Nanotechnologies:

can they solve the world's current problems?

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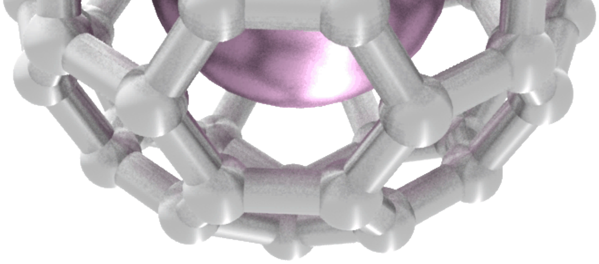


INTRODUCTION

Nanotechnologies: can they solve the world's current problems?

Nanotechnologies are considered to be the new generation of innovative technologies. There are expectations that nanotechnologies will be among the key emerging technologies of the 21st century. As such, applications of "nano" may be discovered at many unexpected places. There are claims that nanotechnologies have the potential to develop new innovative materials, devices and systems with wide-ranging applications, seemingly promising for solving many of the world's current problems, like clean water supply, energy efficiency of renewable energy production, efficient cancer treatments and many others.

As nanotechnologies move rapidly from research and development to commercialization, concerns both among scientists and the wider public have grown on potential risks posed to the environment and human health due to the possible hazardous properties attributed to manufactured nanomaterials. Although commercialization of nanoapplications and nano-enabled products is not proceeding as fast as predicted, the number of nano-enabled professional and consumer products on the market is steadily growing. Still, the information provided on nanomaterials used in the products and their possible potential release is either inadequate or insufficient. Consumers and workers are poorly informed and remain largely unaware.

DEFINITION

‘Nano’: a little word with huge potential

A little word with huge potential has been rapidly working its way into the world's consciousness. This word is ‘nano’, nowadays, frequently used as prefix to indicate that nanotechnology or nanomaterials are used to add specific properties to products. The prefix nano refers to the size of the materials being a nanometer (nm=10-9m).
Modern synthetic chemistry has reached the point where it is possible to control and manipulate matter at atomic, molecular or macromolecular level and manufacture components at the ‘nano’-scale
(dimensions between 1 and 100nm).

What is nanotechnology?

Nanotechnology is a collective term referring to the application of nanomaterials or techniques at the nanoscale. It is an innovative enabling technology with the potential to develop novel materials able to introduce new nano-specific properties to products, devices and systems in wide-ranging professional and consumer applications, in almost all industrial sectors, including medicines, cosmetics, electronics, energy production, etc. Therefore, generally the more appropriate plural form **‘nanotechnologies’** is used.

The essence of nanotechnologies is the ability to work at the molecular level, atom by atom, to create larger structures with fundamentally new molecular organization.[1] At the **nanoscale** one enters a world where physics and chemistry meet and develop novel properties of matter, where the most fundamental properties of materials and machines depend on their size in a way they don't at any other scale.[2] Nanotechnologies take advantage of these properties and aim to fabricate improved materials, devices and systems that have new properties and functions.

Nanomaterials (also called nano-objects) are defined as particles with one, two or three dimensions at the nanoscale. Based on their structure they can be classified into one of the following categories:

Nanoplates - particles with only one dimension at the nanoscale and the other two dimensions being significantly larger (differing by more than 3 times) that may not be in the nanoscale (i.e. a nanoclay).

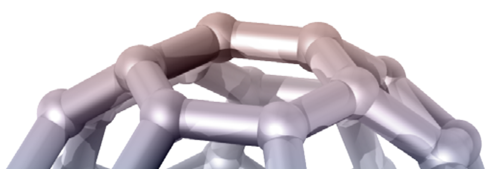
Nanofibers - particles with two dimensions at the nanoscale and the third dimension significant larger (i.e. single wall carbon nanotubes and multiwall carbon nanotubes).

- **Nanotube** - a nanofiber possessing a hollow tub-like structure (i.e. carbon nanotube);
- **Nanowire** - a massive, flexible nanofiber;
- **Nanorod** - a massive, rigid nanofiber.

Nanoparticles - particles with all three dimensions at the nanoscale (i.e. nano-titanium dioxide).

Nanomaterials may be suspended in a gas (e.g. nanoaerosol), suspended in a liquid (e.g. nanocolloid or nanohydrosol), or embedded in a matrix (e.g. nanocomposite).

1 Ali Mansoori. Principles of Nanotechnology. Molecular-based study of condensed matter in small systems. World Scientific Publ, 2005.
2 Goddard W. Brenner DW, Lysevski S, Lafrate GJ. Handbook of Nanoscience, engineering and technology. CRC Press, Taylor & Francis, 2nd ed., 2007.



Defining nanomaterials: a challenging task

After several years of scientific and policy dispute over how exactly to define nanomaterials, in October 2011, the EC adopted the Recommendation on the definition of nanomaterials, according to which 'nanomaterial' is defined as "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm - 100nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. [...]".

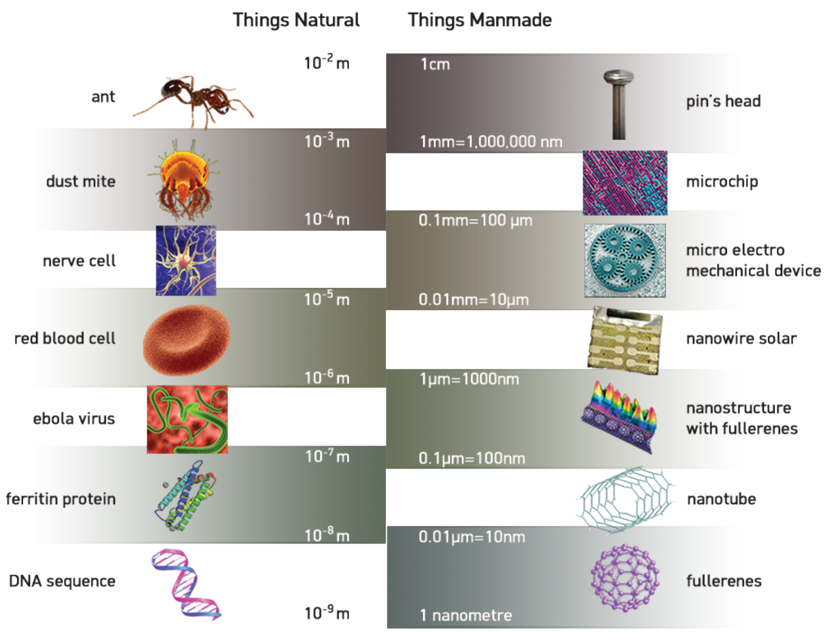
The issue of defining nanomaterials has been a challenging task and even though the proposed definition is rather 'narrow', it is a solid starting point for further discussions. The requirement that at least 50% of the number of particles should be in the size range of 1nm - 100nm is expected to be further explored and take into account future scientific findings, in the foreseen definition review in 2014.

It is worthwhile noting that according to the EC definition, nanomaterials are not exclusively synthesized/manufactured nanomaterials. The term also covers particles originating from natural processes and heating/combustion processes (incidental nanoparticles), which may pose similar risks to human health and the environment.

It may not be obvious to most people, but definitions of substances, threats and issues are what underpin the legal instruments regulating them.

The scale of things

Towards the molecular dimension.
Nanoscale structures.



A historical journey into the Nano World

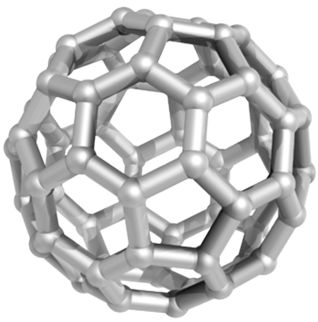
The fundamentals of nanotechnologies were gradually set over many decades of research in many different scientific fields. The dawn of the nano world can be traced back to 1959, when a physicist at Caltech, Richard P. Feynman, later Nobel Prize Winner in Physics, gave a talk titled "There's Plenty of Room at the Bottom".[3] In his talk which is widely considered to have been prophetic, Feynman hypothesized that atoms and molecules could be accurately manipulated, like building blocks, though he never explicitly mentioned the term "nanotechnology." He suggested that it would be possible to create small-scale machines able to manufacture objects with atomic precision. As the scale got smaller and smaller the properties of matter such as gravity would become more negligible, while both Van Der Waals attraction (forces which are relatively weak compared to normal chemical bonds) and surface tension would become very important.

In the late 1970s and early 1980s the researcher and author Eric Drexler established the fundamental principles of molecular design, protein engineering and productive nanosystems. In 1986 Drexler introduced the term "nanotechnology" in his book "Engines of Creation" to describe engineering at the nanometer scale.[4] The term though, had been used previously in 1974 by Norio Taniguchi in Japan, referring to precision micromachining.

Are Nanotechnologies new?

Even though nanomaterials are often perceived as new materials this is not the case. All biological cells are comprised by smart materials that have been positioning atoms since time immemorial and nanostructures are associated with natural processes. There are hundreds of examples of **naturally occurring nanomaterials** present in the environment, such as volcanic ash, ocean spray, mineral composites, ferritin, lipoprotein particles and others. There are the **incidental-nanomaterials** which are often by-products produced as a result of industrial or other processes (also called process-generated nanoparticles) such as combustion of fossil fuels, mining, biomaterial degradation, etc. The third category includes **manufactured nanomaterials** which are materials that have been deliberately created and designed for specific functions.

Research at the nanoscale level has catalyzed the development of nanotechnologies which involve purposeful manipulation at atomic level and structural assembly to achieve predetermined properties and functions of materials or products.[5]



What makes 'nano' special?

The nano world is full of surprises and potential. The reason that nanoscale materials and structures are so interesting is that size constraints often produce qualitatively new behavior. At the nanometer scale matter has different, sometimes unexpected, physical and chemical properties. At the nanoscale the chemical, electrical, magnetic, mechanical and optical properties of matter are quite different than in the bulk form of the same materials. For example, bulk silver is non-toxic, whereas silver nanoparticles are capable of killing bacteria and viruses upon contact, and therefore are used as biocides. Also, the same metal can become a semiconductor or insulator at the nanoscale. A key element contributing to the exceptional properties of nanomaterials is their increased surface-to-volume compared to bulk materials. This is important in catalysis (the process in which the

3 Feynman R. There is plenty room at the bottom. Journal of Microelectromechanical systems, 1(1): 60-66, 1992. (http://media.wiley.com/product_data/excerpt/53/07803108/0780310853.pdf)
4 Drexler KE. Engines of Creation. The coming era of Nanotechnology. Anchor Books, New York, 1986. (http://e-drexler.com).
5 Environmental Protection Agency (http://epa.gov/ncer/nano/questions/)

rate of a chemical reaction is either increased or decreased by means of a chemical substance known as a catalyst) and detection processes, as it results in increased surface reactivity.[6]

Fundamental concepts of nanotechnologies

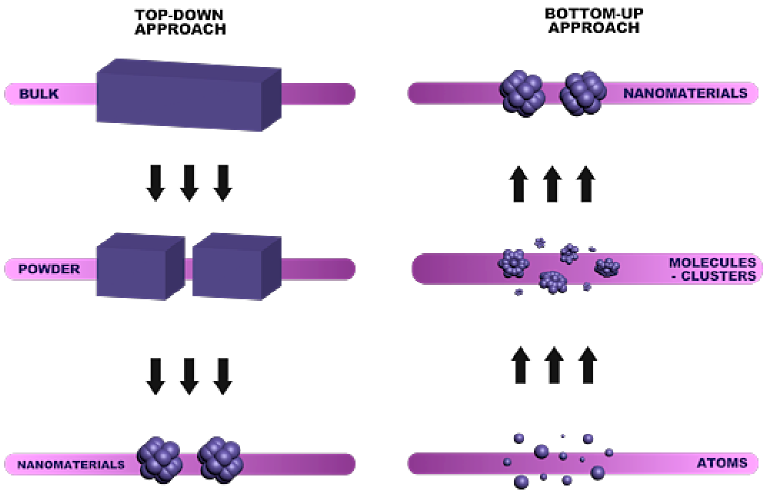
Atoms as basic units of matter can be combined to form more complex structures such as molecules and compounds. Nanomaterials as arrangements of matter at the nanoscale can be fabricated either **bottom-up** or **top-down**.[7]

The **bottom-up approach** is the process where nanostructures are created atom-by-atom. One bottom-up approach called **self-assembly** refers to the tendency of some materials to organise themselves into ordered arrays. This self-assembling nature allows different atoms, molecules, or nanomaterials when mixed together to spontaneously organize into stable, well-defined structures, with unique geometries and electronic structures.

The **top-down** approach refers to the way of fabricating nanomaterials of a desired size or shape by being carved out of a bulkier one.

6 Filiponi L, Sutherland D. Nanotechnology: A brief introduction. Interdisciplinary Nanoscience Center, University of Aarhus, Denmark, 2007.
7 Miller JC, Serrato RM, Represas-Cardenas JM, Kundahl GA, Graffagnini M. The Handbook of Nanotechnology. Business, Policy and Property Law. John Wiley & Sons, 2004.

Bottom-Up and Top-Down approach



Nanotechnologies and nanomaterials: fields of application

Due to the unique chemical, physical and mechanical properties nanomaterials possess, they are used in a wide variety of applications of advanced materials, devices and products. Some fields of nanotechnologies and nanomaterial applications are listed below:

Medicine: improved diagnosis of diseases through the use of sensitive nanotech detectors, treatment of diseases through more targeted drug therapies or "smart drugs" that use nanostructures, prevention of diseases through nanotechnology immune stimulants which prevent the propagations of infections, etc.

Environment: monitoring of the environment, reducing pollution impacts through air and water nanofilters, by using less material, reducing emissions through improved fuel catalysis, remediation of contaminated sites, etc.

Energy: miniaturized data storage devices that use less energy to operate, better insulation materials, improved efficiency of renewable energy sources, etc.

Electronics: enhanced computer and telecommunications properties, etc.
Consumer goods: improved production processes, safety and packaging of food, self cleaning surfaces, water- and stain-repellent or wrinkle-free textiles, etc.

Commercialisation of nanotechnology applications and products is proceeding quickly, with a large number of products identified already in the market (>1000 products). Some of the commercially available nanoproducts are computer processors and hard disks, nanotube tennis rackets, nanodynamic golfballs, nanofilm window sprays, deep penetrating skin creams, titanium dioxide sunscreens, silver nano toothpaste, footwarmers, washable bed mattresses, nano silver anti-odor socks, stain resistance clothing, antibacterial kitchenware, nano vitamin sprays, nano tea, nutritional drinks, etc.[8,9,10]

8 Top Ten Nanotech products (http://www.forbes.com/2005/01/12/cz_jw_0112soapbox.html)
9 The project on emerging nanotechnologies.(http://www.nanotechproject.org/)
10 Georgia Miller, Rye Senjen. Out of the laboratory and onto our plates. Nanotechnology in Food & Agriculture. Friends of the Earth Australia Nanotechnology Project. 2nd edition, April 2008. (http://www.foe.org/pdf/nano_food.pdf)

Nanotechnology products available on the market

Environmental protection, promotion of the use of renewable energy resources and securing good water quality supplies are considered to be the most urgent challenges of the present and the future. Nanotechnologies are regarded as new and revolutionary cornerstone technologies of the 21st century which offer enormous possibilities in providing technological solutions to address many of these problems.

However, although exposure to nanoparticles may not be a new phenomenon, the rapid development of commercial applications which involve the use of a wide variety of engineered nanoparticles, result in the introduction of ever increasing amounts of manufactured nanomaterials into the natural environment with minimal regulatory review and monitoring, while little information is available on their potential harmful effects.

Potential benefits

Environmental protection, promotion of the use of renewable energy resources and securing good water quality supplies are considered to be the most urgent challenges of the present and the near future. Nanotechnologies are regarded as new revolutionary cornerstone technologies of the 21st century which offer enormous potential in providing technological solutions to address many of these problems.
Some of the main application areas for nanotechnologies in environmental technologies are:[11]

Sustainable energy production, transformation and storage[12,13]

- Novel hydrogen storage systems
- Dye sensitized solar cells
- Nanocatalysts for hydrogen generation

Water treatment and remediation

- Nanomembranes for water purification, desalination and detoxification
- Nanosensors for the detection of contaminants and pathogens
- Nanoparticles for water treatment and remediation
- Selective catalytic converters for degradation of water pollutants

Air pollution and remediation[14]

- Nanoarticle-based photocatalytic degradation of air pollutants in self-cleaning systems
- Nanocatalysts for more efficient, cheaper and better-controlled catalytic converters
- Nanosensors for detection of toxic materials and leaks
- Gas separation nanodevices

Nanotechnologies have certainly built up great expectations for overcoming some of the technological limitations and providing solutions for certain environmental problems. However, at present relatively little is known about the environmental and human health impacts of nanoparticles, though in some cases chemical composition, size and shape have been shown to contribute to toxicological effects.15 Therefore, it is important to develop appropriate methods in order to assess whether the potential benefits of nanotechnologies outweigh the risks.

11 Uses of Nanotechnology in Environmental Technology in Hessen, Innovation potential for companies. Papre Series 1, Aktionslinie Hessen-Nanotech. Frauhofer- Institut für Arbeitswirtschaftund Organisation (www.wirtschaft.hessen.de).
12 Filiponi L, Sutherland D. Applications of nanotechnology: Energy. NanoCap Paper (http://www.nanocap.eu/Flex/Site/Download.aspx?ID=2260).
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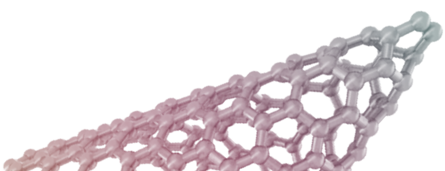
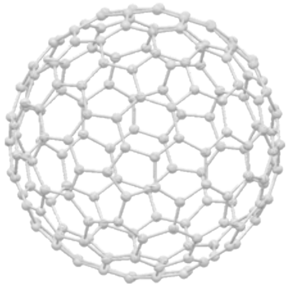
14 Vaseashta A, Vaclavikovac M, Vaseashtaa S, Gallios G, Roy P, Pummakarnchana O. Nanostructures in environmental pollution detection, monitoring, and remediation. Science and Technology of Advanced Materials, 8: 47–59, 2007.
15 Rickerby DG, Morrison M. Nanotechnology and the environment: A European perspective. Science and Technology of Advanced Materials, 8: 19–24, 2007.



Potential risks



Although environmental exposure to nanomaterials may not be a new phenomenon, the rapid development of commercial applications involving the use of a wide variety of manufactured nanomaterials, may result in the introduction of increasing amounts of nanomaterials into the natural environment, while little information is available on their probable harmful effects.

Potential pathways of nanoparticles into the environment (air, soil and aquatic systems) include point sources such as production facilities, landfills or wastewater treatment plants or diffuse sources such as wear and tear from materials containing nanoparticles. Accidental release during production or transport is also possible[16]

At present, after more than twenty years of dedicated research, relatively little is known about the environmental and human health impacts of nanoparticles. The general hazard and risk patterns of nanomaterials differ from other chemical substances. For nanomaterials the surface area, size, shape, charge, solubility and persistence are predominant factors, much more than their chemical composition per se, determining their fate and impact.[17]

It is complex to determine the environmental exposure of manufactured nanomaterials as there is little information on their actual use in nano-enabled products and their potential to be released. As a consequence environmental risk assessment has to rely on estimations. Studies on environmental transport (and fate) show that nanoparticles can be highly mobile in the environment, but they have a large tendency to aggregate and attach to mineral surfaces.

Once nanoparticles enter the natural environment they might cause adverse effects to biological organisms. Due to their small size and high surface area, coupled with other physico-chemical features, nanomaterials may well have unpredictable toxic and genotoxic properties.[18] In general, nanoparticles affect organisms through the disruption of membranes and the formation of reactive oxygen species resulting in oxidation of proteins (including enzymes) and interruption of energy transduction. They may also cause DNA damage directly, by passing through cellular membranes if small enough, or indirectly, by promoting oxidative stress and inflammatory responses.[19] While these responses can be clearly shown in in vitro cell culture studies, measurable responses in organisms (primarily fish and daphnia) are less predictable because of dependencies on temperature, physical/chemical properties of the exposure medium, differences in species, chemical composition of the nanoparticles and their properties.[20]

Although information about the toxic or ecotoxic effects of nanoparticles is still limited and fragmented, scientific literature on nanotoxicology is constantly growing, identifying the harmful effects of some engineered nanoparticles in biological organisms. For example, recent studies showed that exogenous nanoparticles, containing zinc and aluminum, exert toxic effects on germination and growth of roots in the seedlings of plants.[21] Other studies demonstrated that tungsten carbide and tungsten carbide cobalt nanoparticles are able to enter the cells of gills of rainbow trout and exert toxic effects.[22,23] The toxicity of C_{60} fullerenes and titanium dioxide was witnessed in an aquatic invertebrate, Daphnia magna.[24]

In conclusion, before introducing nanoparticles into the environment or in consumer products, a comprehensive, valid, scientifically sound, quantitative, evidence-based risk assessment is needed in order to conduct risk evaluation and risk management.

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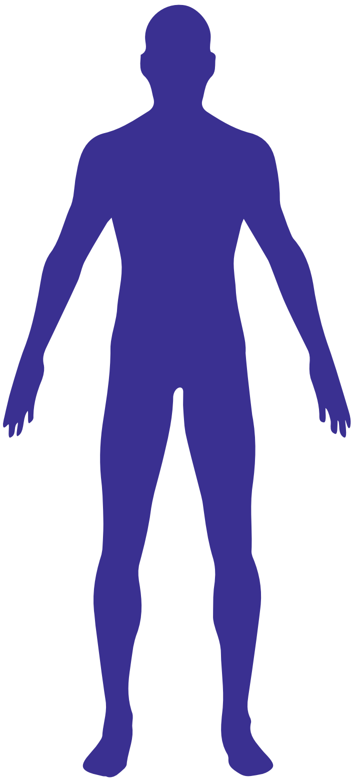
A promising field of nanotechnologies is Nanomedicine, which has created a myriad of new opportunities for advancing medical applications and disease treatment in human health care. Nanomedicine could be defined as the science and technology of diagnosing, treating and preventing disease and traumatic injury, of relieving pain and of preserving and improving human health, using nanomaterials and/or nanotechnological techniques and devices.

However, the successful application of manufactured nanomaterials in nano-enabled products may lead to emissions in the environment with an incomplete hazard and risk assessment. The 'invasion' of new manufactured nanomaterials and nano-enabled products into nearly every aspect of modern life has raised concerns and increased calls for the application of the precautionary principle to safeguard the health of humans and the environment.



Potential benefits

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The fundamental concept of nanomedicine in influenced by the visionary idea that nanorobots and related machines could be designed, manufactured, and introduced into the human body to perform cellular repairs at the molecular level. Today this idea has moved away from the nanorobots idea towards passive and active targeted medicine, which has branched out in many different directions, each of them promising to bring enormous benefits in the research and practice of medicine. Some of the application fields of nanomedicine include drug delivery, gene delivery, bio-imaging and detection, cardiac therapy, dental care, cancer therapy, etc.[25]

A key field for nanomedicine is the early detection, diagnostics, prognostics and targeted cancer treatments. While the potential benefits of nanotechnologies in this field appear to be overwhelming and with an enormous impact on the quality of human life, the way from research to practice is long. This means that many promising applications are not yet available for the general public to use.[26]

Nanotechnologies in oncology encompass many applications such as:

Molecular imaging and detection: Molecular imaging of live cells and whole organisms is an important tool for studying cancer biology and determining the efficacy of tumor therapies.[27]

Drug delivery: Improved therapeutic index of drugs through their more efficient delivery to the biological targets and reduced toxicity with appropriate application of nanotechnologies.[28]

New drug therapies: Safer cancer drugs characterized by adequate drug concentration in the body to allow for an effective dose at the tumor site.[29]

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Potential risks

When released in the workplace or the environment nanomaterials may be dangerous. The **skin**, **gastrointestinal tract**, **nasal olfactory structures** and the **eyes** are the major portals through which nanoparticles can enter the body as a result of occupational or environmental exposures.[30] After exposure, nanoparticles can travel through the blood and lymph circulating system reaching distant organs including the cardiovascular system and brain.[31,32]

Of primary concern in occupational settings are **inhalation** of nanoparticles and **skin exposure**. So far, healthy skin has shown little penetration potential, however, there are several studies that illustrate that the condition of the skin (barrier integrity, anatomic structure, skin diseases, etc.) may influence uptake.[33] Inhalation is the most relevant exposure route of manufactured nanomaterials and the lungs and pleura are the primary targets for adverse effects. It is possible for the inhaled nanoparticles to penetrate the lungs and deposit themselves in the respiratory system. It is believed that inhaled nanoparticles have reduced clearance from lungs relative to larger particles and can have increased transfer into the blood stream.[34,35] Inhaled ambient ultra-fine particles can be found in the heart, bone marrow, liver, kidney and even the central nervous system.[36]

When nanomaterials have entered the human body they can take part in reactions within cells, with the potential to exhibit adverse health effects. The primary toxicity concern of nanoparticles is the damage that is caused by free radical generation, which can provoke intense oxidative stress, inflammation and cell damage in the body.[37,38] Oxidative stress is defined as an imbalance between oxidants and antioxidants inside cells, in lung lining fluid or tissue fluid.

Preliminary data indicates that acute toxicity and systemic effects on different organ systems, including the immune, inflammatory and cardiovascular systems may occur.[39] Furthermore, genotoxicity and possible carcinogenesis and teratogenicity may occur, but no data on these latter endpoints is available yet.[40]

The form of nanomaterials is an important issue in hazard and risk assessment. Carbon nanotubes (CNT) were shown to be able to induce asbestos-like alterations in the mesothelium of the mouse peritoneal cavity[41] and increase the likelihood of mesotheliomas in sensitive mouse strains.[42] Long CNTs may give an acute inflammation leading to progressive fibrosis of the pleura, while this is not the case for short CNTs.[43]

In conclusion, much is still unknown, but it is clear that nanomaterials are likely to interfere with cellular organization and affect biological functions in ways that cannot be deduced from previous experience with macro- or micro particles.[44] Therefore, there is an urgent need for improved characterization and reliable toxicity screening tools (all still very limited) to elucidate health and environmental impacts, as it has been shown that the ones available (targeted to bulk chemicals and substances) might not be suitable for the assessment of nano-risks. Relevant in this respect is to further operationalize the paradigm change in risk assessment from a mass-based approach towards a particles' number based approach.

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39 Park EJ, Yi J, Chung KH, Ryu DY, Choi J, Park K. Oxidative stress and apoptosis induced by titanium dioxide nanoparticles in cultured BEAS-2B cells. Toxicology Letters, 2008, 180 (3): 222-229.
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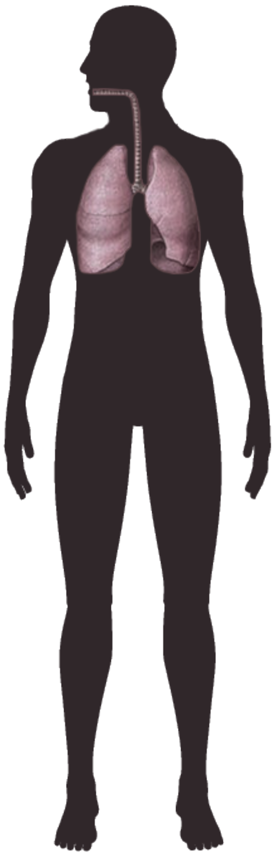

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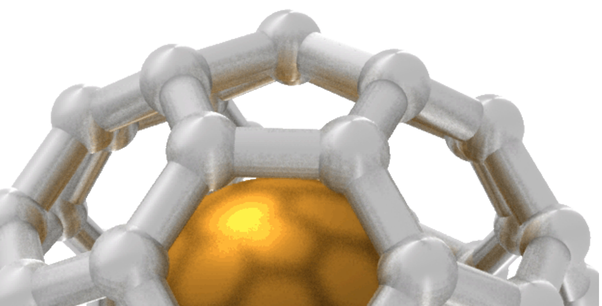
43 Murphy FA, Poland CA, Duffin R, Al-Jamal KT, Ali-Boucetta H, Nunes A, Byrne F, Prina-Mello A, Volkov Y, Li S, Mather SJ, Bianco A, Prato M, MacNee W, Wallace WA, Kostarelos K, Donaldson K.Length-Dependent Retention of Carbon Nanotubes in the Pleural Space of Mice Initiates Sustained Inflammation and Progressive Fibrosis on the Parietal Pleura. American Journal of Pathology, 178(6):2587-2600, 2011.
44 Kagan VE, Shi J, Feng W, Shvedova AA, Fadeel B. Fantastic voyage and opportunities of engineered nanomaterials: What are the potential risks of occupational exposures? Journal of Occupational and Environmental Medicine, 52(9):943-946, 2010.



Nanotechnologies are expected to spawn an array of societal and ethical issues, a fact that has been ignored to date. Addressing the societal and ethical aspects associated with nanotechnologies is certainly a challenging task. This technology is in its infancy and the predicted applications are immense, very diverse and highly specuxlative. Most of the applications are far from realisation and in some instances, the analysis of their social and ethical implications through the "if and then" pattern approach has generated credibility for far-fetched scenarios[45], which is misleading for the public.

The immediate ethical concerns from the first generation of nano-products are the relevant environmental, health and safety effects. However, some of the major areas that have raised ethical and societal concerns for the future include the following:[46,47]

Equity and nano-divide: The potential benefits of nanotechnologies may be in the coming, but in the meantime the technology is controlled mainly by the developed countries and multinational corporations, that is, through patents and conditions in technology licenses. This is a process which primarily benefits large transnational corporations and consumers in the developed countries raising the issue of a deeper divide (nano-divide) between developed and developing countries. On the other hand, some claim that nanotechnologies will help to bridge the divide because they allegedly will be cheap enough for developing countries to invest in.

Nano-medicine: Nanotechnology applications in medicine show tremendous promise for improving medical diagnosis, treatment, and prevention, but also raise a variety of ethical concerns[48]. Apart from the limited information on the toxicity of the nanoparticles used in medicine, these concerns include the potential for increased individual responsibilities and role changes because patients would receive information about their health status they never asked for, possible misuse of health related data by insurance companies, access to these technologies which are not likely to be inexpensive and will be accessible only to those who can afford them, etc. These technologies could also be used for genetic interventions posing other crucial questions. In the long run technologies like labs on a chip, that can monitor your bodily functions at home, could change our concept of "illness" and "health" and what we associate with "hospitals" or "doctors".

Privacy: Nanotechnologies are expected to have impacts in terms of monitoring and surveillance, thus raising questions about the relevant benefits, such as increased safety and security, costs, privacy, control over access to personal information. Concerning surveillance technology, but also on a much wider scale, nanotechnologies make it possible that technological infrastructure that surrounds us is no longer visible to us and therefore is withdrawn from our control and from our consent.

Research funding and priorities: Huge amounts of money are being invested in nanotechnologies research and development. On the other hand funds for environmental and human health impact assessment are limited, exposing humans and the environment to potential hazards. In addition, because of this funding the entire scientific community is affected in various ways. Also, most of the nano-products present in the market which are of 'accessory' nature (non-sense products) and do not serve any impelling human or environmental needs, indicate that nano-research and technical application in many occasions is not driven by real societal needs and priorities based on ecological, social and sustainable development considerations.

Military applications: There are concerns about potential misuse of nanotechnology applications to serve the military. For example, the development of smart robotic weapons miniaturized and intelligent, target-seek-

44 Kagan VE, Shi J, Feng W, Shvedova AA, Fadeel B. Fantastic voyage and opportunities of engineered nanomaterials: What are the potential risks of occupational exposures? Journal of Occupational and Environmental Medicine, 52(9):943-946, 2010.
45 Alfred Nordman. Future and Present. Basic Ethical concepts. The Ethics Porfolio. Technical University Darmstadt for NanoCap. 2009.
46 Allhoff F (ed). Lin P, Moor J, Weckert J. Nanoethics: The Ethical and Social Implications of Nanotechnology. John Wiley & Sons, 2007
47 Allhoff F, Lin P (eds). Nanotechnology & Society. Current and Emerging Ethical Issues. Springer Netherlands, 2008.
48 Resnik DB, Tinkle SS. Ethical issues in clinical trials involving nanomedicine. Contemporary Clinical Trials, 28: 433–441, 2007.

ing ammunition without reliable remote off-switches, pose risks to human health and the environment.[49]

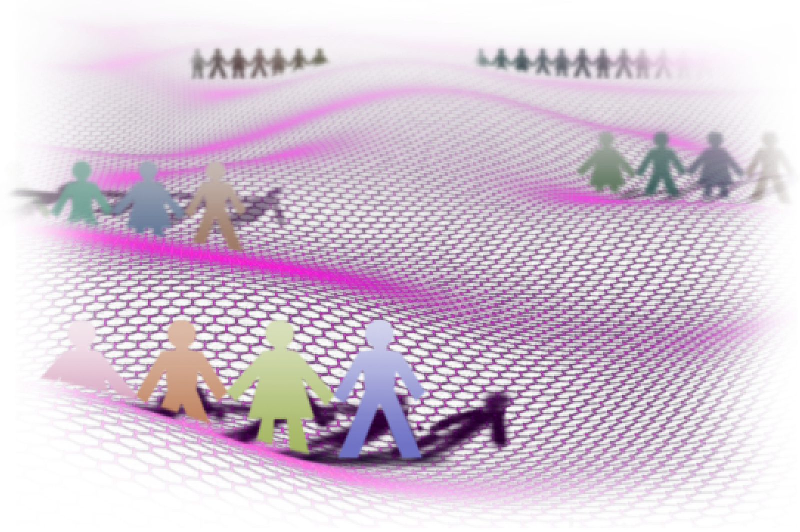
Regulation: Nanotechnologies will certainly pose challenges to existing legal and regulatory schemes. A global concern is who will regulate it and how will it be ensured that the technology is not abused.[50] Also, what will happen to the developing countries where e.g. they might serve as potential dumping places for nano wastes or might be an 'easy non regulated market'. A major problem of regulatory efforts is that there is such a complete lack of knowledge concerning the properties of nanoparticles, that it is impossible to set regulations in terms of prescriptive limits or legal frameworks. Whether and how to set up voluntary codes of conduct to be adopted by industries is a field of ethical inquiry.

The progressively increasing ability of humans to "build small" has caused ethical issues affecting our present and future. Rarely has a society been able to consider the importance of monitoring the development of a new technology in the early stages of its emergence. In order to ensure that this technology moves in the right direction, leading to responsible governance of nanotechnologies, it is essential to take into consideration all the ethical and societal aspects which deal with well founded predictions already at our doorstep. Otherwise, speculative nano-ethics will lend credibility to far-fetched visions, thus diverting attention from more imminent questions.[51] A few more ethical philosophical issues can only be hinted at here: central terms of the debate, like "risk" have to be analyzed – what do we talk about when we mention "risk"? Is it the same concept as in toxicology or do we also take into account broader concepts such as risk assessment? Who takes a risk, who is exposed to danger when we talk about societal aspects?

It is also a task for philosophical analysis to analyze the metaphysical research *behind* the efforts in nanotechnology. Central issues such as miniaturization, the concept of m echanization and how unpredictable the properties of materials are, are dealt with in the debate. Also, the speculative nature of the nanodebate doesn't make clear certain presuppositions that tend to make the debate shady.

49 Glenn JC. Nanotechnology: Future military environmental health considerations. Technological Forecasting and Social Change, 73 (2): 128-137, 2006.
50 Sheetza T, Vidal J, Pearson TD, Lozano K. Nanotechnology: Awareness and societal concerns. Technology in Society, 27: 329–345, 2005.
51 Gammel S. Nano-Ethics. Basic Ethical Concepts. The Ethics Porfolio. Technical University Darmstadt for NanoCap. 2009.

Nanotechnologies are expected to spawn an array of societal and ethical issues



The rapid growth of nanomaterials' applications has by far outpaced information and data about the associated safety and health risks. The questions raised, so far, and the limits and gaps in information and data, pose serious challenges to regulation and policy makers.

So far, REACH, the main legislative framework for regulating chemicals and their safe use at European level, has no provisions specifically addressing nanomaterials. REACH deals with substances, in whatever the size, shape or physical state and thus in principle covers substances at the nanoscale.

According to the European Commission and its Second Regulatory Review on Nanomaterials (EC 2012)[52] the current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials". This review concludes also that 'in the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required. The definition of nanomaterials will be integrated in EU legislation, where appropriate".

However, unless REACH is amended to refer to the definition of nanomaterials and the current volume limits are amended to include nanomaterials with lower production volumes (i.e. lowered to 10 Kg/year to take into account the increased reactivity of nanomaterials), nanomaterials will continue to "slip through". Similar amendments should be made to other relevant legislative frameworks such as the regulation on Classification, Labelling and Packaging (CLP) of products, the Occupational health and safety (OHS) related directives, etc.

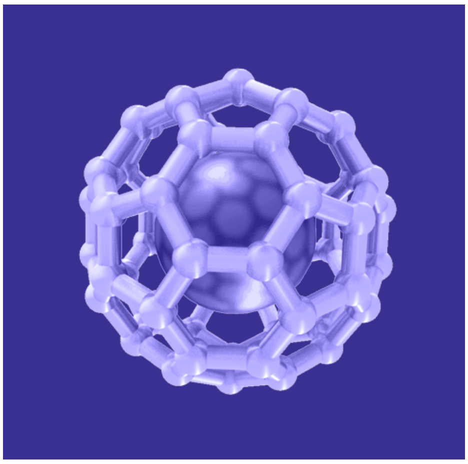
A further regulatory review with a focus on occupational health and safety issues is ongoing, and expected to be reported to the EC in 2013 focusing on the way "nano" is addressed in the OHS directive, the Chemical Agents Directive, the Carcinogens Directive and other related directives.

In the meantime, revisions regarding nanomaterials were introduced in the Cosmetics directive, the Biocides directive, food legislation and medicines. From 2013 the EU requires nanoparticles in cosmetics to be labeled on the ingredients list with the suffix "nano" and require increased safety testing for cosmetics containing nanoparticles. It also prevents nanomaterials from being placed on the food market until being subject to nano-specific, standardized, safety assessments free of animal-testing.

Due to the uncertainty and ambiguity of the information and data about the impacts of nanomaterials and nanotechnology applications to human health, the environment and society, public authorities, industry, academia, NGOs and TUs recognize the need for the adaptation or amendment of existing regulation to secure proper governance of nanotechnologies.[53] In particular, NGOs and TUs call for the adoption of fundamental principles of sustainable and responsible development taking as a starting point the application of the precautionary principle when dealing with nanotechnologies.[54] TUs and NGOs formulated explicit resolutions and position statements regarding the governance of nanomaterials and their safe use (ETUC 2008[55], 2010[56]; EEB 2009[57,58]; Client Earth, CIEL and BUND 2012[59]; MIO-ECSDE 2009[60], 2013).

Several initiatives to set up a voluntary reporting for nanomaterials' use in Member States have failed (e.g. UK), due to underreporting of the industry.

51 Gammel S. Nano-Ethics. Basic Ethical Concepts. The Ethics Porfolio. Technical University Darmstadt for NanoCap. 2009.
52 EC 2012.Communication from the commission to the European Parliament, the Council and the European Economic and Social Committee, Second Regulatory Review on Nanomaterials, COM, 2012.
53 Fairbrother A, Fairbrothe JR. Are environmental regulations keeping up with innovation? A case study of the nanotechnology industry. Ecotoxicology and Environmental Safety, 72 (5): 1327-1330, 2009.
54 NanoCap NGOs and TUs positions on Nanotechology. (http://www.nanocap.eu/Flex-/Site/Page.aspx?PageID=15407&Lang=UK)
55 ETUC (2008) Resolution on nanotechnologies and nannomaterials.http://www.etuc.org/a/5163
56 ETUC 2nd resolution on nanotechnologies and nanomaterials, 2010.
57 EEB position paper on nanotechnologies and nanomaterials, 2009.(http://www.eeb.org/-publication/2009/090228_EEB_nano_position_paper.pdf)
58,59 Bund_2012_ High time to act on nanomaterials - A proposal for a 'nano patch' for EU regulation. http://www.ciel.org/Chem/Nano_EU_13Nov2012.html
60 MIO-ESCDE Position Paper on Nanotechnologies, 2009 (http://www.mio-ecsde.org/articles.asp?cMC=7&cID=43&aID=54)



This led regulators in France, Denmark and Belgium to launch mandatory reporting for the use of nanomaterials in preparations and products. In France the decree is applicable from January 2013 and requires companies that manufacture, import, distribute nanomaterials in quantities larger than 100 g to submit to the competent authorities an annual declaration containing the quantity and use related information of nanomaterials.

When it comes to monitoring or mandatory reporting of the use of nanomaterials the European Commission has not taken initiatives so far. This has led to a collective initiative of many EU Member States, led by the Netherlands, calling for the introduction of relevant legislation for market surveillance and registration of manufactured nanomaterials and nano-enabled products and the amendments of REACH.

Looking beyond Europe, the USA, Canada and Australia on the issue of regulating nanotechnologies and in particular Canada and Australia explicitly identify the need to adopt a precautionary approach.[61]

Alongside the above mentioned activities regarding the so called "hard" regulation, different "soft" measures have been introduced as means to facilitate best practice in risk assessment and management, to initiate a constructive dialogue with stakeholders and combine evidence based risk assessment with a precautionary approach.[62] These soft measures include self regulation via codes of conduct, multi-stakeholder dialogue and continuous observation of developments through observatories. However, such measures are not adequate to meet the challenges posed by nanotechnologies.[63]

Although it is unclear what type of measures the regulatory regime ought to impose in order to contain the perceived danger posed to humans and the environment by nanomaterials and nano-applications, numerous countries have agreed on the need to adapt existing regulatory systems to tackle emerging nanotechnologies.[64] Lessons learnt from earlier technological revolutions (e.g. genetically modified organisms) clearly articulate the need for finding a balance between industry innovation and risk reduction, through an appropriate regulatory framework.[65] The top priorities of the future regulatory agenda should first focus on workers safety and the higher risk sectors in which nano-products have already been commercialised (chemicals, cosmetics, foods and materials). In addition, attention should be paid to specific risks that might affect developing countries due to their particular environmental and social conditions.

61 http://www.observatorynano.eu
62 International Risk Governance Cycle (IRGC) workshop briefing paper. Appropriate risk governance strategies for nanotechnology applications in food and cosmetics. Geneva, 28-29 April, 2009.
63 Gammel S. Soft Regulation. Basic Ethical concepts. The Ethics Porfolio. Technical University Darmstadt for NanoCap, 2009.
64 Van Calster G. Regualting nanotechnology in the European Union. European Environmental Law Review, August/September, 2006.
65 Bowman DM, Hodge GA. Nanotechnology: Mapping the wild regulatory frontier. Futures, 38:1060–1073, 2006.

NanoVirtualium:
Raising awareness on nanotechnologies through a holistic take

▶ www.mio-ecsde.org/nanovirtualium

NanoVirtualium is a virtual reality dome inviting you to enter into the developing world of Nanotechnologies. It provides both basic and advanced information on this new emerging technology and it sets out related implications on our health and safety (workers), society at large and the environment.

The main aim of NanoVirtualium is to deepen peoples' understanding on nanotechnologies, their characteristics and potential applications and to offer them the opportunity to take a critical stance on the issue. In this respect, a holistic approach is taken, presenting a wide array of related environmental, health, regulatory and ethical implications. Furthermore, an attempt is made to address nanotechnologies in a balanced manner by presenting both the potential benefits and risks and drawing a line between facts and fiction.