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Implementation of the Strategic Approach: New and emerging policy issues

Report on nanotechnologies and manufactured nanomaterials

Note by the secretariat

1. Resolution II/4 E of the second session of the International Conference on Chemicals Management, invited Governments and stakeholders to develop a report focusing on nanotechnologies and manufactured nanomaterials including, in particular, issues of relevance to developing countries and countries with economies in transition.

2. The secretariat, based on initial work undertaken by Switzerland and the United Kingdom, developed an outline for the report and invited comments from SAICM stakeholders. A consultant was commissioned to write the report using the inputs received including recommendations from SAICM regional meetings.

3. The secretariat has the honour to circulate, for the information of participants, the report on nanotechnologies and manufactured nanomaterials contained in the annex to the present note.

* SAICM/OEWG.1/1/Rev.1

ANNEX

NANOMATERIALS : APPLICATIONS, IMPLICATIONS AND SAFETY MANAGEMENT IN THE SAICM CONTEXT

This report has been prepared for the SAICM Secretariat and uses the inputs which the Secretariat received from stakeholders. It has been drafted by Rob Visser in co-operation with Georg Karlaganis, Vladimir Murashov and Seonghee Seo.

Table of contents

Nanomaterials: Applications, Implications and Safety Management in the SAICM context

Executive summary

Background

Nanomaterials have special characteristics which mean that they can be used in various new applications, some of which have already been marketed for decades. Much research on new uses for nanomaterials is ongoing and, while currently the production volumes for them are not very large compared to traditional chemicals, many other applications are foreseen in the near future and production volumes are expected to increase significantly over the coming decade.

These special characteristics of nanomaterials can, however, also be a challenge, because these materials might have different implications for human health or the environment than the traditional chemicals. At this point in time it is not yet determined to what extent the classical testing and assessment approaches used in toxicology, which are the basis for the safety management decisions regarding traditional chemicals, will apply to nanomaterials. Also in this field research programmes are ongoing.

SAICM pays attention to nanotechnologies and manufactured nanomaterials as an emerging issue with respect to chemical safety. The Resolution II/4-E of ICCM2, in its section 9, "Invites Governments and other stakeholders to develop a report that focuses on nanotechnologies and manufactured nanomaterials including, in particular, issues of relevance to developing countries and economies in transition, and to make the report available to the Open-ended Working Group at its first meeting and to the International Conference on Chemicals Management at its third session".

This report has been prepared to address this invitation. Inputs from thirteen stakeholders have contributed to the report. Recommendations made at Regional SAICM meetings for the content of the report, based on an outline, have been taken into account.

Introduction

The report gives a brief overview of the current market situation, and of expected developments. It describes possible applications of manufactured nanomaterials for industrial and consumer uses, but also addresses their beneficial uses for health and the environment, and gives special attention to the situation in developing countries and economies in transition. The report then describes the state of knowledge regarding risk assessment and risk management. It describes where science is with regard to material characterization, human health (including worker related aspects), the environment, information management and risk management. The report also highlights uncertainties in the science and on which issues more research is needed.

Risk assessment and risk management

One of the conclusions regarding this subject is that on the one hand much knowledge is available regarding possible health and environmental effects of traditional chemicals and exposures, but that, on the other hand, such knowledge cannot all be transposed directly to nanomaterials. In many cases, however, the robust methods applied to and frameworks used for traditional chemicals, will provide an adequate basis for dealing with manufactured nanomaterials. A widely applied policy is to use available provisions as far as possible and follow a precautionary approach. At the moment therefore often a case-by-case evaluation has to be relied upon, and qualitative outcomes have to be used when risk quantification is not possible. Precaution is then applied in those cases where an unacceptable level of uncertainty or concern is identified. In this context issues related to waste management, specifically in developing countries and economies in transition, require special attention.

Policy Making

Currently no countries have specific legislation in place to deal with the safety of nanomaterials. Meanwhile existing legislations requiring a duty of care are used to cover nanomaterials. Several specific suggestions have been made for better addressing nanomaterials, such as the inclusion of nano-aspects in Safety Data Sheets, establishment of a government register for products including nanomaterials, a provision by industry of information about potential risks of nanomaterials and integrating a chapter about the management of nanomaterials in National Profiles for chemicals management.

Clearly, however, more research is needed to get a better insight into those aspects for which the methodology has to be adapted for nanomaterials risk management, and into the possibilities to quantify the risks. In general, civil society organizations are rather critical about the way the risks of nanomaterials are currently being managed.

Economic, social and ethical matters

The report also discusses the economic, social and ethical aspects of the introduction of nanotechnology, how public dialogue on this issue is being progressing and the work of international and intergovernmental organizations.

Capacity Building

The report further addresses the issues of learning, training and capacity building in relation to nanotechnology and defines in this respect two related, but distinct elements. One is ensuring that all countries have the capacity to undertake research in order to use nanotechnologies to help them to possibly better address a number of the societal challenges. Concerns that developed countries will benefit more from nanotechnology and that developing countries will suffer more from potential risks are highlighted and the need that this issue has to be fully considered in order to avoid that a nano-divide will be created, is emphasized. The establishment of research partnerships is mentioned as a way forward here. The second element is that all countries should have a capacity to assess the health and environmental safety aspects of manufactured nanomaterials in order to be able to make well founded and effective decisions on the use of these materials in their countries, while the

science regarding nanomaterial safety assessment methods is evolving. It is crucial to strengthen the capacities in this field in developing countries and in economies in transition. Suitable means to achieve this should be made available.

Recommendations on nanomaterials' safe management

The report concludes with a number of suggestions for actions which could be taken up in the SAICM context. The detailed recommendations are listed below:

1. Facilitation of information exchange on nanotechnologies and manufactured nanomaterials in order to improve global transparency and allow better decision making processes. Such information exchange could involve several aspects. For example it could be recommended that, possibly through the IOMC and its participating organizations:
    - an international "nano-portal" for safety information be set up;
    - a clearinghouse of ongoing research activities be set up;
    - a mechanism be established for sharing technical, legal and institutional information;
    - awareness raising activities in the SAICM regions be continued and deepened.
2. Development of internationally applicable technical and legal guidance and training material for the sound management of manufactured nanomaterials, possibly through the IOMC and its participating organizations. This could involve:
    - guidance material on the assessment and management of the safety of nanotechnologies and manufactured nanomaterials;
    - guidance material on the integration of nanomaterial safety in existing national chemical safety programmes, including the updating of National Profiles;
    - guidance material on the adaptation of national legal frameworks to include the sound management of manufactured nanomaterials;
    - training materials based on the guidance;
    - training activities;
    - pilot projects which could also be used to test the guidance material;
    - education materials for the public.
3. Supporting the development of Regional SAICM strategies concerning manufactured nanomaterials, which could include arrangements for cooperation on research and on risk assessment and risk management issues.
4. Facilitation of technology transfer, in particular related to applications which are beneficial for health and environmental protection. This could include various types of partnerships which should be financially supported in order to achieve their objectives. Partnerships could be among:
    - developing countries and/or economies in transition and developed countries;
    - public and private institutions in a country or region, including civil society organizations as they could contribute in various ways, for example by providing expertise, review and insights.
5. Updating the Global Plan of Action with a specific work area which includes activities on nanotechnologies and manufactured nanomaterials.
6. Including the possibility of financing projects related to nanomaterial safety in any possible future SAICM financing mechanisms in order to enhance the preparedness of countries to

deal with the safety issues when larger volumes of products containing nanomaterials will reach the market.

7. Inviting industry to step up their stewardship role and responsibilities in relation to nanotechnologies and manufactured nanomaterials, 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.
8. Recommending to the UN Committees of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals the urgent preparation of a work plan for the adaptation or development of GHS criteria to address the safety of manufactured nanomaterials.
9. Recommending to the Conferences of Parties of the Rotterdam, Stockholm and Basel Conventions to consider specifically addressing if it would be useful (and if so how) to consider applications and implications of manufactured nanomaterials which could fall under their respective mandates.
10. Continuing to support the public dialogues on all aspects of nanotechnologies and manufactured nanomaterials, for example by holding Seminars or a Global Conference with participation of all stakeholders in order to discuss progress on addressing issues related to manufactured nanomaterials which are of wide public interest.

1.INTRODUCTION

Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. A nanometer (nm) is one-billionth of a meter. A sheet of paper is about 100,000 nm thick, a human hair is approximately 80,000 nm wide, a red blood cell 7,000nm wide, a strand of DNA is 2.5 nm of width and a single gold atom is about a third of a nanometer in diameter.

The fundamental properties of matter change at the nanoscale. The physical and chemical properties of nanoparticles can be quite different from those of larger particles of the same substance. Altered properties can include, but are not limited to, color, solubility, material strength, electrical conductivity, magnetic behavior, mobility (within the human body and within the environment), chemical reactivity and biological activity.

Such different type of properties mean that manufactured nanomaterials can be used in various new applications, some of which have already been marketed since decades such as in paints, coatings and cosmetics. Much research on new uses for nanomaterials is ongoing and, while currently the production volumes for them are not very large compared to traditional chemicals, many other applications are foreseen in the near future and production volumes are expected to increase significantly over the coming decade.

The same types of properties that give its practical uses to nanomaterials in these new applications, however, can also be a challenge, because nanomaterials might also have different types of implications for human health or the environment than the traditional chemicals. At this point in time it is not yet determined to what extent the classical testing and assessment approaches used in toxicology, which are the basis for making the safety management decisions regarding traditional chemicals, will apply to nanomaterials. Also in this field research programmes are ongoing.

One of the international events where the safety aspects of manufactured nanomaterials was discussed, was at the sixth session of the Intergovernmental Forum on Chemical Safety held in Dakar, Senegal, in 2008. One of the recommendations of the Forum was that the second session of the International Conference on Chemicals Management (ICCM2) to be held in 2009 in Geneva, Switzerland, would consider the outcomes of the Forum.[1] At the request of a number of stakeholders, the topic of "Nanotechnologies and Manufactured Nanomaterials" was included in the agenda for ICCM2 as an emerging policy issue. Discussions were supported by a background document.[2]

ICCM2 adopted a Resolution on "Nanotechnologies and Manufactured Nanomaterials".[3] The Resolution, in its section 9, "Invites Governments and other stakeholders to develop a report that focuses on nanotechnologies and manufactured nanomaterials including, in particular, issues of relevance to developing countries and economies in transition, and to make the report available to the Open-ended Working Group at its first meeting and to the International Conference on Chemicals Management at its third session".

A draft of an outline for the report was prepared by Switzerland and the United Kingdom and put on the SAICM website in early 2010 with a request for comments by 1st May 2010. Reactions from five stakeholders were received. The SAICM Regional meetings of Africa [4] and of Latin America and the

Caribbean [5] gave a number of recommendations for the content of the report, based on an outline. In April 2011 a revised outline for the report was put on the SAICM website and inputs to for the report were requested. Inputs were received from thirteen stakeholders: Egypt, EU, ICCA, IPEN, Korea, the Nano-Authorities Dialogue (Austria, Germany, Liechtenstein, Switzerland), OECD, South Africa, Switzerland, Thailand, UNITAR, US and WHO. The inputs can be found at the SAICM website.[6] They have been used extensively in the drafting of the report, but are not further quoted in the text. Information from other sources than these inputs is specifically referenced.

2. NANOMATERIALS AND THEIR APPLICATIONS

2.a Applications

Consumers have been using manufactured nanomaterials for many years in the past in products used in their everyday life often without knowing it. But many more applications are envisaged. The specific properties of nanomaterials mentioned above, make them useful for many applications in a variety of areas. Many research efforts in industry and academia are ongoing, often organized through national or regional initiatives.[7] [8] Applications which lead to beneficial uses for health and the environment will be addressed in some further detail in section 3. In this section some examples of industrial and consumer uses of different types of nanomaterials will be highlighted. Overviews of the variety of recent applications are given in studies of the US National Center for Manufacturing Science[9] and the OECD. [21]

The light weight, mechanical properties of nanomaterials will result in uses in different kinds of re-inforced construction materials like cement, metals, ceramics, wood, rubber and plastics. The conductivity properties will lead to applications in, for example, conductive inks in micro-electric applications to increase processing speeds. Nanomaterials consisting of metal oxides (aluminum, cerium, iron, zinc, titanium), silicon dioxide, metals (gold, silver), carbon allotropes (carbon black, single walled or multiwalled nanotubes, fullerenes or bucky balls) and nanoclays (layered mineral silicates) are mainly used in matrices for various applications.

Examples of product categories using nanomaterials are cosmetics, electronics, pigments, coatings, paper and pulp, textile and leather, food contact products, catalysts, semiconductive materials, drilling and cutting equipment, fillers and plastic additives. Some examples of specific products which can make use of nanomaterials are: various types of batteries, computer chips, paints, sporting goods like bicycle frames and tennis rackets, waterproof clothing, sunscreens and other creams, microfiber cloth, cleaning products, antibacterial agents (which can be applied in products like refrigerators, washing machines, kitchen ware or computer equipment) and antifogging agents (on car windshields, camera lenses). Low-cost photovoltaic solar cells (e.g. solar “paint”) and safe storage of hydrogen are applications which could be useful in the clean energy field.

In the health care domain a range of applications are envisaged: miniaturized diagnostics that could be implanted for early diagnosis and monitoring of illness, nanoscale coatings to improve the bioactivity and biocompatibility of implants, ultra-precise nanostructured drug delivery systems, sensors for labs-on-a-chip, and new materials for bone and tissue regeneration. Enhanced

membranes for water purification, nanostructured filters for removing pollutants from industrial effluents, improved remediation methods (e.g. photo-catalytic techniques) can be effective and efficient for environmental protection.

Nanomaterial applications can also address specific needs of disadvantaged people. Communities with no access to electricity are now lighting up their homes and schools with low cost printed nano-solar cells that power special lights made from nano-LEDs (light emitting diodes). Nanomaterials can also help to increase agricultural production by applications related to pesticides and fertilizers.

2.b Market situation

A recent RIVM report mentions a six-fold increase of consumer products in the European market with a claim to contain nanomaterials, growing from 143 products in 2007 to 858 products in 2010 Product categories which show the largest increase are personal care products and cosmetics like sunscreens, and various coating products such as anti-rain products for shoes and textiles. [10] According to Soldatenko currently some 1300 products are in use. [11] In April 2011 the Woodrow Wilson Center Consumer Products Inventory included 1317 products with nanomaterials. These products were produced by 587 companies in 30 countries. [12] This number could be higher due to the difficulties of identifying the products which contain nanomaterials.

Governments and the private sector invest significant amounts in research and development of nanomaterials. The public sector in the US for instance invested $ 12 billion since 2001. Germany, which is in this respect the frontrunner in the EU and ranks fourth on the international level (behind the US, China and Japan) allocated € 400 million to nanotechnology in 2010. [13] A small part of the funding is allocated to research related to risk assessment and management. For example, Switzerland allocated SF 12 Million to safety research for the period 2010 to 2015 for the National Research Programme on Opportunities and Risks of Nanomaterials.[14]

The market situation of four classes of nanomaterials (fullerenes, carbon nano tubes - CNT, metals and metal oxides) was described in the 2009 ENRHES report: [15]

- the **fullerenes market** was worth around $ 58 Million in 2007. The energy sector is the most prominent for fullerenes (fuel cells, solar cells, batteries).
- there is a great demand for **CNT**, especially in the electronics and polymers sectors. In 2006 the global CNT production capacity was estimated 271 tons per year (WTEC 2006). The price for 1 kg CNT used to be up to $ 1000, but has been lowered due to research efforts. The market for CNT was approximately $ 168 Million in 2008.
- **metals:** Nano- metals include cobalt, copper, gold and silver. Silver nanoparticles are applied most, because of the anti-microbial properties. It has been reported that in 2008 the silver nanoparticles production was 500 tons per year.
- **metal oxides**: Metal oxide nanoparticles are manufactured and applied worldwide for cosmetics, coatings, solar cells and plastics, such as cerium oxide for car catalysts and for diesel fuel additives; zinc oxide for metal work; ceramic nanoparticles for scratch-resistant automobile coatings; titanium dioxide for paints, plastic stabilizers and sun screens. The

global nano-titanium dioxide production was estimated between 5 000 and 64 000 metric tons for the year 2008.

2.c Expected market developments

While market demand has not matched the considerable hype that nanotechnology has generated in the last decade and a half, nanomaterials have managed to attain an appreciable commercial presence. Market information about manufactured nanomaterials has a commercial value; it is collected and sold by many private companies and is not freely available. This is one reason why there is no overview about the situation. Other reasons are the wide application of manufactured nanomaterials in all sorts of product categories and the absence of information in governments about which products contain nanomaterials. Many of the projections for the size of the future global market might therefore not be very accurate and will depend highly on the assumptions and definitions which were used in these studies. While there is an apparent general agreement on an important growth potential for the nanomaterial market, factors which make it difficult to estimate its future more accurately include: high processing cost; intellectual property issues; health and environmental regulations and safety concerns. A wide variety of numbers about the expected market size can be found, and these numbers are not always in accordance. Nevertheless, some of the information is provided below as an illustration.

One estimate indicates that the global market for pure nanomaterials to grow from $ 413 million in 2005 to $ 3.6 billion by 2010. [16] In 2007 the global market was worth around $ 1.6 billion. Azonano projects that this will reach $ 10 billion by 2012, and there are projections which mention that the market will be worth $ 20.5 billion in 2015.[17] It has been reported that global nanomaterial demands will continue to rise by 20 % per year. Another estimate mentions that by 2025 nanomaterials are expected to reach over 34 billion in sales, having still only scratched the surface of the market potential. [18] According to a Greenpeace report[19], the market of nanomaterials is estimated to be over $ 340 billion within a decade. The US National Science Foundation projected in 2001 that by 2015 the size of the nanotechnology market will be $ 1 Trillion.[20] Breaking down this market size figure into nanomaterials, nano-intermediates and nano-enabled products shows that actual nanomaterials contribute less than 0.5 %. An OECD report lists numbers found in the literature for the global market forecast for nanotechnology enabled products in the range from $ 750 – 3100 billion for 2015.[21]

It has been estimated that the area of nanoelectronics (semiconductors, ultra capacitors, nanostorage and nanosensors) will be worth around $ 450 billion in 2015. The information and communication technology market is projected to see an increase due to the use of nanomaterials in displays, with a forecast of $ 1.1 billion by 2015. Health care (nanobiotechnology including medical applications, drug delivery and microbiocides) was the second largest market for nanomaterials in 2008, but is expected to overtake electronics as the leading outlet in 2013 and beyond.[18] It has been reported that the total market for nanobiotechnology products was $ 19.3 billion by 2010 and is growing to $ 29.7 billion by 2015.[22] The global market for nanotechnology products used in water treatment was worth an estimated $ 1.4 billion in 2010 and is expected to grow at a compound annual growth rate of 9.7% during the next 5 years to reach a value of $ 2.2 billion in 2015.[23]

Currently the market is mainly focused on the fields of electronics and health care, but it is expected that the market will become much broader in terms of the variety of products and producers.

3. BENEFICIAL USES OF NANOMATERIALS FOR HEALTH AND THE ENVIRONMENT

Manufactured nanomaterials not only have industrial and consumer product applications. These materials can be also of use in the health area (nanomedicine) and in the environmental field. Some of them are already in use, while others are in a more or less advanced stage of research or experimental use. In many research programmes, especially in developing countries and economies in transition, these aspects get priority attention. In the NANOTEC research programme of Thailand, for example, six of the eight so-called flagship projects are directly related to health and environmental applications. Some examples of beneficial uses of nanomaterials for health and for the environment are discussed below.

3.a Health benefits

Most applications of nanomaterials in nanomedicine focus on the areas of drug delivery and diagnosis. Nanoparticles can be used to improve drug bioavailability. This can be done by nano-engineering the pharmaceutical in such a way that it can better reach those parts in the body where it is has to act specifically, or in a way that makes it available in the body over a better determined period of time. For example, for cancer therapy certain functional groups could be attached to a nanoparticle, which then could target certain tumor cells. The size of nanoparticles also could allow them to preferentially accumulate at tumor sites. Such “tag and drag” approaches could improve the effectiveness of drug therapies in a major way and help to avoid unwanted side-effects. It has been reported that the main diseases for which health-related nanotechnology patents exist are cancer (35%), hepatitis (12%) and acne (4%), with a host of others in the 1 – 4% range. [24]. The European Medicines Agency (EMA) has hosted the first international scientific workshop on nanomedicines in September 2010. [25] In view of the potential of nanomaterials to be of good use in health care, a lot of research is ongoing in nanomedicine. However, the number of clinical trials is still small. The European Foundation for Clinical Nanomedicine CLINAM reported 12 ongoing clinical trials in 2011.[26]

Nanomaterials can also be used in various techniques to improve biomedical imaging, disease screening and health monitoring. For example, dyes using so-called quantum dot nanomaterials attached to proteins could be used to track cells or follow the distribution and metabolism of pharmaceuticals in the body.

Early diagnosis of a disease is often very important because it can increase the chances that a therapy will work. It is shown that nanoparticles can have the potential for detecting fragments of viruses, pre-cancerous cells, disease markers, and indicators of radiation damage. Nanoparticles could be nano-engineered with different types of bio-molecules such as antibodies, or fluorescent markers and this could be used for example to detect virus particles left after completion of a drug therapy or specific proteins, antibodies, and other disease indicators.

Poverty-related diseases are also being addressed and were the focus of Africa's first Nanomedicine Workshop. The five day workshop, titled "Nanomedicine for infectious diseases of poverty - perspectives and possibilities" took place in 2011 in South Africa. [27] It is estimated that approximately 14 million people die annually due to poverty related diseases including malaria, tuberculosis, sleeping sickness, chagas disease, as well as HIV/AIDS. Nanomedicine could also help to combat these diseases. [24]

A UNESCO report mentions that nanotechnology can offer for developing country health care "safer drug delivery, new methods of prevention, diagnosis and treatment of diseases". [28] Another report outlines the top ten nanotechnologies which can contribute to reaching the Millennium Development Goals and addressing global challenges.[29] Reports explains that some of the benefits of more sophisticated nanotechnology based drug delivering systems, especially for developing countries, is that it has the potential to free up trained medical personnel which are currently engaged in administering pharmaceuticals for urgent other tasks. Nanotechnology based diagnostics could empower local health care auxiliaries in rural settings, thereby limiting the need for technical involvement of trained specialists, who could then attend more and better to patients requiring higher qualifications. Another benefit, especially in remote areas, would be the increased use of slow release drugs.[30]

The use of nanomaterials for cleaning water is mentioned under the section on environmental benefits, but this can of course also be very important for preventing diseases. In particular if it involves purification of the supply for drinking water, this would be a great benefit for public health protection.[31]

3.b Environmental benefits

Manufactured nanomaterials are also providing critical technological advances that have the potential to help environmental clean-up, prevent or reduce pollution, promote cleaner production and improve energy generation, storage, and use. Some of these technologies are already deployed, while others are currently undergoing commercial development. A number of examples are discussed below. In 2009 an OECD Conference on the "Potential Environmental Benefits of Nanotechnology: Fostering Safe, Innovation-Led Growth," identified a number of potential technologies that might reduce impacts on the environment either directly or indirectly. [32] For example, certain nanomaterials are used as light weight, strong construction materials. This has some generic environmental benefits compared to traditional materials in view of the facts that less material is used, because of the lower weight they require less energy for transport and in the waste phase they represent less material. Nanomaterials can also be used to replace chemicals known to be hazardous.

Nanomaterials can be used in environmental clean-up and remediation. Nanoscale iron metal can directly reduce environmental pollution, for example in remediating sites contaminated with organo-chlorine waste; this material can also be used for the cleaning up of waste water or of ground water which could be used in the supply of drinking water. In the provision and management of clean water, solar photocatalytic processes to disinfect water are enabled by nanomaterials.

With respect to pollution prevention or reduction, nanoclays can be used as a substitute for brominated flame retardants that have been targeted for phase-out due to environmental and human health concerns. A wide range of nanoscale materials can be used as coatings that provide alternatives to possibly more toxic chemicals, while simultaneously improving the durability and functionality compared to older technologies. Cerium oxide can be used as a fuel additive to reduce particulate emissions and increase fuel efficiency.

Cleaner production processes that could prevent pollution can be achieved through the use of nanoscale catalysts, and the bottom-up self-assembly of materials. This can result in processing efficiency, reduction of waste in manufacturing, and stronger materials with fewer defects. In addition, the ability to enhance and fine tune chemical activity can result from catalysts that improve, for example, the efficiency of chemical reactions in automobile catalytic converters, power generation plants, and manufacturing facilities. Nanoscale catalysts can reduce the waste generated and energy consumed from a wide range of industrial processes. Nanoscale iron can be applied to create self-cleaning surfaces to reduce urban NOx levels. Nanomaterials can also be used in environmental sensing methods which can help to detect early on in processes releases of air pollutants or particles and make fast corrective action possible.

Solar collectors using fullerenes and lighter and stronger wind turbines that incorporate carbon nanotubes make green energy generation more efficient and more affordable. Improved batteries using nanoscale electrode materials like carbon nanotubes and nanostructured membranes are enabling the development of improved hybrid and electric vehicles with faster recharging, longer lasting charges, and more charge/discharge cycles, while reducing consumption of fossil fuels and generation of emissions.

While these environmental applications are of use to all countries, important environmental applications are specifically of practical use in developing countries. Up to 1.2 billion people are currently at risk of getting diseases caused by polluted water. Nanotechnologies are poised to enable water distribution and purification systems, for example by using nano-filters to sterilize water by removing and/or deactivating the infecting microorganisms.

4. RISK ASSESSMENT AND RISK MANAGEMENT

4.a Material characterization

The International Organization for Standardization (ISO) has been working on developing a vocabulary and core terms for nanomaterials and nanotechnologies since 2005; it was agreed to refer to the size range between approximately 1 nm and 100 nm. Questions have been raised about the scientific justification of single lower and upper boundaries for regulatory risk management purposes for all nanomaterials given that the boundaries of nano-specific phenomena vary with material composition and property under consideration. Nevertheless, it is widely recognized that size is universally applicable to define all nanomaterials and is the most suitable measurement parameter. Moreover, an understanding of the size distribution of a nanomaterial is essential and the number size distribution is the most relevant consideration".[33]

Risk management of nanomaterials requires their extended physical-chemical characterization. A number of lists describing physical-chemical properties needed for different aspects of risk characterization have been developed by international organizations. A more comprehensive list includes seventeen physical-chemical parameters (agglomeration/ aggregation, catalytic properties, composition, concentration, crystalline phase, dustiness, fat solubility/ oleophilicity, grain size, hydrodynamic size/particle size measurement/ distribution, length, purity, shape, specific surface area, surface charge, surface chemistry, water solubility/ hydrophilicity, zeta potential), which have been identified as a necessary pre-requisite for risk characterization of nanomaterials. [34] Even though, only three of those seventeen properties (concentration, surface charge and catalytic properties) did not have standard measurement methods developed or under development by international organizations, more work is needed to further validate and refine physical-chemical characterization methods for nanomaterials for regulatory purposes. This need for standardization of methods for nanomaterial characterization is further highlighted by the strong dependence of measured values on the method used.

As stated by the U.S. National Nanotechnology Initiative (NNI), there are several issues that pose important challenges for the development of accurate, precise, and reproducible measurement tools for nanomaterials. [35] These tools are essential for comprehensive characterization of nanomaterials so that measurements are not questioned and specific studies are not unnecessarily duplicated. Requiring that measurements be performed in various media adds significant complexity to the design of instruments, the packaging and handling of reference materials, and the specificity of protocols. Determining the large number of risk-relevant properties of each nanomaterial-media system is time-intensive, and can only be made feasible through the development of high-throughput, high-content-generating instruments and protocols. Real-time, in-field testing of exposure media requires new instrumentation concepts and novel approaches to the development of protocols and reference materials. Significant efforts are needed for national and international harmonization and validation of measurement tools. Finally, greater collaboration between academia, government, and the private sector is essential to establish a comprehensive measurement infrastructure.

Lack of characterization could lead to different laboratories reporting discordant results on seemingly the same test material. For that reason good characterization, using a minimal characterization data set, should be applied in all studies.[36]

Regarding measurement methodology, the needs for reference materials and protocols are perhaps of greatest immediacy. Because the time and cost associated with certification of reference materials is quite high, there is a short-to-intermediate need for “study” materials that are designed for specific applications and well-characterized and widely available, preferably in a centralized repository. A database that includes all available measurement tools would be a valuable resource for all environmental, health, and safety assessments of nanomaterials.

4.b Human health

The potential health risk of a substance is generally associated with the magnitude and duration of the exposure, the persistence of the material in the body, the inherent toxicity of the material, and the susceptibility or health status of the person.

Manufactured nanomaterials can have varying chemical and physical characteristics and may be structurally and compositionally homogeneous or heterogeneous or even be multi-functional. All these can affect release, transport and deposition of nanomaterials in the environment and, therefore, their exposure potential. As the size of the particle is made smaller, a greater fraction of the atoms is at the surface, which can affect the surface reactivity and toxicological properties of the particle. At the same time, nanoscale particles have a tendency to agglomerate and form larger structures, which influences their dynamics in the environment and deposition on biological surfaces. Few data about the effects which size, agglomeration state and other physical-chemical properties have on the deposition and fate of particles in the human body are available for nanomaterials. Some data exist on dynamics of nanomaterials in the air, less is known about their dynamics in other media.

Exposure

Even though a number of case studies looking at exposure assessment for specific nanomaterials to workers, consumers, general population and the environment are underway, so far only a few workplace measurements of nanomaterial exposures and a few modeling studies of consumer exposures have been reported. Exposure assessment studies that have been conducted are frequently constrained by the absence of having a defined exposure metric (e.g. mass, particle number concentration, surface area) to measure exposures that correlate with evidence of a toxic effect. Interpretation of exposure measurements is further compounded by the presence of unintentional (i.e. not manufactured) nanoparticles from other sources (e.g. diesel exhaust, combustion products, electrical motors, photocopiers). Since unintentional nanoparticles can exist in a variety of shapes, sizes, and compositions, their airborne presence often interferes with the quantitative assessment of exposures to manufactured nanoparticles. The lack of an understanding of the toxicity mechanisms associated with specific manufactured nanomaterials confounds the ability to identify a specific exposure metric (particle dimension, size, and surface area) that can be used to assess the potential hazard of many nanomaterials. Therefore, multiple parallel measurements are recommended to characterize exposures to nanomaterials.

Exposure to nanomaterials can occur primarily through inhalation, skin contact and ingestion routes. The inhalation route is of most concern, especially in the workplace. In addition, some nanomaterials have the potential to cross biological membranes and distribute from exposure site systemically to interact with cells, nucleic acids and proteins in internal organs such as the liver, brain, spleen and kidneys. However, it is not well known how this translocation process may be influenced by the chemical and physical properties of the nanomaterials. It was shown that smaller nanoparticles which are deliberately stabilized to remain non-agglomerated in dispersions can penetrate intact skin, while mostly agglomerated and aggregated nanomaterials were unable to penetrate intact skin.

Potential effects on human health

Due to the relative novelty of many nanomaterials, biological dose-response data necessary for quantitative risk assessment is lacking for most nanomaterals. However, a large body of research

linking exposure to unintentional nanoparticles, which are often called “ultrafine particles”, can be used in the hazard assessment of manufactured nanomaterials. For example, the nanoscale fraction of air pollution was associated with lung and cardiovascular diseases. Experimental animal studies have shown that at equivalent mass doses, insoluble ultrafine particles due to their higher surface area per mass are more potent than larger particles of similar composition in causing pulmonary inflammation, tissue damage, and lung tumors. It is also believed that some respirable, biopersistent, long and rigid nanofibers may penetrate in the lungs which may ultimately result in mesotheliomas. This physio-pathological mechanism is commonly named the fiber paradigm and was derived using data for microscopic fibers such as asbestos fibers.

Despite a relative wealth of in vitro toxicity data for broad range of nanomaterials, paucity of data on actual human exposure levels, inadequate physical-chemical characterization of study nanomaterials and lack of validated and standardized toxicity testing protocols are an important limitation to the use of those data for hazard assessment. A comprehensive testing program for thirteen representative nanomaterials aims to fill in the gaps in our understanding of the nanomaterial hazard potential[37]

Initial experimental studies in cell cultures and laboratory animals have shown that the biological response to certain nanoparticles can be greater than that of the same mass of larger particles of similar chemical composition. In addition to the particle number and combined surface area, other particle characteristics may influence the biological response, including solubility, shape, charge and surface chemistry, catalytic properties, adsorbed pollutants (and other intentional and unintentional surface changes), as well as the degree of agglomeration.

In regards to mechanisms of biological activity of nanomaterials, a review of toxicological studies suggests that some nanomaterials could potentially:

- pose hazard due to dissolving ions (e.g. the toxicology of nanoscale silver due to silver ions) and due to their physical shape (e.g. toxicity of long, rigid fibers);

-act as carriers of other material due to high adsorptive properties, and therefore can deliver hazardous chemicals present in the ambient air to biological compartments which would otherwise not be accessible to those chemicals;

- exert biological activity through protein parts deposited on nanomaterial surface in biological environments; and

- exhibit immunological functions, genotoxic action, or catalytic potential.

Airborne particulate research involving sensitive and vulnerable populations has demonstrated differences in the uptake, metabolism, and excretion components of the exposure–response relationship that could shift risk management guidelines for particular populations. Therefore, human health research should examine impacts not only to healthy individuals, but also to vulnerable populations with acute and chronic disease, and developmentally sensitive populations such as embryos, fetuses, children, and the elderly.

A 2009 summary of available general national and international guidelines shows that under the conditions of the paucity of hazard and exposure data, most published guidelines adopt precautionary measures aimed at minimizing exposures to the extent technologically and economically feasible. [38]

Several tools have been developed which utilize generic risk evaluation and management frameworks and apply them to nanomaterials throughout their life stages. One such tool developed by the International Organization for Standardization (the Nanomaterial Risk Evaluation technical report) covers potential occupational, environmental and consumer risks during manufacture, use and disposal of nanomaterials.[39] This framework describes how a site specific risk management programme can be created by answering a series of questions aimed at identifying relevant information and therefore, it can be used as a tool to organize, document, and communicate what information the user has about nanomaterials.

While there has been progress in understanding human responses to nanomaterials, researchers have not yet achieved the critical data sets needed to understand fully the potential for exposure and develop science-based nanotechnology-related health and safety guidelines and support for regulatory decision making for all nanomaterials.

Understanding of physical-chemical property–response or dose–response relationships is essential for accurate, science-based decision analysis by regulatory agencies and development of robust predictive models that will improve nanomaterial design, maximize biocompatibility, and minimize adverse health and environmental effects. Activities in this area are underway.

Inherent in the life cycle concept and applicable to research on human exposures and health effects is the longitudinal examination of exposures to nanomaterials across life cycle stages from R&D to large-scale production, product incorporation, use, and disposal. Furthermore, research on human health effects often involves complex, interrelated concepts that are investigated most efficiently and effectively by research programs conducted in parallel rather than serially.

Development of Exposure Limits

Given the paucity of validated dose-response data for nanomaterials, presently there are practically no Exposure Limits (ELs) specific to nanomaterials that have been adopted or promulgated by authoritative standards and guidance organizations. The vast heterogeneity of nanomaterials limits the number of specific ELs that are likely to be developed in the near future, but ELs could be developed more expeditiously for nanomaterials by applying dose-response data generated from animal studies for specific nanoparticles across categories of nanomaterials with similar properties and modes of action.

Examples of this approach include occupational ELs for titanium dioxide and carbon nanotubes. Results from experimental animal studie$_s$ show persistent pulmonary inflammation and lung tumors for both microscale and nanoscale TiO_2 in which the dose-response correlated best with particle surface area.[40] These findings of pulmonary effects were consistent with data from other poorly soluble, low toxicity particles of microscale and nanoscale sizes. NIOSH recommended two mass occupational exposure limits for the two size fractions of TiO_2: 2.4 mg/m^3 for microscale particles and 0.3 mg/m^3 for nanoscale particles. A standard risk assessment model is used in the development of

these exposure limits which relies on animal toxicity data and modeling to translate those data into exposure limits. Since this risk assessment approach relies on animal toxicity data rather than observations of adverse health effects in people, it is suited for proactive risk assessment of other nanomaterials and facilitates introduction of anticipatory risk control measures.

NIOSH has extended the approach developed for TiO_2 to carbon nanotubes and nanofibres. [41] It uses benchmark dose modeling methods based on animal studies, which are translated into an exposure limit in the absence of data about adverse effects in workers. The proposed recommended EL for carbon nanotubes and carbon nanofibres of 7 $\mu g/m^3$ is constrained by the limitations in the sampling and analysis and thus the mitigation of risk focuses on the control of exposure to as low as practical.

4.c Worker-related issues

Workers are often the first and most exposed population group to emerging hazards. This is also true for nanomaterials. At each stage of their life cycle, nanomaterials can have different exposure potential to workers thus changing their occupational risk potential. Therefore, it is important to identify the life cycle stages and sources of nanomaterials where exposure to workers may occur (e.g. during research and development, manufacture, processing, use, 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 particle, particles encapsulated in a polymer), and the hazards of materials to which workers are potentially exposed.

There are no guidance documents available for assessing personal exposures of workers to nanomaterials and only a few national and international guidance documents on assessing emissions of nanomaterials in the workplace. One guidance document describes a procedure for the initial assessment to identify sources of emissions, and includes information on identifying potential sources of emissions, conducting particle number concentration sampling, and conducting filter-based area and personal air sampling.[42] This and similar techniques were used in several reported field studies, which demonstrated that nanomaterial emissions as well as exposures to workers do occur to varying degrees, and can be detected and quantified with this method. This technique was, for example, used to assess exposure to multi-walled carbon nanotubes (MWCNT) in several manufacturing facilities ranging in size from laboratory to large scale production. The study supports the notion that conventional exposure monitoring methods, such as personal and area sampling, combined with newly emerging nanoparticle measurement techniques can be very effective in measuring MWCNT exposure concentrations. Nanoscale and microscale particles were most frequently released after opening the reactor and during spraying, CNT preparation, and ultrasonic dispersion. In general, the highest potential for exposure exists when handling nanomaterial powders (especially spray applications) and friable nanomaterials or nanomaterial containing products. Some lower-cost real-time measurement techniques specific to certain nanomaterials have started to appear and will facilitate collection of exposure data. Emissions can be profoundly affected by many factors such as work practices and the presence/absence/effectiveness of engineering controls.

In the absence of occupational exposure limits for most nanomaterials, qualitative techniques aiming to facilitate the development of site-specific risk mitigation programs (often referred to as control banding) have been developed and are available as web-based tools.[43]

Precautionary measures aimed at minimizing exposures to nanomaterials in the workplace are widely adopted. For example, a 2010 compilation reviewed and summarized twenty specific nanomaterial guidelines relating to laboratories working with nanomaterials, fourteen general nanomaterial guidelines applicable to laboratories, and two general laboratory guidelines applicable to nanomaterials. [44] The surveyed guidelines agree on the majority of aspects of occupational risk assessment and management and exhibit only minor deviations. As an example, it is generally regarded as essential to use precautionary measures to minimize risk in laboratories. Further aspects, which are regarded to be essential, refer to the general application of risk assessment, use of safer manufacturing approaches, technical and organizational measures and personal protective equipment.

Research on designing out hazards and on the effectiveness of engineering controls and personal protective equipment to minimize potential risk of nanomaterials is increasing.[45] Specifically it has been reported that there are known methods to decrease toxicity, which can be used to modify some manufactured nanomaterials and which could lead to reduced risk in the workplace and to the downstream users. It has been shown that exposure mitigation techniques developed to reduce exposures to unintentional nanomaterials, such as those found in welding fumes and diesel exhaust, can be effective for manufactured nanomaterials. However, questions remain regarding the effectiveness of certain techniques for specific nanomaterials and processes. For example, dispersing nanomaterials in liquids does not necessarily reduce the potential for exposure to zero. It was shown that manufactured nanomaterials can become airborne when mixed in solution by sonication, especially when such nanomaterials are functionalized or in water containing natural organic matter. Most urgent research needs for protecting workers from potential risks of nanomaterials include developing real-time personal nanomaterial-specific exposure measurement techniques, collecting exposure data in workplaces, designing and implementing an epidemiologic strategy for studying nanomaterial workers, and validating the effectiveness of existing controls being applied to nanomaterial processes. Recommendations and guidance about prudent approaches to nanomaterial handling in the workplace aiming at low and medium-income countries are urgently needed.[46]

4.d The environment

Environmental hazard characterization is the first step in a process which also includes the eco-toxicity and environmental exposure assessments and which should lead to a risk characterization. However, it still has to be determined to what extent conventional methodologies for toxicity and exposure assessment which are applied for traditional chemical substances throughout this process, can be used for nanomaterials. Mass may not be the most important parameter that determines how the material acts or reacts. For example, the size of the nanomaterial, its shape, surface properties and chemical composition will also play a role. This could have implications for establishing dose-response relationships, which form the basis of making a quantitative risk characterization.

As regards exposure, releases of manufactured nanomaterials can occur at any stage during the product life cycle. Like for human health, exposure measurement and calculation is dependant of the metrology used. The physical-chemical properties of materials are often the basis for understanding how they will move, deposit, accumulate, and transform in environmental matrices under the often-changing conditions in which they may be released. These properties differ for thedifferent types of

nanomaterials, and therefore it will not be possible to make generic statements about nanomaterials. The well known models to calculate the distribution of a chemical over the environmental media may not always be applicable in a straightforward way. The behavior of for example fullerenes or nanotubes will be different than that of metals or metal oxides. Possible degradation of materials via biological and/or photochemical processes or contact with water may reduce environmental persistence and has to be taken into account in determining environmental exposure concentrations. Similarly the potential for bioaccumulation has to be considered. Much of the necessary information concerning these aspects is lacking.

For chemical substances there are generally more data available for human health than for environmental hazard assessment. This is also the case for nanomaterials. In a regulatory context, information on the effects of chemicals in the environment are most commonly derived from tests done with aquatic organisms (fish, crustaceans, algae) or terrestrial organisms (earthworms, plants, bacteria). Such effects again tie back to fundamental physical-chemical properties, as well as to a host of other factors such as exposure route, possible metabolism in the organism, and the sensitivity of the species. Testing for adverse effects should consider not only the parent nanoparticle, but also transformation products and other toxic chemicals associated with nanoparticles in the environment. Fate and transformation of nanoparticles can be assessed in microcosms and/or mesocosms. To understand ecosystem-wide effects, the sources (production/use/disposal), the pathways and the key environmental receptors need to be understood. Over recent years increasingly computer models involving (Quantitative) Structure Activity Relationships – (Q)SARs – have been used for traditional chemicals to estimate data on environmental effects, biodegradation or bioaccumulation. In 2004 was still not clear to what extent these (Q)SARs could be used to estimate similar data for manufactured nanomaterials.[47] However, since then much research in this field has been ongoing and examples of the use of (Q)SARs for making estimations regarding properties of nanomaterials have been published.[48]

Technical barriers impede progress in research on environmental fate and effects of nanomaterials. Methods or approaches must be developed to identify, characterize and measure exposure to nanomaterials, and to follow their path and transformation through the environment and accumulation in organisms. Improved models for predicting environmental release and exposure to nanomaterials require more empirical data and mechanistic understanding of processes. Research on environmental transport is hampered by limited understanding of particle coating chemistries and formulations used for consumer product applications, and limited analysis of sources that may release nanomaterials, such as industrial point sources and consumer non-point sources.

A very extensive report entitled “Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES)” has been prepared by five European scientific institutes in the context of the 7th Framework Programme for Research of the European Commission was published in 2010.[15] This report also addresses environmental exposure, fate and behavior and eco-toxicity. With regard to this area a main conclusion is that more research needs to be done to get full insights in the environmental safety on nanomaterials, particularly in the mechanisms of toxicological action. The report mentions that technical problems associated with testing in the aquatic environments, such as dissolving the materials which are to be tested, need to be addressed with priority. It also identifies a lack of knowledge about degradation and accumulation of nanomaterials. While on the one hand

most toxicity tests which have been done are short-term tests, rather than long term tests, the reports also notes that on the other hand the doses which are used, are often much higher than is environmentally realistic. Since the eco-toxicological testing of nanoparticles is only in the beginning, such type of information is, however, considered valid for risk assessment purposes in terms of ranking and benchmarking. It is also emphasized that no studies are as yet available to support extrapolation of effect levels from laboratory tests to environmental scenarios.

4.e Research on human health and environmental impacts

Much research on the applications for nanomaterials, including those with health and environmental benefits, is going on. Many countries have research programmes which receive considerable government support. In such programmes the part devoted to research on the health and environmental safety aspects of nanotechnologies ranges from 4% to 6%. The US National Nanotechnology Initiative has recently been increasing the level of research on health and environmental safety.[49] Also the European Commission, in the 7th Framework Programme for Research, addresses a wide range of issues related to health and environmental safety. An overview of research activities related to nanomaterial health and safety can be found in the OECD Database on Research into the Safety of Manufactured Nanomaterials. [50] This database includes over 800 current and past projects related to Environment, Health and Safety research in OECD member countries and in non-member economies. This database is connected to similar databases of the International Council on Nanotechnology and the US National Institute for Occupational Safety and Health.

As the use of nanomaterials increases rapidly, it is of vital importance that the risk assessment community understands the complexities of the issues surrounding the manufacture, use, and disposal of nanomaterials, the potential of environmental and occupational exposure to human populations, as well as potential adverse health outcomes. For this to happen, it is necessary for the scientific community to understand the needs of risk assessors for information used in risk characterization, and which research will provide that information; in addition, researchers need to know the decision contexts within which their research findings will be applied. Risk management of nanomaterials requires also more information about the human and ecological effects of exposure to a variety of nanomaterials.

The research needs in relation to health and environmental safety cover a variety of fields: metrology and detection, health impacts, environmental impacts, human and environmental exposure assessment and risk management methodology. An important starting point for the health and environmental safety management is the safety testing. It is at this moment not clear to which extent the classical tests which are carried out in this context for traditional chemicals can be applied to nanomaterials. A programme aimed at answering this question is organized by the OECD and is sponsored by its member countries and by non-member economies and industry.

A list of 13 representative manufactured nanomaterials has been selected for use in this programme. The list includes fullerenes, nanotubes, metals, metal oxides, dendrimers and nanoclays, and forms a set of reference materials to support research related to measurement, toxicology and risk assessment of nanomaterials. The manufactured nanomaterials on the list have a practical

significance, because they are already on the market or will soon enter into commerce. These nanomaterials will be studied with the current methods for testing for physical-chemical properties and material characterization (17 endpoints), environmental degradation and accumulation (16 endpoints), environmental toxicology (7 endpoints), and mammalian toxicology (9 endpoints). Details concerning this Sponsorship Programme can be found on the OECD website.[51]

A preliminary review of testing related to physical chemical properties (including material characterization) concluded that 4 of the 22 test guidelines for physical chemical properties are applicable to nanomaterials.[34] 16 guidelines might be applicable under some circumstances or to some classes of nanomaterials. Two guidelines are not applicable to nanomaterials or, if applicable, provide no useful information. 13 of the 22 guidelines require further assessment before modifying these guidelines. With regard to mammalian toxicity the preliminary conclusion is that most of the 52 test guidelines are applicable for investigating the health effects of nanomaterials, but that in some cases, a specific modification will be needed. In all cases, 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 of 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 nanomaterials. Some of the test guidelines for degradation and accumulation were found not to be applicable for testing of nanomaterials. Many of them are applicable with limitations or specific conditions. In general it was confirmed that for toxicity testing the key issues are sample preparation and dosimetry; these need priority attention for development of guidance.

In many countries and on behalf of the European Commission, intergovernmental and international organizations, scientific committees or advisory groups are considering how best to deal with the health and environmental safety aspects of manufactured nanomaterials. An overview of these activities can be found at the OECD website under Current Developments on the Safety of Manufactured Nanomaterials.[52]

4.f. Information management

Databases

Global exchange of information about hazardous properties of chemical substances is extremely important and is facilitated by a number of international and intergovernmental organizations such WHO (the INCHEM database) [53] and UNEP. [54] In addition, many national governments and regional organizations have databases with hazard related information on chemicals. The eChemPortal allows the simultaneous search of 23 databases of the participating organizations and countries. [55] UNEP also supports the Chemical Information Exchange Network (CIEN), which builds on a UNEP/US-EPA partnership to provide electronic equipment and training to government agencies, thereby enabling access of chemical information on the Internet.[56]

Improved data sharing is a crucial need to accelerate progress in risk characterization of nanomaterials for regulatory purposes. This would involve the removing of the barriers presented by

the current “siloed” data environment and providing semantic search and sharing of data and models, and web-enabled tools for rapid initiation of collaboration across disciplines. This would enhance the ability to gather information regarding similar and different nanomaterials, structures, environments, mechanisms, and pathways. One of the main outcomes of establishing such a collaborative informatics infrastructure would be the development of computational models of nanomaterial structure-property-activity relationships to support the design and development of nanomaterials with maximum benefit and minimum risk to humans and the environment. Such models would also facilitate anticipatory risk management of nanomaterials.

In light of this, an effort to ensure that information relevant for the risk assessment and management of manufactured nanomaterials would be worldwide easily available and accessible, would be of great use. This could be done by setting up a portal for such information, possibly organized in the IOMC context, maybe following the model of the eChemPortal. Similarly it would be helpful if an international clearinghouse function could be created where national and regional risk management measures would be collected.

It has also been suggested that, in the context of risk management, a government register of products containing manufactured nanomaterials would be useful as a precautionary tool. This is further discussed under section 4.g.

Hazard communication

Classification and labeling of hazardous substances is conducted according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). [57] The GHS ensures that information on chemical hazards – through labels and safety data sheets – is made available to workers, farmers and consumers in a harmonized and comprehensible format in countries around the world. It is an important tool that countries can draw upon as a basis for the establishment of sound national chemical safety programmes. The GHS covers all hazardous chemicals and also applies to nanomaterials to convey information about hazardous nanomaterials. At present nanomaterials should be classified based on available information of their hazards from manufacturer pre-marketing testing, the publicly available information from the sponsorship programme or from the literature using the current classification criteria of the GHS. Criteria which are specific for nanomaterials need to be developed as soon as possible.

The main tools of chemical hazard communication within GHS are labels and safety data sheets (SDS) that contain the hazard information in the form of hazard pictograms, signal words and other communication elements. The aim of these tools is to provide hazard information in a comprehensible form for chemicals that may constitute a health, property or environmental risk during normal handling or use. Safety Data Sheets communicate hazard information to take into account during manufacture, storage, transport or other occupational handling activities. With respect to their use, a precautionary approach is recommended until hazards of nanomaterials are fully known given that there is increasing evidence that some nanoscale materials have different hazard profiles from the bulk materials with the same chemical composition. [58] This precautionary approach would include a number of information items as additional (non-mandatory) parameters to be reported in Safety Data Sheets for nanomaterials. For example, a draft ISO Technical Report 13329

"Safety Data Sheet (SDS) preparation manufactured nanomaterials" recommends stating that the material is a nanomaterial, identifying the surface modification of nanomaterials, indicating risk mitigation measures specific to nanomaterials and characterizing additional physical-chemical properties.

Given the progress in developing guidance for preparing SDS for nanomaterials in other international organizations, the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals in its report of the 18th session held on December 9-11, 2009 stated that "…noting that work on different aspects of nanomaterials was currently being performed at international level (e.g. European Union, OECD, ISO Technical Committee 229), the Sub-Committee decided to postpone the consideration of this issue until more information about their intrinsic properties and characteristics was available" .[59]

4.g Risk management across the life cycle

The term "manufactured nanomaterial" includes a wide category of nano-substances with very different structural characteristics, such as fullerenes, carbon nanotubes, metals or metal oxides. The structure plays, in addition to chemical properties, an important role in determining the hazard characteristics.[60] This is not a new finding, because it is well known that for asbestos its structure is the key factor in determining its hazards. In the discussion about the possible risks of nanomaterials, the resemblance in the structure between asbestos and carbon nanotubes has been one of the early concerns.

Risk assessment involves the application of analytical tools, data, and expert knowledge for the evaluation of the potential exposure of humans and the environment to nanomaterials and the hazards that exposure might engender. Risk management methods for nanotechnology identify and implement strategies to address potential hazards. Nanomaterials are produced through the use of a new technology, which means that at the moment there is still a lack of good quantitative information for each specific substance. This means that the spectrum of possible responses to controlling nanomaterial exposures ranges from, at one end, the full application of the precautionary approach, which could be considered as inaction with respect to advancing a new technology, to inaction regarding the management of the health and environmental safety aspects while developing novel materials, at the other end. The former is typified by an assumption that new materials are highly hazardous until proven otherwise, while the latter assumes the inverse: negligible hazards until proven otherwise. Both extremes disregard risks of conventional technologies such as existing chemicals that nanomaterials are replacing. Of course there are intermediate approaches within this range.

Precaution

Early indications suggest that biological activity of some types of nanoparticles might not be mass-dependent, but dependent on physical and chemical properties, such as chemical composition, size, shape, crystal structure, surface area, surface chemistry, surface charge, solubility, and adhesion. This makes it difficult to identify the key characteristics – or combinations of key characteristics – that are responsible for hazards described in (eco)toxicological studies of these nanoparticles.

Additionally it remains unclear whether a 'no effect threshold' can be established, what the best hazard descriptor(s) of nanoparticles are and what the most relevant endpoints might be.

To be able to fully assess the potential impact of a particular nanomaterial, it is necessary to have information on the entire lifecycle of nanomaterials, for example, precise levels of nanomaterial production levels and nanomaterial-based consumer products on the market, air and water emissions of nanomaterials, the uses of nanomaterials for wastewater treatment, amounts and types of nanomaterials discharged into landfills, waste storage, and waste treatment facilities, size of accidental releases of nanomaterials, and intentional uses of nanomaterials for environmental remediation and treatment. Such information is not always available.

As a result of the lack of data, establishing dose-response relationships in risk assessment currently holds a number of important limitations; and moreover, different from conventional toxicology, a mass-based dose metrics might not be toxicologically relevant for many nanomaterials. In light of such incompleteness of information on possible hazards and exposure, it is considered that it is not possible to make a full hazard characterization and that therefore precaution should be applied. This could include considering concepts like:

- Prevention - a duty to prevent rather than to control;
- Polluter Pays - place the burdens on all parties responsible for, or benefiting from, polluting activities;
- No Regrets - favor options that simultaneously satisfy economic, environmental and wider criteria and consider the availability of technical alternatives;
- Clean Production - adopt only those technologies which are demonstrably of lowest impact;
- Biocentric focus - recognize the intrinsic value of non-human life and recognize the vulnerability of the natural environment;
- Limited knowledge - acknowledge the limitations of science, our knowledge and the possibility of surprise;
- Uphold the rights of those who are adversely affected by technologies.

Risk assessment and management methods in use

While precaution is one risk management concept, another approach is to apply to the extent possible the experience obtained with managing the uncertainties surrounding the application of any new technology through technology assessment and the knowledge and science obtained in dealing with the safety of traditional chemicals.

New technologies have been introduced in the past many times, and usually there are to some extent concerns about uncertainties regarding the safety of the technology. Technology assessment investigates the use of new technologies within their societal context. Analyses provide the basis for developing technological and organizational design alternatives and regulatory measures which may be required. The overall aim is to foster a development which is balanced for society and the environment, and which maximizes societal benefits from technological progress while avoiding negative impacts.[61] Some of the major fields where technology assessment has been applied are : information technology, hydrogen technologies, nuclear technology, molecular nanotechnology, pharmacology, organ transplants, gene technology, artificial intelligence, the internet and many

more. Well established methodologies for technology assessment exist and have been the basis of dealing with the uncertainties regarding the safety aspects which a new technology might bring with it.[62] [63] Such methods could also be relied upon for addressing the possible risks of nanotechnology in a generic way.

There is a wealth of knowledge available regarding the assessment of possible health and environmental effects of traditional chemicals and exposures. While it is clear that this cannot all be transposed directly to nanomaterials, in many cases the robust methods applied for traditional chemicals will be of use and there is a lot of expertise available to consider when these methods can be applied and when not. For example, countries like France, Germany, Switzerland, the UK and the US, and the European Union have all published reports dealing with (aspects) of the safety of manufactured nanomaterials. [64] [65] [66] [67] [68] [69] [70] [71] [72] [73]

An effective risk management framework involves the use of all relevant information to guide science-based, risk-based management decisions. The risk assessment process incorporates the best available data on the potential health effects of a nanomaterial and the exposure potential to humans and to the environment. The quality of the results of the studies and data obviously determines the reliability of risk estimates. Risk management aims to quantify risk to the extent possible. It:

- employs basic scientific information;
- uses comparative risk assessments for different nanomaterials with different properties, applications, or intended uses that can affect effects and exposure, and result in different risk parameters and decision making;
- integrates life cycle considerations; and
- considers ethical, legal, and societal implications (ELSI) such as stakeholders' values, communication needs, and other aspects of decision analysis; risk research will play an important role in understanding these factors and integrating them into an effective risk management scheme.

Obviously further research is needed regarding the specificities which nanomaterials present compared to traditional chemicals. Several scientific bodies have looked at the applicability of the methods used for risk assessment and management of traditional chemicals to nanomaterials. For example, the Scientific Committee on Emerging and Newly-Identified Health Risks of the European Commission concluded with respect to nanomaterials:

"While risk assessment methodologies for the evaluation of potential risks of substances and conventional materials to man and the environment are widely used and are generally applicable to nanomaterials, specific aspects related to nanomaterials still require further development. This will remain so until there is sufficient scientific information available to characterize the harmful effects of nanomaterials on humans and the environment. The methodology for both exposure estimations and hazard identification needs to be further developed, validated and standardized. The highest risk, and thus concern, is considered to be associated with the presence or occurrence of free (non bound) insoluble nanoparticles either in a liquid dispersion or airborne dusts." [33]

An FAO/WHO Expert meeting on the application of nanotechnologies in the food and agriculture sectors concluded that:

"The current risk assessment approach used by FAO/WHO and Codex is suitable for engineered nanomaterials in food and agriculture, including the effects of engineered nanomaterials on animal health. FAO/WHO should continue to review its risk assessment approaches, in particular through the use of tiered approaches, in order to address the specific emerging issues associated with the application of nanotechnologies in food and feed." [74]

The Scientific Committee of the European Food Safety Authority considered that:

"The risk assessment paradigm (hazard identification, hazard characterization, exposure assessment and risk characterization) is applicable for enineered nanomaterials", and it adds that "the specific properties of the engineered nanomaterials in addition to those common to equivalent non-nanoforms" should also be considered.[75]

More information can be found in the OECD Report of the workshop on risk assessment of manufactured nanomaterials in a regulatory context.[76] In summary, as regards the application of the risk management methods used for traditional chemicals to manufactured nanomaterials, it is considered by many scientists that the current frameworks are in principle adequate and appropriate for dealing with manufactured nanomaterials, but that more research is needed to get a better insight into those aspects in which the methodology has to be adapted for nanomaterials risk management, and in the possibilities to quantify the risks. At the moment therefore often a case-by-case evaluation has to be relied upon, and on qualitative outcomes when risk quantification is not possible. In those cases where an unacceptable level of uncertainty or concern is identified, precaution is applied.

ISO has prepared a Nanomaterial Risk Evaluation Framework which builds on the Nano- Risk Framework developed by a Nano-Partnership of the Environmental Defense Fund and Dupont.[39] [77] It includes six steps:

1) Describe material and application
2) Material profiles
3) Evaluate risks
4) Assess risk management options
5) Decide, document and act
6) Review and adapt

Lifecycle and waste management

A life cycle approach involves the application of the cradle-to-grave life cycle perspective to chemical design, manufacture and use, with the aim to manage potential risks of exposure. It addresses the sustainability aspects of the chemical throughout the life cycle and analyzes at what points in the life cycle, what types of vulnerabilities to man or the environment can be identified, and what these

vulnerabilities—when coupled with potential impacts— mean for the estimation of risks posed by a material.

To develop scientific information that leads to improved understanding of how to better create and manage nanomaterials, three important considerations must be addressed: the nanomaterial life cycle, inherent material properties, and sustainability. Changes in any of these three dimensions changes the potential of the substance to produce environmental impacts throughout its life cycle and affects sustainability metrics, such as eco-efficiency (i.e. the ratio of value delivered to resources consumed).

Investigating environmental sustainability involves three principal dimensions: what the nanomaterial is; how it is made; and how it is used. Two main aspects of sustainability can be identified: the consumption of environmental resources, including materials, energy, water, and other ecosystem services; and the effects of emissions, use and the generation of waste on human health and the environment. For example, one question could be whether the use of toxic starting materials is really necessary in making a particular nanomaterial if less-toxic starting materials are available. If alternative starting materials are not available, it could be investigated whether there are aspects of the current synthesis process that could be changed to mitigate the impacts of toxic inputs into nanomaterial synthesis and production. This is the approach known as green chemistry. Another question relates to the use of a raw material feedstock that requires a significant input of water and energy. Possibly an alternative feedstock could be identified which has a smaller environmental "footprint" in terms of carbon emissions and resource consumption.

A full understanding of sustainability requires accounting for these environmental impacts over the full life cycle of a nanomaterial, including resource extraction, transport, production, incorporation into products, product distribution and use, and eventual disposal or recycling of the product and its constituents. Moreover, it is important to understand the potential positive and negative social and economic implications of the nanomaterial life cycle, including issues such as environmental justice and competitive advantage.

Each point in a nanomaterial's life cycle presents an opportunity to avoid or otherwise address concerns about possible impacts. One should consider the decision context for nanomaterials from the perspective of risk prevention for new nanomaterials and risk management for existing nanomaterial. Approaches such as green chemistry may be feasible for decision making on either existing or new nanomaterials, but they may have greater advantages during design or development phases. When green chemistry approaches are not viable, the only way to mitigate impacts from some existing and new nanomaterials will be through risk management and applying controls.

Risks for human health from exposures at the work place or during use, and risks to the environment resulting from direct releases during production and use, have been addressed above. The waste management of nanomaterials is an aspect that needs further consideration. During all phases of the lifecycle nanomaterials can end up in waste. For waste generated through research and production (industrial waste) often classification systems exist to indicate the degree of hazard such waste represents. Such a classification could be applied, where possible, to nanowaste and the waste could be treated according to the hazard category. For example, Switzerland divides the industrial waste into non -hazardous waste (which can be treated as municipal waste) and hazardous waste (e.g. CNT)

which will be treated as special waste and will be exported only according the rules of the Basel convention.

The nanowaste resulting from disposal of products is very diverse and will normally end up in the municipal waste, unless, like is done for some types of waste, such as batteries, pharmaceuticals, pesticides, paints or electronic equipment, special collection regimes are established. Characterization of products which would require such special collection regime because they contain a nanomaterial which is considered as hazardous, needs to be further developed. Several existing general environmental policy concepts, such as Environmentally Sound Management of waste and Extended Producer Responsibility, could also be applied to the management of waste containing nanomaterials.

Paying attention to the management of waste containing nanomaterials is particularly important for developing countries and economies in transition. According to a report from South Africa there are a number of challenges in this field, particularly for developing countries. [78] The first is that waste management practices in many developing countries are inadequate for conventional and hazardous waste streams generated from manufacturing, commercial mining, agricultural and domestic activities. This results from inefficient waste collection systems, inadequate waste transfer systems, institutional under-capacity and poor disposal practices. Secondly, there is often inadequate availability of human skills in the field of waste management. A third challenge the report mentions is that many developing countries have weak policy and legislative frameworks for addressing industrial and municipal waste.

In view of the fact that the infrastructure for waste management is different in each country, engaging at the national level in a pro-active policy approach, bringing together government, industry and other stakeholders, could help to avoid possible problems when the amount of products containing nanomaterials put on the market will be increasing. According the South African report this could involve investigating the potential risks of waste containing nanomaterials which are in use in the country, applying a classification system, and setting up effective monitoring mechanisms in a format that can be easily presented to policymakers, to allow them to take necessary regulatory action. For the international aspects it might be timely for countries to discuss what should be done in the framework of the Basel Convention.

Regulatory aspects

Currently no countries have specific legislation in place to deal with the safety of nanomaterials. An overview of how countries deal with the regulatory aspects can be found in the Report of the questionnaire on regulatory regimes for manufactured nanomaterials of the OECD prepared in 2010.[79] None of the countries in the survey reported to have legislation specific to nanomaterials. Dealing with these materials is integrated in the existing regulatory framework. Combinations of existing legislations are used as regulatory instruments. The general policy is to use available provisions, such as REACH in Europe, and the Toxic Substances Control Act in the US, and follow a

precautionary approach. A variety of specific attributes to deal with the specific aspects of nanomaterials in these existing legislations has been developed. Countries are also considering integrating nanomaterial management in their National Profiles for chemicals management.

Many countries have voluntary information collection systems in place, whereby industry provides information relevant for the understanding of potential risks. Depending on the country, information is received from several of the players and concerning various stages of the life cycle. It includes: research and development, manufactures (in all cases), processors, importers, placing on the market, users and waste processors. Information on such schemes can be found in the Analysis of information gathering initiatives on manufactured nanomaterials, prepared in 2009 by the OECD[80], and in papers prepared for the Directorate-General of Environment of the European Commission for a project on Information from Industry on Applied Nanomaterials and their Safety.[81] In the OECD report it is suggested that consideration should be given to supplementing voluntary initiatives with mandatory reporting.

At the 5th International Nano Authorities Dialogue among Austria, Germany, Liechtenstein and Switzerland, the establishment by governments of a "nanoproduct register" was discussed. It was considered that providing information to the government about the presence of certain ingredients in a product could serve, in case of an incident, to provide precise information about the formulation of a product; this information would not be publicly accessible. In this way uncertainties regarding potentially hazardous properties of products could be minimized at the level of risk assessment and risk management of the products or their ingredients. The dialogue was of the opinion that a nanoproduct register should not be used to establish particular hazard labeling for "nano". The dialogue mentions that it should thus be ensured that the reason for a nanoproduct register is not because "nano" is particularly hazardous.

The workplace is the first place where people get into contact with manufactured nanomaterials and risk would be first met. The application of occupational risk management measures is considered by many countries (see section 4.c). Control banding might be a promising method to also use for nanomaterials. OECD has prepared overviews of what is in place regarding exposure in laboratories, the identification of sources and releases of airborne manufactured nanomaterials, exposure assessment and mitigation and selection of skin protective equipment and respirators. [82] The inclusion of specific nano-related information in Safety Data Sheets is a further important tool to protect workers and industrial users from possible risks of nanomaterials. In the development of measures regarding the occupational health aspects of nanomaterials, it is good practice to consult with workers and their representartives.

As regards consumers, from the NGO side the use of a "nano" label on products containing nanomaterials has been proposed, in order to, promote transparency for the public. Others have argued, however, that the public is used to labeling which indicates hazardous properties and, because many products containing nanomaterials would not necessarily be hazardous, a label with such generic information would cause confusion. Because a Globally Harmonized System of classification and labelling of chemicals (GHS), which provides information related to hazards, is in use, the better option might be to ensure that the GHS is used to put hazard labels on products for

which this is applicable. Obviously specific criteria to take into account the special properties of nanomaterials would be needed. It would therefore be good if the UN Committees of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals would consider initiating in the near future work to develop such criteria.

At the international level already a number of Conventions exist which address the safety of chemicals or waste (Rotterdam, Stockholm, Basel) or the provision of environmentally relevant information (Aarhus). In light of the national risk management practices, where consideration of the safety of nanomaterials is incorporated in existing frameworks, it might be more efficient for the Conferences of Parties of these Conventions to see how they can be used to incorporate, within their general mandates, elements about the safety of nanomaterials, rather than developing specific nano-related international instruments.

In general, civil society organizations are rather critical about the way riks of nanomaterials are currently being managed. They generally ask for initiatives aimed to deepen and answer scientific and technical issues and to clarify regulatory aspects of nanotechnologies. Some of them require the application of a strict precautionary approach. Their request is to require scientific evidence on safety, to have adequate regulatory instruments in place and to have possibly agreement on the way ethical and social concerns will be addressed prior to commercialization. This is elaborated in reports and at websites of civil society organizations such as ETC, Friends of the Earth and IPEN. [83] [84] [85] [86] [87] [88] [89]

5. ECONOMIC AND SOCIAL IMPACTS

New technologies have been coming to the market all through human history. This has always had economic implications in the market. Sometimes there are situations where all players win, but often there will, in addition to the winners, also be some losers. While on the macro-scale a technology could be beneficial for society, at a more micro-scale there are social implications to consider. This could for example concern changing employment perspectives, necessary training of workers and education of consumers. In view of the globalized economy, such issues will not only play at the national level, but impacts should be considered in a global context. Nanotechnology should not be seen alone, but as one of the elements of the so-called Converging Technologies which are widely seen as the vehicles for future improvement of human performance: information technology, biotechnology, nanotechnology and cognitive science.[90]

The social context

With the development and introduction of nanotechnology, obviously similar considerations as for other new technologies will play a role, including the question of social utility. To answer that question the potential contribution of specific applications from nanotechnologies to solve specific socially relevant problems such as climate change, water shortages and increasing food production should be analyzed. Health and environmental risks and implications for society and economy should be taken into account as well as existing alternative solutions. The merits of particular options may be specific to particular countries or regions.

Technological innovations, including their implications for the labor market, are always difficult to forecast, especially in the current globalized economy. The creation of new companies, or the diversification of established ones towards businesses that incorporates nanotechnology, will eventually affect the labor market. An early forecast suggests that 2 million new nanotechnology related jobs could be created globally by 2015. [21] More analysis will be needed to develop estimates which can show a higher level of reliability. However, in any case a certain reallocation of jobs over different sectors can be expected; the exact extent of this has to be monitored carefully in order to develop the appropriate skills for responding to the adaptations in the labor market. In this respect short term as well as long term visions for an employment and education policy would be needed. There is a responsibility for government, employers and trade unions to establish and support a skills development system that is responsive to the needs of employers as well as workers. It should be ensured that training facilities have timely and adequate capacity.

Another social issue is related to the question is the extent to which a new technology will benefit all layers of a society. At the global level the same issue applies to the variety of countries with different levels of economic advancement. While overall arithmetic can show positive results, care should be taken that all can benefit from this and not selected groups. There is a concern that job losses which could be brought on by changes in the commodity market will hurt the poorest and most vulnerable, particularly those workers in the developing world who do not have the economic flexibility to respond to the demands for new skills. Public dialogue based on adequate communication will be an important element to help develop policies which will deal with the social aspects of nanotechnology introduction in a balanced way.

The economic context

Nanotechnology is often presented as having the potential to produce considerable economic benefits. However, potential risks for human health and the environment, if not adequately managed, might lead to hidden costs for society, which should be taken into account when considering the claim of potential economic benefits. On the other hand there is an expectation that technological innovations, including those resulting from nanosciences and nanotechnologies, can play a key role in promoting a more efficient use of our resources. Natural resources are an important factor in the economy and an important element of our welfare. The way in which we use available natural resources also has effects on our health and on the environment.

For the many developing countries, commodity production is the backbone of their economy. Historically, advances in science and technology have also had important impacts on commodity production and trade. There are concerns that nanotechnology will change the commodity markets, disrupt trade and eliminate jobs. Commodity dependent developing countries must gain a fuller understanding of the direction and impacts of nanotechnology-induced changes in the economy, and, where needed, be supported in determining how nanotechnology and other converging technologies could affect their futures, and in developing responses to sustain their economies.

Currently, nanotechnology innovations and intellectual property protection are being driven mainly by research undertaken in developed countries. The world's largest multinational companies, nanotechnology start-up companies and academic institutions are seeking intellectual property on novel materials, devices and manufacturing processes. The rate of nano-patenting has increased

considerably. This has led to a concern which has also been voiced during the introduction of other new technologies, which is that in certain cases patents are sought which are unnecessarily broad, which hinders progress with further innovations for useful applications in fields close to the application for which the patent has been acquired. Avoiding such practices becomes particularly important when it touches on fundamental sectors like food, agriculture and medicine.

Socio-economic analysis and risk management

Integrating socio-economic analysis (SEA) in chemical risk management decision making has a long tradition. Socio-economic analysis can help to determine whether risk reduction measures which are under consideration, are necessary or desirable. It addresses questions such as:

- what are the different regulatory or non-regulatory options for reducing the risks identified through risk assessment?
- what will be the benefits of risk reduction?
- who will be impacted by the each of the options being considered?
- what will be the costs of implementing each of the options?
- how will such costs be distributed?
- what is the cost/benefit ratio of the options under consideration?

The principles of SEA developed for chemicals risk management can also be applied - mutatis mutandis – to manufactured nanomaterials. In the context of risk management of chemicals a number of methodologies for socio-economic analysis exist, and when adequate information is available, many of them can also be applied to manufactured nanomaterials. For example, SEA guidance documents have been produced for the implementation of the Stockholm convention[91] and by OECD.[92]

6.ETHICAL ISSUES

Ethical issues related to the introduction of nanotechnology have been widely discussed, for example by UNESCO in a report and a book on the ethics and politics of nanotechnologies [93] [94] , in the EU context[95] and in the US National Nano Initiative.[96]

Avoiding a possible “nano-divide”

Nanotechnologies are expected to have considerable effects on economies and societies worldwide. However, there can be positive and negative effects and it has to be considered how the various effects will be distributed across the world. There is a concern that the distribution will be unequal and particularly, that developing countries may benefit much less from the achievements of nanotechnologies – just as they have not benefited in an equal way from other technological achievements. As a result, the technology gap between the advanced and less advanced economies may widen even further. At the same time there is a concern that developing countries will suffer more from potential risks of the introduction of nanomaterials (e.g. occupational health and safety standards may be lower, waste management and waste disposal infrastructure may not be adequate

for nanomaterials and nanomaterials containing products). The potential for nanotechnology to widen existing economic inequities – a "nano-divide"- is a therefore a significant issue. This underscores the importance of carefully evaluating nanotechnology's potential social and economic costs, alongside potential benefits.

Avoiding a nano-divide would be particularly important in the case of products containing nanomaterials that can help to meet basic needs. Basic need products should not be inaccessible to those in need because they are too expensive. An example could be nanofiltration systems for water purification that can help to address the need for clean drinking water. Every human being has the same justified claim to have his or her basic needs fulfilled. Justice here implies strict equality. Considerations regarding other types of products containing nanomaterials, for example those that are not used to address basic needs, could be different.

Nanotechnology research in developing countries may not be able to compete with research in fully industrialized countries. As a consequence, these countries may not be able to develop products such as nano- filtration systems that could be important in order to meet the basic needs of their population. They would then depend on those who do have the means to develop products of this kind. These products, however, may be put on the market at prices which are not affordable for all, not least because of licensing fees due to patents. If something like this would happen, it would be a step towards a 'nano-divide' that would be unjust. Excessive patenting of manufactured nanomaterials may have negative effects on the use of such products in developing countries. Nanotechnology research that could benefit the poorest, for example research on applications that could address the Millennium Development Goals, should be promoted and made available at affordable prices.

Application of precaution

In 1992, in the Rio Declaration, the application of precaution was laid down in Principle 15:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

In the context of the risks of nanomaterials, two aspects could be considered, one related to generic risk acceptance, and another one specifically related to the state of science concerning the safety of nanomaterials. This would involve consideration of the criteria for the acceptability of risks of serious or irreversible damage, and of the kind of precautionary measures which would be sensible, given that there are gaps in our knowledge of the risks associated with manufactured nanomaterials.

As regards the criteria for the acceptability of risks, basically two risk criteria are often mentioned. In the first place, there is a duty of care according to which risks of an activity should be reduced to a point where the occurrence of harm is not to be expected (deontological criterion). Requiring zero risk, however, cannot be justified since this would make social life impossible. That is why societies agree on a normative threshold. Risks exceeding this threshold are prohibited, while risks below the

threshold are considered acceptable. The main idea underlying the other criterion is that there is a duty to maximize expected net benefit (utilitarian criterion). There is an obligation to choose the activity with the highest expected net benefit. When following a utilitarian approach, there is no normative threshold.

There is an ongoing debate as to which criterion is the more plausible one. Depending on which criterion is preferred the risks associated with nanotechnology and manufactured nanomaterials may be regarded as acceptable or inacceptable, albeit for different reasons. However, these criteria are only applicable if the risks can be determined quantitatively or qualitatively. Here is where science is expected to provide insights for the political decision makers. Where possible a science-based approach could be followed, which would ensure a certain level of objectivity as the basis for risk management decisions, rather than for example political or trade interests.

As far as manufactured nanomaterials are concerned, following a full science-based approach will still not be possible in many cases due to a lack of sufficient scientific knowledge regarding the possible harm they may cause and the probability that this harm will occur. Yet there is not a situation of complete ignorance, either. Initial toxicological tests and the experience with the toxicological profiles of related materials can give certain indications about which manufactured nanomaterials may cause serious harm to humans and the environment, if inappropriately used through their lifecycle. In this situation the question arises what should be done with regard to the risk management of these materials.

Concerning this question one finds, roughly speaking, two opposing views in current literature:

- There are those who argue that, although some indications of the risks of some manufactured nanomaterials for humans and the environment can be recognized, there is no reason to assume that these risks are of a kind that would justify the application of the strong precautionary approach, especially the reversal of burden of proof. That does not mean that the production and utilization of manufactured nanomaterials for commercial or scientific purposes does not require any kind of precautionary measures. For instance, requiring producers of nanomaterials and products containing free manufactured nanoparticles to carefully analyze the risks associated with these materials or products and communicate the findings, and requiring them to reduce the exposure in the workplace as much as possible would be perfectly warranted.

- There are those who claim that for the time being at least the use of free manufactured nanoparticles in commercial products and the deliberate release of those particles in the environment should be prohibited. In order to justify this, they invoke the strong version of the precautionary approach. In particular they argue that the suspected risks associated with these particles warrant a reversal of the burden of proof: rather than proof of risk by the government, a product must be proved harmless by its producer. This does not mean that proof of zero risk is required; rather, depending on the selected risk criterion it must be shown, either that the risk is below a certain threshold, or that the risk is justified by the expected net benefit.

7. PUBLIC DIALOGUE AND WIDER ENGAGEMENT

Public dialogue and wider engagement are important to take into account when a new technology is being introduced. In this sense an important lesson has been learned from the way modern biotechnology has been introduced. It is clear that a one-way process where governments and industry try to obtain passive acceptance is not sufficient for gaining public trust. More is needed in terms of public participation. The idea that the public will support new technologies provided they are given enough information and understand the facts has to be changed to a more participatory approach. Promotion of new applications without having the capacity to demonstrate their safety stands out as a very efficient generator of outcry, a sure recipe for commercial disaster. Business and industry have realized that they will benefit from integrating this empirical observation into their strategic thinking process. Stakeholder dialogue can be seen as an early warning system for governments and industry, enabling better assessment of the consequences of different courses of action for product development.

The report "Framing Nano", which has been prepared by a consortium led by the Innovation Society and working under the 7th Framework Programme on Research of the European Commission, gives an in depth analysis of a number of the issues.[97] The study indicates that nanotechnologies are seen by many, on the one hand as an exciting new technological opportunity capable of revolutionizing entire industrial sectors and the quality of life. But on the other hand, their responsible development is considered fundamental for their success. The study found that concerns about potentially harmful effects of nano-related products are at present focused on the situation that no specific regulations yet exist to deal with their risk assessment and management. The fact that nanotechnologies are still at an early stage of development, can give the opportunity to tackle in a timely way the challenges deriving from their use, but the fact that nano-related products are already hitting the market in increasing numbers makes the solution of the problem urgent.

Governments and industry seem to have learned from the experiences with the introduction of biotechnology, because the public dialogue about the way nanomaterials are introduced has started a long time ago, when the technology was still mainly in a research stage. A number of national, regional and international public dialogue initiatives have already been initiated. In France the Special Commission for Public Debate organized a series of debates about the risks and opportunities of nanotechnologies, prior to amending the environmental code.[98] In Germany the Federal Institute for Risk Assessment, the Federal Institute for Occupational Safety and Health and the Federal Environment Agency are undertaking activities to understand public attitudes towards nanotechnology. [99] [100] [101] The United Kingdom is establishing a website to provide balanced information for the public and provide ways of engaging civil society in the development of nanotechnology. [102] At the EU level, the Directorate General for Health and Consumers and the Directorate General for Environment have held stakeholder dialogue events and the European Commission has engaged in other public dialogue activities.[103] [104] [105] [106]

In this context the International Center for Technology Assessment states that the processes for designing nanotechnology devices and systems should be driven by social needs that are identified through informed deliberation and open decision-making among affected people rather than

beginning from the presumption that technological change is inevitable and always beneficial. [107] The Center identifies three key factors for full public participation. First, the process must be open, in the sense that it facilitates equal input from all interested and affected stakeholders, including future generations. Second, it must be meaningful and aimed at informing policy development and decision-making. A meaningful public participation includes requirements for governmental commitment and sufficient funding. Third, public participation must be full, requiring democratic involvement in all processes and at all stages where nanotechnology development is influenced. It must also take place on a continuing basis, ensuring that public concerns, values and preferences inform and guide the development of nanotechnologies and nanomaterials

At the wider international level nanotechnologies and manufactured nanomaterials are discussed in many fora and conferences. After discussions at the Intergovernmental Forum on Chemical Safety[1] in Dakar in 2008, nanotechnologies were also dealt with in the SAICM context. ICCM2 recommended in Resolution II.4 – E in 2009 "to begin or continue public dialogue on nanotechnologies and manufactured nanomaterials [3]". UNITAR and OECD, in a partnership coordinated through the IOMC, held a series of regional awareness-raising workshops on nanotechnology as a follow up to this Resolution.[108] These workshops were held in four UN regions with developing countries and countries with economies in transition in conjunction with SAICM regional meetings, and an additional sub-regional workshop was held for Arab countries. UNITAR has then organized, in a similar way, in 2011 period a round of follow up workshops. This second round of workshops goes beyond awareness raising; the aims are to assist countries with preparations for the SAICM Open-ended Working Group meeting and ICCM3 and to facilitate dialogue and cooperation at the regional level among countries.

In the report “Nanoscience and nanotechnologies: opportunities and uncertainties”, the UK Royal Society and the Royal Academy of Engineering identify a number of benefits that genuine public engagement may include.[47] It will serve to incorporate public values in decisions and improve decision quality and acceptability as well as ensure that socially desirable goals are identified and delivered. Public participation will also contribute to resolving conflict between stakeholders and better anticipate sensitive issues and potential areas of conflict. Lastly, public participation will also contribute to improving trust in institutions and inform and educate the public.

Key issues that emerge for consideration in any dialogue include risks, benefits, uses, evidence, exposure, social values, economic impacts and trust. In this context, transparent communication and effective education regarding scientific issues will contribute directly to the quality and usefulness of the dialogues. Therefore, scientists and science communicators have a crucial role to play. Well informed public engagement offers an effective means for policymakers to learn about community concerns and needs. It helps to find ways in which community priorities can be addressed effectively. Ultimately, a governance approach of nanotechnologies and manufactured nanomaterials which is guided by public preferences will be most sustainable.

Civil society has expressed its frustration on the one-way information model used in, and on the outcomes of certain of, some of the public dialogues. They consider that public engagement should go beyond such one-way processes in that it leads to consideration of the result of the consultation in the decision making procedures.

8. LEARNING, TRAINING AND CAPACITY BUILDING

With regard to learning, training and capacity building there are two distinct, but related aspects. One is ensuring that all countries have the capacity to undertake research on applications in order to use nanotechnology to help to better address a number of the societal challenges. There are concerns as well that developed countries will benefit more from nanotechnology and that developing countries will suffer more from potential risks (e.g occupational health and safety standards may be lower, waste management and waste disposal infrastructure may not be adequate for nanomaterials and nano-enabled products). This has to be fully considered in order to avoid that a nano divide will be created which will widen existing economic inequities.

The second aspect is that all countries should have a capacity to assess the health and environmental safety aspects of manufactured nanomaterials in order to be able to make well founded and effective decisions on the use of these materials in their countries, especially for vulnerable groups such as children, pregnant women and older persons. While the science regarding nanomaterial safety assessment methods is evolving, it is crucial to strengthen the capacities in this field in developing countries and countries in transition. All countries need to be empowered to adequately manage, utilize, and direct the use of nanotechnology. This requires the establishment of cooperation, collaboration and partnerships (between countries and between the public and private sectors, and including civil society organizations) for building up of human resources and of institutional capacity, and encourament dialogue, assistance in training, research and development, dissemination of information, and that appropriate means for this are provided.

8.a Research on applications

Both developed and emerging countries are devoting increasing resources to promoting nanoscience and nanotechnologies in an effort aimed at gaining a leading position in the field and reaping the benefits promised. Industry in many developed countries has initiated important research efforts on nanotechnology. In addition, many of these countries and the European Commission have set up major government supported research programmes. The focus of such research is often on finding new applications. Attention is also increasingly directed towards the environmental, health and safety implications and ethical, legal and social issues deriving from nanotechnology and its applications (see section 4e). Addressing these issues properly and responsibly will be of paramount importance for the success of nanotechnology.

As mentioned above, in many countries research on applications and implications of nanomaterials is ongoing and a number of these efforts have been referenced already. Below some specific examples of ongoing research programmes in developing countries or economies in transition are given.

Brazil

In Brazil the market for nanotechnology products was $ 115 in 2010. There were 115 companies undertaking research efforts on a variety of aspects related to applications and implications of nanomaterials. Also the Brazilian government is involved in a considerable number of research

activities, spearheaded by the Ministry of Science and Technology Information, the Ministry of Labor and Employment, the Agency for Industrial Development and the Council for Scientific and Technological Development. Since 2001 the Institute for Nanoscience and Nanotechnology oversees 10 networks which cover all different research topics. Examples of ongoing activities related to applications are projects on nanophotonics, nanocosmetics, nanotube and molecular nanotechnology. As regards implications, projects cover impacts on workers health and the environment, food and biofuels. Other research addresses questions related to environment and society, and regulatory frameworks.[109]

China

China has three National Centers for Nanotechnology: one for Nanoscience and Technology, one for Promoting and Developing Nanotechnology and one for Nanocommercialization. Researchers from the Chinese Academy of Sciences initiated activities to study the environmental and toxicological impacts of manufactured nanomaterials already in 2001, including recognition, identification and quantification of the biological and environmental hazards resulting from exposure to diverse nanomaterials or nanoparticles. Currently, more than 30 research organizations in China have initiated their own research activities studying the toxicological and environmental effects of nanomaterials or nanoparticles, and techniques of recovering nanoparticles from manufacturing processes.[110]

Eastern European and Central Asian countries

It is also reported that in many of the countries in this region research programmes on nanotechnologies are set up. In the Russian Federation the RUSNANO company is active. In Belarus, Armenia, Azerbaijan, Kazakhstan, Kirgizstan, Tajikistan, Ukraine and Uzbekistan the National Academies of Science are organizing such research. The Commonwealth of Independent States (CIS) has set up in 2009 an International Innovation Centre of Nanotechnologies that will play the role of a locomotive for the formation of a common regional market for the nano-industry within the CIS area. It is an instrument for integration of the processes on nanotechnology development of the CIS countries. The centre should help create an integrated innovation, research and education areas within the CIS. [111]

India, Brazil, South Africa - IBSA

The IBSA is a trilateral, developmental initiative between India, Brazil and South Africa to promote South-South Cooperation and exchange.[112] The IBSA nanotechnology initiative was initiated as a collaborative programme between the Departments of Science and Technology of three participating countries, with an objective of developing trilateral collaborative projects of common relevance and interest. The objective of the IBSA initiative is to formulate tri- and bi-lateral collaborative programmes in the area of nanotechnology, of mutual interests to the participating nations. The accepted priority areas of common national interest to all three countries under this initiative include advanced materials, energy systems, sensors, catalysis, health (tuberculosis, malaria and HIV), water treatment, agriculture and environment. Education and human resource development in nanotechnology has also been identified as one of the major focus areas of the IBSA programme.

Nigeria

Nigeria has made progress in Science and Technology policy issues relating to Nanotechnology and Advanced Materials since the last two years. A Nigeria Nanotechnology Initiative was launched in 2006 under the coordination of the National Agency for Science and Engineering Infrastructure - NASENI. [113] This involves a network of research institutes and university research groups in specific areas of nanotechnology. The initiative was geared towards those applications of nanotechnology that will fast-track technology development relevant to developing economies. Some of the key areas of further interest are to: raise awareness on the subject matter, justify the relevance and importance of nanotechnologies to developing economies, identify any ongoing activities and expertise in this area, identify key stakeholders for capacity development, and develop programmes of action for public and private sector buy-in with the main considerations for accruing benefits to the environment and human health.

South Africa

In South Africa the implementation of the National Nanotechnology Strategy invigorated research and development activities towards synthesis and characterization of nanomaterials in different research centres and universities in South Africa. [114] Nanosciences and nanotechnologies activities supported by the Department of Science and Technology focus particularly on addressing the country's socially-oriented problems such as health, water and energy security, and enhancing economic value of industrially-oriented aspects such as chemicals and bio-processing, minerals and mining, and advanced materials and manufacturing.[115] A second element is a well targeted research programme towards understanding potential safety, health, and environmental impacts of nanomaterials on humans and other ecological organisms. The Council for Scientific and Industrial Research has also set up a research effort covering the applications as well as implications of manufactured nanomaterials.[116]

Thailand

Thailand founded the National Nanotechnology Center (NANOTEC) in 2003. NANOTEC is an autonomous agency under the umbrella of the National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology. [117] Afterwards, a National Nanotechnology Strategic Plan (2007 – 2013) and a Nanotechnology Roadmap were established as frameworks for sustainable nanotechnology development in Thailand. Nanotechnology development is expected to stimulate Thailand to leapfrog in key areas of science and technology. NANOTEC has the dual role of serving as a national research and development centre and as a funding agency to support universities and other research institutes and aims to be an international nanotechnology research center that drives national nanotechnology policy for sustainable results. The goals are to:

- conduct research and development in order to acquire advanced knowledge in nanoscience and nanotechnologies at international level, at the same time, built awareness to society and environment;
- drive national strategies and policies for nanoscience and nanotechnologies in ways that yield concrete and sustainable results;

- transfer the knowledge and know-how in nanoscience and nanotechnologies to the industrial sector while disseminating accurate information to the public;
- undertake capacity building of human resource development in nanoscience and nanotechnology development; and
- develop infrastructure that would facilitate nanoscience and nanotechnology development.

NANOTEC consists of 11 central laboratories located at the Thailand Science Park. These laboratories address: nano delivery system; nanomolecular target discovery; nano-cosmeceuticals; nano safety and risk assessment; nanomolecular sensoring; organic nanomaterials; hybrid nanostructures and nanocomposites; nanomaterials for energy and catalysis; nanoscale simulation; bi-components; a spinning fiber pilot plant; and testing and service. NANOTEC has also realized the benefits of nanomaterials for health and the environment. Therefore it also includes flagship projects related to health and the environment. They are: drug delivery systems; water treatment and remediation; food processing and storage; disease screening, diagnosis and health monitoring; vector and pest detection/ control (e.g. nano coated anti malaria mosquito nets); energy and production, conversion and storage; nanocatalysts for agricultural wastes; agricultural productivity enhancement; and textiles.

Thailand considers that it is emerging as a key player in the arena of nanotechnology in Southeast Asia and expects that this will contribute gaining investors' interest in nanotechnology investment in the country. NANOTEC is also initiating a training program for South-East Asian countries in nanotechnology and nano-safety.

Nano-related research and development in other countries

Important national research initiatives on nanotechnologies have in addition be reported for Chinese Taipei, India, Indonesia, Iran, Pakistan, Philippines, Singapore and Vietnam, while in at least ten further developing countries or economies in transition nanotechnology research is known to be ongoing.[111]

Building up research capacity related to nanotechnology in developing countries and economies in transition, for the applications as well as for the implications, is crucial in order to avoid that a "nano divide" will be created between these countries and developed countries. In the publication "Why is Nanotechnology important for Developing Countries?" of the World Commission on the Ethics of Scientific Knowledge and Technology of UNESCO, it is mentioned that nanotechnology "becomes an attractive field for research and development in third world countries because it can be done with modest resources and relatively low funding". [28] It has been reported that setting up of nanotechnology research facilities is not extremely costly.[24] The SAICM Resolution on nanotechnology "Encourages Governments and other stakeholders to assist developing countries and countries with economies in transition to enhance their capacity to use and manage nanotechnologies and manufactured nanomaterials responsibly, to maximize potential benefits and to minimize potential risks".[3] There are several possibilities to successfully set up local capacities in these countries. Providing direct financial support and transfer of technology, in particular concerning the beneficial health and environmental applications, are obvious options, but setting up partnerships between countries or public/private partnerships is another direction which could be an

interesting win-win option for all concerned, because insights in a variety of needs and technological possibilities could be combined.

8.b Health and environmental safety

Education of the general public and professional training regarding nanotechnology are of course key elements in ensuring safety of nanomaterials throughout the lifecycle. Risk assessment regarding human health and environmental safety and risk management for nanomaterials require expertise and technical resources. Examples of education tools exist.

The Swiss federal government has supported the development of the " Nano-Cube". [118] This is an educational platform for secondary schools and professional education It could serve as an information and training platform for further training activities. It addresses professional education and vocational training, including “Nano-Basics, Products & Applications, Science and Research, Economy, Safety & Risks, Technology & Society, Nano at Daily Work”. It also presents structured information which will be comprehensible to a large audience (while not being over-simplified).

Gathering and evaluating safety information on nanotechnology might pose special challenges to developing countries and economies in transition. The development of an international information clearing house or portal on the safety of manufactured nanomaterials might be an effective first step to improve information availability and accessibility. Such a mechanism for the sharing of technical and regulatory information would allow all countries to benefit from knowledge developed by the countries which are the most advanced in particular areas and would allow better decision making on safety issues. Enhanced information sharing on national and regional levels could also be helpful. In depth dialogue with industry associations and individual companies will also be useful, because industry holds many of the important information elements.

How to follow up on the outcomes of the evaluations in terms of risk management then also requires attention. As mentioned in section 4.f, a host of options can be selected. Support could be provided for incorporating the management of the safety of nanomaterials and nanotechnologies in t national chemicals management programme. As a first step, gaps in the existing framework could be identified and analyzed and then those provisions which are missing to ensure safe practices with regards to the production, use, transport and disposal of manufactured nanomaterials, could be developed.

Learning and training efforts will be needed in a variety of areas such as for environmental and health specialists, workers, industrial hygienists, waste handlers or customs officials. Elements of a generic effective training model, which could also be applied to training concerning the safety management of nanomaterials, could include[119] :

- determining if training is needed
- identifying training needs
- identifying training goals and objectives
- developing learning activities
- conducting the training

- evaluating programme effectiveness: verification of understanding of the material or acquisition of desired skills
- improving the programme

Intergovernmental organizations could play an important role in providing national or regional training progammes. The Guidance Document on integrating the risk management for nanomaterials into the general national chemicals management framework, which is being developed by UNITAR could be an important basis for such training. Workshops on implementation of best safety assessment practices and risk management procedures for chemicals have been a normal practice since many years. Building on this experience, methods like webinars could be put in place for such purposes and would reduce the resource needed.

9. WORK OF INTERNATIONAL ORGANIZATIONS

A number of international and intergovernmental organizations have worked on the safety aspects of manufactured nanomaterials or still have work underway.[120] An overview of the activities of those who are the most relevant in the SAICM context is given below.

FAO/WHO

In response to the accelerating developments in nanotechnology, FAO and WHO convened in 2009 an Expert Meeting on the "The application of nanotechnologies in the food and agriculture sectors: potential food safety implications". [74] The major aims of this meeting were to:

- develop a common view of what the main food safety concerns are associated with actual and anticipated nanotechnology applications in the food and agriculture sectors;
- share lessons learned by those countries that have already initiated programmes to address such concerns;
- agree on priority actions that are needed to control possible food safety hazards associated with nanotechnology applications in food and agriculture; and
- develop guidance on the possible roles of FAO and WHO in promoting sound governance of food safety issues linked to nanotechnology applications.

A report of the meeting with conclusions was published in 2010. The experts agreed that FAO/WHO should continue to review its risk assessment strategies, in particular through the use of tiered approaches, in order to address specific emerging issues associated with the application of nanotechnologies in the food chain. A tiered approach might enable the prioritization of types or classes of materials for which additional data are likely to be necessary to reduce uncertainties.

ILO

At an ILO Meeting of Experts to Examine Instruments, Knowledge, Advocacy, Technical Cooperation and International Collaboration as Tools with a view to Developing a Policy Framework for Hazardous

Substances in 2007, it was decided that the ILO should continue to monitor national and international activities related to safety in the use of new technologies, such as nanotechnologies and possibly contribute to them through ILO participation in relevant intergovernmental groups.

In 2010, ILO published a booklet entitled "Emerging Risks and New Patterns of Prevention in a Changing World of Work," which summarizes new occupational safety and health issues, including those related to technical innovations such as nanotechnology. [121]

ISO

ISO has established Technical Committee 229 – Nanotechnologies. Currently the following four working groups have been established: Terminology and nomenclature; Measurement and characterization; Health, safety and environmental aspects of nanotechnologies; and Material specifications. [122] TC229 published 12 standards and has 32 standards under development. Important documents address: Health and safety practices in occupational settings relevant to nanotechnologies, Terminology and definitions for nano-objects -- Nanoparticle, nanotfibre and nanoplate.[123] [124]

Standardization in the field of nanotechnologies includes either or both of the following:

- understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometers in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications; and/or
- utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.

Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modeling and simulations; and science-based health, safety, and environmental practices.

OECD

In 2006 OECD established a Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of its Chemicals Committee. [125] The objective of the WPMN is to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials among member countries and non-member economies, civil society organizations, industry and intergovernmental organiszations. Currently, the following areas are covered by the work plan of the WPMN:

- development of an OECD Database on Human Health and Environmental Safety Research
- environment, health and safety research strategies on manufactured nanomaterials (including occupational health and safety)
- safety testing of a representative set of manufactured nanomaterials

- manufactured nanomaterials and test guidelines.
- co-operation on voluntary schemes and regulatory programmes
- co-operation on risk assessment
- the role of alternative methods in nano-toxicology
- exposure measurement and exposure mitigation
- environmentally sustainable use of manufactured nanomaterials

In addition, in 2007 OECD's Committee for Scientific and Technological Policy established a Working Party on Nanotechnology (WPN). The work addresses policy issues related to the responsible development and use of nanotechnology and the potential benefits nanotechnology can bring to society, taking into account public perceptions related to advances in nanotechnology and its convergence with other technologies, without forgetting legal, social and ethical issues. The following projects are in the work plan of the WPN:

- statistical framework for nanotechnologies
- monitoring and benchmarking nanotechnology developments
- addressing challenges in the business environment specific to nanotechnologies
- fostering nanotechnologies to address global challenges
- fostering international scientific co-operation in nanotechnologies
- policy roundtables on key policy issues related to nanotechnologies

Further information and publications of OECD's work on manufactured nanomaterials and nanotechnology, are available as free download.[126] [127]

UNEP

Within the United Nations Environment Programme (UNEP), the Chemicals Branch of the Division of Technology, Industry and Economics promotes sustainable development by catalyzing global actions for the sound management of chemicals worldwide. So far, UNEP has not taken a very active role with respect to nanotechnologies. However, since nanoparticles are being recognized as an emerging environmental issue within the SAICM context, UNEP will continue to address the complex implications related to the possible broad dissemination of nanotechnologies with a view to optimize their benefits and to minimize the environmental risks in support of sustainable development. The UNEP GEO 2007 Yearbook has a chapter entitled "Emerging Challenges: Nanotechnology and the Environment". The pros and cons of innovative medical techniques, the savings in materials and energy, as well as advances in detection and remediation of pollution are highlighted.[128]

UNESCO

UNESCO has invited well-known experts in nanotechnology to discuss the state of the art of nanotechnologies, examine the controversy surrounding its definition and explore related ethical and political issues. A 2006 report "The Ethics and Politics of Nanotechnology" "outlines what the science of nanotechnology is, and presents some of the ethical, legal and political issues that face the international community in the near future. [93] UNESCO has also published a book on "Nanotechnologies, Ethics and Politics".[94] The aim of the book is to inform the general public, the

scientific community, special interest groups and policy-makers of the ethical issues that are salient in current thinking about nanotechnologies and to stimulate a fruitful interdisciplinary dialogue about nanoscale technologies among these stakeholders.

UNITAR

In accordance with ICCM2 Resolution II/4-E, UNITAR and OECD set up a partnership, coordinated through the IOMC, to undertake a series of regional awareness-raising workshops on nanotechnology. These workshops, took place from November 2009 to March 2010 in four UN regions: Asia-Pacific (Beijing, China), Central and Eastern European (Lodz, Poland), Africa (Abidjan, Ivory Coast) and Latin America and Caribbean (Kingston, Jamaica). An additional sub-regional workshop for Arab countries was held in Alexandria, Egypt, in April 2010.

A second round of regional nanotechnology workshops was started, organized by UNITAR. Over the April – September 2011 period, this round included workshops in Nairobi, Kenya, in Panama City, Panama, in Lodz, Poland and in Beijing, China. The second round of workshops goes beyond awareness raising; the aims are to assist countries with preparations for the SAICM Open-ended Working Group meeting and ICCM3 and to facilitate dialogue and cooperation at the regional level among countries.[129]

UNITAR also prepares in three countries pilot projects related to the integrating nanomaterials-related safety management into a pre-existing programme for the sound management of chemicals at the national level. Guidance is being developed by a group of experts from SAICM stakeholders. The guidance, which will be tested in the pilot projects, is intended for wider use and gives suggestions for a specific methodology for such integration. Pilot project deliverables and key activities include:

- undertaking preparatory activities, including identification of a lead agency and key ministries and other stakeholders involved in and interested in nanotechnology issues;
- updating of the National Profile for chemicals management to include a new chapter on nanomaterials;
- development of a national policy or action plan on the safety management of nanomaterials;
- identification of key health and environmental protection-related priorities concerning nanomaterial safety;
- targeted training; and
- including nanomaterial safety as part of the country's national programme for the sound management of chemicals.

WHO

WHO is developing Guidelines on "Protecting Workers from Potential Risks of Manufactured Nanomaterials". These Guidelines aim to facilitate improvements in occupational health and safety of workers potentially exposed to nanomaterials in a broad range of manufacturing and social

environments. The guidelines development will involve preparing a background document outlining critical questions, systematic review of evidence for each question, and drafting recommendations. After the guidelines are pilot tested and their use and impact are evaluated, an Implementation Guide of user-specific guidance and recommendations will be developed as a second part of this project.[130]

IOMC

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 in order to strengthen cooperation and increase coordination in the field of chemical safety. The following are the Participating Organizations of the IOMC:

- Food and Agriculture Organization of the United Nations (FAO);
- International Labour Organization (ILO);
- Organisation for Economic Co-operation and Development (OECD);
- United Nations Development Programme (UNDP);
- United Nations Environment Programme (UNEP);
- United Nations Industrial Development Organization (UNIDO);
- United Nations Institute for Training and Research (UNITAR);
- World Bank, and
- World Health Organization (WHO);

The IOMC organizations hold regular meetings together to ensure co-ordination of the chemical safety activities of the participating organizations. Activities related to nanomaterials have also been discussed at these meeting. Detailed information on the IOMC can be found through their website.[131]

Chemicals related UN Conventions

Several existing multilateral environmental agreements, such as the Stockholm Convention, the Basel Convention, the Rotterdam Convention and the Aarhus Convention may have the potential to deal with certain aspects of governing the safety of nanotechnologies and nanomaterials. To date this topic has not been addressed specifically by these Conventions.

10. CONCLUSIONS AND POSSIBLE SAICM ACTIONS

10.a Summary of main issues

Manufactured nanomaterials are substances which have different properties from the traditional chemicals, which mean that they could be used in a variety of new applications. A number of products containing nanomaterials are already on the market for a long time, without being highlighted as such. It is expected that the markets for nanomaterials will develop rapidly in volume over the coming years as much research is currently ongoing on further new applications. Such research includes also applications which can be used in the field of health and in environmental protection. Manufactured nanomaterials may therefore offer many opportunities for the society as a whole to benefit from the advances in such research.

Because of these different properties, however, manufactured nanomaterials also may have different implications for human health and the environment than traditional chemicals.This poses a number of challenges which have to be managed during all stages of the life cycle of these materials, taking into account the vulnerability of certain parts of the population and the environment. In addition, as with other new technologies, the development of nanotechnology raises ethical, legal and social issues.

There are currently a number of important unanswered questions regarding the assessment and management of the risks of manufactured nanomaterials. While much research is ongoing in this field, there are still uncertainties and gaps in knowledge with respect to issues like material characterization; metrology and measurement, especially for exposure; the extent of applicability of the conventional methods used for the testing for hazards; establishment of dose/response relationships; and quantification in risk characterization. This situation calls for the use of precaution, the extent of which has to be considered in a broader context.

There is more knowledge available to risk assessors and risk managers regarding the assessment of possible health and environmental effects of traditional chemicals and exposures, than presently exists for nanomaterials.. As stated by several national and international scientific committees, it is clear that, while this knowledge cannot all be transposed directly to nanomaterials, methods applied for traditional chemicals will be of use. There is expertise available to consider the extent to which these methods can be applied and when not, and much further research is ongoing on this topic.

Many scientists, however, consider that the current frameworks used for traditional chemicals are in principle adequate and appropriate for dealing with manufactured nanomaterials, although further understanding of specific toxicity mechanisms and testing procedures need to be developed. At the moment, governments are using available provisions as far as possible. In cases when risks cannot be quantified due to uncertainties in the hazard and/or exposure assessment, a case-by-case evaluation combined with qualitative analysis is relied upon. Precaution is then applied in those cases where an unacceptable level of uncertainty or concern is identified. In this context issues related to waste management, specifically in developing countries and economies in transition, require special attention.

New technologies have been introduced in the past many times, and usually there is a certain level of concern about uncertainties regarding the safety of a technology. There is a well established methodology for technology assessment which has been the basis for dealing in a generic way with the uncertainties which a new technology might pose. This knowledge can also be relied upon.

Clearly, however, in the case of the risk management of manufactured nanomaterials, more research is needed to get a better insight into those aspects for which the methodology has to be adapted for nanomaterials risk management, and into the possibilities to quantify the risks. It is therefore important that nano-research programmes devote a large part of the efforts, not only to developing applications, but also to clarifying health and environmental safety issues.

Currently no countries have specific legislation in place to deal with the safety of nanomaterials. Combinations of existing legislations are used as the main regulatory instruments. A variety of specific attributes to deal with the specific aspects of nanomaterials in these existing legislations has been developed, or is in the process of being developed or suggested. This includes the suggestion to include nano-aspects in Safety Data Sheets, establishment of a government register for products including nanomaterials and mandatory, rather than voluntary, provision by industry of information relevant for the understanding of potential of nanomaterials risks. Countries are also considering integrating the management of nanomaterials in their National Profiles for chemicals management.

At the international level already a number of Conventions exist which address the safety of chemicals or waste (Rotterdam, Stockholm, Basel) or the provision of environmentally relevant information (Aarhus). In addition the Globally Harmonised System for classification and labelling (GHS) is being implemented world-wide. While the Conventions do not appear to be very well suited to address comprehensively the safety of nanomaterials, it would be relevant for the Conferences of Parties of these Conventions to consider, within in their general mandates, either to extend their scope to nanomaterials, or to further investigate how the Conventions could be used to deal with the applications and implications of nanomaterials. In light of the national risk management practices, where consideration of the safety of nanomaterials is incorporated in existing frameworks, it might be more efficient for international chemical safety management to see how these Conventions could contribute, rather than to develop specific nano-related international instruments. With respect to the GHS, which is an important chemical safety management instrument in countries which not yet have a full legislation in this field, it could urgently be considered how criteria related to the safety of nanomaterials could be developed and incorporated into the system.

In general, civil society organizations are rather critical about the way the potential risks of nanomaterials are currently being managed. They generally ask for initiatives aimed to deepen and answer scientific and technical issues and to clarify regulatory aspects of nanotechnologies. Some of them require the application of a strict precautionary approach. Their request is to require scientific evidence on safety, to have adequate regulatory instruments in place and to have possibly agreement on the way ethical and social concerns will be addressed prior to commercialization.

With regard to learning, training and capacity building there are two related, but distinct issues. One is ensuring that all countries should have the capacity to undertake research in order to develop and use nanotechnologies which are potentially helpful to better address a number of the societal challenges.

The second is 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. This capacity is necessary to ensure adequate and effective decisions on the use of nanomaterials in their counties. 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 potential risks. This needs to be fully considered to avoid the creation of a nano-divide will widen existing economic inequities.

All countries need to be empowered to adequately manage, utilize, and direct the use of nanotechnology. This requires the establishment of cooperation, collaboration and partnerships (between countries, between the public and private sectors, and including civil society organizations) for the building up of human resources and of institutional capacity. It also requires encouraging dialogue, assisting in training, research and development, dissemination and sharing of information, and that appropriate means for are provided this.

Governments and industry seem to have learned from the experiences with the introduction of modern biotechnology, and public dialogue about the introduction of nanomaterials has started when nanotechnology was still at an early development stage. A number of national, regional and international public dialogue initiatives have already been initiated principally in developed countries. Key issues that emerge from these dialogues include risks, benefits, uses, evidence, exposure, social values, economic impacts and trust.

When the introduction of a new technology is foreseen, a wide engagement regarding the management of the risks is critical, for example with respect to risk management issues. Civil society has expressed, however, its frustration on the one-way information model used in, and on the outcomes of certain of, some of the public dialogues. The idea that the public will support new technologies, provided they are given enough information and understand the facts has to be changed to a more participatory approach. A one-way process where governments and industry merely try to obtain passive acceptance is not adequate for gaining public trust. Public engagement should go beyond such one-way processes in that it leads to consideration of the result of the consultation in the decision making procedures. Stakeholder dialogues can be used as an early warning system for governments and industry and can enable better assessment of the consequences of different courses of action for research and product development.

Transparent communication and effective education regarding scientific issues will contribute directly to the quality and usefulness of the dialogues. Therefore, scientists and science communicators have a crucial role to play. A well informed public engagement process offers an effective means for policymakers to learn about community concerns and needs. It helps to find ways in which community priorities can be addressed effectively. Ultimately, a governance approach for nanotechnologies and manufactured nanomaterials which is guided by public preferences will be most sustainable.

10.b Possible actions in the SAICM framework

As the primary global forum for addressing chemical safety in an overarching way, SAICM has an important role to play in the safety management of manufactured nanomaterials. A number of actions could be envisaged in this context. An overview of such possible actions is presented below. They are to a large extent based on the outcomes of the Regional Awareness Raising and Capacity Building Workshops on Nanotechnologies and Manufactured Nanomaterials which were held in the SAICM framework from 2009 tom 2011. A first round, supported by UNITAR and OECD was held between November 2009 and March 2010; and a second round was initiated by UNITAR in April 2011. Documents reflecting specific nano-related outcomes were produced and agreed in the African and Latin American Caribbean Regional meetings. Because SAICM is a voluntary mechanism, the recommended actions focus on facilitating cooperation, information exchange and mutual understanding among stakeholders and recommending other actors in the chemical safety field to undertake certain actions.

Overview of possible SAICM actions

11. Facilitation of information exchange on nanotechnologies and manufactured nanomaterials in order to improve global transparency and allow better decision making processes. Such information exchange could involve several aspects. For example it could be recommended that, possibly through the IOMC and its participating organizations:
    - an international “nano-portal” for safety information be set up;
    - a clearinghouse of ongoing research activities be set up;
    - a mechanism be established for sharing technical, legal and institutional information;
    - awareness raising activities in the SAICM regions be continued and deepened.
12. Development of internationally applicable technical and legal guidance and training material for the sound management of manufactured nanomaterials, possibly through the IOMC and its participating organizations. This could involve:
    - guidance material on the assessment and management of the safety of nanotechnologies and manufactured nanomaterials;
    - guidance material on the integration of nanomaterial safety in existing national chemical safety programmes, including the updating of National Profiles;
    - guidance material on the adaptation of national legal frameworks to include the sound management of manufactured nanomaterials;
    - training materials based on the guidance;
    - training activities;
    - pilot projects which could also be used to test the guidance material;
    - education materials for the public.
13. Supporting the development of Regional SAICM strategies concerning manufactured nanomaterials, which could include arrangements for cooperation on research and on risk assessment and risk management issues.
14. Facilitation of technology transfer, in particular related to applications which are beneficial for health and environmental protection. This could include various types of partnerships which should be financially supported in order to achieve their objectives. Partnerships could be among:
    - developing countries and/or economies in transition and developed countries;

- public and private institutions in a country or region, including civil society organizations as they could contribute in various ways, for example by providing expertise, review and insights.

15. Updating the Global Plan of Action with a specific work area which includes activities on nanotechnologies and manufactured nanomaterials.
16. Including the possibility of financing projects related to nanomaterial safety in any possible future SAICM financing mechanisms in order to enhance the preparedness of countries to deal with the safety issues when larger volumes of products containing nanomaterials will reach the market.
17. Inviting industry to step up their stewardship role and responsibilities in relation to nanotechnologies and manufactured nanomaterials, 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.
18. Recommending to the UN Committees of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals the urgent preparation of a work plan for the adaptation or development of GHS criteria to address the safety of manufactured nanomaterials.
19. Recommending to the Conferences of Parties of the Rotterdam, Stockholm and Basel Conventions to consider specifically addressing if it would be useful (and if so how) to consider applications and implications of manufactured nanomaterials which could fall under their respective mandates.
20. Continuing to support the public dialogues on all aspects of nanotechnologies and manufactured nanomaterials, for example by holding Seminars or a Global Conference with participation of all stakeholders in order to discuss progress on addressing issues related to manufactured nanomaterials which are of wide public interest.

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