Nano –
The great unknown

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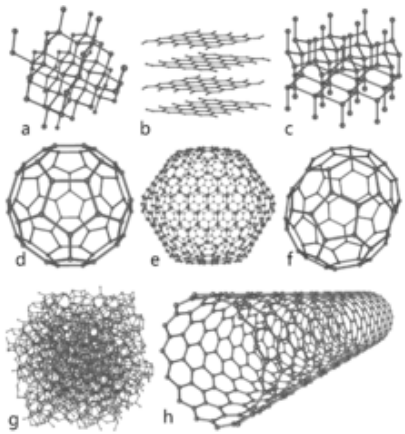

Nanotechnology, the latest buzzword in the global technology revolution, is the science of 'small things': the designing, manipulating and engineering of materials at nanoscale.[1] Already applications of these socalled Manufactured Nano Materials (MNM's, also known as Engineered Nano Materials) range from consumer products like cosmetics, household and health care products, textiles, paints and electronics, to medicine, industrial chemicals (eg. silicium dioxide, titanium dioxide, carbon black), biocides, pesticides, information and communication technologies, agriculture and environmental engineering.

What is nanotechnology and how is it used?

Simply put, nanotechnology is the ability to manipulate and/or produce and use tiny structures or particles on a very small scale, from a single atom to a structure of several hundred nanometers.
To put this scale in context: the width of a human hair is 80,000 nanometers.
As consumers we are already using nanomaterial in our everyday products.
The number of consumer products on the world market claiming to contain nanomaterials exceeded 1300 already by 2010, and there are probably more, as the actual presence of nanomaterials is difficult to identify. New children's products with nanoclaims are increasing fast: pacifiers, toothbrushes, baby bottle brushes, and stuffed animals.[2] Other common uses are to keep sunscreen transparent, packaged food fresher, and aid in the absorption of medicines. They are used as anti-bacterials in clothes and to make surfaces dirt resistant. These 'first generation' nanomaterials include nanoparticles (e.g. metal oxides), nanotubes (needle shaped fibres), nanowires, quantum dots and carbon fullerenes (buckyballs), to name only a few. These man made nanomaterials, some of which did not exist in any form in nature before, enter the environment and can lead to human and environmental exposure at numerous points along their life cycle.
The ones that cause the most concern are those particles that do not break down, disintregrate, agglomerate or aggregate. This means that they might be around as free particles indefinitely.
Although market penetration is increasing, and thus exposure to consumers, the potential impacts on human health and the environment have only been assessed to a very limited degree. We eat them, inhale them, put them onto our skin or wash them into our rivers, but we still don't know what they do in our bodies or the greater environment.

Are nanosubstances dangerous?

Nanomaterials can have very different properties and toxicological profiles compared to the same substances used in bulk form. For example aluminium is stable in the 'big world' but behaves as an explosive as a nanoparticle. Differences are related to various factors such as size or shape and surface properties such as charge and reactivity or surface area.

The specific properties are also related to quantum effects, which are greater the smaller the particle. In the present state of knowledge, it is not feasible to produce a general toxicity profile for nanomaterials, because no appropriate screening processes are known.[3]
Studies conducted thus far suggest that certain types of nanomaterials have the potential to cause oxidative stress leading to inflammation, which ultimately can be toxic for cells or genetic material (cytotoxicity and genotoxicity).[4] Early findings identified that some carbon nanotubes may in the long-term cause mesothelioma (cancer of the lining of the lungs) as does asbestos[5]. Some scientists even warn of a time bomb comparable to that of asbestos for carbon nanotubes and other inhalable nanosubstances.[6] Furthermore, because of their very small size, once absorbed by the human body, nanoparticles can have the ability to enter cells, the placenta and body tissue[7].
Other studies have also demonstrated that some nanoparticles can induce changes in heart rate variability [8].

While very little is known about the ecotoxicity of nanomaterials, the lack of studies addressing degradability and accumulation is striking[9]. Another concern is the lack of suitable methods to identify them in the environment[10]. Ecotoxicological data would classify the most used nanoparticles from "extremely toxic" to "harmful" for organisms in the environment. Remarkably, none of the nanosubstances that have been studied so far were classified "not harmful" for the environment.[11]
Additionally, some early findings show a much higher environmental impact of most nanoparticles and their production processes compared to the manufacture of bulk chemicals[12]. In consequence, possible environmental gain of nanomaterials may be outweighed by the environmental costs of their production[13].

Lack of risk assessment and research

Basic data to assess the risk for humans and the environment is lacking or largely insufficient. Neither the industry nor public authorities have shown adequate leadership and willingness in addressing these concerns. The budgets for research on health and environmental risks are tiny compared to the money spent on the development and marketing of new products containing nanomaterials.
A related problem is that testing methods and equipment lag behind the rapid pace of product development. Testing methods need to be developed and validated to adequately assess the hazards associated with nanomaterials.
Many governments and companies in the industry promote nanotechnology, claiming that it will not only revolutionize our daily lives, but will also bring environmental benefits like cleaner and more efficient production, reduced energy consumption, environmental remediation and monitoring, water filtration, and reduction of agricultural pollution, and not forgetting 'the cure for cancer.'
However, what is really available for the consumers are rather commonplace products with questionable added value, unsubstantiated, hyperbolic claims - and potentially very serious health risks. What to think about a drink containing only water and nano-silver or the nano-silver teether, the nano-silver wet wipes or the nano-silver baby bottle? Suppliers of these products claim their products will help the immune system of the body to resist bacteria [14]. However, most probably these products will endanger the normal intestinal bacterial growth and the immune system of the body.[15] Nano silver has the potential to contribute to medicine as a weapon against dangerous germs. But when commonly used in consumer products it could lead to resistances and thus to a loss for medicine. The German Bundesinstitut für Risikobewertung (BfR) takes the position that no nanosilver should be used in everyday products or food until more data is available.

Despite a growing awareness of the high uncertainties and risks surrounding their (eco)toxicity, Manufactured Nano Materials, and products containing them, are still mostly unregulated

Labelling is so far limited to the new cosmetics directive in the EU.[16]
A differentiated approach of risks of nanomaterials as such is needed, as this differentiation implies different risks and different issues. Manufactured Nanomaterials and the products they are applied in raise questions about the risk of toxicity, for human health or the environment.
The growing application of MNM's raises ethical, legal and governance issues that could have far more outreaching consequences for our human societies: these need to be specifically addressed in a public debate.
In developing countries even less is known about nanotechnology. Yet poor countries may disproportionately bear nano-risks by hosting manufacturing that wealthy countries reject, or becoming dumping grounds for waste. This is particularly dangerous as regulation and its implementation is often weaker in these countries.
Against this background, WECF calls for applying the precautionary principle, and the principle of "no data no market" for all nanomaterials. They should be treated as new substances and undergo a case-by-case risk assessment before they reach the market.[17] Regulation has to ensure there are no harmful effects from nanomaterials to either human health or the environment. A special safety threshold for vulnerable groups and children in particular, and a gender-differentiated risk assessment should apply. WECF demands that full information about possible risks of nanoparticles as well as access to information on which products contain nanomaterials should be provided to the public (including developing countries) without delay.

Lack of regulation

Insufficient EU regulation

While authories claim that the regulatory framework is theoretically sufficient, it ignores the specificities of nanomaterials. As a result, the European Parliament adopted a resolution in April 2009 asking the EU Commission to review all relevant legislation within the next years to ensure safety for all applications of nanomaterials over their life cycle, stating that "Those [current] rules are about as effective in addressing nanotechnology as trying to catch plankton with a cod fishing net."[18]
The resolution also calls for labelling of nanomaterials in all types of products.
To date, only the new Cosmetics Directive (EC) No 1223 / 2009 and two passages in the Directive on Food additives (EC) No 1333 / 2008 address nanomaterials. When it enters into force in 2013 the new Cosmetics Directive will impose prior notification, specific risk assessment and the labelling of nanomaterials. In 2011 an obligation to list the presence of nanomaterials on the Safety Data Sheet was added to the REACH regulation, but lacking is a definition and verification procedures.
Nano-specific provisions were also proposed by the European Parliament for the new regulation on the risk of hazardous substances in electric and electronic equipment (RoHS), for the Biocides Regulation, the Novel Foods Regulation and for rules in food labelling. However these propositions were not adopted, except for the new Biocides regulation which requires all nanomaterials contained in biocidal products to be followed by the world "nano" and justification of appropriateness of tests methods applied to

nanomaterials. The Novel Food regulation and the rules for labelling nanomaterials in food were rejected in March 2011. Even labelling of nanomaterials in food is now not required, although food containing nanomaterials can already be bought in supermarkets all over Europe.

REACH is not nanoproof

Similarly, although theoretically applicable to nanomaterials, REACH is not fully equipped to deal with the specificities of nanomaterials for three main reasons. First, due to the absence of a definition for nanomaterials or substances in nanoform under REACH. The European Commission has published a first version of a definition, but this is still under review and has met with many objections from stakeholders. Secondly, because the REACH methodology is tailored to bulk chemicals and the principle that the toxicity of the chemical relates to its mass rather than the surface area per volume. Finally, REACH does not require risk assessment for substances produced or imported in quantities under the 10 tonnes/ year which is a very high tonnage limit for nanomaterials typically handled in much lower tonnages.[19]

Outside the EU

Other regulatory entities too are working on developing the first laws that can address the concerns on nanomaterials. Canada and the state of California, for example, took the step of imposing mandated disclosure requirements on nanomaterial use and toxicity assessment. Canada's law of January 2009 targets domestic companies and institutions that manufacture or buy more than 1 kilogram of nanomaterial per year. According to these new regulations, these entities must now reveal how much nanomaterial they use, how they use it, and what they know about its toxicity. California's law, issued February 2009, limits its scope to carbon nanotubes, a class of nanomaterials widely used including in electronics, optics, and biomedical applications. Under the new regulation, by February 2010 companies that manufacture, import, or export carbon nanotubes in California must disclose information about their toxicity and environmental impacts.

On the international level

In 2008, the International Forum on Chemical Safety (IFCS) in a resolution called "Dakar Statement on Manufactured Nanomaterials" adopted by 71 governments, 12 international organisations and 39 NGOs, including WECF, called for the precautionary principle to be applied in the management of nanotechnologies, and the labelling of all nanomaterials[20]. Currently nanotechnology and nanomaterials are discussed in two OECD working groups and as an emerging issue under the SAICM (Strategic Approach of International Chemicals Management. At the regional SAICM meetings in Africa and South America, a resolution was unanimously adopted calling for a stronger recognition of the position of developing countries and countries with economies in transition. The resolutions require e.g. that wastes containing nanomaterials are not transferred to countries that lack the capacity to handle them adequately. NGOs highlight the need for a discussion that includes governments and civil society from developing and transition countries as well. Therefore WECF and many other NGOs prefer the SAICM rather than the OECD as forum for discussions, as the OECD does not include developing countries and countries with economies in transition.

Lack of information

Except for cosmetics sold within the EU after 2013, there is currently no right of information for consumers or a requirement for companies to label products containing nanomaterials, or to register their presence in a product. No specific safety standards exist to protect the environment or anyone coming into contact with the substances. This means there is no way for consumers to avoid or manage exposure or to prevent environmental nano-pollution.

WECF's position concerning nanotechnology

Nanotechnology and in particular, Manufactured Nano Materials are very often discussed in terms of benefits and risks. WECF recognizes that MNM's (or any new technology) could bring long-term profits and overall societal benefits. However, in order to make an overall judgment, data is needed regarding the hazards, exposure, risks and ethical consequences for humans, the environment and our society as a whole. WECF is very concerned about human exposure to nanomaterials without assessment, and the lack of regulation regarding the risks involved. WECF believes that the precautionary principle must be applied in order to safeguard health, particularly that of children. Lessons learned from the past and the potentially devastating effects of using innovative materials without proper risk assessments - such as asbestos - should be remembered. To avoid health and environmental damage, consumers and the general public must be informed and involved in decision-making regarding nanotechnology and nanomaterials. And finally, companies must be engaged in assuring the long-term safety of their products.

Children, Gender and nanotechnology

WECF works for a toxic-free future. Human exposure to nanosubstances may happen at the workplace, at the point of disposal, in cleaning products, cosmetics, and food packaging. Gender as well as generational-differentiated risks should be explicitly addressed. We are especially concerned about the effects of nanomaterials on the health of women, children and other vulnerable groups. Exposure of pregnant women might lead to the exposure of their babies to nanosubstances through the uterus (womb) or breast milk. Studies on mice showed worrying effects on the genitals and cranial nerve system of the fetus as early as 2009.[21] Research on rats shows that nanosilica and titanium dioxide in nanoform – already widely used and so far unrestricted – can enter the placenta and be found in the brain and liver of fetuses and can cause birth defects.[22] WECF is greatly concerned about the effects nanomaterials can have on the development of the brain and other vital organs of the foetus. Children are more vulnerable because their bodies and organs are not fully developed and their body mass is smaller, allowing for greater absorption of toxic substances and lifelong damaging effects.

WECF calls for seven actions to be taken on nanomaterials:

Nanosubstances should be treated as new substances

WECF demands that manufactured nanomaterials are treated as totally new substances. Therefore WECF demands a standardized nomenclature including individual CAS-numbers for nanosubstances to make a clear distinction between them and the corresponding bulk chemicals. As a consequence related regulations must be adapted.

Application of the principle "no data, no market" for all nanosubstances

- WECF demands the application of the principle "no data no market" – and in the case of REACH, this is to be in-

dependent of tonnage. Registration of nanomaterials under the corresponding bulk chemical should by default be prohibited.
- All regulations, including REACH, must be made nanoproof.
- A broad and inclusive legal definition for nanomaterials must be promptly adopted to allow for specific regulatory requirements. This definition must include all particles that exhibit properties that are characteristic to the nanoscale - including aggregates and agglomerates of primary particles which could disintegrate into nanoparticles.

Nanosubstances should be subject to a far-reaching risk assessment (health, environment)
- Because due to their unique properties it is often unclear how damaging nanosubstances can be to the human body and to the environment. Furthermore, it is unknown how they react with other chemicals. These risks need first to be assessed through research before their widespread use is allowed.
- Assessments through the whole life cycle must demonstrate the safety of the product.
- They should be subject to a case-by-case gender-differentiated risk assessment with special attention for vulnerable groups, in particular children.
- The knowledge gaps regarding nanosubstances must be closed. Research funding has to be prioritized on risk research and risk assessment. Research must be undertaken regarding the impacts and risks of nanomaterials throughout their whole life cycle on the functioning of natural and human systems. The development of proper methodology and reliable data are necessary for a thorough risk assessment.

Implementation of the precautionary principle and producers' liability
WECF asks decision-makers specifically to implement the precautionary principle and introduce producers' liability immediately; this will render companies already producing or using nanomaterials accountable for possible damage caused by their products. This is necessary until enough data exists to fully understand and manage their risks. These principles will be an incentive for producers to research and assess the risks of using nanotechnology in their products.

Immediate compulsory labelling of all products containing nanomaterials
All consumers and workers in manufacturing, processing, and transport and disposal industries have the right to information about the products they are in contact with, particularly when the effects are unknown. Their right to know and their right to choose have to be explicitly recognized in respect to nanotechnologies and nanomaterials. Consumers should have the chance to decide for themselves if they want to take the risks of exposure to this potential danger or not. Therefore products which include manufactured nanomaterials must be clearly labelled. Publicly available information registers allow further transparency.

Citizens must be informed and involved in decision making
Any "technological revolution" requires public participation and involvement. Women and men should have their voices heard and concerns listened to.
WECF demands a wide-ranging citizens' dialogue on the risks and benefits of the new technology. The decision making procedures have to become more democratic and need to be adapted to cover dynamic technological revolutions such as nanotechnology.
Thus WECF demands the right of countries to accept or reject manufactured nanomaterials.

All products for children and pregnant women must be MNM-free
until it is proven that they present no health risks to those specific groups of consumers. WECF considers the sale of products including manufactured nanoparticles without adequate risk research as absolutely irresponsible. Our children's health must be guaranteed. Therefore, we demand that products for or used near children remain MNM-free until valid data is available proving that they are safe.

1 *typically with one or more dimensions of a few hundred nanometres (nm) or less, as well as the ability to visualize matter at the atomic/molecular level.*
2 *Rejeski, D. (2009). Nanotechnology and Consumer Products. www.nanotechproject.org*
3 *Center for International Environmental Law. (2009) Addressing Nanomaterials as an Issue of Global Concern.*
4 *AshaRani, P. V. et al. (2009). Cytotoxicity and Genotoxicity of Silver Nanoparticles in Human Cells, ACS Nano 2009 3 (2), pp. 279-290*
5 *Ryman-Rasmussen, J P et al (2009). Nature Nanotechnology, (doi: 10.1038/NNANO.2009.305)*
6 *for a list of research on the subject see the Friends of the Earth Australia "Mounting evidence that carbon nano tubes may be the next asbestos", 2008, pp 2 and 3 of the summary*
7 *Wick,P. et al (2009). Barrier Capacity of Human Placenta for Nanosized Materials. Environmental health perspective: http://ehp03.niehs.nih.gov/article/info%3Adoi%2F10.1289%2Fehp.0901200*
8 *Among others: Schulz (2004) http://www.akpf.org/health2009/data/Health-VERT-2009/ETH-Healt_effects/2004/Presentations/Schulz.pdf*
9 *Wijnhoven, Susan W. P. et al. (2009). 'Nano-silver - a review of available data and knowledge gaps inhuman and environmental risk assessment', Nanotoxicology, pp 1-30*
10 *Engineered Nanoparticles: Review of Health and Environmental Safety - ENRHES, 7th Framework Project http://nmi.jrc.ec.europa.eu/documents/pdf/ENRHES%20Review.pdf*
11 *Kahru, A., Dubourguier, H.-C. (2009). From ecotoxicology to nanoecotoxicology. Toxicology. (doi:10.1016/j.tox.2009.08.016)*
12 *Şengül, H, et al (2008). Towards sustainable nanoproducts: An overview of nanomanufacturing methods,J Indust Ecol, 12(3), pp. 329-359.*
13 *Khanna, V. et al (2008). Carbon nanofiber production: Life cycle energy consumption and environmental impact, J Indust Ecol, 12(3), pp. 394-410*
14 *http://www.nanotechproject.org/*
15 *Meyer, D. E. et al. (2009). An Examination of existing Data for the Industrial Manufacture and Use of Nanocomponents and Their Role in the Life Cycle Impact of Nanoproducts. Environ. Sci. Technol. 2009, 43 (5), 1256–1263.*
16 *This Directive comes into force in 2013.*
17 *See for more on the risk assessment options: The German Advisory council on the Environment, Precautionary strategies for managing nanomaterials, report of september 2011*
18 *European Parliament, Draft Report on Regulatory Aspects of Nanomaterials, Committee on the Environment, Public Health and Food Safety, 2009*
19 *For amounts from 1-10t however, only basic data is required*
20 *Intergovernmental Forum for Chemical Safety (2008). Intergovernmental Forum for Chemical Safety. Available at: http://www.who.int/ifcs/forums/six/en/index.html*
21 *For example: Takeda K. et al 2009. Nanoparticles transferred from pregnant mice to their offspring can damage the genital and cranial nerve systems.*
22 *Kohei Yamashita et al (2011), Silica and titanium nanoparticles cause pregnancy complications in mice, Nature Nano, see Articles*

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