debat de mens vooruit? Nanotechnologie en ons lichaam : eeuwig leven als cyborg?* [Report of the debate on human progress. Nanotechnology and our bodies: eternal life as a cyborg?] Louis Hartlooper Complex, Utrecht: 14 June 2005. Den Haag: Rathenau Instituut, 2005. - 5 p.

2004

R. van Est, I. Malsch & A. Rip, *Om het kleine te waarderen ... : een schets van nanotechnologie : publiek debat, toepassingsgebieden en maatschappelijke aandachtspunten* [Appreciating the small things.. a sketch of nanotechnology: public debate on areas of application and societal issues]. Den Haag: Rathenau Instituut, 2004. - 84 p. - (Werkdocument; 93). - ISBN 9077364056

L. Hanssen & R. van Est, *De dubbele boodschap van nanotechnologie: een onderzoek naar opkomende publiekspercepties* . Den Haag: Rathenau Instituut, 2004. - 32 p.

L. Hanssen & R. van Est, [The double message of nanotechnology : research into rising public perceptions], summary. The Hague: Rathenau Institute, 2004. - 2 p.

J. van Kasteren, *Duurzame energie dichterbij met nanotechnologie : essay over de (on)mogelijkheden van nanotechnologie voor een duurzame energievoorziening* [Sustainable energy, drawing closer with nanotechnology: essay on the (im)possibilities of nanotechnology for a sustainable energy supply]. Den Haag: Rathenau Instituut, 2004. - 13 p.

I. van Keulen & R. van Est, *Gezondheids- en milieurisico's van nanodeeltjes : achtergrondinformatie voor de Themacommissie Technologiebeleid* [The health and environmental risks of nanoparticles: background information for the Theme Committee for Technology Policy]. Den Haag: Rathenau Instituut, 2004. - 10 p.

Verslag workshop kansen en risico's van nanodeeltjes [Report of the workshop on the risks and opportunities of nano particles]: Theater Concordia, Den Haag, 17 February 2004. Den Haag: Rathenau Instituut, 2004. - 47 p.

Verslag workshop nano-electronics en ambient intelligence [Report of the workshop on nano-electronics and ambient intelligence]; Holiday Inn, Eindhoven, 25 March 2004. Den Haag: Rathenau Instituut, 2004. - 8 p.

J. van Kasteren en C. Enzing, *Verslag rondtafelgesprek nanotechnologie in de agrofoodsector* [Report of round table talks on nanotechnology in the agrofood sector]: De Wageningse Berg, Wageningen, 8 April 2004. Den Haag: Rathenau Instituut, 2004. - 49 p.

F. Biesboer, *Verslag workshop biomedische nanotechnologie* [Report on workship on biomedical nanotechnology]: stadskasteel Oudaen, Utrecht, 7 July 2004. Den Haag: Rathenau Instituut, 2004. - 12 p.

Woordelijk verslag van de publieke bijeenkomst over nanotechnologie : kleine technologie - grote gevolgen [Verbal report on the public meeting on nanotechnology: small technology –huge implications]: Oude Zaal Tweede Kamer, Den Haag, 13 October 2004 Themacommissie Technologybeleid & Rathenau Instituut. Den Haag: Rathenau Instituut, 2004. - 36 p.