



BUND Position "For the Responsible Management of Nanotechnology"
A preliminary discussion paper focussing on the example of nanoparticles

(Resolution by the National Executive Committee on April 12, 2007)

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1 Summary

Today many technical fields of nanotechnology apply in a targeted manner new substances that are smaller than 100 nanometres (nm) in size. The special and previously unknown properties that these substances and materials possess at these scales can be used for many industrial applications and products. For this reason, nanotechnology is already being used today in, among others, cosmetics, medicines, food and electronic products.

There are, however, a large number of potential health aspects and environmental risks associated, which make it imperative to take a critical and comprehensive view on nanotechnology. It is, for example, currently hardly known what effect nano particles have on the environment when they are released through their production, use and disposal.

So far, the development of nanotechnology has not been accompanied critically either by laws being passed or executed, nor has the public been sufficiently informed. A hesitant public debate is only now beginning; it cannot be predicted how binding possible results will be. These are all reasons for concern for non-governmental organisations such as BUND. It is high time for BUND to deal with nanotechnology, because for this still very young development, the course needs to be set urgently towards a technological path which makes it possible to adapt to new insights before the situation becomes irreversible. In particular, this initial analysis and the definition of initial recommendations in the restricted case of nanoparticles should form a contribution to the development of a common European policy of Friends of the Earth on this subject. The recommendations listed should thus be treated with some reservation. More established and further developed statements are expected in the relatively near future, not least due to the dynamic nature of this field.

So far, two aspects can be seen which must be treated distinctly in view of necessary further developments and recommendations:

- Potential environmental benefits are offered by nanotechnology, which must be developed further with a view to a viable future and sustainable development;
- The fear of risks and hazards posed to humans and the environment by the use of nanotechnologies, which must be examined at an early stage and according to sufficient precautionary criteria.

A simple evaluation of nanoparticles is difficult as the precise properties that make them potentially useful are also those which pose a possible risk. For instance nanoparticles are able to overcome the protective mechanisms developed by evolution (such as the blood-brain barrier and the placenta barrier).

A great variety of nanomaterials are used industrially: from fullerenes (football-shaped carbon particles) and carbon nanotubes through to known materials such as nanoparticles made of zinc or titanium oxide, whose new chemical and physical properties are wanted for the use in new products.

The greatest risk is posed by nanoparticles, which are emitted as free particles or are contained in products in an uncombined state so that people and the environment can become exposed to them. Almost all products, however, have in common that the nanoelement of the product has not been tested sufficiently in terms of its effects on humans and the environment. Various problems have been identified that have been observed in a variety of animals and humans. These include inhalation of nanoparticles, nanoparticles in food and animal feed, and dermatological contact. Dermatological contact can occur, for instance, through titanium oxide particles in UV protection creams and in cosmetics. Further negative effects have been observed in aquatic systems and in soil.

In addition to the discussion on models for sustainable nanotechnology, an important result is the creation of a comprehensive catalogue of recommendations. The ten core recommendations are:

1. Strict application of the *precautionary principle* in the use of nanotechnologies.

2. The *reversibility* of nanotechnology must be ensured. Developments that enable self-replication are rejected in principle.
3. Public *transparency* with respect to findings, data, developments, use and application of nanotechnology. The creation of a framework of *obligatory* information/transparency respectively *registration*.
4. The classification and treatment of "nanochemicals" as new substances in terms of legislation governing the use of chemicals. New methods for the evaluation of toxicity of nano substances using the approach of a *reversed burden of proof*.
5. Reduction of the lack of regulations in legislation governing water, waste, industrial plants, chemicals, etc. Measures and obligations to obtain a permit must be included in the new designated *environmental German law code* where the risks posed by nanomaterials need to be addressed specifically.
6. The *ban of products* for all applications open to the environment leading to exposure of humans or the environment.
7. A consideration of the effects on *vulnerable groups*, weakened people or organisms.
8. Research efforts into ecological and health effects, but also into societal, ethical and social aspects of nanotechnology must be *greatly increased* (10-15% of research funds).
9. Efforts to reach a goal-oriented and clearly structured dialogue must be *concentrated* procedurally and institutionally (to create a federally agreed upon dialogue concept involving all stakeholders).
10. The setting-up of a "governing body" which will process the stated recommendations responsibly and independently. This body must create an *integrated concept* to deal with nanotechnology (an *institutional solution*).

2. Introduction: What is understood by the term nanotechnology?

The term nanotechnology is often used as an umbrella term to refer to the various branches of the nanosciences and technologies. Nanotechnology originally meant science and technology at atomic and molecular level.

This definition is particularly inexact as the term nanotechnology is used to describe a range of technical disciplines whose only common feature is the targeted application of substances measuring between one and one hundred nanometres in size. One nanometre is equal to 0.0000001 mm. The diameter of an iron atom, in comparison, is around 25 nm. Thus nanotechnology deals with particles, which are little larger than single atoms, and is thus less of a definite technology and rather a collective term for a variety of applications and products that, by containing these smallest of particles, (can) gain previously unknown properties. For this reason nanotechnology is gaining in recognition worldwide and is said to be the technology of the future in the coming years. In the USA, Japan and the EU, research into nanotechnology is receiving massive state funding.

The core novelty of this technology can be described by the word "targeted", as nanometre-sized particles are also randomly created in combustion processes (see chapter 4.1 for further differences). Colloidal chemistry, for example, has made use of particles of this size in an "untargeted" way for a long time. It has been possible to make particles in the nanometre range visible and to alter them in a targeted way since the mid-1980s through the application of new analytical methods.

The "new" properties of these specially manufactured "nanoproducts" are increasingly being exploited by industry. In this way, nanotechnology is already being used today in cosmetics, medicines, food and electronic products and the trend towards the production of nanotechnological products is increasing rapidly. Perhaps the most widely known application today is the so-called "lotus effect". By imitating the surface structure of a lotus plant, surfaces become so dirt-resistant that the film of dirt can be washed off simply with water. This example also shows that it is perfectly possible that the use of nanotechnology can be beneficial for the environment. The cleaning of dirty surfaces is currently reliant on highly energy-intensive processes and often the use of environmentally damaging detergents in particular. The use of the lotus effect can help to save energy and protect the environment. There are further examples specifically in the field of bionics that show that environmentally beneficial effects can be achieved through the adoption of biological construction principles. But nanotechnology also offers considerable potential for the development of highly efficient electricity storage media.¹

There are certainly, however, a wide range of environmentally relevant issues and potential environmental threats, which make it, seem necessary to deal with Nanotechnology in a very critical and comprehensive way. The emphasis of this discussion will lie on nanoparticles and materials created in a "targeted" manner. The ultra fine dust particles, which are equally on a nano scale, created particularly in combustion processes, can partly carry the same level of potential risk, but should be separated from the following examination and demands².

The following issues are particularly relevant to the discussion on nanotechnology:

- **The possible change in chemical behaviour.** The chemical behaviour of a substance can change when it falls below a certain size threshold (usually below 20 nm). This means that a particle of 10 nanometers *can* behave in a completely different way chemically from one of 100 micrometers in a chemical compound of the exact same substance. This is one of the reasons for the particular properties of nanotechnological products. It is equally possible that substances that are known to be and registered as completely harmless can become toxic solely on the basis of their small size or that normally inert substances can suddenly become highly reactive. The commonly used and accepted method of defining maximum levels through mass by volume without regarding and setting a limit to the particle size is completely inadequate in these cases.
- **New "artificial" nano-structures:** nanotechnology makes it possible to produce synthetic substances which are markedly different in their atomic structure to naturally occurring substances and whose effect on humans and the environment is thus completely unknown. The best-known example for this is the so-called "fullerene", a carbon compound

¹ Energieversorgung sichern durch elektrochemische Energiespeicher - auch durch Nanomaterialien. Hedderich, R., in: Nanotechnik 02/2007

² See BUND background on dust/fine dust (PM) of March 2005 and on fine dust exposure of March 2006

created by creating a new structure of carbon atoms. Fullerenes are already being used in cosmetics although neither their toxicological nor ecological harmlessness has yet been proven.

The impact of nanoparticles on the environment, when released through the manufacturing process, use and consumption/disposal is currently hardly known. Regardless of this, silver nanostructures are already being used today for sterilising clothes, for example. There are also shampoos, toothpastes and soaps available on the market containing nano silver, and making use of the antimicrobial effect of silver ions. This silver, however, finally makes its way into water systems and is highly toxic to the creatures that live there. The Environmental Protection Agency in the USA (EPA) has taken the first steps in this instance to introducing laws to regulate this. Manufacturers must test products that contain silver nanoparticles and claim anti-bacterial properties for their environmental harmlessness. Equally, there has been no research as yet into possible anti-microbial effects when these substances enter the soil. This lack of knowledge, however, does not prevent the industry from putting these products on the market, and this is only one of many examples. This approach cannot be justified in terms of sustainable development (precautionary principle). The sustainable development of a new technology requires that the potential threats to humans and the environment must be analysed before its use and that products are only put on the market once an evaluation of the threat to humans and the environment through its production, use and consumption/disposal has been identified as being improbable.

3 Context and aim of this position paper

Until now, the development of nanotechnology has neither been accompanied by a critical regulation through legislation nor any supervision worthy of note by the authorities nor has the public been sufficiently informed. A tentative public debate is only just beginning to emerge; the liability of possible results is not yet clear. These are all grounds for concern for non-governmental organisations such as BUND. It is high time for BUND to deal with nanotechnology, because for this still very young development the course needs to be set urgently towards a technological path which makes it possible to adapt to new insights before the situation becomes irreversible. Demands for a critical examination of this technological development need to be voiced. This examination could also result in the rejection of specific developments in nanotechnology. This initial analysis and list of initial recommendations should in particular contribute to the development of a common European policy of Friends of the Earth on this issue.

If one takes an open-minded look at the expectations and visions, nanotechnological developments will affect the basis of life, ecosystems, energy production, in fact all human activities. In light of the enormous financial investment being made in the manipulation of living organisms at a nano-scale, it seems certain that there will be a multitude of effects and results. The creation of living materials through synthetic biology is not a dream of the future, but already a reality in laboratories.

The development of nanotechnology will cause – if one listens to some of the statements – a paradigm shift in our technology-oriented economy to the model of "sustainable technologies" which are "inherently safe" or "biodegradable". It is advisable to view this sceptically. Thus the granting of patents, for example, could greatly change existing economic structures. Holders of certain patents could exercise their power over other industrial branches resulting in industrial mergers, alliances and processes of concentration. Even the restructuring of the work environment could become a problem. It is to be expected, however, that the ecological and

medical uses of this technology will not provide everything that its proponents currently promise.

- The past shows, that new technologies have not brought more social justice, but rather enriched and made even more powerful those who were already rich and powerful. Poverty, social inequality and need will hardly be overcome by the development of nanotechnology.
- Previous technological developments have also, on the other hand, meant that new expectations and uses were created, which exhausted the previously praised environmental benefits or have shifted the problematic flow of materials either geographically or temporally, or have thrown up completely different fields of problems. One example is the new electronic memory media (such as the CD-ROM), which raised the expectation that the use of paper would be drastically reduced in the near future. Instead, in spite of the increased use of these technologies and the greatly increased possibilities for processing and saving, the use of printing and paper has also risen.
- Even the environmental improvements in Europe highlighted by environmental reports (such as the decoupling of raw materials/the use of energy from GDP) must be traced back partly to the shift in the use of resources and environmental impact between the regions of the world's economy (from the highly-developed industrialised nations to the less developed areas of the south)³.

In addition to this, one can also state that (superficial) beneficial effects for the environment and raw materials from new technologies have often merely diverted attention away from the need for actual changes in behaviour. One example is the introduction of catalytic converters in cars in the middle of the 1980s. In order to achieve comparable air quality, there would have had to have been 80% fewer cars in use today⁴. The superficial concentration on technical solutions, which are marketed as technologies of the future, diverts the focus from sustainable development, whose solutions should actually go to the root of the real causes – such as the unsustainable lifestyles of the highly developed industrialised nations.

For this reason, it is particularly important to establish in advance which goals BUND wishes to achieve, against which the questions and aspects arising from nanotechnology can be measured. The previous findings on nanotechnology and discussions can be viewed from two angles, which should be differentiated between, particularly in the light of necessary further developments and recommendations:

- The potential environmental benefits of nanotechnology. These must be further developed in a way that is sustainable in future (see chapter 5).
- Fears of the risks and dangers posed to humans and the environment through the use of nanotechnologies. These must be examined early and against sufficient criteria of precaution (see chapter 6).

³ Schütz, H.; Moll, St.; Bringezu, S. (2003): Globalisierung und die Verlagerung von Umweltbelastungen. Die Stoffströme des Handels der Europäischen Union. Wuppertal (Wuppertal Paper)

⁴ Cf. DIE ZEIT No. 41 of 05.10.2006, p. 26, Interview mit Andreas Troge, Präsident des Umweltbundesamtes

Thus it is necessary to differentiate clearly between the positive, possible environmental beneficial aspects of these technologies from the hazards connected developments and thus to form differentiated recommendations. This is not always easy, particularly in view of developments, which are often not yet predictable. In addition, the process of forming a policy on this subject has only just begun, so that further and more strongly supported and more precise statements can be expected in the relatively near future. The recommendations listed here are thus made with certain reservation.

Particularly in view of possible risks and dangers the new materials must be regulated through appropriate legislation, instruments and processes. The industrial manufacture of nanomaterials and nanoproducts is, however, occurring so quickly, that regulation of these developments is lagging behind. Several initial aspects essential to this regulation are listed in section 6. The politically responsible and critical exertion of influence seems to be particularly urgently needed due to the fact that researchers and producers of nano-goods are bringing products to market with unknown risks and often dubious benefits ("taste sensation", "permanent underwear" "transparent sun cream" etc.) without stating the composition, active ingredients and side-effects and on the other hand as consumers are not asking the critical questions and are not avoiding the use of nano-goods with unknown risk factors.

Because of the breadth of the topic, an initial shortened exposition of the problems will be given of the opportunities and the risks associated with the focus on the example of nanoparticles. The fundamental recommendations already derived from these, form the emphasis for a critical and sustainable way of dealing with this technology in the future. Aspects of work-place protection and other problem areas will be excluded initially.

4 The effects on and consequences for humans and the environment (a selection)

4.1 The effect on and risks to health through nanoparticles

As a result of their large surface areas, nanoparticles are able to absorb, fix and transport substances such as medicines, test substances and proteins to a specified area of the body (therapeutic applications). On the other hand, nanoparticles can, through an indirect entry through environmental media such as the soil, water and air lead to a direct effect on human health (increased rate of mortality and sickness), which will be addressed later in this paper. The particular special qualities of nanoparticles (and this makes a simple evaluation difficult) are that the exact properties, which are potentially useful, are the same properties, which give rise to a possible risk. Thus nanoparticles are able to overcome the protective mechanisms developed through evolution of the blood-brain barrier or that of the placenta, for example.

The following simplified differentiations can be made for nanoparticles less than 100 nm in size:

- There are naturally occurring ultra-fine particles (as a mixture of large, fine and ultra-fine dust, created through combustion processes, for example).
- Fine and ultra-fine particles of non-natural origin, created in the technical process of combustion and manufacturing of all types, i.e. from road traffic, (diesel soot, catalytic converter exhaust, wear from tyres, clutch and brakes), in the home (through the burning of candles, boiling, frying and grilling), cigarette smoke or dust from mining. An initial overview of the creation and distribution of atmospheric particles can be shown by the high number

of particles found at street level (with over 50,000 particles/cm³)⁵. In contrast, typical concentration levels in rural areas lie between 1,000 and 4,000 particles/cm³. The three largest source groups are the anthropologically created aerosols from local combustion processes (in particular vehicle traffic), supra-regional enrichment through anthropologically influenced aerosols in large masses of air and through photochemical processes in the atmosphere forming new aerosols.

- The industrial use of substances at a nano scale in articles, which have been offered to end-users for quite some time. Here one must draw a distinction between the inorganic nanoparticles of metals, metal oxides or carbon particles, organic nanoparticles and nano coatings. The number of these products is rising continuously. It is estimated that nanoparticles are presently found in 500-700 products – an Internet database revealed that in August 2006 there were already 276 in almost all areas of life⁶, ranging from creams, pastes, cosmetics to sun screen, toner for laser printers, additives for diesel fuel and food to paints, varnishes and glues.

A wide variety of nanomaterials is used industrially: from fullerenes (football-shaped particles of carbon), to carbon nanotubes to less exotic materials such as nanoparticles of zinc and titanium oxide whose chemical and physical properties are being used for new products. The problem can be made clearer through the example of titanium oxide: produced in large quantities and used as a white pigment, this product was not seen as problematic before it started to appear in small-sized particles as the relevant tests carried out on the macro-size of the particles had produced no negative results.

Test results for titanium oxide in the form of nanoparticles, however, show that these particles can have an ecologically toxic effect⁷. The observation that the properties of a substance in nano format differ from that of the same substance in non-nano format has also been made with regard to other substances⁸.

What nearly all of these products have in common is that the effect of the nano component has not been sufficiently tested. Toxicological tests are not a requirement as most of industry and its associations are of the opinion that the basic materials and their chains of effects are already known in principle. However, nanoparticles of a substance can have completely different toxic effects than that which occur in previously used micro and macro forms. This phenomenon is due to physics: the smaller a particle is, the greater its surface area is in comparison to its mass. This means that materials made of a given chemical compound can be notably more reactive in nanosize than larger particles of the same chemical compound. It is possible, even,

⁵ Birmili, Wolfram (2006): Räumlich-zeitliche Verteilung, Eigenschaften und Verhalten ultrafeiner Aerosolpartikel (<100nm) in der Atmosphäre, sowie die Entwicklung von Empfehlungen zu ihrer systematischen Überwachung in Deutschland. Text 26/06 of the Federal Environment Agency des Umweltbundesamtes (UBA-FB 000942)

⁶ Study by the "Project on Emerging Nanotechnologies", Washington, see: <http://www.nanotechproject.org/index.php?id=44>, Viewed 09.08.2006

⁷ Cited from. Führ, M. et al. 2007 (Rechtsgutachten Nano-Technologien (ReNaTe). Bestehender Rechtsrahmen, Regulierungsbedarf sowie Regulierungsmöglichkeiten auf europäischer und nationaler Ebene. Erstellt für das Umweltbundesamt): Hund-Rinke, K.; Simon, M.; Ecotoxic Effect of Photocatalytic Active Nanoparticels (TiO₂) on Algae and Daphnids. In: Environ. Sci. Pollut Res 13, 225-232 (2006), pp. 225 ff.

⁸ Cited from Führ, M. et al. 2007 (Rechtsgutachten Nano-Technologien (ReNaTe). Bestehender Rechtsrahmen, Regulierungsbedarf sowie Regulierungsmöglichkeiten auf europäischer und nationaler Ebene. Erstellt für das Umweltbundesamt): Nel, A.; Xia, T.; Mädler, L.; Ning, L.; Toxic Potential of Materials at the Nanolevel. In: Science 311, 622-627 (2006), p. 622

that the toxicity of a substance increases proportionally with its reduction in size, as its surface becomes catalytically active and causes unwanted reactions. Biological barriers, such as the blood-brain barrier or the placenta are apparently passed by nanoparticles. Also on the cellular level, the cell membrane clearly does not provide a barrier. It is assumed that the non-degradable nanoparticles build up in the detoxifying organs.

The hazards increase the more nano-scaled materials enter the market. The highest risk is posed by nanoparticles, which are emitted as free particles or are contained in products unbound, which can lead to people and the environment being exposed to them. The risks appear to be markedly lower where particles are bound in materials. The effects that nanoparticles which have been manufactured artificially over the past few years have on organisms, especially the long-term effects, have so far been studied so little that the degree of risk posed by them can be hardly estimated^{9, 10, 11}. While it is known that the smallest particles, when breathed in, can affect the heart and circulation system and the autonomous nervous system and that "exposure (to these) can reduce life expectancy by up to two years".¹² This kind of data has not yet been recorded in the application of products containing artificially created nanoparticles. The exposure through the lungs to inhaleable dust can be seen as a crucial way for the most relevant effects on health¹³ and thus for the technologically created nanoparticles. In the absorbing organs of the stomach and the intestinal tract, as well as the skin and lungs, this can lead to local effects in tissue kinetics. In addition, systematic effects can be caused after absorption and distribution of nanoparticles that can even lead to the end of the functioning of the above mentioned organs.

A decisive question is where the nanoparticles end up once they have entered the body and what effects they can cause there. It is known that the inhalation of fine and ultra-fine particles can cause damage to the epithelial layer of the lung, so that their ability to fend off pathogens is weakened and inflammation can be caused as a reaction. The particularly damaging effect of nanoparticles can be explained by their specific surface area and the electro kinetic potential of metallic particles. Once inhaled, the nanoparticles pass into the blood circulation system through the alveoles as the macrophages are insufficiently able to remove the tiny particles. The following effects have been proven so far, for example:

- Various types of carbon nanoparticles of between 30 and 35 nm in diameter can pass through the sensory nerves of rodents and into the brain. "It is possible that nanoparticles can reach parts of the body that larger particles cannot reach, due to their small size. They can cross barriers (such as the blood-brain barrier) and then cause a reaction"¹⁴. Inhalation experiments using rats have shown that inhaled carbon particles could lead to considerable lung damage and that the potential toxicity rose with a reduction in particle size and rise in surface area.

⁹For more comprehensive information: Oberdörster, G.; Oberdörster, E.; Oberdörster, J. (2005): Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles, *Environmental Health Perspectives* 113 (7), pp. 823-839, 2005

¹⁰Hoet, P.H.M.; Bröske-Hohlfeld, I.; Salata, O.V.: Nanoparticles – known and unknown health risks, *Journal of Nanobiotechnology* 2004, pp. 2-12

¹¹Borm, P.J.A. et al. (2006): The potential risks of nanomaterials: a review carried out for ECETOC, *Particle and Fibre Toxicology* 2006, pp. 3-11

¹²Eikmann, T., Seitz, H. (2002): Klein, aber oho! Von der zunehmenden Bedeutung der Feinstäube. *Umweltmed. Forsch. Prax.* 7, pp. 63 – 64

¹³Oberdörster, G. (2001): Pulmonary effects of inhaled ultrafine particles. *Int. Arch. Occup. Environ. Health* 74:pp. 1-8

¹⁴Oberdörster, G. (Toxikologe an der University of Rochester), zit. Ross, Philip E.: Angst vor den Nanogiften. <http://www.heise.de/tr/artikel/73533> of 25.05.2006, viewed 09.08.2006

- Fullerenes had a toxic effect on fish in aquatic systems and led above all to the oxidation of lipids in the brain¹⁵. Given this background, it should be judged critically when fullerenes are already being used for their "anti-oxidant" properties in cosmetics.¹⁶
- Nanotubes of carbon are of great importance given their outstanding mechanical, electrical and magnetic properties. They can attain lengths of several micrometers and can certainly be ingested by cells. Researchers at the NASA Johnson Space Center in Houston have demonstrated that they can cause damage to the lungs of mice, which increased over a longer period of time. It was shown that the carbon nanotubes were more toxic than soot, in some cases even more toxic than quartz, which is known as a hazard to health in work-safety regulations.

These and further examples (see table 1) show that the risk for people in the workplace, in the proximity to plants through emissions, and for users of articles urgently need to be defined more clearly and must be prevented as far as possible through workable, legally-binding regulation. Large gaps in the understanding of their toxicology make it necessary to carry out systematic investigations with a view to producing dependable and comparable methods, reference material and exposure scenarios just as into the aspects of human and environmental toxicology. One must also note that causal links may possibly never be proven beyond reasonable doubt. In addition to suitable measuring processes and monitoring methods, important information on toxic kinetics, deposition and accumulation is also lacking.

Oral Exposure

Oral exposure has been examined even less, so a meaningful toxicological assessment can hardly be undertaken. The absorption and distribution of nanoparticles by the body is carried out principally by the intestines in that they can absorb insoluble particles that then reach the lymphatic system. From here, the particles are able to enter the bloodstream and are distributed throughout the body. The toxicity of the insoluble particles depends on local and systemic distribution. Therefore, the use of nanoparticles in food and animal feed requires a discussion on measures to be taken, which would range from labelling requirements (enabling a conscious avoidance of such articles) to a ban on the use of such materials.

For example, in the food industry, Kraft Foods is working on so-called nanocontainers-transport molecules, that are between ten and a hundred nanometres in size and usually consist of fat molecules. The tiny containers are filled with dyes and flavour additives that are first released when stimulated – by shaking or in the microwave. Enriched "Functional food" will have its health additives packed in nanocontainers that deliver them to the correct place in the body (the stomach or intestines). The first such articles are already on the market: Rape seed oil with phytosterols (plant material that prevents the absorption of cholesterol in the intestines, from the Sheman company, Israel) or bread with tuna fish oil which only releases the healthy Omega-3 fatty acids in the stomach and prevents the bread from tasting of fish (George Weston Food, Australia). The question in Germany is whether such uses already cross the border into medicinal

¹⁵ Oberdörster, E. (2004): Manufactured nanomaterials (fullerenes, C60) induce oxidative stress in the brain of juvenile largemouth bass. *Environ. Health Perspect.* 112: pp. 1058-1062

¹⁶ Krug, H. F. (2006): Gibt es Gefährdungen oder Risiken durch Nanopartikel? In: *Nanotechnologien nachhaltig gestalten - Konzepte und Praxis für eine verantwortliche Entwicklung und Anwendung.* Hrsg. von Markus, P.; Kühling, W.; Henn, S., Tagungsprotokolle des Instituts für Kirche und Gesellschaft, Iserlohn 2006, p. 67-77

use and should therefore be regulated under German drug legislation. The packaging industry is already making use of nanoparticles made of silver to protect food from bacteria.

Dermal Exposure

There is insufficient knowledge of intact or damaged skin as to whether nanoparticles can enter the gaps in the upper layer of skin or through the root of the hair into the skin. With regards to dermal exposure (titanium dioxide nanoparticles that are already on the market as UV protection and in cosmetics), there appears to be no penetration by particles into healthy and undamaged skin if the particles are larger than 20 nanometres in size¹⁷. Some questions, however, remain unanswered. Butz¹⁸ found minimal titanium dioxide residue that could have only been deposited through cracks in the skin during application. There are no studies using damaged skin cells yet. Sunburn often leads to moist skin, which could ease the titanium dioxide particles way through the skin and into the body. Furthermore, the results are only valid for particles of over 20 nanometres in size. What must be feared is that particles under 2 nanometres in size can penetrate the skin without difficulty¹⁹. It is also suspected that titanium dioxide nanoparticles damage nerve cells when they come into direct contact with brain cells in mice²⁰. As long as such a wide range of questions remains unanswered, a ban on such products should be put in place until the opposite is proven.

¹⁷ Wiench, K. (2006): Nanotechnologie – Produktsicherheit. In: Nanotechnologien nachhaltig gestalten - Konzepte und Praxis für eine verantwortliche Entwicklung und Anwendung. Hrsg. von Markus, P.; Kühling, W.; Henn, S., Tagungsprotokolle des Instituts für Kirche und Gesellschaft, Iserlohn 2006, pp. 79-85

¹⁸ Tilman Butz, Head of the EU research project "NanoDerm" in the *taz* of 11.07.2006 (WOLFGANG LÖHR)

¹⁹ *ibid.*

²⁰ Thomas C. Long, Navid Saleh, Robert D. Tilton, Gregory V. Lawry, Bellina Veronesi: "Titanium Dioxide (P25) Produces Reactive Oxygen Species in Immortalized Brain Microglia (BV2): Implications for Nanoparticle Neurotoxicity." In: *Environmental Science & Technology*, Vol. 40(2006), No. 14, 15.07.2006, pp. 4346-4352

Mixed Findings on Toxicity

Group	Key findings	Caveat	Reference
David Warheit, DuPont Haskell Laboratory (2004)	Instilling nanotubes in the lungs of rats can cause adverse reactions.	Not a realistic model of exposure: the study had no findings on the effects of rats' inhaling nanoparticles.	„Comparative Pulmonary Toxicity Assessment of Single-Wall Carbon Nanotubes in Rats," <i>Toxicological Sciences</i> 77: 117–125
Günter Oberdörster, University of Rochester (2004)	Inhaled nanoscale particles can get into rats' brains via the olfactory nerve.	Results might not apply to humans. The study did not demonstrate toxicity or study common manufactured nanoparticles.	„Translocation of Inhaled Ultrafine Particles to the Brain," <i>Inhalation Toxicology</i> 16 (6–7): 437–445
Eva Oberdörster, Duke University (2004)	Fullerenes can damage cells in the brains of fish by increasing peroxidation.	Cells in the gills and liver showed decreased peroxidation after exposure to fullerenes, for undetermined reasons.	„Manufactured Nanomaterials (Fullerenes, C ₆₀) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass," <i>Environmental Health Perspectives</i> 112: 1058–1062
Daniel Watts, New Jersey Institute of Technology (2005)	Nanoscale alumina can stand root growth in corn, soybeans, and other plants, suggesting nanoparticles can be toxic to plants as well as animals.	Chemically altering the surfaces of the particles dramatically reduced their toxicity.	„Particle Surface Characteristics May Play an Important Role in Phytotoxicity of Alumina Nanoparticles," <i>Toxicology Letters</i> 158: 122–132
Joseph Hughes, Georgia Institute of Technology (2005)	Fullerenes can damage microbes. (This study and the next elucidate the mechanisms of toxicity and may help scientists predict the effects of a range of nanoparticles.)	The study models just one aspect of how nanoparticles will interact with the environment.	„C ₆₀ in Water: Nanocrystal Formation and Microbial Response," <i>Environmental Science and Technology</i> 39: 4307–4316
Jennifer West and Vicki Colvin, Rice University (2005)	In human cells, fullerenes can cause damage like that seen in the brain cells of fish.	Particles may behave differently in the body than they do in cell cultures.	„Nano-C ₆₀ Cytotoxicity Is Due to Lipid Peroxidation," <i>Biomaterials</i> 26: 7587–7595
Kevin Ausman and Vicki Colvin, Rice University (2006)	Modifying the surfaces of carbon nanotubes with functional molecules can increase their toxicity.	Functionalizing nanoparticles can negate the very properties that make them useful for some applications.	„Functionalization Density Dependence of Single-Walled Carbon Nanotubes Cytotoxicity in Vitro," <i>Toxicology Letters</i> 161: 135–142

Table 1: Extracts from the spectrum of scientific research on the health dangers of nanotechnology (Source: Ross 2006)

4.2 Effects on the environment

Due to their special characteristics, nanomaterials can also have an effect on the environment. In order to estimate the risk, it is crucial to know in which form these materials come into contact with the environment. What needs to be clarified is if and in which form nanomaterials

can enter the environment through deterioration and decomposition as well as disposal and recycling. A view of the entire lifecycle is a prerequisite for an estimate of the environmental threat to be made.

Nanoparticles can enter living cells. They therefore have the potential to accumulate both in organisms and in the food chain. Based on the few tests on organisms, it is known that water fleas, depending on the application, die in water with a relatively low concentration of C60 particles (fullerenes) and nano-scaled titanium dioxide. C60 particles are ingested by young trout through the gills, pass the blood-brain barrier and damage the brain even in small concentrations. The bacteria killing effect of some nanomaterials can also have an effect on aquatic systems.

Nanoparticles can also have unexpected undesired effects on the soil. There are, however, hardly any tests in the area of soil ecosystems to date. For example, aluminium nanoparticles result in reduced root growth in different agricultural crops whereas larger aluminium particles do not have this effect. The feared negative results of a bacteria-killing effect of some nanomaterials are applicable here as well. The toxic effects of nanotubes and buckyballs (fullerenes) in soils and bodies of water are also increasingly under discussion²¹.

An increasing number of silver nanoparticles enter the market that release antibacterial silver ions in distinct amounts and are added to wash water in washing machines, so the laundry is protected from bacteria and the development of smell. These particles wind up in the waste water system and then in sewage treatment plants. Titanium dioxide particles from façade, roof and window coatings may also possibly enter the soil and water system without sufficient knowledge of the effects that might then occur.

5 BUND-Considerations on the sustainable development of nanotechnology

While the "traditional" technology is based upon material conversion and material processing with more or less high-energy use and "unavoidable" waste production, metabolic processes in the "nano factories" of nature run with a minimised use of (solar) energy and minimised production of waste, which in turn is recovered in the metabolic cycle. Could it not be possible to imitate and emulate the functions of these biological systems? This would be an expansion of bionics. The aim of the new technological model would have to be to break through the linear flow between resource consumption and refuse production and put a circulation-based production model in place.

Starting with the problems of a sufficient prognosis of a technological impact assessment and how to deal with the lack of knowledge, it is furthermore essential to carry out a rational technology assessment that takes the rather well known interference of the technology as a starting point and not the relatively unknown impact on the endpoint (humans/environment)²². Technologies do not emerge from the law of nature, they are the result of acting persons putting the technology with available instruments into understandable constellations; they are "created". It should also not be forgotten that the overwhelming number of nanotechnological developments are applications developed to capture future markets and based on the necessity

²¹ Hoon Hyung et al. (2007): "Natural Organic Matter Stabilizes Carbon Nanotubes in the Aqueous Phase", *Environ. Sci. Technol.*, 41 (1), pp.179-184

²² As above, Arnim von Gleich (2004): *Mit Nanotechnologie zur Nachhaltigkeit? „Charakterisierung der Technologie“ und „leitbildorientierte Gestaltung“ als Auswege aus dem Prognosedilemma der Technikbewertung* (Manuscript)

of sustainability and competitiveness in the economy and is therefore rather offer-driven ("molecule seeks market") than needs- or demand-driven. These lead to some overvaluing of the opportunities and a playing down of the risks. Therefore, models play an important role in active development of technologies that follow the aim of sustainable development (Table 2)²³.

Sustainability can be achieved in this context in three ways: efficiency, consistency and sufficiency. Efficiency is based on the more productive utilisation of matter and energy, so on resource productivity. Consistency is the search for ecologically sound technologies that use the materials and the performance of the ecosystem without destroying it. Sufficiency strives to decrease the consumption of materials and energy through a lower demand for goods and services that use a large amount of resources (with a correspondingly lower return). Nanotechnologies can then be sustainable when they enable procedures for the manufacture of products comprising ecological management (efficiency, consistency) and lead to products whose use follows ecological criteria as well (efficiency, consistency, sufficiency).

Model	Issue	Focus	Examples
Resource efficient nanotechnology	Environmental improvement, environmental technology Low resource intensity with - high benefit - low consumption - low damage	Quantity of energy and material flow (whole life cycle) in relation to societal benefit	Surfaces with low tear and friction (mechanical engineering), highly specialised membranes (biotechnology, fuel cells)
Consistent and inherently safe nanotechnology	No negative impact on health and adapted to the metabolic principles and capacities of nature Inherent safety, low level of interference, high tolerance to human error	Quality (and quantity) of material and energy flow with respect to the environment, health and technical risks	Fast decomposition or closed applications Recycable nanotubes in light construction Spider silk
Nanobionics	Technology following the model of nature, supporting life, cooperating with self-organising principles of nature	The quality of technology (way of dealing with nature)	Bio-catalysts, enzyme technology in substance conversion Biomimetical material synthesis

Table 2: Models of sustainable nanotechnologies with varying ranges (Source: Gleich 2004)

The mentioned key conceptions require a reliable substantive frame that, if possible, all participants can accept. This frame could be aligned therefore with the model of "sustainable development"²⁴. Although this concept seems to have lost popularity over the years, there is no actual alternative, if one deals thoroughly with the requirements of development viable in future. Sustainable development is only given a reliable chance when society as part of the human-environment system regulates and governs the economic activities (and not the other way round). The basis of this can be examined scientifically: While interacting, the triangle forming key areas of economy, ecology and society are not independent and interchangeable, but the limitation and non-arbitrary changeability of the natural basis of life leads to a

²³ *ibid.*

²⁴ Term for a development where the needs of the current generation are met without endangering the needs of future generations. cf.: Wuppertal-Institut: "Zukunftsfähiges Deutschland", BUND/Misereor (ed.), Jan. 1996

hierarchical view, called "supporting framework" (Figure 1)²⁵: This understanding of the connections also supports the fact that the economy is to be seen as a part of society and not independent and in isolation.



Figure 1: Natural resources take on the function of a supporting framework for society on which the economy is based (Source: Hildmann 2003, p. 30)

6 BUND-Recommendations for the responsible handling of nanotechnology

6.1 General Recommendations

1. The hazards already partly visible to people and the environment in connection with the high consequences of social, economic and ethical aspects make the strict use of the *precautionary principle* urgently necessary when dealing with nanotechnologies. Public *transparency* of knowledge, data, use, applications, etc. is just as indispensable.
2. As inferred from these basic considerations, the design and intended use of products cannot depend predominantly on their potential market value (see section 5). Nanotechnology therefore requires immediate clear and strict regulations that are supervised by society. Therefore, the importance and the magnitude of the collection, analysis, evaluation and regulation of nanotechnological risks and hazards require an *institutional solution*. Such a responsible, independent body must develop an *integrated* concept for the handling of nanotechnology (in research, production, use and disposal) that gives consideration to risk analysis, risk assessment and risk management, to the concept of sustainability and to ethical implications as well as to communication and transparency (through endorsement and implementation of the suggestions made by the

²⁵ Hildmann, C.: Mängel und Perspektiven einer umweltbezogenen Raumplanung: eine ökologische Sicht. In: Kühling, W.; Hildmann, C. (ed.): Der integrative Umweltplan – Chance für eine nachhaltigere Entwicklung? Dortmund: Dortmunder Vertrieb für Bau- und Planungsliteratur 2003, pp. 29f

German risk commission²⁶). This also includes the early development of energy balance and life cycle assessment or the estimation of social and economic consequences.

3. As long as hazards and risks to people and the environment by nanotechnologies cannot be excluded, there should at least be a ban on products open to the environment. BUND understands that this is a very far-ranging recommendation. Existing developments and decisions whose risk potential is estimated to be too high should be openly and transparently discussed and be made reversible through legal regulations. The aim, therefore, in the creation of further recommendations, is especially to show which control and guidance systems must be introduced to enable reversion and repair strategies for developments in the sense of a responsible handling of risks.
4. The *reversibility* of nanotechnologies must be guaranteed in all developments, applications, etc. Developments that enable self-replication are therefore fundamentally rejected by BUND.
5. *New methods to assess* the toxicity of nanomaterials are needed (they must be clearly labelled as "new substances") in order to ascertain the qualitative difference between nanosubstances and the original macrosubstances. In this case, the burden of proof must lie with the producers resp. formulators who must provide the required data.
6. The assessment of the *exposure* of people, animals and plants as well as the identification and estimation of risks will be required in the following respects:
 - Compilation of exposure scenarios through the *entire lifecycle* (production, use, disposal) of nanoparticles.
 - Consideration for the effects on vulnerable groups, weakened people or organs (e.g. inflamed mucous membranes, damaged skin), etc. At the same time, long-term observations are required.
 - Particular focus on persistence and bioaccumulation.
7. Application of the *precautionary principle* in nanotechnologies at different levels:
 - Introduction of sufficient *security factors* given the unreliability of the current data.
 - Expansion of *operator duties* for facilities subject to authorisation and not subject to authorisation to prevent risk, even when this risk cannot be quantified but possible hazards are indicated.
 - Establishment of *product standards* which include precautionary protection from risk.
 - As long as there is indication of risks from substances, products, etc., emissions and immissions are to be minimised (by use of environmental legislation on *risk minimising principles* analogous to the requirements of the German Technical Instructions on Air Quality Control for cancer-causing emissions).
 - In addition to life cycle and energy assessments, comprehensive *sustainability assessments* are required that also address societal and ethical questions.

²⁶ Risk Commission (2003): Final report by the Risk Commission (ad hoc commission) "Neuordnung der Verfahren und Strukturen zur Risikobewertung und Standardsetzung im gesundheitlichen Umweltschutz der Bundesrepublik Deutschland", Geschäftsstelle der Risikokommission, Bundesamt für Strahlenschutz (ed.)

6.2 Recommendations for the normative scope of regulation

1. A coordinated, *EU-wide (and international)* approach is required.
2. With the introduction of new products using nanotechnologies, the *reversal of the burden of proof* is necessary, as often as a result of the lack of sufficient information, a proof of hazard beyond reasonable doubt cannot be provided in the sense that current legislation requires. The principle "no data – no market" must be enforced. The requirements on product and environment liability must be correspondingly framed.
3. The adaption of a class "nanochemicals" and its classification as at least "hazardous to the environment" under chemicals legislation and the regulation on hazardous substances.
4. Also, the creation of information/transparency as well as *mandatory registration* for the use and application of nanomaterials is imperative as is the *mandatory labelling* of nanoproducts to reflect the unreliability of the current state of knowledge. This applies to research and production as well as use and disposal.
5. Regulatory deficiencies in both water and disposal legislation as well as in production plant legislation must be addressed urgently²⁷. This is demonstrated below by the example of the immission control laws:
 - If the operator duties under the Federal Immission Control Act are assumed to be sufficient, present considerations concerning an integrated approval of facilities in the new German environmental law code have to include additional regulations and approval obligations to respond to the risks of nanomaterials. The definition of a new substance class is imperative.
 - A *new threshold category* is required especially in regard to immission control legislation, which would e.g. include the surface area of particles (e.g. physical size of the surface tension).
 - The Technical Instructions on Air Quality Control need to be expanded to include requirements for the respective emissions and immissions, and for the application of appropriate test control procedures.
 - Access to test results of emissions in companies using nanotechnology must be provided through the German Environmental Information Law.
 - Reference documents on best available technologies (best available technology bulletins) must include references to nanoparticles.
 - All facilities using nano-sized materials (even facilities not requiring authorisation) should be subject to an authorisation procedure.
 - In addition, test facilities for the production of nanomaterials should not be given permission through a fast-track procedure without public participation.
 - Facilities for the manufacture of nanoparticles require a safety-related design according to the German statutory order on hazardous incidents. For this reason, it is necessary to incorporate the substance class "nanochemicals" as an individual substance with a low threshold value into appendix 1 of the German statutory order of hazardous incidents.
 - Further regulation on nano-sized feedstocks, production etc. must be made in §§22f of the German Federal Immission Control Act.
 - The public (especially those living near facilities) require a legal right to the minimising of risks.

²⁷ For a complete overview see: Führ, M. et al. 2006: Rechtsgutachten Nano-Technologien. Abschlussbericht Entwurfsfassung Stand: 04.09.2006, Fachgespräch Nanotechnik am 28. September 2006 im Umweltbundesamt.

6.3 Recommendations for social dialogue and duty of information

1. Data and information on nano-sized materials must be transparent and readily accessible to the public. This also includes minutes of scientific advisory boards, etc.:
 - This especially applies to the possible release of nanoparticles and safety inspections.
 - Every use and every application of nano-sized materials is to be documented and made readily accessible to the public.
 - Company confidentiality is to be narrowly interpreted.
 - Relevant bodies are to be set up (institutionalisation) to ensure access to information and the publicly accompanied assessment and communication of risk.
2. Sufficient information and communication is necessary, so that users can act in a responsible manner.
3. A dialogue concept is necessary that includes all important stakeholders, whose objectives are made transparent, and which is consistently updated.
4. Efforts toward creating a targeted and clearly structured dialogue must be concentrated procedurally and institutionally. The dialogue must also incorporate questions from the "average citizen". (Who should initiate the dialogue? What does an organised, clear dialogue look like? How is it organised hierarchically and at which level? The main question is: Who structures, stages and organises the dialogue?).
5. A discussion on the necessity for products and materials is a part of the dialogue.
6. The responsibility for compiling, preparation and the selected provision of data and information falls to the administration and must be fulfilled in a timely manner. This especially includes comprehensive product labelling on the type and size of the used substances, their possible side effects, etc. The construction of a database, working on the same principle as Wikipedia, that represents the entire spectrum of opinions/research should be considered.

6.4 Recommendations for research

1. The data records with regard to potential risks to health, safety, environmental and consumer protection, etc. require urgent improvement.
2. Research efforts on ecological and health effects, as well as on the societal, ethical and social aspects of nanotechnology must be considerably strengthened (rising to 10-15% of research funding). Required funds are also to be provided by business.
3. A scientific infrastructure is to be created in cooperation with civil society groups in order to guarantee this research.
4. With regard to the allocation of public funds for research, criteria for the participation of relevant civil society groups are to be introduced. Requirements such as notification or authorisation obligations for privately funded research projects are also to be introduced.
5. The planning and realisation of public and private research is to be made transparent, i.e. information on type, objective and result of the research and people and institutions involved must be made public.
6. Research on effects should be integrated into general research, training, and development in the field of nanotechnology.
7. Integration of suggestions and positions of the public through a regular public discourse.

6.5 Necessary institutionalisation

From the preceding point the necessity for the creation of a „responsible body“ arises that will follow up and take responsibility for the stated recommendations. It could be a body, which collects data and information transparently and manages the participation of stakeholders (especially non-governmental organisations) with regard to the responsible handling of nanotechnology. Three steps are required for this:

1. The creation of a pluralistically composed nano-commission (including non-governmental organisations) that develops and makes recommendations. Experts from institutions and committees in the field of nanotechnology (with the inclusion of all essential stakeholder groups) should be called into a time-limited nano-commission by parliament. One task of this commission is the development of an integrated nano-strategy that merges the scientific and technological competencies in the field of nanotechnology as well as to comprehensively collect the ecological, health, social, legal and ethical questions raised by nanotechnology and include these in an interdisciplinary review of research funding. Among other things, this commission must develop criteria for the responsible management of nanotechnology, test methods to estimate risk potential and the organisation of communications (analogous to the experiences and results of the risk commission 2003):
 - For the focus of state funding in the fields of technology development, assessment of effects (environment, health), precaution research, risk research and accompanying research;
 - for societal needs in which nanotechnology could have a substantial impact (jobs, environment, health, etc.);
 - for criteria for the responsible management of nanotechnology;
 - for suitable test methods to estimate risk potential;
 - for necessary measures in the field of standardisation, regulation, legislation, etc.;
 - for the organisation of the communication of risks, measures to strengthen transparency and access to information, the state and results of research in the field of nanotechnology;
 - for the coordination of measures in the area of public information, citizen dialogue and measures in the field of education and qualification.
2. The creation of a permanent, independent nano-institution (nano-council) with sufficient finances and personnel resources (agency) for the implementation of nano-commission recommendations. Further criteria for the future responsible handling of this new technology can be developed here, i.e. strategies for appropriate handling of the lack of knowledge and insecurities in this field or the development of a nano impact assessment.

7 Further information, addresses

<http://www.bfr.bund.de/cd/template/index> (Federal institute for risk management)

http://www.bmu.de/gesundheit_und_umwelt/nanotechnologie/doc/37643.php (Federal Ministry for the Environment, Conservation and Reactor Safety)

http://www.empa.ch/plugin/template/empa/986/*/--/l=1 (Research Institute for Material Sciences and Technology, Swiss Federal Institute of Technology, Zurich) BUND-Position "Nano" Page 19

<http://www.ethiknet.de/technik/technik.html> (Platform of scientific institutes in the German-speaking region that deals with ethical questions on natural science, medicine, technology and economics)

<http://www.itas.fzk.de/home.htm> (Institute for technological impact assessment and system analysis (ITAS))

<http://www.nanopartikel.info/projekt.html> (Project NanoCare)

<http://www.nanotec.org.uk/index.htm> (Nanotechnology and Nanoscience, The Royal Society)

<http://www.nanotechproject.org/> (A Nanotechnology Consumer Products Inventory)

<http://www.techportal.de/de/b/2/start,public,start/> (VDI Technologiezentrum GmbH, funded by the Federal Ministry for Education and Research, BMBF)

<http://nano.ivcon.net/index.php> (Publications on nanotechnology)

<http://ogn.ouvaton.org> (Grenoble opposition to nanotechnology)

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