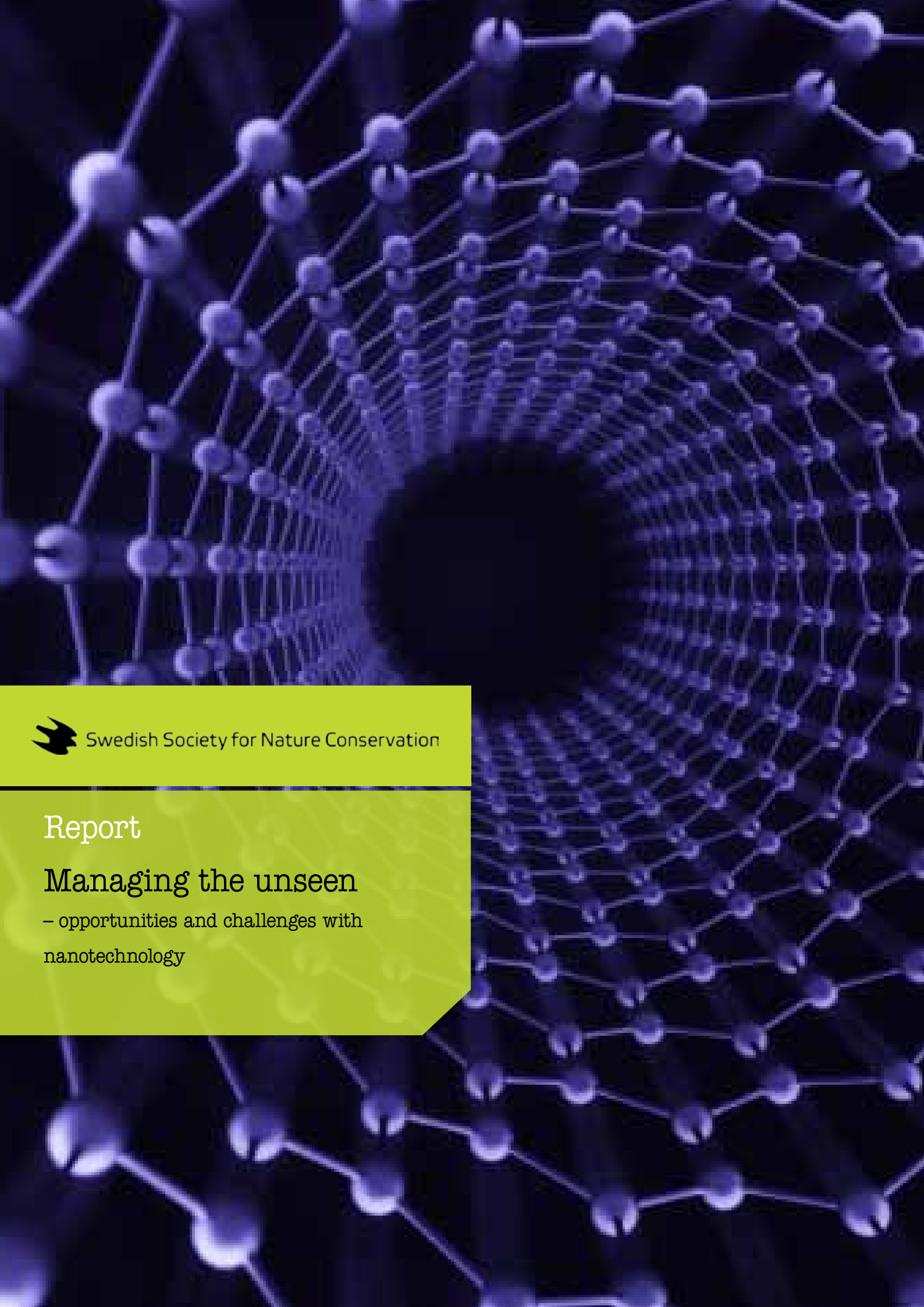

Swedish Society for Nature Conservation

Report

# Managing the unseen

– opportunities and challenges with nanotechnology

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# Preface

Nanotechnology is the collective terminology for engineering at the nano-scale (physical dimensions of the particles in the scale of a billionth of a meter). The purpose is to produce materials with novel qualities, with respect to chemistry, e.g. higher reactivity, physics, e.g. optical and electrical qualities, and biology, e.g. interaction with biological systems, such as the ability to cross certain physical barriers in cells and organs. It is a scientific field under rapid development, with many promising applications to society, e.g. in the generation and storage of power, production of very strong and light-weight materials potentially improving the safety and fuel economy of vehicles, and in the engineering of novel kinds of drugs, medical implants with good biocompatibility, and medical imaging systems.

However, the lack of an internationally standardized and harmonized definition of nanomaterials, internationally standardized and harmonized methods for sample preparation for detecting nanomaterials, proper detection techniques, and internationally standardized and harmonized toxicological and ecotoxicological risk assessment methodologies, is currently seriously impeding the generation of adequate risk assessment data for nanomaterials. Without such information and tools to monitor compliance, it is not possible to adequately address nanomaterials in legislation.

At the same time, available data suggests that risks[1] posed by nanomaterials may be different from that of bulk materials (corresponding parent materials, but not in the nano-scale). Nanomaterials have larger surface areas in relation to their volumes than the corresponding bulk materials, which explain their sometimes differing chemical and physical properties, and consequently differing hazards[2].

This report deals with the challenges, risks and possibilities of nanotechnology. The author addresses, among other things, current discussions on defining nanomaterials, the lack of knowledge of the presence of products containing nanomaterials currently on the markets globally, and reviews some regulatory initiatives for the management of nanomaterials internationally, regionally, and nationally. The intention is not to give a complete and in-depth review of the current status in the field of science and regulation of nanomaterials, rather to give the interested public and decision makers an overview in the topic. The report is published in Sweden, and will be distributed also to the partner organizations of the Swedish Society for Nature Conservation (SSNC) abroad.

The main conclusions that SSNC draws from the report are:

- The European Union (EU) urgently needs to adopt a harmonized definition of nanomaterials, and enforce it in all relevant regulations and directives. Sweden should have an active and proactive role in this work. SSNC fully supports the "nano patch" approach to adjusting REACH to nano materials, as proposed by the Swedish Chemicals Agency (KemI).
- Unlike many other countries, Sweden currently lacks a national strategy for dealing with the safety of nanomaterials. This needs to be addressed urgently. SSNC supports the proposed Swedish national action plan for the safe management of nano materials, published last fall for the consideration of the government.
- Unlike several countries in the EU, Sweden lacks a national inventory system for nanomaterials. Before the EU regulations and directives are fully adjusted to nanomaterials, Sweden needs to consider a national inventory system to increase its knowledge of nano containing products on the market.

1. Risk is the function of intrinsic hazard properties of a material and exposure scenarios.
2. Hazard is an intrinsic property of a material, e.g. its toxicity.

- The EU needs to considerably increase its support for work with the Strategic Approach to International Chemicals Management (SAICM)[3] prioritized policy area "Nanomaterials", to developing countries and economies in transition, financially and with technical expertise. Sweden should also increase its bilateral support in this area.

- Sweden, through the EU, should work for the establishment of an international nano council, within the frames of SAICM, to overarch capacity and knowledge differences between the Global South[4] and North.

Mikael Karlsson

President
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3. SAICM: Strategic Approach to International Chemicals Management is a voluntary policy process under the United Nations Environment Programme (UNEP), for addressing chemical safety issues outside legislative requirements from multilateral agreements.
4. Global South and Global North are terms commonly used in international aid for denoting developing countries/economies in transition and traditionally industrialized/wealthier countries, respectively.





# Introduction

Nanotechnology commonly refers to the branch of science and engineering devoted to the production of matter at a molecular, or atomic scale, or nanoscale. Nanotechnology developed out of a wide range of scientific and technical fields including physics, chemistry, biology, material science, and electronics. The field of nanotechnology is thus broad and covers a multitude of materials, techniques, scientific and commercial applications and products.[1]

The resulting materials from nanotechnology are measured in nanometers (nms) and are commonly called "nanomaterials" (NMs). A nanometer is a unit of measurement that is one millionth of a millimeter (10-9 m). For example, A DNA strand measures roughly 2 nm, a red blood cell is approximately 7000 nm, and a human hair is approximately 80000 nm.

NMs commonly have properties distinct from materials of the same chemical composition that are larger in scale (also called bulk material or material in the bulk form). NMs' distinct properties result from a combination of an increased surface area and a so called "quantum effect." A material's surface area is essential to its reactivity and it is where chemical reactions and interactions with biological systems occur. In comparison to bulk material, nanomaterials have a much larger specific surface or interface area, i.e., a larger surface area to mass ratio. As for any object, the relative external surface of the material increases as the size of a material decreases (See Figure I), leaving more atoms on the outside of the material available to react. Therefore, NMs are generally much more reactive than the same mass of bulk material.
In addition, as a consequence of their small size, NMs may migrate more easily in biological systems such as the human body. Particularly, some NMs are able to cross biological barriers in the lung, gut, or the brain, thereby causing unexpected and unusual exposure.[2]

Furthermore, the behavior of individual atoms and molecules can best be understood within a quantum physics-based framework; quantum effect gives NMs different optical, electrical, thermal, mechanical (resistance/flexibility) and magnetic properties. Gold is a commonly used example: in the bulk form, this well known metal is yellow. However, gold becomes red when engineered at the scale of 30 nm and it becomes green when engineered at the scale of 1 to 3 nm. Other properties of gold such as its electrical, thermal or magnetic properties may also change in relation to the size of the material.

Although some NMs can be found in nature (for example, as a result of volcanic explosions, wildfires, or other natural processes), nanotechnology aims at engineering specific materials for new properties that do not exist in a natural state. Products engineered through nanotechnology are commonly referred to as engineered NMs or manufactured nanomaterials.

The techniques used to manufacture the large range of NMs are extremely diverse, but can be roughly divided into two groups: top-down and bottom-up techniques. Bottom-up techniques aim to manufacture functional structures by organizing smaller sub-units. These techniques include but are not limited to chemical vapor deposition, plasma or flame spraying, spinning, and self-assembly.[3] On the other hand, top-down techniques involve starting from a larger unit of material and etching or milling it down to smaller units of a desired shape. Top-down processes include high energy ball milling,

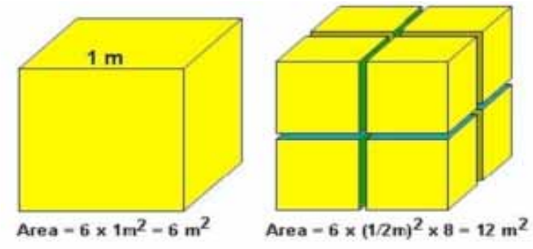


Figure I. Surface area increases as size decreases

etching, sonication, and laser ablation. Each approach, whether it is a top-down or bottom-up technique, poses specific challenges. A critical challenge for top-down manufacturing is to create smaller and smaller structures with sufficient accuracy. Whereas, bottom-up techniques have difficulties making structures large enough that are of sufficient quality.[4]

The potential overall impact of nanotechnologies on society has been heralded as being on- par with the industrial revolution, and few technologies have triggered as many comments, hopes, fears, and radical statements as nanotechnology. Nanoscience and nanotechnologies are revolutionizing our understanding of matter and are likely to have profound implications for all sectors of society. Products incorporating NMs (commonly referred to as nanoproducts) are already on the market in sectors as diverse as agriculture and food, energy production and efficiency, the automotive industry, cosmetics, medical appliances and drugs, household appliances, sporting equipment, textiles, computers, and weapons.

This report provides a general overview of NMs (Section 1), their potential impact on health and the environment (Section 2), the current market situation of NMs and nanoproducts (Section 3), and a general study of regulatory initiatives relating to the management of NMs (Section 4). To conclude, recommendations for the design and implementation of adequate regulatory mechanisms to safely manage NMs are presented (Section 5). The special situation in the Global South is highlighted throughout the report.





# 1. The question of definition

Because nanoscience and nanotechnology have emerged rapidly and recently, the vocabulary used in the contributing disciplines is not always consistent. There has been and continues to be serious challenges in defining NMs. Various countries, organizations, and institutes developed several definitions of "nanotechnology" and nanotechnology-related terms (e.g., "nanomaterials"). These emerging definitions were often formulated for specific purposes.[5]

One of the most prevalent ways to define NMs consists of using size cut-offs. For example, the International Standardization Organization (ISO)[6] and the working definition from the Organization for Economic Co-operation and Development (OECD)[7] use the nanoscale range ("approximately between 1 and 100 nm") to define nanotechnology, nanomaterials, and other nano objects. Sized-based definitions are used by many other organizations and groups as well. However, the absence of clear scientific basis for an exact size cut-off leads to conflicting definitions and controversies.[8] As a consequence, sized based definitions generally use the word "approximately" in describing the cut-off, making them unfit for use in a regulatory context.

Other organizations as well as certain jurisdictions have developed definitions focused on specific novel properties or more generally on a combination of size and novel properties. Such definitions can be found in the Australian National Industrial Chemicals Notification and Assessment Scheme,[9] in the Canadian working definition,[10] and in the United States National Nanotechnology Initiative.[11] However, the fact that the specific properties of these NMs appear gradually as the size decreases, and the difficulty to identify properties that are unique to NMs makes these types of definitions inappropriate for use in a regulatory context as well.

In the late 2000s, numerous NMs were being developed for commercial purposes, and a number of products containing NMs were being brought to the market.[12] The increased use of NMs and NMs products triggered an increase in demands for regulation adapted to the specificities of these new materials. Such a regulatory approach required a legal definition of NMs. In April 2009, after years of intense advocacy by civil society,[13] the European parliament adopted a resolution on regulatory aspects of nanomaterials. [14] As a necessary prerequisite for the development of required specific regulatory measures, the resolution called on the European Commission (the Commission) to introduce *"a comprehensive science-based definition of nanomaterials in community legislation,"* and to *"promote the adoption of a harmonized definition of nanomaterials at the international level."* [15]

This report led the Commission to ask the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to issue an opinion on the scientific basis for the definition of the term "Nanomaterials." On December 8, 2010, after a series of public consultations, a SCENIHR opinion was adopted.[16] Based on the adopted opinion, the Commission released a Recommendation for the definition of nanomaterial on October 18, 2011.[17] It defines NMs 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 dimension is in the size range of 1 nm – 100 nm.*

*In specific case where warranted by concerns for the environment, health and safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%."* [18]

The Commission's definition differs extensively from the existing working definitions used in other parts of the world and from the definition included in pre-existing sector-specific regulations in the EU. It also diverges from the above-mentioned SCENIHR opinion (in particular the SCENIHR opinion recommended the use of a 0.15% thresholds, several orders of magnitudes below the one finally adopted by the Commission). Its adoption has ignited considerable debate and controversy. Arguments included categorical opposition to a one-size-fits-all policy-based definition,[19] and the questioning of the use of particle numbers as a metric instead of mass. The main point of contention focused on the 50% threshold, considered too high to take into account the key physico-chemical characteristics associated with risks by some,[20] while considered too small by certain industries to realistically distinguish NMs from existing bulk powdered materials.[21]

Although imperfect and complex, the Commission's proposed legal definition of NMs was a necessary first step to allow enacting NMs legislation. It is, therefore, an important achievement. The Commission's definition is slated for review in 2014 to assess how it fares in practice.[22] The revision process will be supported by a report with three sections (covering the main measurement issues, assessment of the existing definition, and recommendations for possible revision, respectively), to be published in November 2014 by the Joint Research Centre. A preliminary draft of the first section of the report was presented to group of experts in Brussels on 19 March 2014, in a meeting organized by the European Commission.





# 2. Early warnings and documented concerns: Potential adverse impacts of nanomaterials

An increasing number of databases hosting scientific articles and other forms of data about the health and environmental risks of diverse engineered NMs commonly used in nanoproducts and industrial applications are becoming available.[23] This reflects growing recognition and concern that certain NMs may pose significant risks for people and the environment.

The evidentiary basis of growing concern about the specific toxicity and eco-toxicty of NMs is discussed below. This includes evidence of carcinogenicity, pulmonary effects, endocrine effects, cardiovascular effects, and others. In addition, a brief consideration of the broader ethical questions following in the footsteps of these technologies concludes this section.

## 2. 1 Toxicity

Past experiences with the toxicity of ultrafine particles (airborne particles less than 100 nm) and asbestos provide a foundation for current hypotheses and research into the toxicity of NMs. The toxicity of asbestos is well known and documented. Exposure to certain ultrafine particles) is linked to increased morbidity and mortality from cardiovascular and pulmonary diseases, including lung cancer.[24] It is hypothesized that the unique physico-chemical properties of nanoparticles relative to their bulk counterparts may also give chemicals at the nanoscale unique intrinsic hazard profiles as well. These properties include size, shape, crystal structure, surface area, surface chemistry and surface charge.[25] These factors influence the toxicity and fate of nanoparticles, as well as their uptake into and distribution within, and clearance from the human body, i.e.: the toxokinetics of nanoparticles. [26]

Evidence of the effects of NMs on cancer, the pulmonary system, and endocrine system are discussed below, in the order of the availability of data.

### *2.1.1 Evidence of carcinogenicity*

The most numerable data on NM toxocoty is for carcinogenicity. A study done on the effects of nano-sized $TiO_2$ on rats shows a statistically significant increase in malignant lung tumors following the chronic inhalation of nano-sized $TiO_2$.[27] Based on this finding, in 2011, the US National Institute for Occupational Safety and Health (NIOSH) determined that ultrafine $TiO_2$ should be considered a potential occupational carcinogen.[28] Products containing nano $TiO_2$ include sunscreen, cosmetics, clothing, plastic-based containers, household and industrial cleaning products, electronics, hair styling devices, air-filtration devices, environmental remediation, and photovoltaic (solar) panels.[29] Notably, NIOSH noted that the carcinogenicity of ultrafine $TiO_2$ was primarily related to particle size and surface area, raising questions with regard to other NMs.[30]

In a recent research by NIOSH), the potential for other NMs to be linked to cancer was also investigated. Preliminary results indicate the potential for multi-wall carbon nanotubes (MWCNTs) to increase the risk of cancer in mice exposed to a known carcinogen.[31]

### *2.1.2 Evidence of pulmonary effects*

Inhalation is one route of exposure to NMs. Inhalation of nanoparticles is more likely to be problematic for pulmonary systems than larger (e.g., micron-sized) particles due to their higher lung deposition, higher retention, and greater likelihood for translocation to the blood.[32]

Animal studies link inhalation of carbon nanotubes (CNTs) to inflammation in the nasal cavity, larynx and trachea, as well as alveolar lipoproteinosis (a rare and heterogeneous group of disorders characterized by abundant deposition of surfactant-like material in the alveoli).[33] Other in vivo studies have linked single wall CNTs (SWCNTs) exposure to pulmonary toxicity, namely granulomas (collection of immune cells, i.e., a special type of inflammation) in the lungs.[34] Findings suggest that the severity and incidence of effects on the lungs from inhalation of CNTs is concentration dependent.[35]

Further, studies of ultrafine particles have shown the danger of pulmonary disease to be inversely proportional to the size of the particle, where the smaller the size for the particle, the greater the danger.[36] Several studies have found that the length of multi walls carbon nano tubes (MWCNTs) can affect their biological activity.[37] In one in vivo study, long MWCNTs produced length-dependent effects on a surrogate for the protective lining that covers many of the internal organs (mesothelial lining) of the chest cavity. These effects included inflammation, foreign

body giant cells, and granulomas.[38] These findings were qualitatively and quantitatively similar to the foreign body response caused by long asbestos.[39]

In addition, in vivo studies found prolonged exposure to nanosilver particles via inhalation to produce an inflammatory response and alterations to lung function.[40] These findings of inflammation are consistent with findings from as early as the 1990s for 20 nm $TiO_2$ and 30 nm aluminum oxide ($Al_2O_3$).[41] Other nanoscale metal oxides, such as zinc oxide (ZnO), copper(II) oxide (CuO) and nickel oxide (NiO), consistently show pulmonary toxicity in animal studies.[42]

*2.1.3 Endocrine effects*

Mechanisms of potential nanotoxicity in the endocrine (hormone) system remain largely unexplored.[43] Endocrine related diseases and disorders include: cancers; genital malformations and infertility; diabetes, obesity and other metabolic syndromes; thyroid dysfunction; early onset of puberty; impaired immune systems and autoimmune diseases; cardiopulmonary effects; and diseases and disorders of the central nervous system, such as Alzheimer's, Parkinson's, and learning disabilities.[44]

A recent review of toxicological studies on nanoparticles found several studies linking nanoparticles with endocrine disruption.[45] For example, several studies are quoted with regard to observed effects of quantum dots on reproductive dysfunction, thyroid hormone signaling, estrogen receptor activation, and endocrine disrupting activity.[46] In addition, the review found other studies showing that metal and metal oxide nanoparticles may exert endocrine-associated toxicities.[47] The authors recommended that endocrine-related systems or organs, in addition to those involved in reproduction, should be targeted for future investigation.[48]

*2.1.4: Reproductive toxicity*

Increasingly more data demonstrates that nanoparticles may interfere with the reproductive system, particularly for the male reproductive system.

It has been demonstrated in vivo in rats that nano titanium dioxide cross the blood-testes barrier and cause lesions in the testis and lower spermatogenesis.[49] Changed gene expression and hormone levels were observed in this study. In two studies where pre-pubertal male rates were exposed to nano silver, puberty was delayed, and the adult males had lower sperm concentrations and an increased frequency of abnormal sperms[50], [51], changes in the morphology of the seminiferous epithelium[51], as well as changes to cell membrane integrity and mitochondrial activity[51]. Trans-generational effects have also been demonstrated, eg. in a study where mice were exposed prenatally to nano carbon[52]. Lower sperm counts were found in the second generation.

In vivo testing in mice has shown that nano titanium dioxide may interfere with the ovary function in a number of ways, among them altered gene expression, hormone levels, mineral metabolism, cause oxidative stress, and abnormal pathological changes to the ovary and its follicles.[53], [54], [55]

*2.1.5 Cardiovascular effects*

Based on observations some concern exists on the possible effect of manufactured nanoparticles on the cardiovascular system.[56] A scientific committee of the European Commission found that studies of the effects of combustion-derived nanoparticle suggest a risk for interaction by manufactured NMs with the cardiovascular system.[57] One recent survey of available literatures concluded that "there are no observational studies linking exposure to [manufactured NMs] and cardiovascular events;" however, a number of studies have reported that exposure to manufactured NMs can cause effects that "may plausibly contribute to" heart disease.[58]

In addition to the direct effects described above, a large body of uncertainty remains in relation to the interactions between NMs and biological systems. For example, the understanding of NMs toxokinetics (e.g. how a particular substance moves around in the body, and where it is stored, cleared) remains very limited. However, similarly to the direct health impacts, some early warning signs warrant precaution in dealing with these materials.

For example, it has been showed that some NMs have the ability to cross the blood-brain barrier[59] and cause the death of lab mice brain stem cells.[60] Some NMs have been shwown to cross the placental barrier and affect male embryos, so that their ability to produce sperms after puberty is reduceed.[61] Other research have shown that silver nanoparticles can interact with genetic material, modifying it and affecting its replication,[62] and that zinc oxides can cause damage to the DNA of human epidermal cells, even at low concentration.[63]

## 2.2 Ecotoxicity and biomagnification

Obviously, potential toxicity of NMs is not limited to human health and may also affect other biological organisms in the environment ('ecotoxicity'). There is evidence of uptake of some NMs into the food chain and of eco toxicity of NMs. Silver is known to be ecotoxic.[64] While some studies have documented a more pronounced effect of nanosilver relative to its bulk counterpart, the data is not conclusive about their relative ecotoxicities.

A 2009 review of scientific evidence regarding nanosilver concludes that there is "…evidence of the harm of silver nanoparticles at low concentrations on aquatic invertebrates, which suggests that the environmental release of silver nanoparticles will be detrimental to the environment."[65] More recent studies confirm this conclusion, showing adverse responses of plants and microorganisms to low doses of silver nanoparticles applied in field experiments via a likely route of exposure, sewage sludge (biosolid) application.[66] Also, studies exploring the effects of nanoparticles on plant cells, have found that CNTs can induce cell death in plants.[67]

Titanium dioxide nanoparticles have also been shown to induce oxidative stress, organ pathologies and the induction of anti-oxidant defenses in rainbow trout.[68]

The potential for NMs to enter into the food chain and biomagnify has been demonstrated by several studies. An international research team recently determined that certain metalic nanoparticles can enter the food chain.[69] The researchers note that, "[o]ur results have also shown that cerium oxide ($CeO_2$) nanoparticles can be taken up by food crops when present in the soil. Cerium has no chemical partner in the plant tissue and is not biotransformed in the soya bean, but still reaches the food chain and the next soya bean plant generation…. One must keep in mind that once engineered nanoparticles enter the food chain, this is an accumulative process."[70] The researchers also showed the uptake of zinc nanoparticles.[71] Other studies showed uptake of nanoparticles by earthworms and microbes.[71] A recent study has shown the potential for gold nanoparticles in plants to biomagnify in caterpillars, suggesting continued biomagnification up the food chain as predators eat herbivores. [73]

## 2.3 Assessing the hazards of NMs in a regulatory context

Chemical risk is usually assessed as a function of hazard and exposure. Large unknowns remain about the specific hazards of NMs and the current level of human and environmental exposure to NMs.

Research is currently ongoing to reduce this knowledge gap. However, it is to be noted that the investment in toxicology and eco-toxicology research (i.e., identifying the potential hazards of NMs) so far represents less than 3% of all nano-research. The remaining 97% of the current ongoing research focuses principally on developing new applications.[77]Therefore, increasing investments in research to understand the potential impact of NMs is crucial. However, even if the investments in nano-toxicology and eco-toxicology were to increase significantly, a certain level of uncertainty would still remain. Uncertainty would revolve around the safety of nano-materials and product due in part to the large variety of NMs on the market or in development and because of the fast paced evolution of fundamental science and product development. How to deal with this uncertainty is a key question that should be tackled in order to adequately manage the risks of NMs. The critical importance of the precautionary principle in this regard has been highlighted by a large number of countries (see Section 4.2 below) as well as by several prestigious scientific institutions[78],[79] and civil society organizations around the world. Section 4 addresses the current regulatory and governance frameworks in place for NMs, and their strengths and weakness.

## 2.4 Additional considerations

Ethical issues related to the introduction of nanotechnology have been discussed for a number of years. For example, UNESCO published a report and a book on the ethics and politics of nanotechnologies.[80] Ethical considerations have also been addressed by European authorities[81] and by the

United States government.[82] In particular, concerns are prevalent regarding the potential for nanotechnologies to intensify the gap between rich and poor countries because of their different capacities to develop and exploit nanotechnologies, leading to a so-called 'nanodivide'.[83]

As evidenced by the discussions mentioned above, in the long-term, nanotechnology could possibly generate benefits for global society such as better methods for disease diagnosis and treatment or better nanobased water filtration systems. However, there is a major risk that different capabilities to develop and exploit new technologies will increase the divide between rich and poor nations in the more immediate future. Indeed, the high cost of developing new procedures and a skilled workforce would impede poorer nations from benefitting from many useful NM applications.

In effect, nano research in developing countries may not be able to keep track with research in developed countries. As a consequence, these countries may not be able to develop (and manufacture) products that can be used to address the basic needs of their population, such as nano-based water filtration systems. They would have to depend on those who do have the mean to develop (and manufacture) products of this kind. These products may however, be too expensive for the poor. Not the least because of royalties due to patent.

### Testing guidelines for nanomaterials and the OECD Working Party on Manufactured Nanomaterials

The Organization for Economic Co-operation and Development (OECD), whose main objectives include supporting economic growth and contributing to growth in world trade,[74] was the first international organization to address the subject of nanotechnology. The OECD first acknowledged the opportunities and challenges posed by nanotechnologies in 2005, and in September 2006, it formed the Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of its Chemicals Committee. The declared aim of this Working Party is to "promote international co-operation in human health and environment safety related aspects of manufactured NMs, in order to assist their safe development."[75]

In that context, the OECD WPMN set up a number of work streams, including the testing of representative sets of NMs for their physical and chemical properties, environmental fate and behaviour, ecotoxicity and toxicity (so-called sponsorship program); the assessment of the existing testing guidelines applicability to NMs; as well as the development of guidance on sample preparation and dosimetry for NMs; and exposure measurement.

In 2012, OECD released a communication, summarizing the work undertaken in the WPMN first years of existence, which mentions that "the approaches for the testing and assessment of traditional chemicals in general are appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials". This sentence has been wrongly quoted as indicating that existing test guidelines are valid for testing NMs hazards.

However, based on a preliminary review of testing related to physical chemical properties (including material characterization), it was concluded that only 4 of the 22 test guidelines for physical chemical properties are applicable to nanomaterial. 16 guidelines might be applicable under some circumstances or to some classes of NMs. Two guidelines are not applicable to NMs or, if applicable, provide no useful information. 13 of the 22 guidelines require further assessment before they can be modified. With regard to the 52 test guidelines for mammalian toxicity, the preliminary conclusion indicates that the test guidelines need to be modified to ensure that appropriate consideration is given to adequate characterization of the nanomaterial tested, and also to the actual exposure in the test system. For 24 test guidelines related to eco-toxicity, it was found that the guidance on sample preparation, delivery, measurement, and metrology is currently insufficient for testing of NMs. Some of the test guidelines for degradation and accumulation were found not to be applicable for testing of NMs. Many of them are applicable with limitations or under specific conditions.[76]

In conclusion, if the general approach for testing bulk chemicals (i.e.: formulating risk as a function of exposure and hazards) to test NMs appears indeed appropriate, it also appears very clear that the existing test guidelines cannot be considered adequate to assess the safety of NMs.





In the words of a landmark UNESCO report: *"The danger created by excessive patenting in nanotechnology is that of the 'patent thicket' or the tragedy of the anti-commons. Patents on basic nanoparticles and processes using nanoparticles cold end up being so finely and acutely propertized that the ability to create a novel material – for instance a water filtration system that uses carbon nano tubes to produce clean drinking water – could face nearly unnavigable complexity in terms of competing and overlapping patent claims."*[84]

Another issue that could arise is that enthusiasm for developing a 'technical fix' to a range of global and societal ills might obscure or divert investment from cheaper, more sustainable, or better low-technology solutions to health and environmental problem.

Other potential management issues specific to developing countries include: displacement of traditional markets, the imposition of foreign values, the fear that technological advances will be extraneous to development needs, and the lack of resources to establish, monitor and enforce safety regulations.[85]

Should the question of a North-South nano-divide be ignored or insufficiently considered, the potential benefits of nanotechnologies would be unequally distributed and the existing technological divide between regions of the world (or between rich and poor populations within a country or region) would increase.

These ethical questions, although discussed academically, are seldom considered in the overall initiatives to support the development of the technology and in the debate regarding the adequate management of risks from NMs.

Finally, the uncertainty regarding NMs' hazards is only made worse by the extremely limited information available regarding exposure to NMs, in particular in the Global South.

# 3. Products and markets

There are many speculations about the size, value, and evolution of present and future markets for NM and products containing such NMs. The figure of a 3 trillion dollars market in 2015 is commonly mentioned, but estimates and forecast vary tremendously, from an estimated 11 billion in 2009 to a range of 26 billion to 3 trillion dollars[86] in 2015. However, the latter estimate is based on calculations including the entire value of nanotechnology-impacted products, as opposed to only the value of nanotechnology-based components. For example, if a car uses nanotechnology-enhanced paint, the entire value of the car is integrated into the estimate rather than estimating the value of the paint alone. Thus, the lower estimate is likely to provide a more accurate picture of the short- to mid-term future of nanotechnology.[87]

There is currently no comprehensive and accurate database listing products that contain NMs. The lack of a database makes identifying products containing NMs, or products manufactured with the help of nanotechnlology, and the establishment of exposure scenario for NMs particularly challenging. Various inventories of nano-consumer products have been developed by several institutes and organizations across the world.[88] All or most of these inventories rely on (unregulated) nano claims—claims made by the manufacturer or retailer of the product that the product contains nano or was manufactured using nanotechnology—to identify these nano products . Some inventories focus on specific NMs,[89] on specific products (such as sunscreen),[90] or on particular markets or geographic areas.[91] The limitation in scope of these inventories is often due to the limited resources of their initiators and to the complexity of the task. One of these complexities is the increased use of the Internet for online shopping of products (nano or not), which can now be ordered online and are therefore available globally.

In 2006 the Woodrow Wilson Institute for Scholars' Project on Emerging Technologies developed one of the most commonly known and quoted inventory of nano consumer products.[92] This ambitious global database shows an increase from 54 consumer products containing NMs in 2006 to 1317 products in October 2011 and up to 1564 at the last update in October 2013.[93]

NMs have penetrated all sectors. Products include cosmetics and functionalized textile, hair straightener, kitchen appliances, industrial chemicals, paints, food contact materials, and food additives.

According to the Woodrow Wilson Institute's database, over half of the nano products fall into the health and fitness category (788 products), followed by home and garden (221), food and beverage (192),automotive (142), cross cutting (83), electronics and computers (61), appliances (48), and goods for children (29). (See Figure 2).

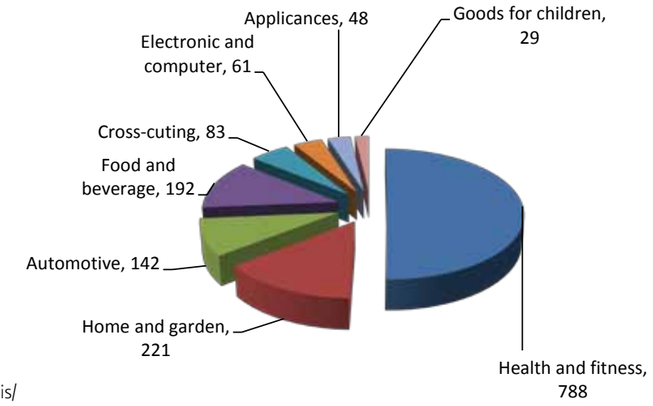


Fig 2. Source, Woodrow Wilson Institute, http://www.nanotechproject.org/cpi/about/analysis/





Within the health and fitness category, the largest subcategories are personal care (292), clothing (187), cosmetics (154), sporting goods (119), Filtration (43) and sunscreen (40) (see figure 3).

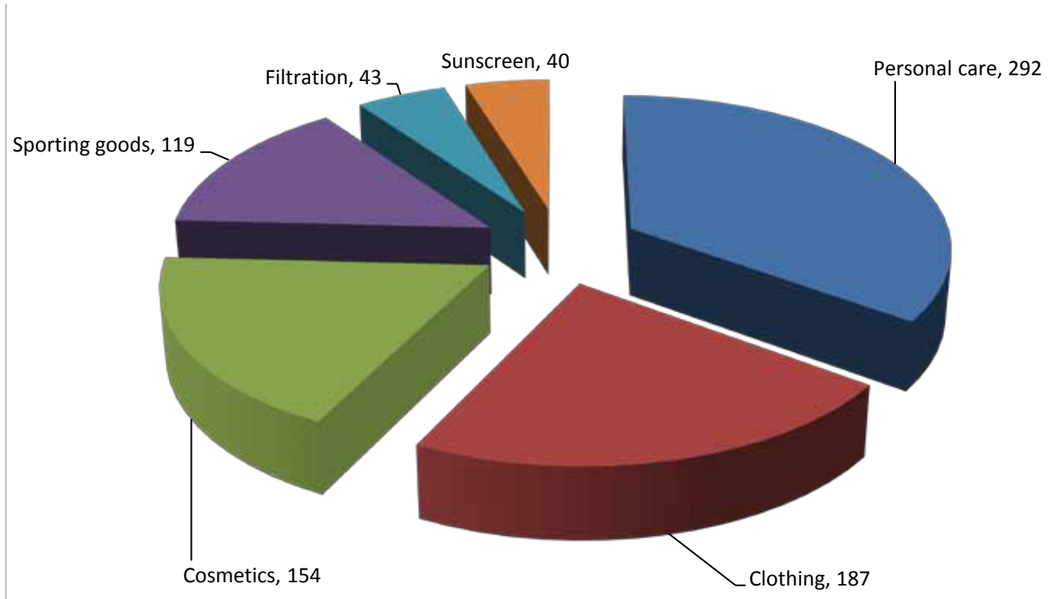


Figure 3: Health and fitness produt breakdown. Source Woodrow Wilson Institute, http://www.nanotechproject.org/cpi/about/analysis/

It is important to consider the uncertainty attached to the aforementioned figures. In the absence of any regulatory obligations, and in the context of a highly competitive and fast evolving market, information about NMs in products is inconsistent and patchy at best. Nano claims vary depending on the potential market advantage that the release of information may afford. In certain regions, such as the EU, where the public perception of NMs is generally tainted with a growing skepticism and concerns about their potential adverse health and environmental effects,[94] many products may contain NMs, without being advertised as such. Conversely, in numerous regions, for example in several emerging markets of Asia, the use of a nano claim can provide a significant market advantage and thus incentivizes false claims, further complicating the task of compiling reliable information about NMs. This makes assessing the existing and potential exposures of workers, the public, and the environment to devise appropriate risk management measures extremely complicated. A critical public might also lead to beneficial nanoproducts not being taken in use.

The food sector in particular is one of the most secretive and controversial when it comes to its use of NMs. Nanomaterials may be used in the product itself to homogenize the texture of a product, to enhance the flavor, to reduce a product's fat content, or used as edible films or in food packaging.[95] Although seldom advertised, and sometimes denied, the use of NMs in the food industry appears to be widespread and larger than reflected in the available figures. A 2008 report[96] identified over one hundred food-related nano applications, ranging from agricultural products, food packaging, food supplements and food additives. This number has surely increased in the past 5 years. In 2006, studies indicated that there were

between 200 and 400 companies, including some major food and beverage companies involved in research and/or production of food related nano applications.[97]

Most existing inventories and databases, including the Woodrow Wilson Institute's inventory, indicate, where possible, the nature of the nanomaterial found in consumer products. The most common nanomaterial used is nanoscale silver, followed by titanium (including titanium dioxide), then carbon (including carbon nanotubes, nanofibers, and fullerenes, also known as buckyballs), silica and silicon, zinc (including zinc oxide), gold, and other NMs (e.g., polymers, clays, quantum dots). A table providing examples of NMs used in products and possible applications, is included in Annex 1 of this report. Additional data relating to NMs on the EU market was released by the European Commission in 2012.[98] This information is mostly based on a private report by Lux Research that is not publicly accessible. The methods used in gathering the information, as well as direct sources are therefore unknown. According to this Commission document, *"by far the biggest use[of NMs] is as a reinforcing agent for rubber in tires and other rubber goods."*

In 2012, the Danish Ecological Council and the Danish Consumer Council created a similar database.[99] in collaboration with the Danish Technical University. This is the newest of a series of inventories and databases developed in the EU by civil society organizations and academia.[100] This database includes specific color-coded information about potential exposure to professional end users, consumers and the environment, as well as indications on the potential hazards of NMs used in the products listed. The Danish Ecological Council and the Danish Consumer Council plan to update their database on a regular basis. However, the database comes with a disclaimer that *"the database by no means can be considered complete. In fact, no one knows the number of nano products on the market."*

In light of the early warning signs described in section 2, the uncertainty regarding the nature and importance of exposure to NMs via consumer products is concerning and a serious obstacle to adequately managing NMs. In the absence of reliable information, it is impossible for consumers to exercise their right to make an informed choice. Fragmented information on markets and unreliable information regarding exposure gravely diminishes the capacity of governments and regulators to properly assess and manage the specific risks of this emerging technology. The resulting legal uncertainty was identified by a significant portion of companies using or producing NMs, as the main obstacle to for innovation linked to NMs.[101] Furthermore, the current situation may lead to serious public backlash if a nano related accident was to occur, which would constitute an extremely serious blow to the innovation potential of this new technology.





### "The canaries in the mine": Workers and NMs:

Workers are often the first and most heavily exposed population group to emerging hazards; this is also true for workers and NMs. Workers within nanotechnology-related industries can potentially be exposed to uniquely engineered materials with novel sizes, shapes, and physical and chemical properties. The potential for workers to be exposed to NMs may vary with each stage of the life cycles of theses materials. Therefore it is important to identify the life cycle stages and sources of NMs from which exposure to workers may occur (e.g. during research and development, manufacture, processing, use, cleaning or maintenance operations, and disposal), the pathways and routes of potential exposure (e.g. direct and indirect exposures via inhalation, ingestion, and dermal exposure), the form during which exposure occurs (e. g. unbound particles, or particles encapsulated in a polymer), and the hazards of materials to which workers are potentially exposed.[102]

The World Health Assembly identified the assessment of health impacts of new technologies, work processes, and products as an activity under the Global Plan of Action on Workers Health, which was adopted in 2007. Further, the WHO Global Network of Collaborating Centers in Occupational Health has selected manufactured nanoparticles as a key focus of their activity. Currently, WHO is developing Guidelines on "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH) to address occupational risks of NMs. Activities related to the development of these guidelines started in 2012 for the development phase with an additional year for the implementation phase.[103]

In the absence of occupational exposure threshold limits for most NMs, qualitative techniques aiming to facilitate the development of site-specific risk mitigation programs (often referred to as control banding) are being developed and are available as web-based tools.[104] However, these techniques are crude approaches to the safety of workers. Because of the present situation of extended knowledge gaps in relation to NMs hazards and exposure scenarios, a high level of precaution is necessary when determining threshold limits. For example by using only closed systems for the manufacturing and handling of NMs. Even where NMs are produced or handled in such closed systems, there are still serious risks of exposure at various stages of the life cycle of these materials (such as cleaning, and incorporation in products, etc.). Furthermore, closed systems are expensive and complex to use and are therefore unlikely to be available in developing countries. Therefore there is an urgent need for precaution and increased research in the field.

Most urgent research needs in relation to occupational risks of NMs include developing real-time personal nanomaterial-specific exposure measurement techniques, collecting exposure data in workplaces, designing and implementing an epidemiologic strategy for studying NMs workers, and validating the effectiveness of existing controls being applied to NMs processes. Also needed are recommendations and guidance about prudent approaches to NMs handling in the workplace, aiming at low and medium-income countries.[105]

The majority of countries worldwide have adopted a "wait-and-see" approach to nanomaterial regulation, including in relation to the collection of basic data and identification of products containing NMs. This wait-and-see tendency is further reinforced by the competitive environment in which NMs and nano products are developed. Strong opposition from NMs manufacturers to disclose information relating to their research or products has greatly contributed to this information gap. There has been a number of voluntary information gathering schemes put in place in certain developed countries in the latter half of the past decade.[106] However, these voluntary schemes have failed to provide an accurate and comprehensive picture of NMs production and use.

To address the information gap and concerns about the reluctance of industry operators to volunteer information, a small number of countries mostly in the EU have or are currently setting up mandatory reporting schemes to collect information regarding NMs and products. France is the first country to have implemented such a mandatory information-gathering tool.

The French information-gathering tool was set up by a combination of laws and regulations which entered into force on January 1st, 2013, and is therefore now a

legal requirement.[107] This information-gathering scheme focuses on NMs (rather than products containing them) and applies throughout the supply chain. It uses a definition largely based on the EU recommendation but only applies to substances intentionally manufactured at the nanoscale. It imposes an annual declaration requirement for all manufacturers, distributors or importers of more than 100 g of NMs/year. if the substances are intended to release nanoparticles when used, and only in substances intended for professional users. Substances intended for research are exempted. The declaration must include the identity of the registrant, the identity of the substance, the quantity produced, distributed or imported over the past year, the users of the substance, and the identity of professional users to whom the registrant has transferred ownership of the substance. Research and development activities benefit from a simplified declaration procedure and the authorities may require further information (such as exposure or toxicological data). The information gathering mechanism further includes provisions to guarantee the confidentiality of some information by restricting access to certain information provided by the registrant.

Belgium has also adopted a similar information-gathering tool as France on the 14 February 2013. The Belgian and French systems have different scopes. The Belgian register includes substances intended for research, while it excludes NMs covered by other EU regulations such as Cosmetics, Food, and Biocide[108] . Political discussions are ongoing at the time of writing on whether to include products containing nanomaterials NMs to the register. A decision by the Belgian government is expected in the second semester of 2014.

Other EU countries, notably Denmark and Italy have taken steps to implement similar or comparable mechanisms, either focusing on NMs themselves or nano- products. In Sweden, a governmental committee recently underlined the need to develop a national inventory for nano producs on the market, even though it advised that a broader register over consumer products first hand ought to be developed on EU level.[109] At the regional level, the Commission has expressed reluctance to implement a similar mandatory mechanism across the European Union.[110] The Commission is currently only proposing to create a web platform with reference to all relevant information sources, including registries on a national or sector level, where they exist.[110] Heeding to pressures from Member States and Stakeholders, the Commission has nonetheless indicated that it will prepare an impact assessment of an EU wide inventory, as well as launch a public consultation on the opportunity, feasibility and possible content of such an EU wide inventory in 2014.

Identifying basic data about NMs production, flow, and uses is critical to enable developing adequate risk management measures based on a precautionary approach to the governance of NMs. It follows that databases, registers and similar instruments need to be considered as an integral part of any regulatory mechanism to govern NMs.





# 4. Regulatory initiatives for the management of nanomaterials

The question of whether and how to adapt existing legal frameworks to the specificities of NMs is a contentious one. As David Rejeski, Director of the Woodrow Wilson Center for Scholars Project on Emerging Nanotechnologies notes, "most countries are taking a wait-and-see approach, assuming that existing regulations will deal with nanotechnology, even if new materials emerge with radically different properties."[112]

As a result, less strict governance mechanisms are much more widespread than actual regulatory frameworks. NMs and nanotechnologies governance approaches generally aim at coordinating all aspects of nanotechnology development: from coordination of research, innovation, and investment strategies, managing the risks of these new materials and technologies, to sometimes regulating NMs access to the market. Historically, the development of regulatory and governance frameworks relating to nanotechnologies is gradually (albeit slowly) evolving from instruments designed mainly to support innovation and spur growth of the nanotechnology industry to more comprehensive approaches aimed at capturing some of the more complex issues of nano-related human health and environmental safety aspects.

In the late 1990s and early 2000s, as governments around the world began to identify nanotechnology as a critical technology for the future, governments devised specific innovation support plans such as, for example the 2001 National Nanotechnology Initiative in the United States.[113]

In many other countries and regions, similar plans were later developed. For example, in 2002, the European Union implemented publicly-funded research programs in the context of its Sixth Framework Program;[114] in 2004, China began coordination and investment support plans;[115] in 2009, Russia set up a public company called RUSNANO to develop a Russian nanotechnology industry through investment in infrastructure and venture capital; and, in 2012, Korea developed its first National Master Plan on Nano Safety Management.

Most developed countries and some countries with economies in transition now have an institutional coordination framework with regard to nanotechnologies. However, these institutional frameworks are still an exception in the Global South. Nonetheless, the situation is gradually evolving due to global forums such as the Strategic Approach to International Chemical Management (SAICM)[116] and to the involvement of international organizations such as the United Nations Institute for Training and Research (UNITAR).

Where such coordination mechanisms exist, the exact balance between the different considerations, such as support to innovation, health and environmental issues, workers safety, and product development varies greatly from country to country.

The following section explores selected examples of approaches to NMs and nanotechnology governance around the world. This section also examines the weaknesses and opportunities of governance models in the selected jurisdictions. The EU will be addressed separately and in more detail because it has the most advanced regulatory framework and, to some degree, the only nano specific legally binding provisions in place in the world.

### The Strategic Approach to International Chemical Management (SAICM)

SAICM is a voluntary agreement approved in Dubai, the United Arab Emirates in February 2006 at the International Conference on Chemicals Management. This strategic approach is composed of a High Political Declaration, a Global Political Strategy, and a Global Plan of Action, which together constitute a global framework with the following objective: chemical substances are produced and used in a way that significantly reduces the impact on the environment and health. SAICM is administered by a secretariat supported by the United Nations Environmental Program and the World Health Organization.

SAICM is the only multilateral international space where the development of chemical products over their entire life cycle, including the impact on occupational and environmental health is discussed. SAICM's participants include industrialized countries, countries with economies in transition, developing countries, intergovernmental organizations from the Inter-Organization Program for the Sound Management of Chemicals, industry groups, and public interest civil society groups. SAICM decisions are adopted by consensus. Although it is not legally binding, each member country has the responsibility to develop a national plan to reach SAICM objectives, including the implementation of specific activities in the Global Plan of Action.

### 4.1. Global approaches to nanotechnology governance

In the context of SAICM, all stakeholders of the Second International Conference on Chemical Management (ICCM2) held in Geneva in 2009 recognized and decided that nanotechnology and engineered NMs are a new emerging policy issue that should be addressed by SAICM.[117] The resolution includes a specific recommendation to governments and other stakeholders to assist developing countries and countries with economies in transition to enhance their capacity to use and manage manufactured NMs responsibly. In addition, it calls on government and industry to maintain a dialogue with the workers and their representatives during the creation and implementation of regulations, to protect human health and the environment, and to maintain a more general public dialogue with all interested sectors.

Applying this recommendation, UNITAR and OECD organized a first round of regional awareness-raising workshops on nanotechnology and nanomaterial in every UN region in coordination with the SAICM regional meetings. UNITAR later organized a second round of regional workshops focused on capacity-building. These workshops allowed for an informed consideration of this emerging issue in the context of SAICM regional and global discussions. At SAICM regional meetings in Africa[118] and in the Latin American and Caribbean region[119] , all participants unanimously adopted resolutions calling for the implementation of the precautionary principle, for increased transparency and recognition of a right to information for consumers and workers, for multisectoral participation in decision making relating to the development and management of NMs, and for the prevention of transferring waste containing NMs to countries lacking the capacity to appropriately dispose of them.

Drawing from the outcomes of these two rounds of workshops, UNITAR developed a comprehensive guidance document for developing national nanotechnology policy and programs.[120] This guidance document was tested in a series of pilot projects funded by Switzerland and implemented in 2011 and 2012 in Thailand, Uruguay, and Nigeria.[121] These pilot programs are being followed by additional pilot projects in Armenia, Jordan, and Panama in 2013.

The ICCM2 resolution also called for a report focusing on nanotechnologies and manufactured NMs including, in particular, issues of relevance to developing countries and countries with economies in transition. It was prepared by the SAICM Secretariat and presented to the SAICM Open Ended Working Group in Belgrade in 2011 (hereinafter named the OEWG Nano Report).[122] The OEWG Nano Report presented important recommendations later endorsed by all SAICM stakeholders at ICCM3 in Nairobi in 2012. The recommendations included the recognition that *"all countries should have the capacity to assess and adequately manage the health and environmental safety of manufactured nanomaterials, whether they are producers or mere importers and users. . . . While the science regarding nanomaterial safety assessment is evolving, it is therefore crucial to strengthen the capacities in this field in developing countries and in economies in transition. Failing to address these issues raises concerns that developed countries will be the overall beneficiaries of the technology while developing countries suffer most of the potential risks. This needs to be fully considered to avoid the creation of a nano-divide which will widen existing economic inequities."*[123]

The report recommends the establishment of cooperation, collaboration and partnerships (between countries, the public and private sectors, and civil society organizations) for the strengthening of human resources and of institutional capacity. The report also recommends encouraging dialogue, assisting in training, research and development, dissemination and sharing of information, and that appropriate means for such activities are provided.[124]





The OEWG Nano Report also includes a list of possible actions under SAICM, including:

- The development of internationally applicable technical and legal guidance and training material for the sound management of manufactured NMs,
- The possibility of financing projects related to NMs safety in any possible future SAICM financing mechanisms,
- An invitation to industry to step up their stewardship role and responsibilities in relation to nanotechnologies and manufactured NMs, and to participate (including in financial terms) in supporting awareness raising, information exchange and training activities, as well as in public dialogue by providing, without major conditions, monetary contributions for such international work, and
- Recommending to the UN Committees of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labeling of Chemicals the urgent preparation of a work plan for the adaptation or development of GHS criteria to address the safety of manufactured NMs.[125]

ICCM3, in Nairobi in 2012, adopted a resolution, which derived recommendations from the OEWG Nano Report. These recommendations included encouraging improved transparency and recommending the development of international technical and regulatory guidance and training materials for the sound management of manufactured NMs.

ICCM3 also approved the addition of thirteen new activities to the SAICM Global Plan of Action. This large set of activities range from developing approaches to protect workers, the public and the environment from potential harm from NMs; active involvement of the health sector in order to enhance understanding of possible short-term to long term occupational health impacts of manufactured NMs; the promotion of the availability of information on the presence of manufactured NMs within the product supply and use chain and throughout product life cycles, possibly including labeling, and the review of GHS criteria for manufactured NMs.[126]

The implementation of these activities together with the guidance document for developing nanotechnology policy and program developed by UNITAR can be instrumental in supporting the building of capacity for the safe management of nanotechnologies and NMs in the Global South. Their implementation will, however, require increased political will to address the safe management of NMs, including adequate funding and multi-stakeholder engagement. Further recommendations are included in the conclusions below.

### 4.2. Nano governance and regulatory frameworks for nanotechnology and nanomaterials in the Global South

In the Global South, there is no regulatory framework designed to deal specifically with the safety of NMs. However, a growing number of countries have established a nanotechnology policy program. These countries include South Africa, Morocco, Egypt, Brazil, Nigeria, Argentina, Mexico, Venezuela, Iran, Belarus, Kyrgyzstan, among many others.[127] The policy programs vary greatly in scope and ambition and a large number of them merely enact vague research coordination and innovation strategies with no reference to possible negative impacts. Conversely, Thailand went much further in establishing an incremental policy framework, which evolved from a strict research coordination strategy to a more comprehensive approach.

In 2003, Thailand created the National Nanotechnology Center (NANOTEC) as an autonomous agency under the jurisdiction of the National Science and Technology Development Agency and the Ministry of Science and Technology. NANOTEC has the dual role of serving as a national R&D center and a funding agency to support research activities in universities and public institutions.[128] After the establishment of NANOTEC, Thailand gradually moved forward in establishing a coherent policy framework between 2004 and 2012.

In 2004, a national nanotechnology strategic plan for the years 2004-2013 was adopted. After reinforcing NANOTEC by adopting a master plan for the Nanotechnology Center for the 2007-2011 period, Thailand is now expanding the reach of its governance approach by deve-

loping a nano-safety road map and nano-safety guidelines, by holding workshops and public hearings on human health and environmental impacts, and by increasing its collaboration with the Working Party on Manufactured Nanomaterials of the Organization for Economic Co-Operation and Development (OECD). NANOTEC Thailand has also announced that it will start releasing new nano based applications designed for Thai farmers in the coming year.[129] Due to the high profile of nano-innovation in Thailand and the related increase in unregulated nano-claims in product advertising, Thailand is also developing a nano-certification scheme called "Nano-Q." This voluntary certification scheme labels certain products containing NMs to guarantee the presence of NMs in products in order to prevent false nano claims.

### 4.3. The regulatory situation in the EU

As mentioned in the introduction to Section 4 of this report, the EU developed its first strategic approach to nanotechnology in 2004 with the adoption of a Communication from the Commission, titled "Towards a European strategy for nanotechnology."[130] The aim of this Communication was to bring the discussion on nanoscience and nanotechnologies to an institutional level. It proposed an integrated and responsible approach to the development of nanotechnologies for Europe. The Commission later adopted an Action Plan for Europe 2005-2009,[131] a code of conduct for responsible nanoscience and nanotechnologies research,[132] and in 2008 the Commission presented its first regulatory review of NMs.[133] This first regulatory review was accompanied by a Working Staff document[134] that provides more details on existing legislation that could be used to address nanotechnology management-related issues.

This first regulatory review, in accordance with the general approach of the time, concluded that *"[c]urrent legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation."*[135] The review's conclusion was criticized by a number of stakeholders, in particular by the European Parliament in its April 2009 report, which focuses on regulation of NMs.[136]

In the report, the European Parliament expressly:
*"Does not agree, before an appropriate evaluation of current Community legislation, and in the absence of any nano-specific provisions therein, with the Commission's conclusions that a) current legislation covers in principle the relevant risks relating to nanomaterials, and b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks;"*

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

*"Calls on the Commission to review all relevant legislation within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle, and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed."*[137]

Following this call by the EU Parliament, a number of EU sector regulations have been reviewed, including nano-specific provisions and a lively debate on the adequacy of REACH to the specificities of NMs also developed.

#### *4.3.1. EU's sector regulations' inclusion of nano-specific provisions*

##### *4.3.1.1 Cosmetics*

The EU regulation on cosmetic products of 30 November 2009[138] was the first legally binding text in the world to include a specific nano-provision. Although it is imperfect in many respects, it represented a breakthrough at the time of its adoption.

The 2009 regulation requires any use of NM as UV filters, colorant, or preservatives to be listed on a positive list.[139] In these cases the regulation requires a specific authorization for a nanoform of a substance already authorized in the bulk form. For NMs used for a purpose other than the three categories listed above, the person or company responsible for placing the nanomaterial on the market must notify the Commission six months in advance, and provide a set of data, including physical, chemical, toxicological, eco-toxicological and exposure data.[140] The regulation further imposes a specific labeling obligation, whereby the NMs must be specifically mentioned in the list of ingredients (with 'nano' in between brackets, next to the name of the ingredient).[141] This new regulation entered into force in July 2013.

Unfortunately, this regulation was adopted before the Commission's recommendation for a nanomaterial definition, and as a result, NMs are defined in a very restrictive way: "An insoluble or biopersistent and intentionally manufactured material between 1 and 100 nm in at least one dimension."[142] This narrow definition de facto limits the benefit of the specific safety evaluation and notification provisions to a small sub-portion of NMs used in cosmetic products. However, a revision clause is included in the regulation and allows for the possibility for its harmonization with other regulation by 2018.

##### *4.3.1.2 Information to consumers on food products*

In March 2011, a revised version of the EU Novel Food regulation, which included several specific provisions related to NMs (including labeling and specific safety evaluation obligations), was not adopted due to a disagreement between the Council and the Parliament on the issue of meat from cloned animals. This marked a serious set back in the movement to regulate the use of NMs in food products. Another attempt to revise the Novel food regulation has been announced.

A few months after the failed attempt to revise the novel food regulation, nanomaterial-specific provisions were successfully included in the regulation on the provision of food information to consumers.[143] This regulation, after recommending the consideration of the specificities of NMs in the future review of the Novel food regulation,[144] imposes a labeling obligation akin to the obligation already included in the Cosmetic regulation (the word nano in brackets should follow the name of the ingredient in the ingredient list).[145] The definition of NMs includes all intentionally produced materials between 1 and 100 nm in at least one dimension, as well as aggregate and agglomerate outside of this size range that retain properties that have characteristics of the nanoscale or properties that are different from the properties of the bulk form of the same material.[146] This definition differs from the Commission's recommended definition and should therefore be revised for greater regulatory consistency. It is, however, more inclusive than the definition included in the cosmetic regulation. This regulation also includes a clause allowing for revision of the nanomaterial definition. A proposal based on the Commission's recommended nano definition for such a revision was put forward by the Commission in December 2013. However, because the proposal excluded all food additives already on the market from this definition (and thus from additional nano regulation and disclosure obligation), the EU parliament opposed it. Due to the novelty of the procedure used to amend this regulation (delegated act as introduced by article 290 Lisbon Treaty)[147], at the time of writing, it is still unclear what the next steps may be in that respect, and whether and when the definition of NMs in the regulation on the provision of food information to consumers would be revised.

##### *4.3.1.3 Biocide*

On May 10, 2012, the European Council adopted the Biocide regulation, which contains specific provisions for the use of NMs.[148] The Biocide regulation is the most robust example of nano-regulation ever adopted so far.

The Biocide regulation largely incorporates the definition of NMs from the Commission's recommended definition of nanomaterials,[149] excluding only incidental nanomaterials from its scope.

The Biocide regulation imposes prior authorization

for use of both active substances in biocides and biocidal products at either an EU or individual Member State level.

Approval of an active substance does not include approval of the same active substance containing NMs unless explicitly mentioned.[150] The toxicological and ecotoxicological data must specify that the data provided is appropriate for NMs, as well as the technical adaptations and adjustments that have been made in order to respond to the specific characteristics of the materials.[151]

The regulation further specifies that NMs are not eligible for the simplified authorization procedure, and that their risks to the environment and to human and animal health have to be assessed separately.[152] As with active substances, test data submitted for authorization of a biocidal product must provide details on why the data is appropriate for NMs.[155]

The regulation further mandates that biocidal products containing NMs and articles treated with biocidal products containing NMs must be labeled accordingly. Both are required to list on their labels the name of all NMs, followed by the word "nano" in brackets. However, producers of biocidal products containing NMs have a further obligation to identify "any specific related risks," an obligation that goes further than any other labeling requirements for NMs to date. This regulation entered into force on September 1, 2013.

### REACH

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is the EU's comprehensive chemical regulation. Its purpose is to ensure a high level of protection of human health and the environment from chemicals manufactured, imported, marketed or used within the European Union, while enhancing competitiveness and innovation.[153] When adopted in 2006, REACH replaced dozens of existing EU chemical laws, including laws from the 1970s that presumed the safety of tens of thousands of chemicals already in commerce. This presumption of safety for existing chemicals in use by the 1970s is still in effect in the United States for industrial chemicals, but many countries around the world are moving towards REACH-like systems.

Reversing the presumption of safety for existing chemicals, REACH is premised on a "no data, no market" policy. Chemicals manufactured or imported in quantities greater than 1 ton per year must be registered with the European Chemical Agency (ECHA). To this end, the manufacturer and importer must report some of the chemical's intrinsic properties. Under REACH's tiered system, chemicals manufactured in the highest quantities or those known to have hazardous properties require more tests and are to be registered earlier in the process.

According to the Commission Staff Working Document accompanying the second regulatory review of NMs, "chemicals regulation, and in particular REACH, constitutes a cornerstone for addressing health, safety and environmental risks in relation with NMs."[154]

*4.3.2. The REACH and the nano debate*

REACH, the primary EU regulation on chemicals, is assumed to be the regulatory cornerstone for addressing the health, safety and environmental risks of NMs. In particular, REACH registration is commonly described as the ideal tool to fill the problematic knowledge gap on NMs. However, the limited information gathered in the first registration phase demonstrates that REACH is not living up to the expectations with regard to NMs.

In its second regulatory review published in response to the European Parliament report, the Commission restates the opinion that REACH sets the best possible framework for risk management of NMs, although it concedes that more specific requirements within the framework have proven necessary.[156] Unfortunately, the Commission failed to adequately identify serious loopholes and gaps of the REACH framework when applied to NMs and therefore proposed an insufficient adaptation thereof.

There are four main areas that were not adequately considered or addressed in the Commission's second regulatory review in relation to REACH:[157]

- *Phase-in status of NMs:* REACH distinguishes between substances that were already on the market before its entry into force (so called "phase-in substances") and new substances (so called "non-phase-in substances"). Currently, if a material is considered a phase-in substance in its bulk form, then a nanomaterial sharing the same chemical composition will automatically benefit from the bulk version's phase-in status, regardless of its newness or distinct properties and profile.[158] As a consequence, such NMs were not registered by the June 1, 2013 deadline if they were manufactured or imported in quantities above 100 tons per year per registrant. Such materials manufactured or imported in quantities of 1-100 tons per year per registrant will not be registered until 2018, further extending the knowledge gap surrounding NMs. Because most NMs currently on the market are derived from "parent substances" that benefit from phase-in status,[159] the vast majority of NMs currently marketed benefits from delayed registration deadlines in direct contradiction with the "no data, no market" principle underlying REACH.
- *Tonnage thresholds and NMs:* Production volumes play a significant role in determining whether and how substances are accounted for under REACH. The overall rule of thumb is that the higher the volume, the more data is required, and the sooner the registration.[160] REACH registration requirements apply only for production volumes of one ton or more per year per manufacturer or importer. This volume threshold is grossly inadequate for NMs, which are usually produced in much smaller quantities.[161] Furthermore, in the few cases in which NMs are produced in volumes above the one tonne per year per registrant threshold, most of those NMs will benefit from a phase-in status. As a result, the information required by the registration dossier will be limited to the physicochemical properties of the substance, excluding any toxicological and ecotoxicological information, which may otherwise be required as well as exposure information,[162] that is currently required only for substances of "very high concern." Similar concerns apply to the availability of information down the supply chain.
- *Risk assessment provisions:* According to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[163] and to independent researchers,[164] and notwithstanding other limitations discussed above, any risk assessment information made available on a nanomaterial in the context of REACH would be based on testing guidelines that fail to consider the specific hazards and exposure pathways of NMs[165]. Furthermore, if a bulk substance is not classified as hazardous, as is the case for the vast majority of substances from which NMs are derived, this characterization will be extended to the nano-form of the substance, with no additional requirements to generate data on specific nano-form effects. Therefore, a nanomaterial could move through its entire life-cycle without further requirements to assess its properties.[166]
- *Identifying NMs:* Finally, REACH does not currently define NMs, instead leaving to the registrant the final decision of determining whether a substance is a nanomaterial. This decision will be made in a large measure according to the registrant's own criteria. The absence of definition in the regulation itself will prevent the uniform implementation of any measures that are developed to address the first three gaps explained above. The inclusion of a definition of NMs (based on the Commission's proposed definition of nanomaterials) in the REACH guidance document will be insufficient to clarify this confusion and will do little to address this problem as guidance is not legally binding. In addition to creating confusion in the implementation of REACH, this situation is likely to severely impair efforts to use REACH as the main regulatory tool for gathering information about NMs currently on the market and will impair efforts to define and implement appropriate risk management measures. Given these limitations, REACH in its current form does not equip decision-makers or users of a substance, to manage the risks of NMs.

Considering the complexity of REACH revision processes, and in particular the complexity of the process to revise the core of the text, a number of stakeholders, including the Commission, have questioned the advisability and feasibility of renegotiating REACH itself. In this context, these stakeholders recommend addressing the identified shortcomings of REACH, especially in relation to NMs, through alternative methods.

In order to avoid modifying REACH itself, while ensuring its effectiveness in addressing the unique characteristics of NMs, a number of stakeholders have suggested the possibility of addressing its shortcoming through a "nano patch" to the regulation in the form of

a stand-alone regulation.[167] Such a nano patch regulation would specify how REACH tools and provisions should be applied with respect to NMs. After being proposed in a report from March 2012[168], the consideration of such a solution was urged by a group of representatives of Member States and stakeholders at a workshop organized by The Netherlands.[169] Similarly, this issue was discussed in the following Environment Council meeting in June 2012. Eleven Member States (Austria, Belgium, Czech Republic, Denmark, Finland, France, Italy, Luxembourg, Spain, Sweden, and The Netherlands) and one acceding country (Croatia) sent a formal letter to the Commission asking it to close the above-mentioned REACH loopholes either through a "nano patch" or *"whatever is most appropriate given the urgency."*

Other stakeholders and Member states have also developed analysis of the REACH gaps in relation to NMs and proposed alternative ways to address them. Among them, Germany's Federal Institute for Occupational safety and health published a background paper reflecting the position of the German REACH competent authority on the regulation of NMs under REACH.[170] The paper recommends updating the REACH regulation itself to clarify what special testing obligations are required for NMs, what tonnage thresholds are to apply for [them] and how surface-treated NMs are to be regarded. The paper proposes, in particular, a modification of the tonnage thresholds of REACH with the creation of simplified registration for all NMs produced above 100 kg and more detailed registration requirement for all NMs produced over 1t per year, and a new annex detailing the quantity-dependent, and specific data requirements needed for NMs.

The Commission has so far refused to address those requests, including in its second regulatory review of NMs published in October of 2012. Concerned with the ongoing de facto regulatory gap for NMs, stakeholders such as NGOs[171] and the Swedish Chemical Agency[172] are moving forward and have proposed actual drafts of what the "nano patch" regulation would look like. In March 2013, the Netherlands convened a follow-up workshop to their March 2012 event entitled "building blocks for EU nano regulation".[173]

Finally, in June 2013, the Commission launched a process that should lead to the revision of REACH annexes in the course of 2014. To that effect, the Commission presented a set of possible annex revision options ranging from 'status quo', to "lightening the regulatory burden for nanomaterials from REACH" to "additional emphasis to produce targeted information to reduce uncertainty."[174] Although necessary to incorporate nano-tailored risk assessment provisions, the revisions of REACH annexes will be insufficient to address the full extent of gaps identified in the REACH regulation in relation to nanomaterials even if based on the best possible scenario (i.e. the "additional emphasis to produce targeted information to reduce uncertainty" scenario).

A public consultation, intended to provide the Commission with the best possible evidence base for its work with the revision proposal, is now completed.[175] However, it is now clear that the Commission will face extreme delays in completing the task. In the meantime, it is most unlikely that REACH delivers the information necessary for the assessment of NMs.

Throughout its history, the EU has served as a model for the regulation of chemicals in general, albeit still having a long way to go in order to implement a precautionary policy for a non toxic environment. As many countries in the Global South are currently updating their chemical regulation on the model of REACH and are looking at the EU to assess whether and how to regulate the production and use of NMs, it is critical that the EU adapts its REACH-based regulatory framework for NMs to drive the adoption of a global precautionary approach for the development and use of nanotechnologies.





# 5. Conclusions and recommendations:

Nanomaterials are different from bulk materials in many ways. The differences in physico-chemical properties are often reflected in differences in toxicological and eco-toxicological hazards. These differences, which make NMs promising for the development of new applications, also often imply new risks to health and the environment.

The new risks need to be properly managed across the full life cycle of NMs in order to avoid irreversible impacts on human health and the environment. To successfully manage NMs, existing legal frameworks must be adapted and new legal instruments may be necessary.

At present, risks of NMs cannot be properly assessed due to extremely limited information about exposure and hazards of these new materials as well as lack of fully validated test methods. Research efforts to bridge this knowledge gap are critical and should be enhanced. However, even with a sharp increase in nano-toxicology and nano-eco-toxicology research, it is unlikely that the knowledge gap will be sufficiently bridged in the short or medium term due in part to the large variety of NMs on the market or in development, and rapid evolution of applied science and product development.

Therefore, regulatory frameworks addressing NMs require a precautionary approach to account for existing early warning signs and enduring uncertainty. In effect, the precautionary approach is specifically designed to address areas of uncertainties when there is a potential for severe adverse impacts.

A better knowledge of NM markets and products containing NMs is essential to all actors, from the regulator to workers handling NMs and to the consumer. Experience has shown that voluntary instruments are not reliable to provide this information. Setting up mandatory registers of NMs and nanoproducts is a necessary element in ensuring an efficient regulatory process and adequate traceability of materials.

However, if regulatory frameworks that fully address the unique risks and properties of NMs are put in place, these nano registers should ideally be made integral with registers for chemicals in bulk forms.

Today, workers are the first and most heavily exposed population group to potential health impacts of NMs. This situation requires informing potentially exposed workers throughout the supply chain (including at the waste treatment stage). Adequate protective measures should be adopted such as prioritizing the substitution of potentially hazardous materials, use of as closed systems as possible and other engineering controls, and use of protective equipment adequately designed to address the specificities of NMs. Taking into account existing uncertainties relating to hazards, assessments of exposure scenarios and appropriateness of protective measures, bio-monitoring of workers involved in the production, handling or disposal of NMs is recommended to safeguard workers' health, and increase our understanding of potential impacts of NMs.

Labeling of products containing NMs, in particular consumer products, may be necessary to ensure the right to informed choices of the consumers. In light of the ongoing uncertainty, transparency is key in ensuring the safe use and reasonable development of this technology. Particularly, in the EU:

As the review of existing sectoral legislation continues, specific provisions related to NMs shall be included, and existing regulations already incorporating specific nano-provisions need to be revised to provide consistency, in particular where the definition of NMs is concerned.

The loopholes of REACH, such as the identification of NMs, current phase-in status of NMs, inadequate tonnage thresholds, and relevant information requirements, need to be closed for the regulation to provide a useful and efficient instrument. A REACH 'nano patch', as proposed by stakeholders and the Swedish Chemicals Agency, appears as the best solution. The nano dimension should also be integrated in all relevant legal frameworks.

Finally, it is of the utmost importance that special consideration is given to North-South inequalities and inequities when considering the development of nanotechnologies and use of NMs. The Global South is facing unique challenges linked to a severe lack of financial and technical resources to address nano specific issues, including in relation to treating nano waste. Additional issues include the risk to increase the existing North-South divide by adding a nano-divide element.

In this respect, global initiatives need to be encouraged and adequately supported, including providing

support to developing countries and countries with economies in transition. Where this is not yet the case (in particular in the Global South), risk management from NMs production, use and disposal need to be integrated and considered in the development of national chemical management plans.

Scholars[176] have called for a new international network to assess emerging technologies for development, identify the potential risks and opportunities of nanotechnology incorporating developed and developing world perspectives, and explore the effects of a potential 'nano–divide'.

Such a global network would serve as a focal point to commission and collect research results, promote awareness of the potential applications of nanotechnology for development, create new regulatory regimes (or build upon existing ones) for managing risks and promoting global public goods, and provide a forum for all stakeholders – government, industry, academia and citizens groups – not just in developed but also developing countries, whose interests to date have been largely ignored.

Since 2009, SAICM has been filing part of these roles, in particular the role of forum for all stakeholders to discuss specific issues relating to NMs with a particular focus on the Global South situation. In order for SAICM to realize its full potential and advance a global precautionary approach for the development and use of nanotechnologies, sustained political will and funding for nano related activities under SAICM must be guaranteed. The development of internationally applicable technical and legal guidance and training material for the precautionary management of manufactured NMs is particularly needed. An inclusive and transparent process should be launched as early as possible to that effect.





## Annex 1: Indicative table of nano Applications[177]

| Sector | Category of product | Product example | Remarks |
|---|---|---|---|
| Appliances | Batteries | Batteries for cordless power tools<br>Car batteries<br>Lithium-Ion battery<br>Nano-titanate battery | Battery technology is presented as one of the most promising fields for nano-applications and is the object of numerous research projects around the world. The number of batteries using nanotechnologies and/or NMs currently on the market is, however, limited, but expected to grow sharply. |
| | Energy generation | New generation solar cells<br>Thin films | Most of these applications are still in the development phase and are exploring the use of various organic and inorganic NMs, nanotubes and nanowires. |
| | Heating, Cooling and Air | Air Purifier (room/car)<br>Antibacterial air conditioners | Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties. |
| | Large home appliances | Refrigerators<br>Washing machine | Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties. |
| Electronic and computers | Processors | Computer chips<br>Memory devices | Nanoparticles (including Carbon Nano Tubes, or CNTs) and nanotechnologies are used to take advantage of an array of properties, among which semi-conductor properties and their downsizing capacity. |
| | Display devices | Computer/telephone/TV enhanced screens<br>Flat panel displays<br>Display Protective films | These applications mostly employ LED and OLED technologies as well as CNTs |

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| | Coatings | Antibacterial coatings (for laptops, keyboards, mouses etc…)<br><br>Anti fogging (camera lenses) | Very large numbers of electronic and computer devices are now incorporating nano silver coatings for antibacterial purposes. |
| | Inks | Inks for printers<br><br>Aromatized inks | Nano ink applications (using various NMs) are being investigated for the printing of semi-conducting and insulating circuitry. Nano ink application can also be used in decorating techniques while nano varnishes can be used as anti-scratch materials for screens. |
| Food and beverage | Food | Canola oil<br><br>Slim shake<br><br>Tea | Uses nano micelles as a delivery vehicle. Applications of nanotechnologies in food products is a subject of much discussion and debate (both in relation to their very presence in food on the market, their public acceptance, and their potential health impacts) |
| | Food contact materials | Coatings for plastic bottles<br><br>Antibacterial packaging<br><br>Anti-moisture and anti-bacterial edible fruit coating. | Food packaging applications are very commonly discussed. Reliable information on existing application is quite limited so far. |
| | Kitchen ware | Antibacterial cutlery<br><br>Antibacterial kitchen utensils (chopping boards, food containers etc…)<br><br>Non-stick pans | Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties on kitchen ware. |







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| | Food supplements | Vitamins<br><br>Metal (principally silver and gold) colloidal suspensions<br><br>Spirulina nano clusters | Food supplements make large use of micelle technologies as well as other nano-encapsulation technologies. A very large array of products is available on-line. |
| Automotive | Material science | Lighter materials<br><br>Coatings/paints<br><br>Oil/gas additives | NMs are used (or their uses are currently being investigated) to reduce the weight of materials as well as to explore new surface properties (see comments under inks and paints). Oil and Gas nano-based additive are also currently being investigated for their potential capacity to increase motor durability and reduce gas consumption. |
| Health and fitness | Cosmetics | Sunscreens<br><br>Anti-aging cream<br><br>Acne treatment | Sunscreens containing nanoaparticles (mostly nano titanium dioxide and nano zinc oxide) represent the vast majority of sunscreens currently on the market. They also represent the majority of cosmetics products on the market containing NMs. |
| | Clothing | Stainless fabrics<br><br>Waterproof fabrics | The textile industry is now going beyond nano silver and its antibacterial properties to explore the use of a variety of NMs for diverse applications. |
| | Sporting goods | Tennis racket<br><br>Bicycle frame<br><br>Golf clubs | Enhanced performance (lighter, more powerful etc…) sports goods. |
| | Personal care | Nano silver wound dressings<br><br>Body lotion<br><br>Antibacterial hair iron<br><br>Antibacterial shaver | Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties. |

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| Home and garden | Cleaning products | Degreaser<br><br>Floor/surface cleaning<br><br>Micro fiber cloth | A large number of products are advertising the presence of NMs. Nano cleaning products have stirred a number of controversies (either on whether they actually contain NMs or whether they have health impacts when they do) |
| | Construction material | Paints (anti-bacterial, anti-graffiti, anti-scratch etc…)<br><br>Glass (self cleaning)<br><br>Coatings (surface protection)<br><br>Insulation materials | Nanoparticles are used in construction materials mostly to add new properties to surfaces. A large number of potential future applications are also being currently investigated. |
| | Travel | Luggage (lightweight or anti-bacterial)<br><br>Umbrella | Nanoparticles are mostly used for their antibacterial and/or water repellant properties. |
| | Pets | Antibacterial pet products<br><br>Anti stain fabrics (for cushion etc..)<br><br>Fish tank cleansing | Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties. |
| "Health and environment" application | Water purification | Desalinization<br><br>Water purification<br><br>In situ Water decontamination | Nanotechnology approaches to water filtration are very diverse (from the use of nanoscopic pores in filtration membranes to the use CNT or alumina fibers for nano-filtration). Most of these applications are still under development, although a small number are already available. |
| | Soil remediation | In situ soil remediation | According to US EPA, in situ soil remediation (mostly using nano zerovalent iron) has the potential to facilitate soil remediation and to reduce its cost. It is currently being tested in a number of sites around the world, principally in the US. |





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| Medical applications | Disease diagnosis | "Lab on a chip"<br><br>Quantum dots for medical imaging and labeling<br><br>Extra sensitive nano-sensors | Nano medical technology is a fast-growing and very promising field. Due to the long evaluation and testing requirements for these kinds of applications, most of them are still either in the development stages or in the clinical trial phase. |
| | Drug delivery | Nanoparticle delivery vehicles for active therapeutic agents | |

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This report deals with the challenges, risks and possibilities of nanotechnology. Current discussions on defining nanomaterials, the lack of knowledge of the presence of products containing nanomaterials currently on the global markets, and some regulatory initiatives for the management of nanomaterials internationally, regionally, and nationally are addressed. The special needs and challenges for developing countries and economies in transition are touched upon.

The intention is not to give a complete and in-depth review of the current status in the field of science and regulation of nanomaterials, rather to give the Swedish and international public, and decision makers, an overview in the topic. It can aid decision makers in finding the right priorities, without defining the exact actions to take.

Based on the report, the Swedish Society for Nature Conservation, however, does reflect on some concrete actions to be taken by Swedish decision makers. This is reflected only in the preface of the report.