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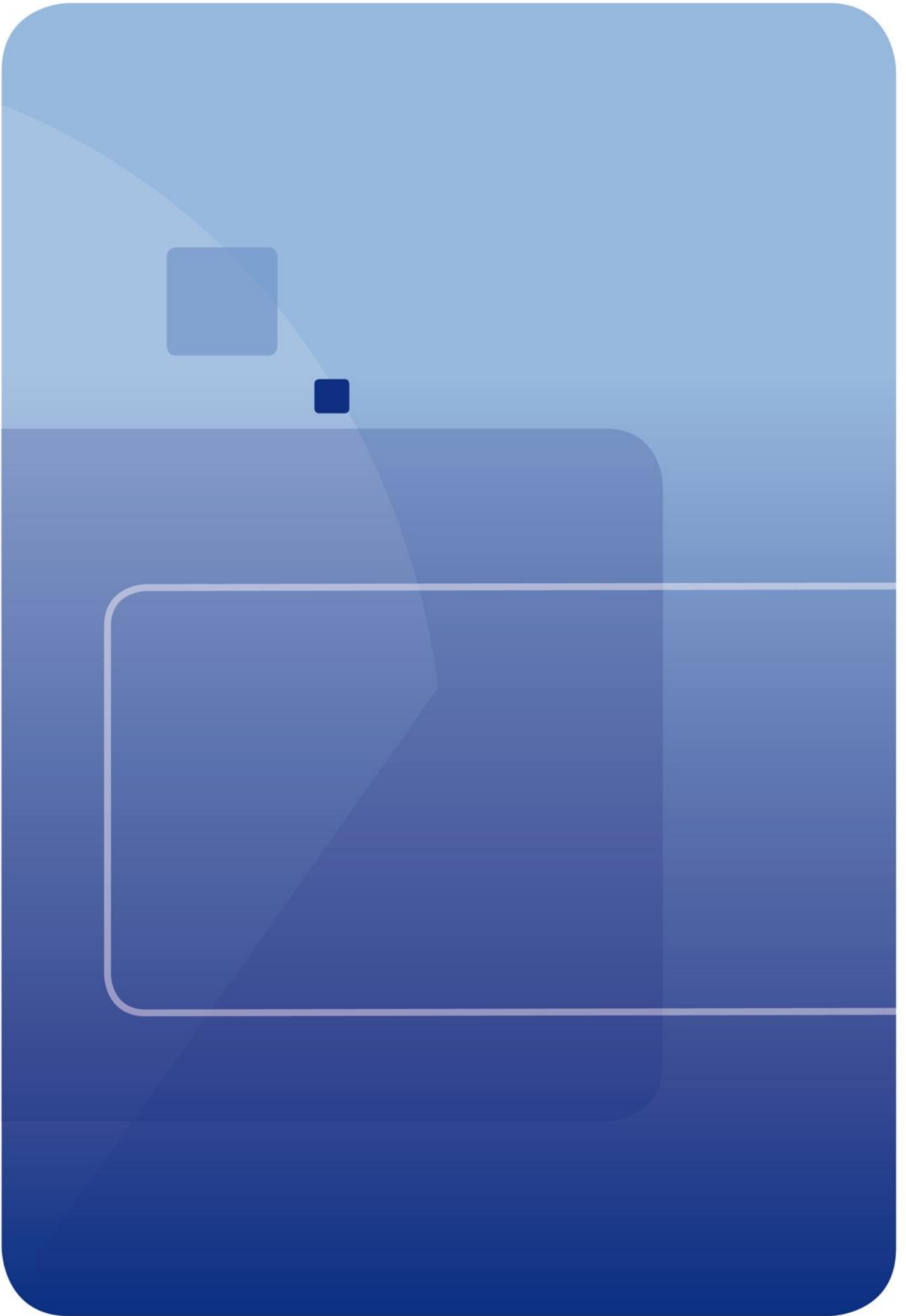
United Nations Institute for Training and Research

Guidance for Developing a National Nanotechnology Policy and Programme

PILOT EDITION 2011



Knowledge to lead



■ About this Document

With the support of the Government of Switzerland, three countries are conducting a UNITAR-guided pilot study on nano safety during 2011-2012. These countries are expected to present initial results at ICCM-3 in 2012 and to share their experience with other countries in their regions. The work is also related to existing or developing programmes for the sound management of chemicals at the national level.

This guidance gives suggested ideas to address nano issues, whether the users are pilot countries with UNITAR or are working without such direct international support. The guidance also provides an introduction to nano, including the latest developments both regarding nano applications and research on potential risks to the environment and human health. The guidance is further enriched with examples of progress on addressing nano issues from various countries.

Following the pilot phase and based on country experiences and lessons learned, it is expected this guidance will be updated and made broadly available for all interested stakeholders.

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Executive Summary

There has been a remarkable development and application of nanotechnology, manufactured nanomaterials, and nano-enabled products¹ throughout the world, which have many potential benefits, as well as potentially creating health, environmental risks, and social concerns. In response to the recognition that nanotechnology and nanomaterials constituted an emerging issue at ICCM-2 and that countries should prepare a national report on their use and management of such materials, UNITAR has drafted this pilot guide for use during awareness-raising and capacity-building workshops and the development of national nano policies and programmes.

This nano policy and programme guidance document provides, in Part A, a brief overview of nanomaterials, their applications and approaches towards institutional governance, risk management, and ethical and social implications of this innovative technology. A more detailed document (SAICM Report on Nanotechnologies and Manufactured Nanomaterials, 2011), which describes nanomaterials within the SAICM context, should be referred to for ongoing progress with the emerging policy issues associated with these materials.

Part B of the guidance, provides a draft methodology to assist countries to undertake awareness-raising and an analysis and assessment of their national strengths, weaknesses, and gaps in the management of nano. The suggested methodology addresses the need to prepare a comprehensive stakeholder-driven nano policy that includes a national nano assessment in a manner comparable with the preparation of a country's National Profile for Chemicals Management. Subsequent steps in the development of a national nano policy are outlined for stakeholders to gather data and information necessary to understand their national nano situation, which is needed to prepare their policy. These steps include establishing a coordinated and cooperative nano programme to unify the issues associated with nano management, the establishment of national priorities, and the targeted training of a wide range of stakeholders who may be potentially exposed to nanomaterials. Implementation of the policy to establish a programme for the safe management of nano is then outlined. Progress with implementation of the nano programme can then be evaluated whether it meets specific national or international targets. The resultant report should be nationally adopted as an official reference document suitable for transmission to ICCM-3 or other relevant meetings².

¹ This document uses the short form "nano" to refer generally to nanotechnology, manufactured nanomaterials and nano-enabled products.

² It is recommended that such a report be submitted to the government to alert decision-makers to the need for financial support for an ongoing programme. The results arising from this document could also be incorporated into the national mainstreaming for traditional chemicals management.



Glossary

EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GPA	Global Plan of Action (of SAICM)
ICCA	International Council of Chemical Associations
ILO	International Labour Organisation
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
IPEN	International POPs Elimination Network
ISO	International Organisation for Standardisation
IUFoST	International Union of Food Science and Technology
IUPAC	International Union of Pure and Applied Chemistry
MDGs	Millennium Development Goals
MEA	Multilateral Environmental Agreement
NGO	Non-Governmental Organization
OECD	Organisation for Economic Co-operation and Development
SAICM	Strategic Approach to International Chemicals Management
UNEP	United Nations Environment Programme
UNITAR	United Nations Institute for Training and Research
WHO	World Health Organization
WPMN	OECD's Working Party on Manufactured Nanomaterials
WPN	OECD's Working Party on Nanotechnology

■ Part A. Background and Introduction

Nanotechnology is a relatively “new” area for sound chemicals management. It is also a rapidly developing field, with new applications and uses of nanotechnology being identified on a regular basis in many countries around the world. Many new products are coming into the marketplace as the result of the manufacturing of novel, nano-containing products. With the introduction of such new products and manufacturing processes, and taking into account the sometimes unique physical properties of chemicals as they interact in their “nano” form, a new area of sound chemicals management is emerging. Regulators and others who are responsible for nano issues are attempting to ensure that the environment and human health are protected from the potential negative effects of nano products and production processes.

1. Working Definition(s) of Manufactured Nanomaterials and Nanotechnologies

Nanotechnology is the set of technologies that enables the manipulation, study or exploitation of very small structures and systems that deals with the research, the production and the application of these structures and systems, which display novel properties of chemicals. It includes different types of analysis and processing of materials, which have one thing in common: their size is, typically, at least in one dimension, one to one hundred nanometres (one nanometre is one millionth of a millimetre). By way of comparison, a sheet of paper has a thickness of approximately 100,000 nm. Nanotechnology makes use of the special characteristics of many nanostructures. The mechanical, optical, magnetic, electrical, and chemical characteristics of these very small structures do not only depend on their original material but also on their size and shape. Applications are in energy technology (fuel cells and solar cells), in environmental technology (materials cycles and disposal) or in information technology (new memories and processors) but also in optics, the healthcare area, and in consumer products (see Annex I for examples). A precondition for Nanotechnology has been the discovery of the possibilities of working with individual components of matter, as well as the related growing understanding of the self-organization of these components.

Typical nanomaterials are illustrated in Boxes 1 and 2

Box 1

What are manufactured nanomaterials?

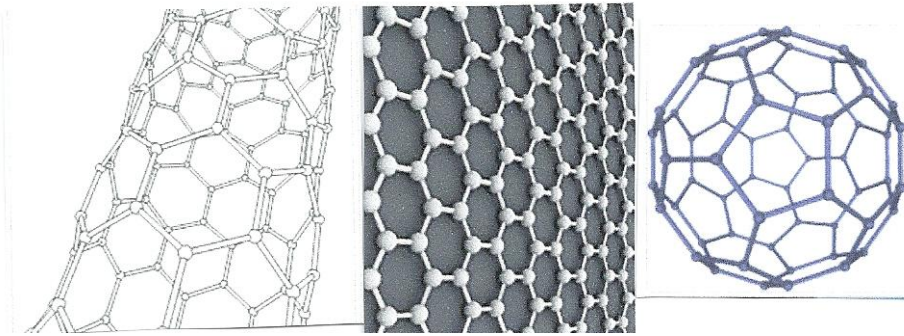
Manufactured nanomaterials are chemicals at the nano-scale (1-100 nm typically), that can be:

- ✓ new materials with new properties developed from old materials (*carbon black*) or, existing chemicals (TiO_2)
- ✓ new chemicals (*fullerenes*)

Box 2**Illustrations of typical manufactured nanomaterials**

Carbon nanotube, graphene and a C-60 fullerene (left to right)

Curling, rolling and stacking can turn graphene into fullerenes, nanotubes and graphite.



Nanomaterials have previously been found in the work place and in the environment. For example:

- Incidental nanomaterials are produced as a by-product of a process such as welding fume and diesel emission particulates; and
- Natural nanomaterials are a result of natural processes such as particles arising e.g. from volcanic emissions, sea spray, and atmospheric gas-to-particle conversion.

With the rapid development of nanotechnology in the last few years, many new manufactured nanomaterials have been developed, studied and eventually marketed and used - this has led to discussions about possible risks of these materials for people and the environment. Therefore different definitions of these materials were developed. Several national and international standardisation bodies, organisations, and authorities have developed a definition for the term 'nanomaterial'. In 2006, the Organisation for Economic Co-operation and Development (OECD) established the Working Party on Manufactured Nanomaterials (WPMN) under the OECD Joint Chemicals Programme to address the question of a definition and the risks and opportunities of manufactured nanomaterials. The WPMN adopted a definition based on ISO/TC 229 as an internal working definition for the term 'manufactured nanomaterial'. The definitions of nanomaterials (see Box 3) have been abridged from ISO Standards.

Box 3

Abridged ISO definitions for terms used in nanotechnology and nanomaterials

(the complete definitions accompanied by footnotes are readily available at:
<http://cdb.iso.org>)

Nanoscale^(a): size range from approximately 1 nm to 100 nm

Nanomaterial^(b): material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale

Nanotechnology^(b): application of scientific knowledge to manipulate and control in the nanoscale in order to make use of size- and structure-dependent properties and phenomena, as distinct from those associated with individual atoms or molecules or with bulk materials

Nano-object^(a): material with one, two, or three external dimensions at the nanoscale

Nanostructured material^(b): material having internal nanostructure or surface nanostructure

Nanoparticle^(a): particles with a nominal diameter (such geometric, aerodynamic, mobility, projected-area or otherwise) smaller than about 100nm

Nanofibre^(a): nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger

Nanoplate^(a): nano-object with one external dimension in the nanoscale and the two other dimensions significantly larger

Nanowire^(a): electrically conducting or semi-conducting nanofibre

Nanotube^(a): hollow nanofibre

Nanorod^(a): solid nanofibre

Note: ^(a) refers to ISO/TS 27687:2008; ^(b) refers to ISO/TS 80004-1, 2010.

2. Nano Applications

As described in Section 1, nanotechnology is one of the widest and most multidisciplinary scientific fields, promising an almost unlimited number of potential applications in almost all sectors of human activities. Identifying products manufactured with the help of nanotechnology and containing nanomaterials is critical both to grasp the extent of the “nano-revolution,” as well as to identify the challenges posed for risk management and regulatory purposes. However, the absence of a clear definition for terms such as nano-applications or nano-products makes it a complex endeavor to identify and list such products or applications. Furthermore, in the absence of regulation, uses of nanomaterials in a given product may not be disclosed, while the presence of nanomaterials in some products is falsely claimed for marketing purposes only. Finally, the task of identifying nano-applications is further complicated by the need to distinguish between products already on the market and products at various stages of development.

Research into nanotechnology and applications involving all scientific disciplines is advancing very rapidly (SAICM report on nanomaterials, 2011).³ The table in Annex I provides examples of products currently on the market that either contain nanomaterials or are manufactured with the help of nanotechnologies. Several potential future applications of nanotechnology, currently in development stage, are also presented (and identified as such in the last column) in order to provide a more comprehensive picture.

3. Environmental and Health Concerns of Key Nanomaterials Over their Life Cycle

Products will only be successful if they are safe. The safety of nanomaterials can only result from combined efforts from the researchers, producers, and regulators. Nano research has increased our knowledge over the past two decades. However, many elements are unknown and much remains to be done. Industry has submitted nano specific information together with their notification dossiers in selected cases to government authorities. However, in most countries nanomaterials and methods to determine possible risks are not yet defined, and authorities have no overview of the products on the market. More detailed information including literature references on environmental and health concerns is available in the SAICM report on nano.

4. Worker Health and Safety

Workers are one of the most exposed groups, and nanomaterial exposure measurement methods and understanding are still being developed. To-date, while there have been no confirmed adverse human health effects reported, toxicological laboratory studies in animals have shown a wide range of biological activity resulting from exposures to some nanomaterials. Therefore, prudent measures to minimize exposures to nanomaterials in the workplace have been recommended by a number of national and international organizations. For example, a government has developed national guidance on occupational health and safety aspects of nanotechnologies.⁴ Major international standards setting organizations have established projects developing safety and health standards for nanotechnology. Specifically, the ISO

³ SAICM Secretariat, *Nanomaterials: applications, implications and safety management in the SAICM context*, 2011,

http://www.saicm.org/documents/OEWG/Meeting%20documents/OEWG1%20INF8_Nano%20report.pdf

⁴ <http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf> ; <http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf>

Technical Committee 229 on Nanotechnologies, published its first safety and health standard in September 2008 and is presently developing standards aimed at specifying protocols for exposure measurements, control banding, and exposure mitigation. The OECD's WPMN (see Section 8.4) published a series of documents on the safety of manufactured nanomaterials including guidance on emission assessment, guidance on use of personal protective equipment, a review of OECD test guidance, and guidance for nanomaterial handling in laboratories.⁵ The WPMN has also developed guidance for nanomaterial handling in laboratories and conducts a sponsorship program for toxicity and ecotoxicity testing on selected manufactured nanomaterials (see Box 4). Most recently, the World Health Organization initiated the process of developing guidance for protecting nanotechnology workers in developing countries (see Section 8.4). Consistently published guidelines recommend taking precautionary measures to minimize worker exposures to nanomaterials. For most processes and job tasks, the control of airborne exposure to nanomaterial can be accomplished using a variety of engineered control techniques similar to those used in reducing exposures to general aerosols.

5. Classification and Labelling

One major issue for the management of the broad range of nanomaterials, whether as nanoparticles, nanotubes, nano-enabled products or so forth, relates to how they should be regulated both nationally and internationally to ensure worker and civilian safety and environmental protection. One major issue is how such materials should be classified and labelled throughout their whole lifecycle assuming that sufficient information is available for these purposes.

5.1 Background on the GHS and nano

One very important advance in the last decade has been with the establishment, and increasing adoption throughout the world, of the UN's Globally Harmonized System of Classification and Labelling of Chemicals – the GHS. The GHS promotes information on chemical hazards – through labels and safety data sheets – which is made available *inter alia* to workers, farmers, and consumers in a harmonized and comprehensible format to countries around the world.

The GHS covers all hazardous chemicals, pharmaceuticals, food additives, and cosmetics; however, pesticide residues in food are not covered by the GHS in terms of labelling at the point of intentional intake, although these types of chemicals are covered where workers may be exposed, as well as in transport if potential exposure warrants it. With the development of nanotechnology, its application could be extended more generally to pharmaceuticals, medical procedures, food and food additives, food packaging, cosmetics, and a range of other applications. Paucity of hazard and exposure data and a lack of nomenclature for specific classes of nanomaterials makes their classification and labelling challenging.

Classification of 'traditional' chemicals based on the GHS is done with currently available data and does not require retesting of the chemicals. However, some nanomaterials may exhibit different physical and chemical properties from their 'traditional' chemical, due to their very small particle size, high surface-to-volume ratio, and different electronic properties; thus, meaning that many will require further testing.

⁵ http://www.oecd.org/about/0,3347,en_2649_37015404_1_1_1_1_37465,00.html

Nano is not yet addressed within the GHS, but it may be in the future.⁶ Preliminary discussions have taken place. There was general support for the proposal by the expert from Australia to consider including, in the future, additional information items in section 9 of the safety data sheets (SDS) covering physical and chemical properties of engineered nanomaterials. However, noting that work on different aspects of nanomaterials was currently being performed at the international level (e.g. OECD, ISO Technical Committee 229) and the European Union has amended their safety data sheet format to include information about nanomaterials⁷, the GHS Sub-Committee decided to postpone the consideration of this issue until more information about their intrinsic properties and characteristics is available.

5.2 Classification of nanomaterials

There is general acceptance that the 'traditional' chemical-based risk management framework can be usefully applied to nanomaterials, but may be limited due to the time taken and associated costs to generate useful and reliable hazard and exposure results as data available for bulk materials is unlikely to be fully transposable to nanomaterials. The application of risk management is compounded by the increasing number and types of nanomaterials and nano-enabled products being developed and therefore, how to implement such management throughout the whole lifecycle of the substances.

The hazards from nanomaterials, such as nanoparticles and nanotubes, may differ from those of the same chemicals in the form of larger particle size in the range of micrometers or larger. Therefore the OECD has addressed the safety of manufactured nanomaterials through the activities of a working party (see Section 8.4). Safety information is needed on the effects of nanomaterials through testing, exposure measurement (occupational, consumers and environment), hazard assessment (classification), and risk assessment.

Important for the classification of nanomaterials are appropriate test methods, the results of this testing and the application of the GHS classification criteria to these test data. To achieve this the Working Party on Manufactured Nanomaterials (WPMN) initiated the testing of a set of nanomaterials on the market or close to be marketed like fullerenes, single and multi-walled carbon nanotubes, nano iron and silver, titanium dioxide, aluminium oxide, cerium oxide, and zinc oxide by interested countries and industry (see Section 8.4 and Box 4).

6. Research and Training Activities on Nano

Basic research in solid state physics and materials chemistry over the last 50 years has provided the fundamentals for specific nano research over the last decade. In view of the increasing market opportunities, industrialized countries have spent billions of Euros and Dollars on nano research, mainly on nano applications as outlined in Annex I. However, less than 10% of this research effort has been invested in nano safety research so far.

⁶ Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals: see section 9 of Annex 4 of the GHS Document: ST/SG/AC.10/C.4/2009/11 (Australia).

⁷ Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals, Twentieth session Geneva 7-9 December 2010, UN/SCEGHS/20/INF.25

In addition to North America and Europe, other countries have also been investing in nano research, e.g. Brazil, Russia, India, China, and South Africa, Thailand and many more. For further information, see the 2011 SAICM nano report.⁸

Education of the general public and professional training regarding nanotechnology are key elements in ensuring safety of nanomaterials throughout their lifecycle. The Swiss federal government has supported the development of the "Nano-Cube",⁹ this is an educational platform for secondary schools and professional education that could serve as an information 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.

7. Ethical Considerations

The ethics of nanotechnology have been discussed in the national context of many countries, but also in the international community especially within UNESCO, IFCS, and SAICM. Much of the discussion centres on how nanotechnology should be identified and analyzed so that the general public, specialized groups and decision-makers can be made aware of the implications of this new technology, whether potentially beneficial or harmful, with new links between science, technology and society. Principles of public accountability and transparency in decision-making during the development of nanotechnology are highly relevant to this debate. General principles and guidelines involving a Code of Conduct have also been reported by the European Union. Due respect for the precautionary approach is also another major topic under debate. There is an ongoing debate on the "nano-divide", with regard to whether nano will increase or decrease the gap between industrialized and developing countries. Further elements of the debate, include discussions relating to the impacts of the development of nanomaterials use on the workforce of developing countries, as well as the impact on the primary materials markets and the economy of countries dependent upon them.

8. Relevant International Work

Significant efforts to address nano issues have been taking place at the international level. This section presents some information regarding these international initiatives.

8.1 Intergovernmental Forum on Chemical Safety (IFCS)

At the IFCS (Dakar, Senegal 2008), the nano issue was discussed for the first time at the global level, and a series of 21 Recommendations were endorsed (see Annex II). These included reference to the need for more research and risk assessment; awareness-raising; improvements in information sharing; development of a Global Code of Conduct; and, application of the precautionary principle.

⁸ SAICM Secretariat, *Nanomaterials: applications, implications and safety management in the SAICM context*, 2011 http://www.saicm.org/documents/OEWG/Meeting%20documents/OEWG1%20INF8_Nano%20report.pdf

⁹ <http://www.swissnanocube.ch/>

8.2 Strategic Approach to International Chemicals Management (SAICM)

At the second session of the International Conference on Chemicals Management (ICCM-2, 2009), the topic of “Nanotechnologies and Manufactured Nanomaterials” was included in the agenda as an emerging policy issue and supported by a background document.¹⁰ The conclusions of ICCM-2 on “Nanotechnologies and Manufactured Nanomaterials are reproduced in Annex III. In particular, the Resolution “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 is now available and was also made available at OEWG-1 in Belgrade, Serbia, 14-18 November 2011.¹¹ OEWG-1 also prepared a draft resolution on manufactured nanomaterials and nanotechnologies for consideration and possible adoption at the third session of the International Conference on Chemicals Management in 2012. In addition, Switzerland has proposed that nano be added to SAICM’s Global Plan of Action (GPA).

8.3 International Organisation for Standardisation (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. As of November 2011, TC229 published 21 standards and has 23 standards under development. Important documents address health and safety practices in occupational settings relevant to nanotechnologies, terminology, and definitions.

8.4 UNESCO

Since 1970, UNESCO has been active in the promotion of ethical principles and norms as applied to scientific development and social transformations. Consequently, they have been active in developing ethical principles applied to nanotechnology and manufactured nanomaterials, along with other international organizations.¹²

8.5 The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC)

The IOMC ensures chemicals coordination among international organisations. It consists of FAO, ILO, UNEP, UNIDO, UNITAR, WHO, World Bank, OECD with UNDP as an observer. For more information, see Section 9 of the SAICM nano report.

Organisation for Economic Co-operation and Development (OECD)

As listed in Annex I, nanotechnology offers a wide range of potential benefits, including in helping address a range of societal and environmental challenges, e.g.

¹⁰ SAICM, ICCM-2, INF34, <http://www.saicm.org/documents/iccm/ICCM2>

¹¹ SAICM Secretariat, *Nanomaterials: applications, implications and safety management in the SAICM context*, 2011, http://www.saicm.org/documents/OEWG/Meeting%20documents/OEWG1%20INF8_Nano%20report.pdf

¹² For more information, see <http://unesdoc.unesco.org/images/0014/001459/145951e.pdf>; <http://unesdoc.unesco.org/images/0015/001521/152146e.pdf>.

renewable energy (Silicon nanocrystals for superefficient solar cells), cleaner water (carbon nanotube filters), and environmental sensors (such as nanostructured ZnO gas sensors). However, unlocking this potential requires a responsible and co-ordinated approach to ensure that potential challenges are being addressed at the same time as the technology is developing. As a response, the OECD established two complementary bodies to implement strategic programmes as follows: i) the *Working Party on Manufactured Nanomaterials (WPMN 2006)* and ii) The *Working Party on Nanotechnology (WPN 2007)*.

(i) *OECD's Working Party on Manufactured Nanomaterials (WPMN)*¹³

With manufactured nanomaterials already entering the market, the WPMN is involved in the development and implementation of a rigorous system for safety evaluation and assessment of manufactured nanomaterials, which guarantee human health and environmental safety. (The WPMN is a subsidiary body, and receives its mandate from the OECD Chemicals Committee¹⁴).

The WPMN is also developing information that is relevant for safety assessment through the following mechanisms:

- a) OECD Database on Manufactured Nanomaterials to Inform and Analyze EHS Research Activities
- b) Safety Testing of a Representative Set of Manufactured Nanomaterials
- c) Manufactured Nanomaterials and Test Guidelines
- d) Co-operation on Voluntary Schemes and Regulatory Programmes
- e) Co-operation on Risk Assessment
- f) The Role of Alternative Methods in Nano Toxicology
- g) Exposure Measurement and Exposure Mitigation
- h) Environmentally Sustainable Use of Manufactured Nanomaterials¹⁵

Assessing the safety of manufactured nanomaterials

The first step to ensure the rigorous evaluation of manufactured nanomaterials is to determine whether or not existing test methods used for assessing 'traditional' chemicals are adequate to assess the safety of these new substances. Through the OECD's *Sponsorship Programme for the Testing of Manufactured Nanomaterials*, OECD members, together with non OECD economies, and industry agreed to pool resources and expertise to test a selected number of manufactured nanomaterials (see Box 4) for approximately 59 endpoints (effects measurements and observations) relevant to environment and human health safety. The nanomaterials currently being evaluated are those with commercial relevance, and/ or with an interest on the type of information they can provide.

¹³ Publications and additional information on the program can be found at:
<http://www.oecd.org/env/nanosafety>

¹⁴ Through this Committee, OECD develops *OECD Guidelines for the Testing of Chemicals*. Together with the *OECD Principles of Good Laboratory Practice*, these harmonised, common tools are used by countries to test and assess the potential risks of chemicals, and are set to be accepted by all the member countries through the Council Decision on the Mutual Acceptance of Data (MAD). The work on the safety of manufactured nanomaterials is done in line with this approach.

¹⁵ http://www.oecd.org/departement/0,3355,en_2649_37015404_1_1_1_1_1,00.html

Box 4**OECD's list of manufactured nanomaterials and list of endpoints to which they should be tested**

Manufactured nanomaterials	Endpoints (Human health and environmental safety)
<ul style="list-style-type: none"> ▪ Fullerenes(C60) ▪ SWCNTs ▪ MWCNTs ▪ Silver nanoparticles ▪ Iron nanoparticles ▪ Titanium dioxide ▪ Aluminium oxide ▪ Cerium oxide ▪ Zinc oxide ▪ Silicon dioxide ▪ Dendrimers ▪ Nanoclays ▪ Gold nanoparticles 	<ul style="list-style-type: none"> ▪ Information on the nanomaterials/identification ▪ Physical-Chemical properties and material characterization ▪ Environmental fate ▪ Environmental toxicology ▪ Mammalian toxicology ▪ Material safety

*OECD's Database on Research into the Safety of Manufactured Nanomaterials*¹⁶

Launched in April 2009, OECD's database is a global resource, which collects research projects that address environment and human health regarding manufactured nanomaterials. This database is also intended to be an inventory of information on research programmes to allow: i) the identification of relevant research projects; ii) facilitate future collaborative networks between researchers, and ii) to identify available or missing EHS safety information regarding specific nanomaterials.

*(ii) OECD's Working Party on Nanotechnology (WPN)*¹⁷

Its role is to increase the understanding of nanotechnology in the policy environment, including business and research, and to develop policy advice relevant to nanotechnology. The WPN is currently engaged in the following projects:

- Statistical Framework for Nanotechnology; Monitoring and Benchmarking Nanotechnology Developments; Communication, Outreach and Public Engagement with Nanotechnology; and Policy Roundtables on Key Policy Issues related to Nanotechnology;
- Business Environment Specific to Nanotechnology: Sustainable Energy; and Nanomedicine.
- Regulatory Framework for Nanotechnology in Food and Medical Products.

¹⁶ The database is open to the wide community and it can be accessed at: www.oecd.org/env/nanosafety/database To contribute to the database please contact the OECD Secretariat nanosafety@oecd.org

¹⁷ Publications and additional information on the WPN program can be found at: www.oecd.org/sti/nano

Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO)

In June 2009, FAO and WHO jointly organized an *Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications*¹⁸. Several important points emerged, including:

- The Codex Alimentarius Commission needs to identify and address any gaps in food standard setting arising from the use of nanotechnologies; and
- Potential food safety issues arising from the use of nanoproducts such as nanoencapsulated additives and ingredients that improve the taste, flavor, texture, enhanced nutritional value of foods, and safety of nanomaterials used in food wrappers.

Based on the recommendation made during this expert meeting, FAO organized in collaboration with the Ministry of Agriculture of Brazil (EMBRAPA) an International Conference on safety (EHS) related issues of Food and Agricultural Applications of Nanotechnologies¹⁹. Three Technical Round Table sessions were organized: 1) Food applications of nanosciences and nanotechnologies, 2) Nanotechnologies in agriculture: new tools for sustainable development, and 3) Nanotechnology: the regulatory framework. Each session was co-hosted with the European Food Safety Authority (EFSA), International Union of Food Science and Technology (IUFoST), and the Organisation for Economic Co-operation and Development (OECD). This was followed-up by an FAO/Brazil event entitled "Conference on nanotechnologies in the food and agriculture sectors", which was held in San Pedro Brazil, 20 - 24 June 2010.

A follow-up FAO/WHO activity is the implementation of an e-Discussion Group to develop the "Tiered Approach Diagram for Risk Assessment of Nanomaterials (NMs)". The overall objective of this activity is to seek further scientific advice from the experts on the application of this approach to nanotechnologies for food and feed.

In addition, WHO initiated the development of WHO Guidelines titled "Protecting Workers from Potential Risks of Manufactured Nanomaterials".²⁰ These Guidelines aim to facilitate improvements in occupational safety and health of nanotechnologies in a broad range of manufacturing and social environments by incorporating elements of risk assessment and risk management framework in line with the WHO's position as the United Nation's international health organization charged to assist countries to attain "Health for All."

UNITAR

In accordance with ICCM-2 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 and manufactured nanomaterials from 2009 to 2011. UNITAR is also embarking on three national pilot projects to integrate nano-related safety management into pre-existing programmes for the sound management of chemicals at the national level in order to strengthen capacities to address nanotechnology and manufactured nanomaterials.²¹

¹⁸ The report from this meeting was published and it is available on line at:

http://www.fao.org/ag/agq/agns/files/FAO_WHO_Nano_Expert_Meeting_Report_Final.pdf

¹⁹ The report from the conference is expected to be available in towards the end of 2010.

²⁰ http://www.who.int/occupational_health/topics/nanotechnologies/en/

²¹ <http://www.unitar.org/cwm/nano>

■ Part B. Developing a National Nano Programme

9. Development of a National Nano Policy and Programme

Purpose of Section 9

To establish a series of steps necessary for development of a national nano policy, programme, and action plan based on existing infrastructure and capabilities for managing nano materials.

9.1 Introduction

Many countries have already established their national industrial chemicals policies. Other incentives stem from the need to implement multilateral environmental agreements such as the Montreal Protocol and the Conventions of Basel, Rotterdam, and Stockholm. Another catalyst for the development of these policies was SAICM, which can help countries gain an overview of their existing structures and programs. The general reflections of the guidance for developing SAICM implementation plans are also potentially useful for the development of a nano implementation plan.

An *integrated* approach to sound chemicals management and nano implementation therefore, requires efforts to strengthen coordination, ensuring that contributions are complementary across relevant actors with respect to the various activities undertaken. Under an integrated scheme, in the national context for example, ministries of agriculture, environment, health, industry, labour, science and technology, trade, transport, customs authorities, and others continue to carry out their own sectoral mandates, but their efforts are coordinated to a reasonable degree to avoid conflicting policies, gaps, and unnecessary overlaps. An integrated approach also means involving ministries of finance, foreign affairs, justice or legal affairs, planning, etc. with a view to integrating chemicals management into development planning ("mainstreaming"). From the perspective of the regulated community and others outside government, such coordination would also appear as a more streamlined and rationalized system. Approaching chemicals management from a holistic perspective helps to promote the potential risks to health and environment as the various stages of the lifecycle are taken into account with appropriate measures being put into place to manage and reduce those risks. This approach also helps expose issues or elements within a given stage of the life-cycle that may have "fallen through the cracks" under existing schemes within individual ministries or agencies.

For many countries, the challenge of establishing a coherent, integrated chemicals management framework that coexists with broader national development policies and effectively addresses local needs is still very much a "work in progress." Implementation of SAICM through an integrated approach also provides an important opportunity to streamline national efforts regarding international agreements. For example, coordination of the national focal points with regard to international agreements and related activities could facilitate common national requirements under such agreements, which may include: information exchange and dissemination, risk assessment, risk management decision-making, education and training programs, chemicals analysis and monitoring, and import and export control.

An integrated approach to nano management can provide a great variety of benefits from streamlining administrative procedures to contributing towards a healthier society. Some of those benefits, at the national level, include:

- administrative benefits such as minimizing overlaps and inconsistencies in policies and programs across agencies and programs thus, participating in cost savings;
- communications-related benefits, including improved information exchange within and among relevant parties, and increased awareness for the general public;
- ensuring that nano management occurs at all stages of the life cycle (so that nano-related problems are not merely shifted from one medium to another, thereby increasing protection of human health and the environment); and
- contributing to nano safety and thereby assisting in protecting vulnerable groups and human rights, and advancing public health and human security.

9.2 Establishing a sequence of policy steps

A number of models for organizing a successful national chemicals management programme based on different numbers of steps and relevant activities have been published. This Guidance Document and the series of suggested sequence of steps and relevant activities presented (Box 5) are intended to assist countries in planning and ultimately implementing a national nano programme. Countries may wish to adapt or modify it, depending upon their own national situations, priorities, and extent of nano development and applications within the country.

Checklist A: Establishing a step-wise nano policy and programme

- ✓ Have you established an inception meeting followed by adopting an integrated approach to establishing your national policy and programme?
- ✓ Have you listed the benefits of adoption of an integrated approach?
- ✓ Have you consulted and agreed with all stakeholders on the policy model approach and number of steps involved?
- ✓ Have you planned and agreed on the time-frame for developing the step-wise nano policy and programme? This includes assignment of information/data collection and allocation of necessary resources for undertaking policy-setting?

Box 5

Possible steps in developing a national nanopolicy and programme

1. *Preparatory activities* (includes establishing in a transparent manner, an inclusive group of relevant stakeholders, such as ministries, industry, NGOs etc.)
2. Establishing an inception meeting and *awareness-raising* so that all stakeholders views can be presented
3. Preparation and drafting of a *nano assessment* following involvement of all relevant stakeholders
4. Establishing *priority issues/areas* that should be addressed following involvement of all stakeholders
5. Drafting the elements of a *national nanopolicy* including, coordination mechanisms and an organizational structure
6. *Training* of stakeholders and specific groups of workers who handle, or may handle, nanomaterials throughout their lifecycle and of specific groups such as government representatives and NGOs
7. *Adoption* of the policy and its submission, and *endorsement* by national decision-makers
8. Stepwise *implementation* of the national nanopolicy
9. Periodic *reporting* and amending of the national nanopolicy

10. Developing the National Nano Assessment

Purpose of Section 10

Nanotechnologies and manufactured nanomaterials are an important emerging issue with respect to chemical safety. The purpose of an assessment of manufactured nanomaterials is to provide information in an integrated manner, suitable for national planning, about the many issues associated with the wide range of nanotechnologies and nanomaterials throughout their lifecycle.

10.1 Introduction

One important step in developing a national nano policy and implementation plan is to compile information that places manufactured nanomaterials (also called engineered nanomaterials) into a sound chemicals management infrastructure as promoted by SAICM. Like the National Chemicals Management Profile (“National Profile”), a ‘nano assessment’ provides a baseline compilation of the current state of development and penetration of nanomaterials and nanotechnologies at the national level, as well as a compilation of issues that may impact on a country’s legal, institutional, administrative and technical infrastructure for chemicals management. Such a nano assessment can serve as a key foundation for national priority-setting and action, as well as providing support through capacity building and possible technical assistance programmes.

Drafting the nano assessment relies on a coordinated multi-stakeholder partnership involving different government and non-government organizations, research institutions, academia, NGOs, communities, consumer groups, and public interest organizations. The multi-stakeholder consultation may even be wider than when developing a National Profile for traditional chemicals. The preparatory process must be transparent and guidelines for involvement should be clearly established and explained to all stakeholder groups. The objectives and potential benefits of preparing a nano assessment are listed in Box 6.

While the nano assessment is designed as a brief insight into national activities on nanomaterials in general, it can only be the reference point to current activities as the subject is rapidly developing with many emerging industrial, health, and environmental applications. As a result, consideration should be given to regularly update this assessment. What time interval to adopt for the updating process, depends upon the extent of nanomaterials development and their use within the country.

Box 6**Objectives and potential benefits of preparing a national nano methodology within an existing programme for the sound management of chemicals.**

The objectives of the preparation of a comprehensive nano methodology and assessment entail establishing a step-wise process that involves all stakeholders in understanding nano applications and issues associated with manufactured nanomaterials throughout their lifecycle. Such a methodology should:

- facilitate exchange of information on extensive materials available on aspects of nano substances by engaging all stakeholders;
- provide information to all parties appropriate for establishing draft methodology for national policy development on current and future national needs for the safe use of nanomaterials;
- identify the current state of development and market penetration of nanotechnologies and nanomaterials;
- identify potential economic, social, societal impacts and ethical issues associated with nano;
- identify what laws, regulations and non-statutory activities that may be relevant to nano; and
- review priority issues including hazard, exposure, and risks to human health and the environment relevant to all sectors of national chemicals management but recognizing that these may change over time as further information becomes available.

The potential benefits of establishing a draft methodology and assessment that addresses manufactured nanomaterials are expected to:

- provide an agreed mandate for the development and implementation of a national nano methodology;
- establish key principles and basic methodology applicable for evaluating issues surrounding environmental and health hazards, exposures and benefits to all sectors of government and society;
- provide a baseline assessment of the national situation;
- strengthen national capacities including an established nano policy agenda within the methodology;
- relate priority nano concerns and issues to ongoing chemicals management activities, bearing in mind that priorities may change over time as new nanomaterials are developed and new information on benefits of specific nanomaterials, as well as their hazards, exposures and risks becomes available over time; and
- facilitate potential financial support with suggested time-frames for implementation of a nano policy based on agreed draft methodology.

10.2 Background to the country situation

Countries will shape their assessment based on the extent of nanotechnologies and manufactured nanomaterials within the country and relate such data and information to their National Profile depending upon scientific, political, economic, and social needs and priorities within the decision-making process.

Suggestion: the multi-stakeholder committee comprising all concerned parties should identify what important issues or knowledge gaps arise in the following sections, where the data and information is inadequate or uncertain, and what issues and priorities should be further addressed. The establishment of a high level policy commitment to complete the process and ensure follow-up is considered essential.

Perhaps the first component of an assessment is to assess the extent of publically available information on nano-enabled products available on the market. Such knowledge is essential when developing the country situation. Relevant information could include the topics listed in Table 1.

Table 1. Available data on nano-enabled products available on the market

Company name	Category (electronics, food, beverage, health, pharmaceuticals)	Product name	Product characteristics
Company A			
Etc.			

Further topics of relevance for the nano assessment include a breakdown of the range of national nano activities listed by location, numbers of employees, investment value by economic sector, and by impact sector such as agriculture and food, industry, consumer products, energy, pharmaceuticals etc. (Table 2).

Table 2. Overview of extent of nanotechnologies nationally

Economic sector	Location	Number of employees	Investment value	Impact sector (health etc.)
Industry				
Research institutions				
Academia				
Government				
NGOs				

As nanotechnologies have the potential for major impact on a country's industrial base, including on the employment situation, the nano assessment should also consider the social context, including citizens benefits and concerns arising from their applications and use throughout the community.

While the national background assessment should provide useful data on the extent of nanomaterial development and use in the country, several points may require clarification. These include:

- Can you evaluate whether the data gathered are accurate and reliable? If not what recommendations for action can be adopted.
- Is there a need to gather additional information?
- Are industries required to report the types of nanomaterials being developed and their use or applications?
- Are new initiatives already underway to establish additional companies or institutions involved in research, development and applications?

10.3 Status of research and development

With nanotechnology and development of nano materials being a rapidly emerging multidisciplinary activity involving not only industry but also a range of research and government institutions (as included in Table 2), it is important that such activities as components of national capacities and capabilities are clearly recorded and linked to the national programme for the sound management of chemicals.

(a) Institutions working on nano

A tabular compilation of the locations and specific nano research activities of relevant university and national research institutes, government laboratories and industrial programmes including multinational activities should be recorded (Table 3). A directory of such research institutions could also accompany such a table.

Table 3. Breakdown of institutions involved in nanotechnologies by category

(for category of nano-enabled products, detail whether coatings, paints, catalysts, energy, composites, food packaging, clothing, cosmetics etc;
for categories of nanomaterials, detail nanomaterials, elemental composition and structure such as carbon nano tubes, metal nano particles, fullerenes, etc.)

Institutional activity	Category of nano-enabled products	Category of nanomaterials	Research activities	Application activities
Electronic appliances				
Energy				
Food and beverages				
Automotive				
Health/fitness				
Home/garden				
Health and environment				
Medical				
Sciences and research				

Do national regulations allow the public identification and listing of specific companies producing and handling nano-enabled products or nanomaterials? Such a table may require regular updating in view of the rapidly expanding nature of nanotechnologies. This basic information provides an entry point into any national initiatives that may become important for chemicals management, and for identifying potential health and environmental impacts.

(a) Data access and use

In view of the wide range of nanotechnologies and nano applications, generation of data relevant for assessing potential hazards and risks in terms of human health and the environment, accident preparedness, as well as potential benefits may not be an easy task as they will originate from various institutions and in various industrial sectors working on nano. Nevertheless a tabular collection of material including what

data is available, its accessibility, its type, its location, and the format (paper or electronic) should be assembled (Tables 4 and 5).

Table 4. Data available on nanomaterials

Economic sector	Category of nanomaterials	Sector (health or environment)	Lifecycle stage	National data	International data
Industry					
Research institutions					
Academia					
Government					
NGOs					

Table 5. Data availability on nanomaterials to organizations/individuals

Category of nanomaterials	To government	To industry	To workers	To public	Confidential

Due care must be exercised as some data may be subject to business confidentiality clauses although such data may be made available to emergency responders in situations such as fires and/or earthquakes. In accordance with article 15(c) of the SAICM Overarching Policy Strategy, information on chemicals relating to the health and safety of humans and the environment should not be regarded as confidential.

Another point to be considered is monitoring of data collection and use, and establishing a benchmark for future reference. Is monitoring undertaken by any national government agency to ensure accuracy and reliability of the data included in any table? Furthermore, are the data bases networked so as to improve data availability and hence its use by relevant organizations?

(b) Registration and Review of Nano Activities

For the sound management of chemicals, a national registration process for specific substances/materials may already be in place. One may wish to summarize the national system and determine its applicability for nanomaterials. General registration of chemicals is dependent upon a general definition of a 'chemical,' which is included in the National Profile. With nanomaterials, a generally accepted size range is 1-100nm but a definition of nanomaterials could encompass not only size but also functionality. This raises a number of questions:

- Are current national registration processes and relevant legislation suitable for nanomaterials?
- Is the registration process undertaken by one organization? In view of the wide range of nanomaterials, a traditional agency concerned with registration of chemicals should share basic data and information with other relevant agencies specific for health, environment, agriculture, industry, worker safety etc.
- Can different agencies jointly evaluate nanomaterials throughout their life cycle to avoid any gaps in the registration process?
- Are management processes in place that would enable such a sharing of information and joint registration to take place?
- Arising from the registration process, are there any related 'control-of-use' regulations that would be applicable to nanomaterials?
- Has a quality assurance scheme been introduced to ensure that registrations over time comply with regulations?
- Has the precautionary approach been involved in the general development of the registration process? Can this approach be applied to nanomaterials and resultant controls on their use?
- Arising from the registration process, has a human health and environmental surveillance system been introduced that could alert national regulators, workers, researchers, and the general public to emerging risks? A number of risk assessment decision-support tools as well as compliance tools have been developed. Are any available for use, or have been used nationally?

(c) Technical infrastructure

The compilation of the technical infrastructure at each of the organizations/institutions involved with nanomaterials should be undertaken. Relevant information could include what facilities are available and accredited for laboratory management such as the OECD GLP, ISO accreditation, quality certification, compliance etc. (Table 6).

Table 6. Overview of technical infrastructure for nanomaterials

Category of nanomaterials	Analytical capacity	Accreditation	Certification	Compliance

This section should provide an insight into the array of organizations involved in research and development of nanomaterials. When compiling the assessment it may be necessary to take into account the characteristics of the country, including:

- Does the government have a role in providing a focus for research at any of the institutions listed in the tables?
- Was a standard method of data and information collection used when asking each of the institutions/organizations for feedback?
- Are the organizations/institutions required to provide the government with all of the relevant information and data requested?
- Have any new or emerging issues been identified that requires a particular emphasis on data and information gathering?

10.4 Governance

Governance applied to chemicals has traditionally involved command-and-control approaches and technological-based regulatory approaches. International governance of chemicals in the context of sustainable development provides further opportunities for the safe management of chemicals. With nanomaterials involving multidisciplinary concepts and a wide range of technologies and end-use products, governance that normally includes human health and environmental risks has to encompass industrial innovation as well as public policy concerns throughout the nanomaterials lifecycle. In many ways governance of nanomaterials and nanotechnologies has to involve a 'whole-of-government' approach.

(a) Inter-ministerial commissions and coordinating mechanisms

An overview of national mechanisms for nanomaterials is included in Table 7.

Table 7. Overview of coordination mechanisms and commissions for nanotechnologies and nanomaterials

Name of mechanism	Members involved	Responsibilities	Mandate	In operation?

Inter-ministerial commissions and coordinating mechanisms can be an approach for obtaining inputs and sharing of information from all stakeholders involved in nanomaterials from their design through to disposal. This approach can give rise to an agreed position on information about nanomaterials throughout their lifecycle, create synergies, and avoid duplication at all levels. Information and data gaps, uncertainties, lack of resources, and different sector priorities in management of nano materials can usually be addressed when all of the stakeholders are involved in reaching an agreement. Government decision-making can then be more readily implemented. Bearing in mind the country’s national situation the following topics could be considered when preparing the assessment:

- What was the scope and extent of the discussions;
- Has such a mechanism assisted in establishing benefits and weaknesses of national governance of nanomaterials?
- Can a national nano-policy arise from such meetings and discussions?

(c) Legal instruments and non-regulatory mechanisms for managing nano

A table (table 8) listing current legal instruments and non-regulatory mechanisms for regulating chemicals should be considered and how those nanomaterials and nanotechnologies relate to the current situation.

Table 8. Overview of existing legal instruments and possible applicability for nanomaterials

Legal instruments	Which ministry	Objective	Lifecycle stage	Possible applicability for nano (Y/N)	Comments
Non regulatory instruments					

Such a table should not only consider traditional approaches, including the chemical MEAs (Stockholm, Rotterdam, and Basel Conventions, ILO Chemicals Convention 170, etc.) but also other initiatives (such as in SAICM), Recommendations (UN Transport of Dangerous Goods, UN GHS), Codes (UNEP Code of Ethics in Trade in Chemicals), Guidelines (Various WHO Guidelines), Voluntary Industrial Commitments (Responsible Care, Global Product Strategy), Product Standards (CODEX), Expert Committees (FAO/WHO-JECFA), and market-based Instruments (taxes, etc.).

The multi-stakeholder committee evaluating these potential regulatory issues for the assessment could usefully consider a number of options for the management of nanomaterials, including:

- With the range of legal instruments and other regulatory structures available can the current national system be adapted for use now and into the future, or will new laws, regulations and/or guidance documents be required?
- Given the wide range of new innovative technologies being established can any regulatory gaps be identified within existing frameworks?
- With the introduction of nanomaterials into consumer products can current classification and labelling practices indicate their presence?
- Is the precautionary approach a component of current regulatory policies? Can this approach be adopted for nanomaterials within a wider sustainability policy?
- Can current workplace laws and regulations concerning exposure standards be applied to nanomaterials? Are they adequate? Are they flexible enough for the variety of nanotechnologies involved?

10.5 Positive and sustainable impacts (benefits) of nano

(a) Environment

Although there is a lack of consensus on the risks posed by some nanomaterials released into the environment, especially in terms of ecosystem effects, a range a

benefits have been advertised. Such benefits include not only sustainable resource use but also the fostering of what can be referred to as 'green manufacturing', 'green chemistry', and 'green energy' that relate to resource conservation.

The realization of potential benefits arising from manufactured nanomaterials will depend, in part, upon the range and extent of such materials currently being developed, or in use nationally. A wide range of possible significant environmental benefits have been reported in international literature and in reports from organizations such as the OECD. These could form the basis for a national list. Future benefits could include environmental clean-ups (especially of contaminated water) and remediation of contaminated land. Highly effective sensors that improve environmental monitoring are another area where nanotechnology could provide environmental benefits. Furthermore, due to their high surface to volume ratio, some nanomaterials are highly selective catalysts very active for their weight, which means that smaller amounts of materials are needed. Other potential beneficial uses include the use of carbon nanotubes as structural materials to produce strong light weight materials, or their use in improved solar cell technologies.

It would be useful to list any environmental benefits that have been recognized arising from use of nanomaterials at the national level and identify any ongoing applications where the results are not yet available, or are unclear.

(b) Human health

As the design and use of nanomaterials increases, it is reasonable to assume that the number of beneficial effects will also increase. Considerable research and clinical trials are ongoing in relation to medical and pharmaceutical applications. Health and medical related applications reported in scientific literature include the development of nanomedicine in particular, targeted drug delivery mechanisms (e.g. drug delivery encapsulation), cheap and highly sensitive medical sensors and devices, as well as possible progress for the production or clean-up of drinking water. Nanomaterials such as nanoclays could also be used to replace highly toxic materials such as brominated flame retardants, potentially reducing the health and environmental impacts of Persistent Organic Pollutants (POPs).

It would be useful to list any human health benefits that have been recognized to date arising from use of nanomaterials at the national level, and to identify any ongoing applications where the results are not yet available, or are unclear.

(c) Other

Industry may also benefit from such advances through technical innovations resulting in 'smarter' materials for manufacturing processes. As some of the nanotechnological developments have their origins in university and research institutes, new business ventures extend the industrial base by stimulating the creation of small businesses. Can examples be listed illustrating the beneficial effects of entrepreneurships and other cooperative ventures on the development within the country of nanotechnologies and nanomaterials?

10.6 Activities on management of risks related to nano

Current risk assessment approaches and techniques are considered to be suitable for risk management of nanomaterials. As a result, the management of risks resulting from nanomaterials and nanotechnologies throughout their lifecycle will be dependent

upon the hazardous nature of the substances at the nanosize, their handling and possible release, the exposure (likelihood, frequency and duration), and calculation of the resultant risks at each stage in the lifecycle.

The exposure paradigm constitutes one of the major components of risk assessment and management and is relevant to workers, citizens, the general public, and the environment. Similarly to exposure standards being developed for traditional chemical manufacture and use within industry, have exposure standards been considered for nanomaterials? Are standards being developed for all categories of nanomaterials (soluble and insoluble, nano fibres, nano dots, and other nanomaterials)?

It would be useful to list potential sources of exposure, particularly occupational exposure and the primary route (i.e. dermal, inhalation, ingestion). Consideration should also be given not only to the manufacturing processes but also cleaning, packaging, transport, use, and disposal. Are control procedures, technologies, and protective equipment in place that may mitigate any exposure?

One approach for risk management of nanomaterials could involve the use of 'control banding'. This procedure has on occasions been applied to specific chemicals where exposure limits may not be available and there is limited toxicological information. A control banding approach for nanomaterial handling in the workplace is under development by ISO. Is there any national experience on its use for estimating risk arising from traditional chemicals? The possible adoption of 'control banding' for nanomaterials could also be considered, including by referring to the work being done in other jurisdictions transposable to the national situation.

10.7 Stakeholders and nano risk management

While workers are potentially the most exposed group, general population and consumer exposure may also occur from the use and application of nanomaterials. Much remains to be scientifically established concerning exposure of the general population throughout the nanomaterial's lifecycle, and stakeholder concerns should be carefully addressed.

In addition to regulatory issues, the classification and labelling of nanomaterials on products throughout their lifecycle is considered essential to avoid unnecessary risk to all sectors of the workforce and the general public. How will consumer products containing nanomaterials be labelled nationally, bearing in mind possible hazards, exposures, and risks associated with such materials?

With nanomaterials being a relatively new industrial development, the social context of the technology should also be considered in relation to risk management. A number of questions relevant to stakeholders should be considered:

- Have the potential benefits, hazard, exposures, and risks associated with nanomaterials been presented to the public's attention?
- Is there a public dialogue on nano underway before entrenched views are formed?
- Have the public's perceptions of nano been evaluated and presented to national decision-makers?
- Has a publically available website been established that discusses the concepts of nanomaterials, their benefits and hazards, exposures, and risks?

10.8 Internationally available information on nano and regional needs

Recent information on nanotechnologies and nanomaterials can be obtained from the 2011 nano report for SAICM. This report also summarizes current and ongoing activities of UN Agencies and other organizations. Several organizations can be highlighted:

- The OECD is especially important in view of the definitive reports from two Working Parties dealing with health and environmental safety of nanomaterials and policy implications of nanotechnologies;
- UNESCO has especially investigated ethical and political issues associated with nanotechnologies;
- The WHO has reported on health risks, especially to workers, from nanomaterials and nanotechnologies;
- UNITAR and the OECD have undertaken in partnership regional nano awareness-raising workshops in UN regions as a forerunner to assist countries to prepare for the forthcoming ICCM-3 in 2012;
- The EU has published information on nanomaterials in relation to REACH Regulations;
- Well respected organizations such as the US EPA, EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), and the United Kingdom's Royal Society have published detailed reports on nanomaterials;
- Reports on the application of 'Control Banding' for evaluating risks from nanomaterials have been published by Australia and The Netherlands.

Compile a list of access to and information from UN organizations and other institutions by the country's national institutions and whether the material is held in searchable data bases (Table 9).

Table 9. Internationally available information on nanomaterials and nanotechnologies within the country

Organization	Location	Format	Access	Additional requirements
OECD				
UN agencies				
National sources etc.				

While all national organizations would normally be able to access international and national information from all over the world via the Internet, it may be useful to consider establishing a national focal point at a specific organization. Such a focal point could act as a 'clearing house' for the country by gathering all relevant information in a consistent and comparable format when international reporting is required. Furthermore, a focal point could also provide agreed information in a consistent and comparable format when international reporting is required. As the country will have implemented numerous international agreements relating to chemicals management, thought should be given to whether any of the scheduled focal points for the MEAs could serve in this capacity for nanotechnologies and nanomaterials.

10.9 Resources available and needed for nano risk management

As management of nanomaterials represents a relatively new field of activity, an additional table (table 10) could be developed indicating what additional resources are needed along with a listing of what technical skills are not currently being met but are considered essential for management of nano and development of a national nano policy.

Table 10. Overview of resources available and required for nanomangement within the country

Economic sector	Application	Available: Staff & US\$	Required: staff & US\$	Skill level required
Industry				
Research institutions				
Academia				
Government				
NGOs				

What further educational and training programmes are required to increase staff capabilities to manage, utilize, and scientifically guide the use of nanomaterials could also be tabulated and should be seen within a national chemicals management framework.

10.10 Conclusions and recommendations

As nanotechnology is a rapidly emerging field, and as more products containing nanomaterials are developed and enter into society in general, it is important to establish a national record of all relevant information concerning their development and disposal as suggested in this guidance document. The multi-stakeholder committee responsible for drafting this assessment should not only develop a summary of the facts associated with nanomaterials but could also, should sufficient information be available, list and prioritize outstanding issues in order of significance to workers, the industry, and the public (Table 11). The uncertainties, information gaps, needs and appropriate actions for the short and the long term, should also be identified for subsequent action as appropriate.

Table 11. Overview of the extent of nanotechnologies nationally

Priority issue (Ranked from high to low)	Nanomaterial or nanotechnology	Stage in the lifecycle of the material or substance	Impact on health, or environment or other	Action proposed and by which organization

The conclusions and recommendations arrived at can provide a basis for priority setting and development of an action plan and therefore, constitute an important component of the nano assessment/chapter.

Checklist B: Establishing an effective nano assessment

While each country will have its own approach based on the extent of nanotechnology, nanomaterials, and nano-enabled products, use, and national development, the following topics include some key activities that may help strengthen the national nano assessment process.

- ✓ Have all stakeholders been involved/consulted during preparation of the assessment?
- ✓ Have target groups been identified where training in risk management of nano materials may be required?
- ✓ Have specific issues been identified and addressed through a prioritization process; and, relevant data and information collected?
- ✓ Have potential challenges been identified for each sector whether it is in awareness-raising, education, training, data access, linking with other sectors, etc.?
- ✓ Have existing data sources been identified that can be used to communicate training materials for various target groups?
- ✓ Has this assessment been recommended to senior decision-makers for national adoption and follow-up action?
- ✓ What follow-up activities may be required to periodically update the nano assessment?

11. Priority Setting for Nano

Purpose of Section 11

To list and evaluate, in order of importance, priority issues and topics that must be addressed during nano policy development, following consultation and agreement with all stakeholders.

11.1 Introduction: developing priorities

A key activity for establishing a National nano policy is the development and coordination of priorities (see also Annex IV). These priority-setting processes have often been facilitated through a national coordinating platform.

A *priority* is something that is regarded as being more important than others; to *prioritize* is to arrange in order of importance. A priority in the present context is considered to be a topic/area in which the level of interest (e.g. due to its importance/urgency) and level of support (e.g. organizations and people willing to commit their time and resources) are sufficiently high that a decision is usually taken to initiate action. It is important to recognize that priorities exist at different levels: within ministries, stakeholder groups, national priorities related to foreign affairs, and priorities related to national development planning. Several approaches to prioritization are outlined below. However, each country will be in the best position to develop appropriate criteria to prioritize the issue/topic/area under discussion.

11.2 Organizing the priority-setting process

Defining the priorities to be addressed through centralized and decentralized activities contributing to national nano policy development is an important step in providing input to developing a national nano management and implementation plan. Broad participation among all interested and affected parties is crucial to the success of the priority setting process.

Identification of priorities can be undertaken by various approaches:

- *Pooling stakeholder priority views* provides one approach. One advantage is its high level of support among stakeholders, but the disadvantage is that with different perspectives among specific participant groups some actual risks may be neglected;
- *Risk-based priority setting* provides another approach that has a recognized scientific basis for addressing the issue. One advantage is that it can be used for risk reduction but one disadvantage is that considerable data and knowledge may be required to identify which stage in the lifecycle of nanomaterials should be addressed;
- A *national priority setting* approach uses information already provided and selected from the range of information available. The advantages of this approach are that gaps, deficiencies, lack of facilities and/or weak coordination between relevant stakeholders may already have been highlighted for action. One disadvantage is that the issues identified may not constitute high priorities in terms of management of risks to human health and the environment.

It is important to take into account ongoing work of relevant parties, documented in the drafting of the nano assessment, when identifying priorities. It may not be necessary to develop new priorities for action or new areas of work: a reiteration and

renewed commitment to ongoing work may often be a pragmatic way forward. In fact, a failure to take into account ongoing work during the priority setting process may diminish the interest and commitment of those who are involved in existing projects.

The input of the various parties participating in the process will also aid in identifying areas of priority concern. A priority setting process could generate:

- a list of national nanomaterials management priority issues to be addressed;
- a membership list of key ministries and stakeholders; and
- a work plan and time frame for developing the national nano policy and implementation.

11.3 Keeping the number of priorities realistic

Generally speaking, priority setting involves identifying a broad range of issues/topics based on input from stakeholders. This initial list is then narrowed down and prioritized according to agreed criteria (one practical aspect of prioritization is included in Annex V). Priorities are commonly placed into a tabular format based on the use of a simple scale such as of 'high', 'medium', or 'low' priority (or scale of 1-5) with an estimate of whether the priority may take a short, medium or long-term to achieve the relevant objectives. Decisions will then need to be made on which and how many of the items that appear at the top of the list should be slated for immediate action. This last step is generally a matter of available human and financial resources. Issues/topics for which resources are not currently available are not forgotten, but rather are set aside so that they can be taken up at a later point in time.

A key to this process is the identification of the criteria to be used in deciding what the priorities are for immediate action and what actions can be delayed for attention at a later date. Some possible criteria might include, for example:

- **Feasibility:** Can the problem/issue be effectively addressed (e.g. will a significant positive impact be realized), taking into consideration existing or readily obtainable capacities and resources?
- **Time frame:** Will benefits/results be realized within an acceptable time frame? There may be good reasons to select some issues for which early successes can be assured.
- **Stakeholder commitment:** Is there sufficient interest and commitment among stakeholders, particularly those whose cooperation and efforts would be needed in order to successfully tackle the issue?
- **Potential for support:** If it is an issue that is likely to require external support and expertise are there international organizations and/or other outside parties that are prepared to provide guidance and assistance?
- **Economic impact:** asks for a rudimentary assessment of how the possible measures will affect to economic position of the parties involved, usually the producers, processors, users, and/or consumers (costs and benefits).
- **Assessment:** Will it be possible to track or measure progress achieved in addressing the problem/issue?

Once the criteria are agreed, the various issues/topics can be compared as to how well they measure up. This may often require additional information; thus, it is important to have the involvement of those who are working in relevant areas and who have first-hand knowledge of circumstances and existing constraints. Upon selection of the priorities, it is important to communicate these to all interested and

affected parties. This can help generate interest and support among those whose input may be needed to address the selected issues/topics.

Suggestion: It may be helpful if a 'position-paper' is drafted at this stage, focusing on the agreements reached by all stakeholders on priority issues, that can be forwarded to national decision-makers for both information and agreement, and, more importantly, to seek additional funding should this be a necessary component of any nano action plan.

It is also important to keep in mind that setting priorities should not simply be a one-time exercise. Instead, regular monitoring and evaluation regarding success in addressing priorities should be undertaken as well as revisiting priorities (and re-setting priorities as necessary) at certain points in the future. Specifically with regard to nanomaterials, which are rather new on the market as not all consequences of uses are clearly defined and new information may become available in the course of time; therefore, it is necessary to review/evaluate the priorities on a regular basis. For an example of nano prioritization undertaken at a regional workshop see Annex V. When setting priorities, it is important to also identify key actors responsible for addressing each of the priorities.

Checklist C: Priority-setting for nano

- ✓ Have all relevant stakeholders been consulted and involved in priority setting?
- ✓ Have the identified priorities been listed in order of key concerns?
- ✓ Is sufficient data and information available to enable a listing to be made?
- ✓ Have the priorities listed been scheduled within a short-, medium-, long-term time frame?
- ✓ Are the priorities feasible, practical, timely, do-able, and affordable?
- ✓ Have possible 'actors' been identified who will address the priority issues?
- ✓ Has a document been drafted and submitted to decision-makers that lists and discusses their importance nationally for nano management?
- ✓ Has a time-frame been considered as to when priority issues should be revisited in the future?

12. Establishing a Coordinating Mechanism and Organizational Considerations

Purpose of Section 12

To identify, describe, and facilitate coordination and cooperation among ministries, agencies, industries, and NGOs in addressing management of nanomaterials throughout their lifecycle.

12.1 Introduction

Should national coordination mechanisms for chemicals management already exist, nano related issues may be included to the mandates of these existing mechanisms. Countries without a national coordination mechanism for chemicals management, however, may wish to consider establishing such a mechanism as part of their nano activities, including development of a national implementation plan for nano. To ensure a coordinated approach, it may be possible to link or include nano implementation activities with other on-going processes for chemicals management or broader frameworks (such as national processes working on broader environment and health issues) that may exist at the national level.

Nano management is a diverse field, spanning issues of public health, environmental protection, economics, industry, agriculture, worker protection, international relations, and trade, amongst others. In addition to ministries concerned with, or who have a role in, the management of chemicals (such as ministries of agriculture, environment, health, and labour), other governmental entities (such as central agencies or councils) could also have an interest, including those responsible for trade policies as well as those responsible for the development and implementation of laws, regulations, policies, and activities related to chemicals management throughout their life cycle, and/or aspects of pollution prevention and control.

12.2 Ministries concerned with nano

An integrated approach to sound nano management is complicated by the fact that in most cases different ministries participate in the control of nanomaterials in different phases of the chemical life-cycle. Other elements, such as emergency response, may be dispersed across different ministries and agencies. The allocation of responsibilities can vary between countries. Countries may use different titles for their ministries/agencies. In most cases:

- Ministries of *Agriculture* are generally concerned with the use of agricultural chemicals for the benefit of securing food supplies; nano can play a role in the formulation of these agrochemicals.
- *Customs Authorities* are generally responsible for ensuring that nanomaterials do not enter or leave the country in agreement with government regulations, and tariffs and duties.
- Ministries of *(Civil) Defense* or Ministries of *Interior* are usually responsible for emergency services; such are fire fighting and response to emergencies involving nanomaterials, as well as police services for both protection and law enforcement where nanomaterials may be involved.

- Ministries of *Education* may play an important role in awareness, promotion and training concerning nano safety, both through the formal education system, at the primary and secondary school levels, and through universities and higher education institutions.
- Ministries of *Environment* are generally concerned with the direct and indirect effects of releasing nanomaterials into the environment as emissions and wastes to air, water, and land.
- Ministries of *Finance* have a central role in financial resource allocations for nano related activities.
- Ministries of *Foreign Affairs* usually co-ordinate all international aspects of management of nanomaterials, such as participation in relevant international agreements.
- Ministries of *Health* are responsible for ensuring a high standard of public health and are concerned with the safety of nanomaterials to which the public are exposed (including in emergency settings) and the short and long-term health impacts of nanomaterials, particularly in vulnerable population groups.
- Ministries of *Industry* are often concerned with the production of nanomaterials and the introduction of cleaner production technologies.
- Ministries of *Justice* or *Legal Affairs* are generally concerned with the development and enforcement of laws and regulations (including the publication and distribution of laws, regulations and other government documents which can also play a role in raising public awareness), and often deal with issues concerning public access to information, the protection of confidential business information, criminal and forensic issues, and accidents/incidents/terrorism.
- Ministries of *Labour* are generally concerned with occupational health and safety issues related to the use and handling of nanomaterials at the workplace.
- Ministries of *Planning* primarily deal with economic planning (and land use/regional development). This ministry can also often deal with the donation or receipt of development assistance, which could include chemicals for agricultural use, technical or financial assistance for the development of chemical industries, or technical assistance for the management of nanomaterials.
- Ministries of *Science and Technology* play an important role in deciding the future direction and resource allocations for research and, at least indirectly, action on nanomaterials.
- Ministries of *Trade* are generally responsible for regulating the import and export of nanomaterials and often have the authority to issue relevant trade permits.
- Ministries of *Transport* are generally concerned with the safe transportation and storage of nanomaterials during the distribution phase.

- Local Authorities can have an important role in management of nanomaterials and may be covered at the national level through a ministerial authority, which coordinates local government matters.
- Government printing/publications offices are generally concerned with the publication and distribution of laws, regulations, and other government documents and can be an important local resource for public chemical safety education and awareness campaigns.

Suggestion: it may be useful to tabulate any existing cooperation and/or coordination that already is in place nationally for traditional chemicals management undertaken through National Profile preparation and add nanotechnology and/or nanomaterials. Such a process constitutes one approach to a commitment to coordination that could be strengthened or used as the basis for coordination of all ministries, agencies, NGOs involved in nanomanagement.

12.3 Benefits, challenges, and opportunities for coordination and cooperation

Governmental actors involved in chemicals management often operate on a sectoral basis (e.g. under their own, separate legislation) and thus may not be accustomed to working and sharing information. Other government bodies less directly involved in chemicals activities may not see a clear link between their activities and sound nano management, an area which may be considered to be largely the domain of environmental and health authorities. In addition, several orders of government, e.g. federal, provincial, local governments, also typically share responsibilities (though often without formal collaboration) for the implementation of chemicals management programs, laws, and policies. In fact, in some countries much of the actual implementation of relevant programs and enforcement of nano-related laws is carried out at the local level. Effective coordination among the whole range of those who have responsibility for or a stake in nano issues means that all those involved are familiar with each others' main nano related activities, priorities, and positions, and the underlying reasons for each. Moreover, it suggests that all stakeholders use that information to make better quality and more strategic decisions on nano issues.

Country experiences and international discussions have identified a range of benefits related to inter-ministerial coordination. These include:

- Common positions on issues are identified and reinforced;
- Synergies are created—work can take place in collaboration instead of in isolation, resulting in additional benefits to both (or several) parties;
- Duplication of efforts is avoided where possible, freeing up scarce resources for other priority issues;
- Gaps in chemicals management are identified; and
- Understanding of divergent issues is increased and thus, the potential for misunderstanding is decreased

Challenges to sound inter- and intra-ministerial coordination and cooperation may include:

- Conflicting or competing mandates;
- Poor inter- and intra-ministerial communication;
- Gaps in expertise;
- A lack of resources;

- Differing priorities given to nano issues within or between particular ministry(ies).

For example, where policies are being developed government-wide through an agreed process, each individual committee usually maintains its own mandate and decision-making power— contributing to the integrity of the whole “network” and adding value to its own work. One can visualize varying degrees of formality for such a network, depending upon countries’ needs and preferences. Formalizing national efforts in this regard, e.g. through a decree or law, may enhance its effectiveness. A decree or law can help to ensure that the efforts will have a real impact and that it will continue to function over the long term, notwithstanding changes in personnel or political leadership. Conversely, a less formalized collaboration — where existing committees and ministries merely share information informally — may prove to be a more dynamic forum where participants can share experiences, best practices, and lessons learned with full confidence that their respective mandates may not change as a result of decisions made. Nevertheless, coordination can often require extensive and potentially time-consuming consultations. It is therefore important to find a reasonable degree of coordination on a day-to-day basis that balances the costs and benefits of such efforts.

Suggestion: it may be useful to prepare network diagrams or flow charts for all aspects of nanomaterials nationally indicating their possible coordination, linkages and relationships among and between ministries, agencies and NGOs for each issue. Such a process could start with one nanomaterial throughout its lifecycle and roles and linkages of each of the organizations included in terms of their management of nano including risk management.

12.4 Effective stakeholder participation

Manufactured nanomaterials already play a part in many aspects of modern life. As a result, many individuals and groups in society have an interest in, and are potentially affected by, the way in which nanomaterials are managed and used. Those who produce, sell, and use nano products—from industrial managers to shopkeepers to homemakers—have responsibilities related to their judicious and correct use and sound management. Most stakeholders have established various identifiable organizations. Such organizations include:

- industry associations and industrial enterprises
- the agricultural sector (e.g. farmers, agricultural associations, co-operatives)
- provincial, local, or municipal authorities
- retailers and distributors
- public health professionals
- workers and workers’ unions
- public interest groups (e.g. environmental groups, health advocacy groups,
- consumer protection groups)
- scientific research institutes and academia
- women’s organizations
- indigenous communities
- communities
- individual citizens

The support and engagement of such groups is often critical for the successful implementation of nano management strategies and initiatives. For example, public interest groups may have high credibility with the public—thus making their support of

great added value to any process. The public can also play a role in monitoring commitments to standards of practice and can participate in enforcement of laws. It is of the utmost importance that private industry also be a key partner for nano management—otherwise nano-related regulation and/or other approaches (e.g. voluntary) becomes much more difficult, if not impossible, to implement. Workers who produce or use nanomaterials (and therefore likely have a higher potential for exposure) have a similar, critical stake in the outcomes of any process or program addressing integrated nanomaterials management. Academics can bring expertise and an analytical perspective that may be more “arm’s length” from any process or program and thus, add value as well. Governments should therefore consider how representatives of these groups could be most effectively involved in the identification of priority problems and in the development and implementation of practical solutions. Many stakeholders often have international networks and experiences they can “bring to the table”. This collection of expertise and experiences can be used to inform participants about other potential solutions to challenging problems and to avoid making repeated mistakes.

A set of key principles and processes can be considered in any effort to meaningfully engage stakeholders in national nano implementation. Indeed, many components of these principles and processes are applicable not only to the involvement of stakeholders, but also for inter- and intra-ministerial engagement on nano issues. Key principles and processes include:

- transparency, ensuring roles and responsibilities are clear,
- comprehensive participation, two-way communication, understandable, and timely information disclosure,
- stakeholder education, and
- adequate funding.

Most governments already engage external stakeholders at one or more levels as they deal with nano issues through, for example, their participation on individual committees or initiatives, and often when consulting for general policy advice. Engaging stakeholders in a more integrated structure, however, can remain a challenge. While stakeholder participation is an integral part of efforts for integrated chemicals management in many countries, in some cases, however, maintaining a separation between a body with stakeholder representation and one that is purely governmental in nature can be necessary. Civil servants are an integral part of government, with unique roles, responsibilities, and accountability to the public through their respective ministers.

12.5 Ensuring interest and support of decision-makers

A wide range of national decision-makers are typically involved in policy and budgetary decisions that affect the sound management of nanomaterials including ministries such as agriculture, environment, health, industry, and labour, as well as ministries of finance, planning, and foreign affairs. This important ‘mainstreaming’ process is recognized as being highly important for chemicals management and consequently for management of nanomaterials. Local authorities and parliamentarians may also have a relevant role to play. The support of such decision-makers in the mainstreaming process will be needed to secure necessary human and financial resources. Such support is also needed to ensure that nano management concerns will be taken into account in the development of other policies and programs that although not of direct relevance, will ultimately impact on nanomaterials management concerns (e.g. economic policies, trade, agricultural policies).

Generating support and commitment among decision-makers outside of government, such as industry executives, environmental advocates, and community leaders, is also important.

Suggestion: the management of nanomaterials and even chemicals is often not among the top priorities of high-level decision makers who may be focused on other societal and development goals, such as economic and industrial development, agricultural production, and public health protection, and whose decisions are impacted by driving forces, such as globalization of trade, economics, and international/regional policy commitments. There are, however, very real linkages between these concerns and the objectives of chemicals management, and it is now considered of key importance to integrate management of nanomaterials into development planning. Therefore the key to generating support among decision-makers, including those within as well as outside of government, is to highlight these linkages and illustrate how their priorities and concerns relate to and are impacted by management issues of nanomaterials.

12.6 Awareness raising among key groups

Comprehensive environmental and human risk assessment and risk management for nanomaterials can require significant expert and technical resources, which could be especially challenging for small and medium-sized enterprises. Yet, even basic exposure mitigation measures have been shown to significantly reduce risks of nanomaterials in the workplace. The critical step in ensuring that nanomaterials are treated according to their anticipated hazard level is to inform small and medium-sized enterprises and importers about the hazards and appropriate prudent approaches to mitigate risks. Information raising outreach can take different forms and include dialogue with industry trade associations and communication with individual companies through government business development agencies. Such awareness raising activities aimed at private business sector, should be described in this section.

Targeted training of key groups is discussed within Section 13. However, how to organize training for small and medium-sized organizations may require a separate approach as funding for training programmes is often limited and may only involve a relatively small number of people. Nevertheless, such training is just as important for a few people as for large groups.

Checklist D: Establishing a coordination mechanism

- ✓ Have you consulted with all relevant stakeholders and agreed on an integrated approach?
- ✓ Have you listed/tabulated existing cooperation and coordination?
- ✓ Have you listed the benefits, challenges and opportunities for coordination and cooperation and devised diagrams to illustrate how to ensure attainment of cooperation and coordination?
- ✓ Have responsibilities and the authority been given to the coordination body, or does it operate only as a mechanism to coordinate activities being undertaken by the usual constituent stakeholders?
- ✓ Have you agreed how to keep all stakeholders meaningfully engaged in nano policy development and related decision-making?
- ✓ Have you considered how to engage at the appropriate time with national decision-makers on adoption and implementation of the nano policy?

13. Stakeholder Training

Purpose of Section 13

The purpose of this section is to outline the training requirements for a range of stakeholders involved in a wide variety of elements of risk management during development of nanotechnologies and application of nanomaterials throughout their lifecycle.

13.1 Introduction

The development of nanotechnology, nanomaterials, and nano-enabled products, while being a rapidly expanding series of highly technical developments, has been accompanied by potential health and environmental risks while including a range of actual benefits for specific materials. Consequently, with the ever expanding multidisciplinary and multi-sectoral research fields, it has been widely recognized that comprehensive, flexible, and practical training should be provided to specific target groups who may deal with nanomaterials directly, as well as those who are involved indirectly and/or inadvertently. Such groups include occupational safety professionals and health specialists, workers, researchers (academic, governmental, industrial), government regulators, ancillary NGOs, and other public interest groups. Which stakeholders should be trained, and at what level, will depend upon their actual or potential risk arising from nanomaterials throughout their lifecycle.

The training of workers involved with nanoparticle production and application may require consultation with occupational health physicians and industrial hygienists to evaluate the risk and propose protective measures to limit human exposure. Such training programmes will also encompass best practice guides and safety management procedures. Stakeholders who have achieved such training may be required to complete an accreditation process or other formal certification. Stakeholders with a potential for low exposure may require a modified training programme. Irrespective of the scope of the actual training programme, its aim should be seen as part of an ongoing learning activity with regular follow-ups at specified intervals.

Training materials should be developed that addresses capacity and skills-building in areas such as awareness-raising, risk assessment and management, risk communication, and tailored to address general as well as specific issues. Methods of communicating with trainees and the supply of resource materials may depend upon the needs of each group. Whether e-learning would be an appropriate form of training will undoubtedly depend upon trainee needs and required skills.

The following sections are intended as a guide for the training of several target groups. Countries will undoubtedly tailor training materials to their individual needs and situation.

13.2 Training of industrial hygienists

In many countries, large enterprises are required by law to have qualified industrial hygienists (who are synonymous with occupational hygienists) on staff to supervise occupational safety and health programs. Qualification to these industrial hygienists is granted and maintained upon completion of accredited courses. In some localities, maintenance training for industrial hygienist now includes nanomaterial courses aimed at raising awareness about current state of practice in recognizing potentially

hazardous nanomaterials and in establishing risk mitigation measures. Qualitative risk assessment and risk management methods for the nanotechnology workplace such as control banding toolkits, which could be useful to industrial hygienists, are under development (ISO, WHO, various other national and international organizations).

Industrial hygienists will have a thorough understanding of the main nanotechnology concerns of each of the groups they supervise and will recommend safety precautions to those potentially most exposed to nanomaterials. They may also provide advice to senior decision-makers and others in a position of authority as improvements in working conditions, including additional financial resources, facilities, and equipment that may be needed from time-to-time.

13.3 Health specialists

Health specialists are public health professionals such as physicians, including occupational health professionals. They should be trained on how to recognize potential health effects from exposure to nanomaterials.

Recent examples of unexpected events reported in the scientific literature include two pulmonary disease occurrences in conjunction with exposures to nanomaterials: workplace exposure to multiple chemicals with limited ventilation and personal protective equipment in one country in 2009 and exposures of workers to dust following the catastrophic fire and collapse of major buildings in another country on 11 September 11 2001. These examples illustrate that astute and trained physicians can identify sentinel events and patterns of events; therefore, by investigating the causal factors of these events can provide insight into whether production and use of engineered nanomaterials are creating undue risk that can be controlled.

National and international health profession associations can provide a good resource for training material and training infrastructure. For example, in 2011 the American College of Occupational and Environmental Health Medicine (ACOEM) issued guidance to its members.²² It stated that 'it is uncertain whether screening methods commonly used in medical surveillance, such as spirometry, will have the sensitivity and specificity to detect potential early adverse effects from exposure to nanoparticles'. It further noted that 'robust exposure controls, desirable from a preventive standpoint, will, most likely, prevent any health effects that might be found through epidemiologic or clinical assessments of groups of workers handling nanomaterials. However, if exposure assessment does document exposures in a range where health effects might occur (based on animal or other studies), or if symptoms occur in a population of workers, ACOEM supports the conduct of appropriate targeted medical screening'. Therefore, it is important to engage locally active health professional associations in the development and training for health specialists.

13.4 Researchers in nanomedicine

Researchers developing medical applications based on nanotechnology involved in the study and application of nanotechnology and nanomaterials to humans may well possess clinical qualifications as well as having participated in pharmaceutical and/or other interdisciplinary graduate programmes such as occupational hygiene or public health. What type of additional training, and to what extent, will depend upon the

²² American College of Occupational and Environmental Medicine Guidance Statement: Nanotechnology and Health, JOEM, 53(3), 1-3 (2011).

involvement of the workers with development and/or intended uses of specific nanomaterials and their actual or potentially toxic properties.

Researchers developing medical applications based on nanotechnology can broadly be subdivided into either researchers involved with nanomedicine or more broadly researchers involved with the effect of a wide range of nanomaterials on human health. Nanomedicine is especially concerned with medical applications of nanomaterials and nanosubstances to the diagnosis and treatment of recognized human diseases. Typical research may involve the use of nanomaterials for:

- Enhancement of disease diagnosis using nanosensors and imaging;
- Safer and more effective enhancement of drug delivery to site-specific diseases;
- Development of new materials for specific tasks, e.g. tissue repair;
- Control of biomolecular mechanisms.

It has been generally accepted that the process for estimating the potential effects of nanomaterials on human health is the same as that involved with traditional chemicals, e.g. the recognition of a problem, its evaluation, undertaking control actions, and communication of necessary actions to those who may be potentially affected. Specifically, an evaluation of nanomaterials involves hazard identification, routes of exposure, dose-response, and risk assessment. The management of perceived or actual risk typically is to reduce the probability of exposure using an evidence-based approach. Strategies to reduce or eliminate risk will depend upon the properties of the material being studied throughout its lifecycle, the technical feasibility of reducing exposure through control measures, number of people affected, socio-economic values, and relevance to national legislative mandate. Risk management of nanomaterials is a complex multi-factorial procedure influenced by a variety of physio-chemical properties of the materials, some of which may be poorly understood. The researchers should be trained to be able to undertake a risk assessment using the best available data and information before experimentation with nanomaterials is undertaken.

The application of risk management of nanomaterials to human health is still relatively new. While many laboratory toxicity tests for nanomaterials have been undertaken there is a paucity of data on actual human exposure levels, and inadequate physico-chemical characterization of some nanomaterials. While precautionary procedures are in place in many industries and training underway, attention should be given by researchers to their own personal protection including the potential for accidental exposure.

Results from risk management of nanomaterials can be factored in to risk communication to address public concerns and to assist with the public's understanding of nanomaterials and nanotechnologies and their application to human health problems. Risk communication is in effect a social imperative to ensure public awareness of the benefits and risks associated with these materials. The researchers should be trained in standard risk communication techniques and the use of models to illustrate results effectively. Applications of nanomedicine and its practical use to improve human health will undoubtedly lead to greater public understanding and acceptance of, at least some, nanomaterials.

13.5 Training of employees

General national occupational standards include requirements for employee training as part of the general occupational risk management programs. These standards make employers responsible in training employees in the safety and health aspects of their work. Employee training is widely recognized as an essential part of every occupational safety and health program for their protection from injuries and illnesses. Elements of an effective training model²³ could include:

- 1) Determining if training is needed;
- 2) Identifying training needs;
- 3) Identifying goals and objectives: training goals and objectives specific to the workplace hazard, operations, and environment;
- 4) Developing learning activities;
- 5) Conducting the training by suitably qualified trainers;
- 6) Evaluating program effectiveness: verification of understanding of the material or acquisition of desired skills by workers;
- 7) Improving the program.

In this section, available national guidance and requirements for employee safety training programs general and nanotechnology specific (if any) should be described. Most guidelines for nanotechnology occupational risk management programs²⁴ include the education and training of workers in the proper handling of nanomaterials (e.g., good work practices) as an essential element. Similarly a survey of publically available laboratory occupational safety guidelines for nanomaterials²⁵ revealed that they include training requirements. A common element of a training program is regular training of employees handling nanomaterials on potential hazards of their research activities in addition to general chemical and laboratory safety courses and equipment specific training.

Laboratory workers and workers manufacturing nanomaterials and processing nanomaterials represent the main categories of employees with a distinct set of working conditions.

Training should be provided as a key policy action to a range of technical and ancillary workers involved in activities where the properties and characteristics of different nanomaterials are being studied. Workers where personal protection action should be considered include:

- Laboratory technicians involved in supervised safe handling and disposal of nanomaterials, including washing of laboratory glassware and other equipment;
- Animal house technicians where nanomaterials are being tested on rodents and other animals;
- Field operatives where nanomaterial remediation trials are underway;
- Hospital nursing and ancillaries who are involved in the day-to-day care, including handling of human waste, from patients undergoing nanomedicine treatments;
- University and research institute students experimenting on nanomaterials.

²³ <http://www.osha.gov/Publications/OSHA2254.pdf>

²⁴ <http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf>

²⁵ OECD. Compilation of Nanomaterial Exposure Mitigation Guidelines Relating to laboratories. ENV/CHEM/NANO(2010)14/ADD.

The use of nanomaterials is not just confined to the laboratory or factory. Nanomaterials are now used in cosmetics, clothing, and various household items. Who then can the consumer turn to for advice on safety aspects of products containing nanomaterials? Perhaps another group of workers to whom advice should be given, if not trained, should include pharmacists as they have a tradition of providing practical advice to customers.

In countries where workers are unionized, the relevant officials should be briefed about the risks and benefits of nanomaterials and nanotechnologies to enable them to participate in negotiations on behalf of their members in a responsible way.

13.6 Customs training

All countries employ Customs Officers who are able to analyze, apply, and interpret national compliance procedures, including cargo declarations, tariff classification necessary for the import/export procedures of various categories of goods. For monitoring and controls of international trade in chemical substances, most countries have adopted the World Customs Organizations Harmonized Commodity Description and Coding System (the Harmonized System, HS) involving up to 10 digit HS Codes. For chemicals covered by the Multilateral Environmental Agreements, the Harmonized System Committee has been correlating such products including for example ozone depleting substances. Customs Officers will already be familiar with the movement of restricted goods such as hazardous chemicals, blocking of entry of prohibited goods, and application of the Prior Informed Consent procedure. Indeed the World Customs Organization cooperates with the Rotterdam Convention as well as with the OECD.

With the development of nanotechnology, nanomaterials, and nano-enabled products many materials are imported/exported but retain the basic character of the traditional chemical. For example, titanium dioxide, gold, various catalysts comprise the same traditional chemical element(s) but the difference between them and the substance as a nanomaterial is one of particle size. Currently the same HS codes would apply. Similarly nano-enabled solar cells are still solar cells with the same function as traditional solar cells whose descriptors are well established. Whether new HS codes will be required for many nanomaterials will no doubt be taken-up during the five yearly HS revisions.

Training of Customs Officers will be especially important for them to understand hazards and risks and especially risk management when handling nanomaterials and some nano-enabled products during import/export. Particularly, if the packaging is damaged requiring them to undertake a repair, and if the damaged material is temporarily stored in customs-approved buildings. Basic training should apply to all grades of Customs Officers so they have an understanding and overview of the health and environmental implications of the accidental release of nanomaterials. Should a package be damaged, the training materials should indicate what protective clothing to wear and how to assess the evidence of identity on the goods declaration and any supporting documents. They should also be familiar with the pictograms on transported traditional chemicals following the UN Recommended Transport of Dangerous Goods classification, if not already understood. In addition, the internal packaging may contain additional pictograms following the UN's GHS²⁶, so these should also be understood and precautions undertaken as necessary in the event of damage to packaging and release of materials. While the GHS does not yet apply to

²⁶ The GHS should not be confused with the "HS" noted above.

nanosubstances, basic risk management procedures would be appropriate until more detailed information is available.

13.7 Environmental specialists

Evaluation of the environmental consequences of the development of nanotechnology and application of nanomaterials mainly involve a range of environmental specialists with research experience in, for example, biotechnology, biochemistry, microbiology, ecotoxicology, soil science, water quality analysis with each group usually involved in different components of the environment. Consequently, environmental specialists may hold different professional qualifications, unlike occupational safety and health practitioners where disciplinary qualifications are often proscribed by a professional body. However, some countries do have Environmental Health Officers, whose main role is associated with compliance of local industries, establishments, and outlets with public health regulations they may impact on the local citizens.

An understanding of the lifecycle of nanomaterials, including their possible releases, their entry, and movement into various environmental media, the exposure of, and resultant impacts (if any) on living organisms, including ecosystems, and their ultimate fate, are essential components necessary for environmental specialists to understand. Nanomaterials may enter the environment:

- by fugitive emissions to the atmosphere during manufacture;
- by releases to water from cleaning of equipment/vessels;
- from their applications to specific research programmes;
- from direct releases into the environment during their use in waste water purification, remediation of contaminated soils or use of nanoclays.

Therefore, environmental specialists should work in association with industrial plant operators and/or occupational health specialists to reduce or eliminate indirect releases.

Environmental specialists should be familiar with the basic physico-chemical properties of the range of nanomaterials used or released at the national level, whether they are metals, metal oxides, carbon nanotubes and fullerenes, semiconductors and quantum dots, nanoclays, dendrimers or nanoemulsions. To understand the impacts of nanomaterials on the environment, it has been generally accepted that the basic OECD laboratory and field test criteria for effects of chemicals on various organisms (e.g. *Daphnia*, fish, microorganisms, earthworms, and honey bees) are suitable for assessment purposes but modified for application to nanomaterials. The implications of the test results in terms of calculation of hazard and risks and risks management throughout the product lifecycle represents a major task, especially as considerable research on impacts and fate of nanomaterials in the environment has yet to be undertaken.

Potential impacts on the environment include short and/or long-term exposure of non-human species (other than laboratory mammals), possible bioaccumulation by specific organisms, and perhaps ecosystem effects on terrestrial or aquatic media. Possible impacts of nanomaterials involve complex issues related to the size, composition, surface area, and solubility of such materials and whether they can be modified by aggregation (and the particles are therefore larger than nanomaterials), dissolution, and degradation (biotic or abiotic). Whether such materials interact with soil mineral and/or organic matter and/or with naturally occurring nanoparticles has to be ascertained. Impacts of nanomaterials on specific populations of organisms may

further increase the complexity of environmental measurements required for environmental assessment.

In addition to understanding the lifecycle of nanomaterials in the environment, environmental specialists also need to be able to relate such data to national legislation, regulations, whether as regulatory limits or guidelines, developed for traditional pollutant releases. These regulations typically apply to media-specific command-and-control regulatory structures. While data on fate and effects of nanomaterials in environmental media are sparse, several reports have mentioned that at least for some countries, national legislation can successfully be applied to such materials at least for certain media, such as water or the soil.

What general or specific training is required for environmental specialists in the laboratory or field will depend not only on their professional research experience, but also the specific nanomaterial used or released into the environment and/or specific environmental compartment at the national level.

Checklist E: Establishing a targeted training programme

- ✓ Have the relevant stakeholders discussed and agreed how to identify and address the training needs of the range of stakeholders involved in nanotechnology, nanomaterials and nano-enabled products?
- ✓ Have they identified the level of existing skills among the various stakeholders, and used this knowledge to target the training requirements of specific groups?
- ✓ Do they or the organizations they represent have the necessary trainers 'in-house' and other resources for the identification of hazards, exposure, risks, and management of risks potentially arising from nanomaterials throughout their lifecycle?
- ✓ In the absence of 'in-house' trainers have the skills, which are needed to train the various stakeholders been identified and sourced nationally?
- ✓ Has agreement been reached on the training programmes required for each of the stakeholder groups that require targeted training?
- ✓ Has identification of the priority issues (Section 11) assisted in deciding which specific stakeholder groups should be trained and in which group should the training commence?
- ✓ Have plans been made to award certificates or other acknowledgements to those stakeholders who have received training and successfully applied such knowledge?
- ✓ Are emergency responders included in the training programmes?
- ✓ Have awareness-raising programmes for the public been considered and adopted, as appropriate, using the TV, radio, the Internet or other news media?

Box 7**Example of a list of protective measures for workers (Switzerland, SUVA 2009)****1 Basic Principles****1.1 Minimisation of exposure**

In the sense of prevention and under application of the precautionary principle and of the principle of economic feasibility, the exposure to nano particles should be minimised. This can be reached by the following measures:

- a) Reduce the exposure time;
- b) Reduce the number of exposed workers;
- c) Reduce the concentration of nano particles at the workplace

1.2 Hierarchy of protective measures

There are 4 levels of measures:

- a) *Substitution*: Replace hazardous substances by less hazardous alternatives.
- b) *Collective protective measures*: Technical measures for monitoring, limitation and removal of dangerous gases, vapors, and dusts.
- c) *Individual protection*: Use of personal protective equipment in addition to technical measures.
- d) *Hygiene*: Possibilities for decontamination by washing (water, soap, shower); wear different clothing inside working area and home.

2. Practical protection measures**a) Substitution:**

- Replace powdery preparations containing free nano particles by preparations containing bound nano particles (e.g. dispersions, pastes, granulates, compounds), in order to reduce the release of nano particles.
- Replace spraying applications (which generate aerosols) by aerosol free techniques such as painting or immersing.

b) Technical measures:

- Use closed apparatus.
- Avoid formation of dusts and aerosols.
- Aspirate dusts and aerosols directly at the source.
- Purify aspirated air. Use HEPA-Filters H14 before returning the air into the working area.
- Separate the nano working room and adapt the air conditioning (keep pressure lower in the nano room).
- Clean only by aspiration with suitable equipment. Do not blow air all over the place. Use wet towels for cleaning.
- Concerning the handling of flammable nano particles: in addition to the above stated measures, follow explosion protection measures in case nano particles are present in dusts and in dangerous amounts. Minimum ignition energies may be reduced in case of flammable nano materials. Usually, the requirements of work hygiene should confine the danger of a dust explosion to the inner compartment of an apparatus only, where the nano concentration is high.
- Concerning the handling of reactive and catalytically active nano particles: avoid contact with incompatible substances.

c) Organisational measures

- Minimise the exposition time.
- Minimise the number of exposed persons.
- Limit access to the nano area.
- Train staff about potential hazards and protective measures

d) Personal protective measures

If aerosol formation and/or skin contact cannot be excluded by technical measures:

- Use respirator masks with particle filter P3.
- Use gloves; in case of dispensable gloves use two layers of gloves at the same time.
- Use closed safety glasses.
- Use protection clothing with hood (non woven).
- Do training in decontamination.

e) Efficacy of protective measures

- Do nano monitoring in the air at the production site.

Source: www.suva.ch/nanopartikel

14. Establishing an Action Plan: Planning for Implementation of a Nano Programme

Purpose of Section 14

To establish an action plan for the management of a nano programme based on agreed priorities, the involvement of concerned parties, results from situation and gap analyses, and the nano assessment.

14.1. Introduction

An action plan provides a flexible structure and a focus for the implementation of a nano programme based on earlier cooperation and coordination among all stakeholders, the situation and gap analysis, and results from the nano assessment. Development of a draft action plan or 'road map' provides the last step in the development of a nano management programme. While the action plan development involves a defined start and a conclusion, the plan should be seen as an ongoing process as new nanotechnologies and nanomaterials may be introduced and applied nationally, and additional funding may become available for further actions during the implementation phase.

Various action plans have been proposed by different organizations as a forerunner to programme implementation, but they involve, in essence, a range of comparable steps. The following suggested steps have been abbreviated from modules redrafted from a UNITAR Action Plan for the Sound Management of Chemicals.

14.2 Action plan steps

- Identify the most important problems/issues/topics to be addressed that arose from the prioritization process;
- List the specific activities to be undertaken, to address these problems/issues/topics in order of importance, and the objectives to be achieved for each activity;
- Breakdown the activities into lists of tasks to be undertaken;
- Establish working groups (or technical task forces), agree their roles and responsibilities that will be used to address each activity/task;
- Ensure coordination between the working groups to provide comparability of the groups;
- Consider establishing an information system (or data base) to provide links between the working groups;
- Estimate realistic time-frames and identify necessary expertise and the resources needed to achieve the objectives;
- Develop 'mile-stones' to aim for during the implementation process;
- Draw upon existing expertise to establish indicators that can be used to quantify progress towards achieving the objectives;

- Agree the budget and its allocation; are the funds required separate from, or included within regular budgetary allocations;
- Draft the proposed action plan, the benefits of taking action and how the plan links in with other national chemical priorities, including 'mainstreaming' processes; Are the results of relevance to reporting of actions taken towards national achievement of the Millennium Development Goals;
- Obtain agreement on the action plan from relevant stakeholders;
- Identify whether further financial and/or technical support is required nationally and whether external support should be sought;
- Present the action plan to decision-makers to obtain high-level commitment;
- Implement the plan, monitor and evaluate its progress and revise actions if necessary;
- Hold a workshop at a suitable stage (e.g. after one year) during implementation of the action plan to review progress and identify whether new and emerging issues need to be addressed.

Checklist F: Establishing an action plan and its implementation

- ✓ Is the action plan likely to achieve the agreed results, objectives, and risk reduction if appropriate, given the resources and time allocated/or required?
- ✓ How technically feasible are the objectives?
- ✓ Given the resources and time allocated or required, have some short-term measures been agreed to ensure that the programme can rapidly yield some results?
- ✓ Will the programme be politically and socially acceptable, bearing in mind ongoing national and industrial development policies?
- ✓ Can the action plan be linked with other national chemicals management initiatives to place the nano plan into a wider perspective?
- ✓ Have comparable plans and activities been favourably addressed by other neighbouring countries?
- ✓ If good progress is achieved with the implementation of the nano action plan, have any follow-up actions been considered, e.g. reporting to regional and/or international meetings?

15. Country Examples

15.1 Thailand

The word “nano” has attracted various industries into investing in the manufacturing of nano-products claiming to contain special properties over a regular product due to the quantum effects and super-large surface area of the nanoparticles. Things with “nano” are welcome by consumers where extraordinary functions are expected. Thailand is no exception. Many nano-related products are wide spread in the Thai markets and without any safety regulation. Concerns on nano-risks on nano-hype products are gaining ground and attention from the public. To minimise the risks while maximizing the benefits from the nanomaterials, the National Nanotechnology Center (NANOTEC),²⁷ a member of the National Science and Technology Development Agency, an autonomous organization under the Ministry of Science and Technology, has initiated a nano-safety program since 2005. A national nano-safety and nano-ethics framework was drafted.

In March 2007, the nano-safety and nano-ethics initiatives were part of the local ISO TIS (Thai Industrial Standard) forum. NANOTEC had commissioned Chulalongkorn University to prepare a nano-safety status report in 2007. The main objective of this exercise was to gather international information on all aspects of nano-safety and nano-ethics. Data sources include university centers that receive US government grants related to nano-safety/nano-ethics, independent policy research institutes, independent academics, e.g. in South America, and international organizations such as OECD, SAICM, UNITAR, ISO, and APO (Asian Productivity Organization). In addition, this exercise attempted to familiarize a dozen experts in various fields with the foundation and features of nanotechnology. These experts from the fields of environmental law, consumer protection law, economics, and political science would become invaluable resource persons and reviewers of the national nano-safety guideline.

Currently, the funded nanomaterials safety projects have three objectives: (1) to support R&D in the area of nano-safety, (2) to push nano-safety into policy at the national level, and (3) to establish a nano-standard for an industrial use. In addition, the Nano-safety Strategic Plan is being developed by the Nano-safety Committee, whose members are representatives from Ministry of Science and Technology, Ministry of Public Health, Federation of Thai Industries, and NGOs. At the international level, Thailand actively participates in the working parties of the OECD and ISO TC 229. In 2008, two plenary speakers in the 6th Intergovernmental Forum on Chemical Safety VI: Global Partnership in Chemical Safety Contributing to the 2020 Goal, in Dakar, Senegal were from Thailand.²⁸

At the beginning of 2010, three initiatives related to nano-safety have been driven by NANOTEC. They were (1) the establishment of the National Nano-safety Guidelines, (2) the development of the National Nano-safety Strategic Plan, and (3) the founding of the Nanosafety Information Center of Thailand (NICT), in collaboration with Chulalongkorn University. Also, the concept of Nano-Q as a certified nano-product label or a nanomark has been initiated. Nano-Q is to be implemented by the Nanotechnology Association of Thailand in 2011.

²⁷ <http://www.nanotec.or.th/en/>

²⁸ <http://www.iisd.ca/chemical/ifcs6/16september.html>

In addition, during the past couple of years NANOTEC, via its funding mechanism, has urged researchers to add safety aspects to all nanomaterials in their R&D grant proposals. For example, nanoparticle-coated fabrics were subject to wash-water contamination tests; nano-titanium dioxide (TiO₂) coated fish tanks were tested for toxicity to fish; skin cream containing titanium dioxide nanoparticles were also tested for skin penetration through a model (pig) skin; and, the ecotoxicity of nanosilver in waste water was also tested.

More comprehensive nanomaterials safety data from the Nano Safety and Risk Assessment Laboratory of NANOTEC specifically addresses two main areas regarding safety investigation of nanomaterials: Human health and the Environment. For the human health aspect, the biological interactions, toxic mechanisms, biomarkers, and nano-drug interactions especially in lung and gastrointestinal models are determined. For the environmental aspect, the accumulation, fate and transport, as well as toxic mechanisms of nanomaterials by using ecological model systems are evaluated. Currently, the effects of three nanomaterials, Ag, TiO₂, and Au, have been investigated.

NANOTEC regularly organizes nano-safety public seminars for public awareness and to disseminate knowledge about nanotechnology among the private sectors. At the NanoThailand, the largest international conference and exhibition of nanotechnology in Thailand held in alternate years, 2008, 2010, and 2012, nano-safety sessions were also part of the conference program. A public hearing and focused group meeting on nano-safety was also organized in the conference. In 2011-2012, the nano-safety related activities, topic, and timelines are listed in box 8.

Box 8

“Nano-safety Pilot Project in Thailand” 2011 -2012

Activities	Time
Develop National Nano-safety Guidelines	October 2010-2011
Organize workshop and seminar on National Nano-safety& Ethic Strategic Plan (public hearing focus on human health, environment, and national security)	January 2011
Establish Nano-safety Information and Knowledge Management Center , in collaboration with Chulalongkorn University	December 2010
Develop “Nano Q” as a standard nanomark for selected Thai nano-products to identify types, sizes, and properties of nano-particles	December 2010 - 2012
Collaborate with National Chemical Safety Steering Committee	December 2010-2011
Collaborate with Working Party on Manufactured Nanomaterials (WPMN) of OECD and the Sponsorship Programme	January 2011-2012
Organize workshop and seminar on National Nano-safety & Ethic Strategic Plan	January 2012

Box 9

Research overview on human health and environmental impacts

Research Overview



Human Health and Environmental Impacts

Toxicology (2007 -)

<ul style="list-style-type: none"> • In vitro • In vivo 	<ul style="list-style-type: none"> • Biological interactions • Toxic mechanisms • Biomarkers • Nano-drug interactions 	<ul style="list-style-type: none"> • NMs used in consumer products in Thailand • NMs produced in house • Air-borne nanoparticles
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Ecotoxicology (2011 -)

<ul style="list-style-type: none"> • Plants • Organisms • Water 	<ul style="list-style-type: none"> • Accumulation • Fate and transport • Toxic mechanisms 	<ul style="list-style-type: none"> • NMs used in consumer products in Thailand • Air-borne nanoparticles
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Human and Environmental Exposure (2008 -)

<ul style="list-style-type: none"> • Human-related models • Work place 	<ul style="list-style-type: none"> • Release • Potential exposure • Health effects 	<ul style="list-style-type: none"> • Consumer products in Thailand • Air-borne nanoparticles
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15.2 Switzerland

The Federal Council approved the *Swiss Action Plan Synthetic Nanomaterials* on 9 April 2008. The action plan covers nanotechnology development as well as EHS issues.²⁹

The Action Plan's objectives are:

- Creating framework conditions for responsible handling of synthetic nanoparticles
- Creating scientific and methodological conditions to recognise and prevent possible harmful effects of synthetic nanomaterials on health and the environment
- Promoting public dialogue about the promise and risks of nanotechnology
- Better use of existing promotional instruments for the development and market launch of sustainable applications of nanotechnology

Based on the scientific and methodological principles currently available, no conclusive requirements for the safety of synthetic nanomaterials can yet be formulated. Nevertheless, *safety precautions* must be taken. The regulatory measures must focus first on the reinforcement of the *personal responsibility of industry*. Public information about nanotechnologies in general and possible risks of products using synthetic nanomaterials is an issue to be fostered as well. When the methodological background and well-grounded risk assessments of synthetic nanomaterials are available, statutory framework conditions for the safe handling of synthetic nanomaterials may be created where necessary. There is no legal definition for "synthetic nanomaterials" used yet. Synthetic nanomaterials do not receive special treatment under current legislation. Present legislation implicitly includes synthetic nanomaterials or nanoparticles. Adaptation of legislation is needed when the methodological and scientific background for the risk assessment of synthetic nanomaterials are available.

A list of nanomaterials and/or applications of nanomaterials of great concern does not exist. However the "*precautionary matrix*" was developed to identify nanomaterials applications of high concern where precautionary measures needs to be taken. The main criteria used are potential effects on health and the environment by synthetic nanomaterials and the potential consumer/worker exposure or environmental releases during production, use, and disposal. Processes, products or applications using nanomaterials with a high reactivity and the potential of releasing these nanomaterials during their life cycle are of high concern.

Quantities used in Switzerland: In 2007, a survey among Swiss companies was conducted.³⁰ Carbon black is used in highest quantities (1365 to/year) followed by TiO₂ (435 to/year), Fe Oxide (365 to/year) and polymers (102 to/year).

Regarding EHS, there are three *major agencies involved* in the implementation of the action plan:

- The Federal Office of Public Health is responsible for consumer safety;
- The Federal Office for the Environment is responsible for the environmental safety including disposal and major accidents;
- The State Secretariat for Economic Affairs is responsible for workplace safety.

²⁹ <http://www.bafu.admin.ch/chemikalien/01389/01393/01394/index.html?lang=en>

³⁰ http://www.suva.ch/ist_nanoinventory.pdf

The Swiss accident insurance company's (SUVA) webpage has information pertaining to existing knowledge on risks of synthetic nanomaterials, as well as possible measures that can be taken to ensure safety in the workplace (available in German, French and Italian).³¹

Regarding EHS research, there is the ongoing National Research Programme 64 "Opportunities and Risks of Nanomaterials," which is managed by the Swiss National Science Foundation.³²

There are two main agencies involved in the development of research on nanotechnologies and synthetic nanomaterials. The State Secretariat for Education and Research, which supports basic and applied research at universities, and the Innovation Promotion Agency, which helps to fund projects in applied research and development in nanotechnology. The condition for project funding is collaboration between universities and a business partner. The Swiss Nanotech Report 2010 gives an overview on nanotech education and research in Switzerland.³³

Communication is a key prerequisite for public engagement with new technologies and should therefore extend further than the field of synthetic nanomaterials to encompass all of nanotechnology. The current state of legislation, scientific, and political knowledge and of public engagement should be reflected. Account should be taken of both the promise of nanotechnology and the fears it generates. A common communication strategy among the responsible agencies is under development.

Published documents:

- **Precautionary Matrix** for Synthetic Nanomaterials: The precautionary matrix provides a structured method to assess the "nanospecific precautionary need" of workers, consumers, and the environment arising from the production and use of synthetic nanomaterials. The matrix is a tool to help trade and industry meet their obligations of care and self-monitoring. It helps them to recognise applications which may entail risk and to take precautionary measures to protect human health and the environment. In the case of new developments, the matrix can contribute to the development of safer products. It enables users to conduct an initial analysis on the basis of currently available knowledge and indicates when further investigations are necessary. The precautionary matrix is available to a broad circle of users at home and abroad. It will be further developed in close cooperation with trade, industry, science, and with consumer and environmental organisations. Link: <http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en>
- **Fire and explosion properties** of synthetic nanomaterials - Initial investigations for major accident prevention: The study addresses the question as to whether new criteria for the determination of the quantity thresholds quoted in the Ordinance on Protection against Major Accidents may result from new knowledge derived from hypothetical accident scenarios that take the fire and explosion properties of synthetic nanomaterials into account.³⁴

³¹ http://www.suva.ch/home/suvapro/branchenfachthemen/nanopartikel_an_arbeitsplaetzen.htm

³² http://www.snf.ch/E/targetedresearch/researchprogrammes/newNRP/Pages/_xc_nfp64.aspx

³³

http://www.sbf.admin.ch/htm/dokumentation/publikationen/forschung/Swiss_Nanotech_Report_2010.pdf

³⁴ <http://www.bafu.admin.ch/publikationen/publikation/01539/index.html?lang=de>

Guidance documents in preparation:

- Guidance document on the **disposal of industrial waste** containing synthetic nanomaterials: When disposing of products that contain synthetic nanomaterials, hazardous nanoparticles may enter the environment or affect the recycling of composite materials and plastics. It needs to be elaborated in order for the safe disposal of synthetic nanomaterials to be assured.
- Guidance on **how to conduct the self-supervision**: Trade and industry are obliged to assess their products and applications as part of the existing provisions on self-supervision, if necessary to take measures to reduce risk, and to inform their customers of such measures. As employers, they must take all required measures to protect their employees.

Guidance documents on **nanospecific data in safety data sheets**: The safety data sheet (SDS) is an important tool in chemicals legislation, informing the processing industry about possible hazards and necessary safety measures. Only if the SDS contains the necessary information for the safe handling of synthetic nanomaterials can the processing trade and industry take on the responsibility required to protect employees, consumers, and the environment. The information necessary for the safe handling of synthetic nanomaterials must be contained in the SDS.

ANNEX I: Nano Applications

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

	Inks	Inks for printers Aromatized inks	Nano ink applications (using various nanomaterials) are being investigated for the printing of semi-conducting and insulating circuitry. Nano ink application can also be used in decorating techniques while nano varnishes can be used as anti-scratch materials for screens.
Food and beverage	Food	Canola oil	Uses nano micelles as a delivery vehicle. Applications of nanotechnologies in food products is a subject of much discussion and debate (both in relation to their very presence in food on the market, their public acceptance, and their potential health impacts)
		Slim shake	
		Tea	
	Food contact materials	Coatings for plastic bottles	Food packaging applications are very commonly discussed. Reliable information on existing application is quite limited so far.
		Antibacterial packaging Anti-moisture and anti-bacterial edible fruit coating	
Kitchen ware	Antibacterial cutlery	Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties on kitchen ware.	
	Antibacterial kitchen utensils (chopping boards, food containers etc...) Non-stick pans		
Food supplements	Vitamins Metal (principally silver and gold) colloidal suspensions Spirulina nano clusters	Food supplements make large use of micelle technologies as well as other nano-encapsulation technologies. A very large array of products is available on-line.	
Automotive	Material science	Lighter materials	Nanomaterials are used (or their uses are currently being investigated) to reduce the weight of materials as well as to explore new surface properties (see comments under inks and paints). Oil and Gas nano-based additives are also currently being investigated for their potential capacity to increase motor durability and reduce gas consumption.
Coatings/paints			
Oil/gas additives			

Health and fitness	Cosmetics	Sunscreens Anti-aging cream Acne treatment	Sunscreens containing nanoparticles (mostly nano titanium dioxide and nano Zinc oxide) represent the vast majority of sunscreens currently on the market. They also represent the majority of cosmetics products on the market containing nanomaterials.
	Clothing	Stainless fabrics Waterproof fabrics	The textile industry is now going beyond nano silver and its antibacterial properties to explore the use of a variety of nanomaterials for diverse applications.
	Sporting goods	Tennis racket Bicycle frame	Enhanced performance (lighter, more powerful, etc...) sports goods.
	Personal care	Antibacterial wound dressings Body lotion Antibacterial Hair iron Antibacterial shaver	Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties.
Home and garden	Cleaning products	Degreaser Floor/surface cleaning Micro fiber cloth	A large number of products are advertising the presence of nanomaterials. Nano cleaning products have stirred a number of controversies (either on whether they actually contain nanomaterials or whether they have health impacts when they do)
	Construction material	Paints (anti-bacterial, anti-graffiti, anti-scratch etc...) Glass (self cleaning) Coatings (surface protection) Insulation materials	Nanoparticles are used in construction materials mostly to add new properties to surfaces. A large number of potential future applications are also being currently investigated.
	Travel	Luggage (light or anti-bacterial) Umbrella	Nanoparticles are mostly used for their antibacterial and/or water repellent properties.
	Pets	Antibacterial pet products Anti stain fabrics (for cushion etc.) Fish tank cleansing	Nanoparticles (principally nano-silver particles) are used mainly for antibacterial and anti-microbial properties.

"Health and environment" application	Water purification	Desalinization Water purification In situ Water decontamination	Nanotechnology approaches to water filtration are very diverse (from the use of nanoscopic pores in filtration membranes to the use CNT or alumina fibers for nano-filtration). Most of these applications are still under development, although few are currently available.
	Soil remediation	In situ soil remediation	According to US EPA, in situ soil remediation (mostly using nano zerovalent iron) has the potential to facilitate soil remediation and to reduce its cost. It is currently being tested in a number of sites around the world, principally in the US.
Medical applications	Disease diagnosis	"Lab on a chip" Quantum dots for medical imaging and labeling Extra sensitive nano-sensors	Nano medical technology is a fast-growing and very promising field. Due to the long evaluation and testing requirements for these kinds of applications, most of them are still either in the development stages or in the clinical trial phase.
	Drug delivery	Nanoparticle delivery vehicles for active therapeutic agents	

ANNEX II: Recommendations of IFCS (Forum VI)

1. Governments and industry apply the precautionary principle as one of the general principles of risk management throughout the life cycle of manufactured nanomaterials.
2. Governments and stakeholders initiate or continue dialogue to consider the potential benefits and risks of manufactured nanomaterials.
3. Governments, intergovernmental and international organizations, universities, private sectors, and other stakeholders make information on the use and risks associated with the life cycle of manufactured nanomaterials readily accessible to the general public in order to raise awareness and prepare it for informed decisions.
4. The capacity of civil society is strengthened so that it may effectively take part in decision making related to manufactured nanomaterials.
5. Researchers and academics increase knowledge necessary in evaluating effectively the potential risks of nanomaterials especially for particularly vulnerable groups, e.g. children, pregnant women, and elderly people.
6. Governments and industries continue to fill gaps in knowledge of risk assessment including the whole life cycle of manufactured nanomaterials under real world conditions.
7. Industry involves workers and their representatives when developing occupational health and safety programs and measures, including risk assessment, selection of risk prevention measures, and the surveillance of risks related to manufactured nanomaterials.
8. Measures are taken to prevent or minimize exposure of workers and releases to environment, particularly for hazardous manufactured nanomaterials or where there is uncertainty around the environmental and human health impact of manufactured nanomaterials.
9. Researchers employing manufactured nanomaterials cooperate with environment and health and safety experts and medical communities on existing and planned research programs.
10. The international community continues to develop, fund, and share effective research strategies on potential risks to human health and the environment.
11. Downstream users through the whole supply chain are informed about health and safety risks and novel characteristics of manufactured nanomaterials via Material Safety Data Sheets (MSDS) or other means.
12. Industry continues or initiates communications and awareness raising within their responsible stewardship programs on environmental and health and safety (occupational) aspects of manufactured nanomaterials including workplace monitoring, and instigates further cooperative approaches between industry and other stakeholders.

13. Governments and stakeholders promote and share safety information on manufactured nanomaterials.
14. Countries and organizations establish partnerships, with consideration of financial support, to assist developing countries and countries with economies in transition to build scientific, technical, legal, and regulatory policy expertise related to the risks of manufactured nanomaterials.
15. Governments according to their capacity cooperate in the preparation of national codes of conduct with inclusion of all stakeholders assisted by international organizations, and evaluate the feasibility of developing global codes of conduct in a timely manner.
16. Governments exchange relevant information on manufacturing nanomaterials while exploring the need for changes to current legislative frameworks.
17. International Standards Organisation (ISO) expedites its ongoing development of clear definitions of manufactured nanomaterials including but not limited to size characteristics.
18. Producers to provide appropriate information about the content of manufactured nanomaterials in order to inform consumers about potential risks through product labelling and, as appropriate, websites and databases.
19. Governments, intergovernmental, international organizations and nongovernmental organizations, industry, and other stakeholders support these recommendations.
20. Intergovernmental organizations and other relevant organizations consider how they may assist governments to implement these recommendations.
21. The second session of the International Conference on Chemicals Management (ICCM2) consider these recommendations for further actions.

ANNEX III: SAICM resolution II/4 E on Nanotechnologies and manufactured nanomaterials

The Conference,

Recognizing that there are potential benefits and potential risks to human health and the environment associated with nanotechnologies and manufactured nanomaterials,

Recognizing also that the development of nanotechnologies and manufactured nanomaterials should be consistent with the 2020 World Summit on Sustainable Development goals related to chemicals,

Recognizing further that the relevance of nanotechnologies and manufactured nanomaterials to national development needs to be appreciated by all countries;

1. 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;
2. Requests Governments and industry to promote appropriate action to safeguard human health and the environment, including for example through engagement with workers and their representatives;
3. Recognizes the role of regulatory, voluntary and partnership approaches in promoting the responsible management of nanotechnologies and manufactured nanomaterials throughout their life cycles;
4. Agrees that further research aimed at realizing the potential benefits and understanding better the potential risks to human health and the environment needs to be undertaken;
5. Invites Governments and intergovernmental, international and non-governmental organizations, the industry sector, the academic community and other stakeholders to work together on research in order to maximize synergies and understanding;
6. Recommends that Governments and other stakeholders begin or continue public dialogue on nanotechnologies and manufactured nanomaterials and strengthen the capacity for such engagement by providing accessible information and channels of communication;
7. Encourages the wider dissemination of human health and environmental safety information in relation to products containing nanomaterials, while recognizing the need to protect confidential business information in accordance with paragraph 15 (c) of the Overarching Policy Strategy of the Strategic Approach to International Chemicals Management; SAICM/ICCM.2/15 38

8. Requests Governments and intergovernmental, international and non-governmental organizations, including the private sector, subject to available resources:
 - (a) To facilitate access to relevant information, realizing the needs of different stakeholders;
 - (b) To share new information as it becomes available;
 - (c) To use upcoming regional, subregional, national and other meetings to further increase understanding of such information, for example through the use of workshops if appropriate;
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;
10. Invites relevant international organizations, including the Organisation for Economic Cooperation and Development, other organizations participating in the Inter-Organization Programme for the Sound Management of Chemicals and the International Organization for Standardization, to engage in dialogue with stakeholders with a view to gaining further understanding of nanotechnologies and manufactured nanomaterials;
11. Notes the role of existing information exchange systems such as the Strategic Approach website and its information clearing-house and that additional information exchange could be developed as appropriate.

ANNEX IV: Practical aspects of prioritisation

Below are a few practical suggestions as to the prioritization of nano management issues, based on experiences in various countries.

The first steps would be to:

1. watch out for actions that are very broad (break them down to more tangible activities) or very small (amalgamate into sufficiently large activities)
2. screen to eliminate the large majority of items. This could be within the same category, going through all categories, or even prioritising many items across categories. A few criteria used such as:
 - a. likelihood of getting resources
 - b. likelihood of getting results within 1 to 5 years
 - c. potential to improve governance
 - d. potential to reduce concerns of the public or politicians

A simple score would be used e. g. 1, 2, 3, 4, 5, summed over all criteria. A limited number of activities with high sum scores would go on to the next iteration

3. More intricate discussions on priority considering a larger range of criteria including new ones, which come up in the discussion. Here logical time sequences and amalgamations of the issues would be considered. Discussions might start within categories and end including all categories. A score could be developed if considered useful but would not be compulsory.
4. These discussions should lead to a first list of priority actions as a basis for further elaboration in a workshop.

Objectives

The objectives of a workshop on prioritization of nano issues are to:

- Validate the lists of high priority actions (see above)
- Give insights into how one can formulate and prioritise more precise actions or projects
- Make an inventory and formulate partnership projects.

Workshop program

The workshop program consists of the following steps:

1. Training in basic concepts for the formulation of precise projects
2. Application of these concepts in a few examples
3. Training in basic concepts for prioritisation
4. Application of these concepts in a few examples

Methodology

1. Identify in 5 minutes if there is any indispensable additional action
2. Choose 3-5 actions for elaboration. This maybe a bit difficult because of the shifting character of the enumerated actions. Some groups may feel very bound by the number 3-5 while others amalgamated several into one. Amalgamation can be frequent and may lead to a good result of the exercise. A better way to

formulate the item would be: “when appropriate choose those actions that are closely linked or related in terms of the activities required to accomplish them and merge, into a single action that reflects the complete set...”

3. For each action chosen, reformulate into packages of practical size according to the following criteria:
 - a. Can be finished or well advanced in 1-5 years
 - b. Have a total cost (including salaries of the personnel involved) for example of around 5,000 to 50,000 USD. In general, this may work out well although the basis for the range chosen can be questionable. Perhaps a better description of the type/size of projects in relation to the potential costs (including those internal and external) may help to clarify.
 - c. Each group is expected to work on 2-3 packages. Each package may take about 15-30 minutes to discuss because of the amalgamations;
4. Discuss if there is a logical sequential order between any of the activities (for instance, first establish regulation, then disseminate this regulation, then enforce it; the accomplishment of one activity may be dependent on others that require prior action).
5. For discussions on priorities, choose 3-5 (possibly other) actions or packages that are early in a sequential order.
6. Discuss the priority order of these actions considering the criteria for impact and feasibility. Other criteria might emerge, if so, take note of these.

(Examples showed that many other criteria may emerge. For instance, it was often quoted that 'the time was ripe' and one should act 'before the next election'. This may be the case for many countries where priorities change dramatically with each administration. However, an iterative approach should have been used as described in the beginning of this document.)

Finally:

Examples of criteria for impact

- Compatibility with general policies
- Potential to reduce threats to health and environment
- Potential to improve knowledge about such threats
- Potential to reduce inequality within the population
- Potential to reduce political or other concerns

Examples of criteria for feasibility

- Compatibility with national long term policies
- Compatibility with other national priorities
- Potential to obtain information for the relevant decisions
- Availability of alternatives
- Availability of resources: human, technical, financial
- Availability of existing projects that can be coordinated with the action
- Availability of an organisation that is willing to take the lead
- Possibility of synergies with other actions
- Compatibility with international requirements
- Cost efficiency (for instance the existence of “low hanging fruits”)

ANNEX V: Example of Priority National Actions

After detailed discussions during the UNITAR/OECD/IOMC Awareness-Raising Workshop on Nanotechnology and Manufactured Nanomaterials for the Arab Region held in Alexandria, Egypt from 11 to 13 April 2010 two parallel working groups proposed activities for a country pilot study in the following table. It also indicates who would be responsible for the activities at the national level, what are the proposed priorities, and the foreseen timing and duration of the activities. The activities in the table which are not considered to be complete and prescriptive should be used as a starting point for national discussions within a pilot study. It will depend on the specific situation of a country whether the activities in the table are all relevant, whether additional activities will be added, who is the right actor on the national level, what are the priorities, and what is the timing/duration of the activities.

Activities/Possible Actors	Priority of Activities			Start and Duration of Activities
	High	Medium	Low	
Reference/background, SAICM and international effort on health and safety (HSE) (Ministry of Environment: MOEnv)	x			Short term (first year)
Update chemical national profile for nanomaterials including national assessment of capacity to address EHS of nanomaterials (MOEnv and other authorities: Ministry of Health (MOH), Ministry of Agriculture (MOA), Ministry of Industry and Trade (MIT))	x			Short term
National committee/body for matters related to nanotechnologies/nanomaterials	x			Medium term (2-3 years)
National sub-committee for HSE on nanomaterials (lead by MOEnv or MOH)	x			Medium term
Panel of experts on HSE of nanomaterials (MOEnv, MOH)	x			Short term
Describe current status of national research on nano (Universities and research centers, Ministry of Higher Education and Scientific Research MHESR, other research associations)	x			Medium term
Identify resources needed and available for research and development on nanomaterials (MHESR, MOEnv, universities and research centers, other research associations)	x			Medium to long term
Definition of nanotechnologies and nanomaterials (MHESR, MOEnv, universities and research centers, other research associations)	x			Short term

Identification of nanomaterials entering the country and on the market (MIT, Department of Customs, MOEnv)	x			Short term
Develop/improve analytical capabilities to identify nanomaterials (MHESR, universities and research centers, other research associations)	x			Long term (3 -5 years)
Awareness raising through medias or campaigns (ministries, NGOs, industry)	x			Short to medium term
Capacity building on HSE including institution frame work and training for different stakeholders involved, NGOs, labour associations, industries(academia, IGO, ministries)	x			Short to medium to long term
Legislation/legal control of import, production and use of Nanomaterials (MOEnv, MIT and other authorities)		x		Medium term
Enforcement of legal obligations (inspectorate, customs)		x		Medium term
Test/introduce economic instruments to manage nanomaterials safely (Ministry of Finances (MOF), MIT, and other authorities))		x		Long term
Identify resources needed and available for nano risk management (authorities)	x			Medium term
Assess hazards and risks, and involve stake holders in nano risk management (MOEnv, MOH, Ministry of Labour (MOL)		x		Medium term
Identify/implement methods for proper waste treatment (MOEnv)		x		Medium term
Assess positive and sustainable impacts of nanomaterials on humans and the environment (MOEnv, MOH, MOL, and other authorities)		x		Long term
Regional cooperation among Arab countries (Arab league, national authorities)	x			Short term to medium term
Cooperation with international bodies SAICM/ICCM3 on HSE and nanomaterial (SAICM national focal point, Rotterdam Convention)	x			Short term to medium term



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 Организации Объединенных Наций
 معهد الأمم المتحدة للتدريب والبحث
 联合国训练研究所

Palais des Nations
 1211 - Geneva 10
 Switzerland
 T +41-22-917-8400
 F + 41-22-917-8047
www.unitar.org