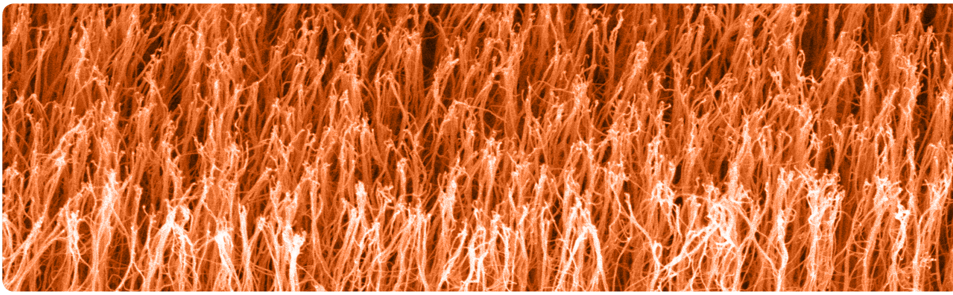
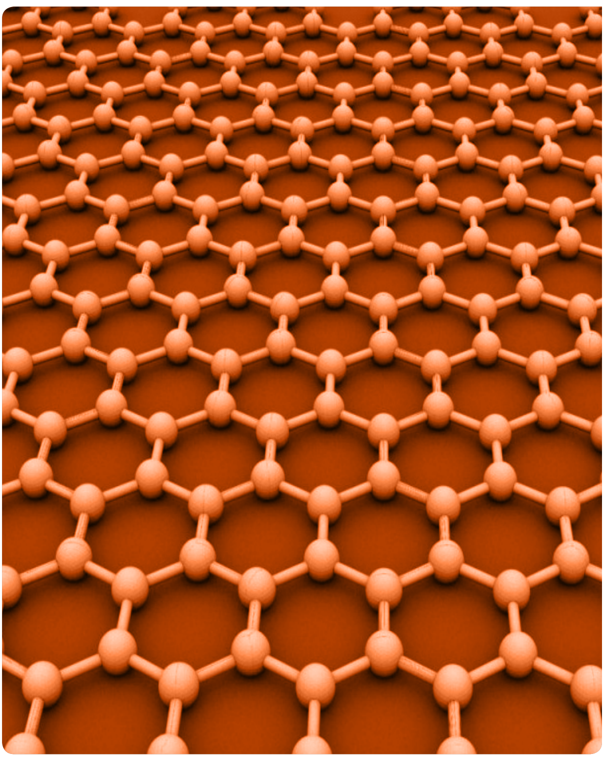


SOCIAL AND ENVIRONMENTAL IMPLICATIONS OF NANOTECHNOLOGY DEVELOPMENT IN ASIA-PACIFIC



David Azoulay
Rye Senjen
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With the collaboration of Noela Invernizzi

Geneva, Switzerland
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NTN NATIONAL TOXICS NETWORK

ReLANS
Red Latinoamericana de Nanotecnología y Sociedad
Rede Latinoamericana de Nanotecnologia e Sociedade

IPEN
a toxics-free future

IPEN is a Global network of more than 700 public interest non-governmental organizations working together for a future free of toxins. In 2009, IPEN established a working group on nanotechnology chaired by David Azoulay, Senior attorney at the Center for International Environmental law (CIEL) and director of CIEL's nano project. For more information please contact David Azoulay at dazoulay@ciel.org, www.ciel.org and www.ipen.org

NTN (National Toxics Network) is a community based network working to ensure a toxic-free future for all. NTN was formed in 1993 and has grown as a national network giving a voice to community and environmental organisations across Australia, New Zealand and the South Pacific. NTN is the Australian focal point for IPEN and works towards the full implementation of the Stockholm Convention on Persistent Organic Pollutants (POPs) 2001 and other global chemical conventions. NTN is a member of the NGO delegation to the POPs Review Committee which is the UN scientific committee assessing new POPs' nominations. NTN supports communities involved in hazardous waste management, pesticides and environmental health issues. Our committee members are involved in a range of national and international advisory bodies, including in the area of nanotechnology. For more information see: www.ntn.org.au

ReLANS (Latin American Nanotechnology and Society Network) is an academic network composed of researchers from diverse disciplines interested in the development of nanotechnologies in Latin America. The network is a pioneer in the analysis of the impact of nanotechnology on the work force, a theme that has been given little consideration in the global discussion despite its significance. The webpage of ReLANS has a section devoted to documents and organizations that focus on this critical theme: www.relans.org

Senjen, R.; Foladori, G. & Azoulay, D. (2013). Social and Environmental Implications of Nanotechnology Development in the Asia Pacific Region. NTN (National Toxics Network Australia) / ReLANS (Latin American Nanotechnology and Society Network) / IPEN (International POPs Elimination Network).

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CONTENTS

INTRODUCTION

All around the world, nanotechnology is being promoted as a technological revolution that will help solve an array of problems. According to the current hype, nanotechnology promises to provide new ways of solving some of the Asia-Pacific Region's chronic challenges, such as treating tuberculosis and malaria, making water drinkable, conserving food, and diversifying energy sources, among other hosts of applications. However, the potential risks and social implications of this new technology are not often discussed or addressed. The overall level of awareness and capacity to address these issues remains very low, in both civil society and government, and prevents these actors from playing their social role in ensuring the public good.

Research on nanotechnology and increased commercialization of products containing engineered nanomaterials (generally called nanoproducts), is currently happening in the Asia-Pacific Region (e.g., Thailand, China, India, Korea, Japan, Australia, and many other countries). In several countries in the region, nanotechnology has been declared a strategic sector of scientific and technological development. To achieve the strategic goals, public funds have been or are being used to encourage nanotechnology development through the establishment of research networks and research centres. While many countries in the Asia-Pacific Region have established national nanotechnology initiatives, actual investments in this area vary greatly from country to country. Japan, China, and South Korea have all heavily invested in nanotechnology research and development, with, for instance, China spending USD$ 1.3 billion in 2011.

Even though potential health and environmental risks of engineered nanomaterials are scientifically documented and numerous uncertainties remain, the public funds dedicated to evaluating these risks are extremely low. As a consequence, the current policies in regard to this technology are far from precautionary as the products enter the market unregulated and unlabeled, neither guaranteeing the safety of the product nor the provision of information to the consumer.

Conscious of the lack of information, regulations, and supervision of nanotechnology, governmental delegations, experts, and representatives of civil society organizations from around the world agreed to address nanotechnologies and manufactured nanomaterials as an emerging issue in the context of the Strategic Approach for International Chemical Management (SAICM)

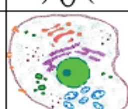
SAICM is a voluntary agreement of the international community envisaged to serve as a global framework in which to discuss methods of cooperation and specific actions that can be taken in relation to achieving safe, responsible, and sustainable management of chemicals. Since 2009, nanotechnologies and manufactured nanomaterials are addressed as an emerging policy issue. Accordingly, regional reunions and general meetings have adopted several resolutions and recommendations. At the Third International Conference on Chemical Management (ICCM3) held in September 2012 in Nairobi, Kenya, specific activities related to nanomaterials were added to SAICM Global Plan of Action, as well as a resolution recommending, among other measures, the development of international technical and regulatory guidance and training materials for the sound management of manufactured nanomaterials (cf. section 7 for more details).

In this context, this informational brochure has been developed to (i) provide an overview of nanotechnology development in the Asia-Pacific Region; (ii) introduce the social, environmental, and health implications of nanotechnology for workers and consumers in this region; and (iii) to stimulate and strengthen stakeholders' participation in the global and national discussions on the actions to be implemented by governments, industry, and civil society to lay out a precautionary environment for the safe development of this technology.

1. WHAT IS NANOTECHNOLOGY?

Nanotechnology is the manipulation of matter at a molecular and atomic scale. It involves the artificial combination of atoms and molecules to create particles and structures with functions different from that of the same material at a larger scale (also called bulk material, or material in the bulk form). For convenience, it is said that nanotechnology works on materials with dimensions of up to 100 nanometres (nm) although new functions often operate at 300 or more nanometres. A nanometre is a unit of measurement one millionth of a millimetre (10-9 m). As an example, a DNA strand measures roughly 2 nm, a red blood cell approximately 7000 nm, and a human hair is about 80000 nm wide. Table 1 illustrates the level at which nanotechnology operates.

TABLE 1. THE NANO WORLD

1 meter (m). The macro world	 1 person = 1.70 meters
1 milimeter (mm) (1000 milimeters = 1 meter). The small world.	 1 ant = 5 milimeters
1 micrometer (µm) (1000 micrometers = 1 milimeter). The celular world	 1 cell = 20 micrometers
1 nanometer (nn) (1000 nanometers = 1 micrometer) **The world of nanotechnology.**	 One virus = 60 nanometers

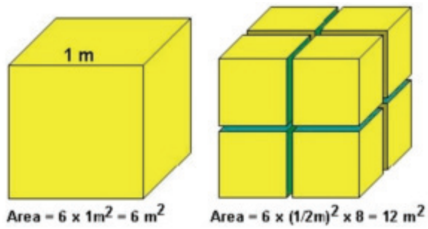
Working with matter on such a small scale represents a revolution in technology because, at this scale, materials reveal uniquely novel physical, chemical, and biological (including toxicological) properties when compared to their bulk counterpart. It is akin to discovering a world of new materials emerging out of existing materials. The changes of behaviour at the nanoscale[1] are due to two different effects: quantum and surface effects.

Quantum effects give nanosized materials different optical, electrical, thermal, mechanical (resistance/flexibility), and magnetic properties. Metals, for example,

1 Nano scale refers to having one or more dimensions in the order of 100 nm or less

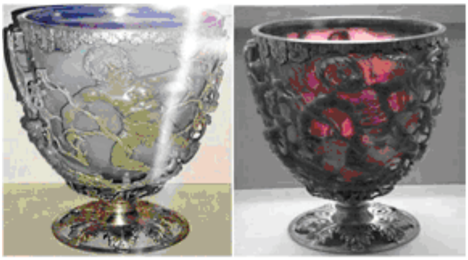
are harder and more resistant at the nanoscale. Carbon in the form of graphite (like in a pencil) is soft, but when processed at the nanoscale and manufactured in the form of tubes, the material created (e.g., carbon nanotubes) is up to 100 times harder than macro scale graphite. The optical properties of materials change; they may acquire new and different colours and reflect light differently. For example, gold becomes red when engineered at approximately 30 nm and green at around 3 nm.

Importantly, the smaller the particle size, the larger the exterior surface area and consequently the greater the reactivity. In the figure below (figure 1), the surface of the first cube is 6 m2,, while, in comparison, the surface area of the 8 small cubes is 12 m2 for the same overall mass. The atoms that are on the external surface interact more easily with the atoms of other neighbouring matter. For this reason, gold, chemically stable in the bulk form, becomes highly reactive when engineered at the nanoscale.



These effects give engineered nanomaterials new properties, including new toxicological and eco-toxicological properties, as for example, in the cases of gold, silver, and copper oxides. The increased reactivity and change in chemical and physical properties, increased mobility and capacity for absorption, and the tendency to agglomerate or de-agglomerate thus motivates the need for new scientific and technological development to understand the potential toxic impacts engineered nanomaterials may pose to human health and the environment.

Nature also produces nanoparticles from sources such as volcanic emissions, clouds, smoke, fires, etc. Human beings may also indirectly produce nanoparticles (e.g., from controlled combustion in engine) and have used some nano properties of materials in the past in making artesian crafts. Examples include when either combining glass with metal powders (see figure 2) or making dilutions to make stained-glass windows, common in the Middle Ages, or in producing the Mayan dye known as “indigo blue”.



Glass with nanoparticles of gold and silver. When reflecting light, it becomes green and when transmitting from inside, red.

Source: British Museum. S. IV A.C.

In some cases, nature may also serve as an inspiration for nanotechnology products. For example, the leaf of a lotus has a surface of hydrophobic nanoparticles which is used as an inspiration for thin films that repel water. Similarly, lizard's feet have nanosized-hairs, small enough to create forces of molecular attraction that help the animal stick to vertical surfaces and even defy gravity.

The novelty of currently engineered nanoparticles is a result of the new ability to precisely engineer new particles, structures, and derived products at the industrial scale. However, biological life forms on earth have not developed mechanisms of coping with the potentially adverse effects of engineered nanoparticles. Furthermore, increasingly available data on the toxicity of engineered nanoparticles from the scientific community is pointing in the direction of potentially very severe adverse effects on humans and the environment. Previous technological revolutions or uses of new materials, such as asbestos or POPs (persistent organic pollutants), have shown that it is much easier and much less expensive to prevent such damage rather than try to adapt or mitigate the damage once it has materialized (if possible at all). Hence, the experience with past introduction of new technologies or new materials calls for a precautionary approach in order to provide a sustainable platform for this technology to thrive. It is therefore critical for society as a whole to question how nanotechnology and nanotechnology products can be implemented and used to achieve the goals of sustainability while avoiding undesirable potential toxic impacts to the environment and human health.

Figure 3. Lotus Leaf (hydrophobic)

2. THE MARKET FOR NANOTECHNOLOGY PRODUCTS

The history of technological developments offers insights on how a given technology develops and survives for decades or even centuries in the marketplace. Nanotechnology is unlikely to be an exception to this. It is therefore illuminating and necessary to understand how the increasing acceptance of nanotechnology by society creates demand for nanotechnology-inspired products, and to illustrate what the economic, production and research funding data may mean in terms of potential effects to society, environment, and human health within the Asia-Pacific context.

Presently, there are many goods on the market that are produced using nanotechnology capabilities or that are nanotechnology-based (generally referred to as nanoproducts). The available products span a number of sectors including food, cosmetics, household appliances, computers, cellular phones, medicines, textiles, ceramics, construction materials, sports equipment, and military weapons.

In food and food production, nanotechnology is used in products, packaging, nutritional supplements, and agricultural production. There are more than 200 companies that investigate and/or produce goods that utilize nanotechnology in this sector. Nanotechnology is used in products themselves; for example, they can be used to homogenize the texture and enhance the flavour of creams or ice creams or to reduce the fat content, as Kraft, Unilever, Nestle, and Blue Pacific Flavours have researched. The latter enables producers to turn these into 'healthy foods.' Increasing taste and color of food products, as well as the use of other additives, is used to speed up production and decrease costs.

Nanotechnology is also used to add nano-encapsulated nutritional supplements, such as omega 3, fortificants, and weight loss supplements. Research on incorporating cosmetics into food products is also being undertaken by, for instance, L'Oreal in association with Nestle or BASF. Nanotechnology is also used in food packaging (known as active and intelligent packaging) to give the product a longer shelf-life, like the nano ceramic bottle by Miller Brewing, or so that raw materials do not spoil. Japan and other parts of Asia have enthusiastically embraced this kind of packaging including nano-films that extend the shelf-life of fruits and vegetables, thaw indicators for supply chain management, and nano-coating for ketchup bottles that eliminate residual waste .

Large seed manufacturing companies, such as Syngenta, Monsanto, Bayer, and Dow Chemical, investigate and produce nano-formulation and/or nano-encapsulated formulas for their agrochemicals and seeds coatings.

The cosmetics industry has the most nanotechnology products on the market. The majority of transnational cosmetic corporations have anti-wrinkle creams, sunscreens, and shampoos that use nanotechnology, including Chanel, Clinique, L'Oreal, Revlon, Johnson & Johnson, Procter & Gamble, and Lancôme. Using nano-scale materials in sunscreen instead of bulk material allows the cream to be transparent and hence avoids the dreaded traditional white colour. Nanotechnology is also used, among other functions, to diffuse light and hide wrinkles. There are toothbrushes and toothpastes with nanoparticles of silver that works as a bactericide. As a result of mounting evidence relating to potential health and environmental risks, the European Union has now reviewed its cosmetic and biocide regulations to include nano specific provisions, such as labelling and specific risk assessments for nanomaterials. Such regulatory tools are only beginning to emerge in the Asia-Pacific Region.

Figure 4. Nano in cosmetics

Various electric domestic products utilize nanoparticles of silver which operate as a bactericide. Examples include air conditioners, refrigerators, washing machines, and dish washers by Samsung or LG. Thin films engineered with nanotechnology are used to cover floors; nanoparticles are incorporated into paint and into aerosols sprays to apply to furniture and floors. Glass is processed with nanotechnology to prevent dust and dirt from adhering and to facilitate drying. In the textile industry, the application of nanotechnology can make clothing stain- and wrinkleresistant. In some cases, nanoparticles of silver are incorporated to make clothing, including not only nurses' or doctors' uniforms but also towels, sheets, and socks, antibacterial.

Nanotechnology is also used in sports equipment, such as tennis rackets, golf clubs, bicycle frames, sports shoes, and weather-resistant clothing. The major computer, cell phone, and video game brands use lithium batteries with nano-coated anodes and deploy nano-electromechanical devices within their products. Luxury automobiles now come with more than 30 parts that contain nano devices or use nanoparticles to enhance material performance, such as anti-scratch paints and antibacterial coatings for interior linings. On the other hand, nano medicines hold important promise, such as targeted delivery of drugs for enhanced efficiency and limiting side effects.

The defence and weapons manufacturing industry is one that most benefits from and most drives nanotechnology development. Developments include precision missiles, super-explosives, sensors, and bullet-proof vests to name a few. Military interest is closely tied to the advancement of nanotechnology.

Practically all branches of industry have nanotechnology products on the market. The in-depth study of the Woodrow Wilson International Centre for Scholars listed in October 2013, 1,631 nanotechnology products on the world market, most of them available through the internet and therefore available all around the world, including in the Asia-Pacific Region. The majority of products are luxury goods and fall into the category of cosmetics (154 products), clothing (187), personal care (292), and sporting goods (119). Key materials used in these product are silver (383 products), titanium (179 products), and carbon (87 products).

Figure 5. Nano products in the marketplace (The majority of products on the market are luxury goods)

Source: David Hawxhurst, PEN

3. NANOTECHNOLOGIES IN ASIA-PACIFIC

The Asia-Pacific Region is a huge geographic area, which comprises about 22 percent of the global land area and almost 60% of the global population. It includes countries in South, North, Insular, South-East Asia and the Oceania-South Pacific Region (see table 2). From a socio-political point of view, i.e. the political economic systems, types of societies, cultures, and underlying values, the Asia-Pacific Region is extremely diverse. Most countries in the region follow a broadly capitalist economic system, albeit with considerable variation in its interpretation. The private sector in most countries plays an important role with varying degrees of governmental involvement in directing the economy and, by implication, guiding technology and research. On a microeconomic level, most people living in this region, with perhaps the exception of the industrialized countries, are engaged in the subsistence sector. Additionally, most countries in the region have at least a small urban elite or even a developing middle class, and overall urbanization is a developing trend. The extent and nature of industrial development in a country will determine to some extent the kind of nanotechnologies that are important to its public and private sectors and the extent of research activities in nanotechnologies

TABLE 2: ASIA PACIFIC REGION COUNTRIES

South Asia	Continental South East Asia	North East Asia	Insular South East Asia	Oceania South Pacific
Bangladesh	Cambodia	**China**	Brunei/Darussalam	**Australia**
Bhutan	Laos	**Japan**	**Indonesia**	**New Zealand**
India	Myanmar/Burma	Korea, DPR	**Malaysia**	Pacific Island Nations
Maldives	**Thailand**	**Korea, Rep**	**Philippines**	
Nepal	**Vietnam**	Mongolia	**Singapore**	
Pakistan		**Taiwan**		
Sri Lanka				

Note: Countries covered in this study are shown in bold.

Key nanotechnology areas that are thought to be of most potential benefit for the Asia-Pacific Region include

- information and communication technology (miniaturization and efficient material development);
- healthcare (diagnostic, cancer treatment, and biosensors);
- environmental protection (reduce carbon dioxide emissions);
- reduction of energy consumption;
- purification, protection, and production of drinking water (arsenic mitigation and nanofiltration);
- renewable energies; and
- agriculture and food security/safety.

There are a number of regional networks, including the Asia Nano Forum (ANF), which includes Australia, China, Hong Kong, Iran, India, Indonesia, Korea, Japan, Malaysia, New Zealand, Singapore, Taiwan, Thailand, UAE, and Vietnam. Other types of public/private partnerships are also relatively commonplace. The Nano Science and Technology Consortium (NSTC), based in India, is an example of a regional industry advocacy organization that engages in support for research, technology transfer, and consultation. Regional workshops have been organized on a regular basis, including a workshop in Sri Lanka organized in 2009 by the Asian and Pacific Centre for Transfer of Technology (APCTT). The high-level workshop included over 40 local and 20 international participants and focused on promoting innovation in nanotechnology and fostering its industrial application. Bilateral and multi-lateral partnerships and exchange programs among various Asia-Pacific countries and Europe, the U.S., or other parts of the world are commonplace and too numerous to detail.

SOUTH ASIA

South Asia or the Indian Subcontinent is densely populated and the home to one fifth of the world population. It includes, for the purpose of this discussion, India, Pakistan, Bangladesh, Nepal, and Sri Lanka.

As part of the larger study "Nanotechnology in South Asia: Building Capabilities and Governing the Technology in India, Pakistan and Sri Lanka, " TERI (India), the National Science Foundation of Sri Lanka, and PINSAT, Preston University, Pakistan organized, in September 2012, a regional dialogue, "Nanotechnology Developments in South Asia: Stake holder's Perspective." Stakeholders from academia, industry, and civil society were present. The absence of regulation of nanomaterials and nanotechnology was one of the key issues raised. Lack of R&D partnerships among the countries of South Asia and increased sharing of the information and experiences among countries with different levels of economic development in the region were also identified as major issues.

INDIA

Research and development

India is the largest country in the Indian Subcontinent and has a population of over 1.2 billion people. While nanotechnology in India is still a largely government led initiative via publically funded research facilities and universities, industry participation is increasing, especially in the form of public-private partnership. These partnerships have chiefly focused on pharmaceutical/ nanomedicine, textiles, nanocomposites, and agriculture opportunities (see http://nanomission.gov.in). There are at least 170 institutions and universities involved in nanotechnology research, international nanotechnology conferences are being organized on a regular basis, and there are two Indian scientific periodicals dedicated exclusively to nanotechnology.

Government led nanotechnology initiatives are coordinated via the Department of Science and Technology's (DST) "Mission on Nano Science and Technology" (Nano Mission). Nano Mission is the primary funding and coordination body for nanoscience and nanotechnology research in India. The technical programs are guided by the Nano Science Advisory Group (NSAG) and the Nano Applications and Technology Advisory Group (NATAG). Nano Mission has financed close to 200 projects since 2002 and has also established 'Centres of Excellence (CoE) for Nanoscience and Technology' to develop specific applications. Other government departments supporting research into nanotechnology include the CSIR (Council of Scientific and Industrial Research), a network of 38 laboratories that engages in scientific and industrial R&D, and the SERC (Science and Engineering Research Council).

Additional important institutions involved in supporting nanotechnology research and development include the Department of Biotechnology (DBT), the Department for Information Technology (DIT), the Defense Research and Development Organization (DRDO) and its National Program on Micro and Smart Systems (NPMASS), the Department of Scientific and Industrial Research (DSIR), the Indian Council of Agricultural Research (ICAR), the Department of Atomic Energy (DAE), and the Ministry of Communication and Information Technology (MCIT). The Council of Scientific and Industrial Research (CSIR), an autonomous body under DSIR, has established a range of working groups involved with nanotechnology research at the National Physical Laboratory (NPL), the Structural Engineering Research Centre (SERC), the National Institute of Science, Technology and Development Studies (NISTADS), the National Environmental Engineering Research Institute (NEERI), the National Chemical Laboratory (NCL), the Indian Institute of Toxicology Research (IITR), and others. Other public institutions involved with nanotechnology research and development include the various Indian Institutes of Technology (IITs), the National Research Development Corporation (NRDC), and other institutes of higher education that are, for the most part, publicly funded.

The intensity of nanotechnology research, development, and policies varies greatly at the sub-federal level. For instance, Karnataka, with its capital Bengaluru (Bangalore), seeks to become the leading nanotech state in India. Andhra Pradesh hosts the ICICI Knowledge Park (IKP) in Hyderabad with research programs in nanotechnologies. Other notable nanotechnology research centers include the Amrita Centre for Nanosciences (ACNS) in Kochi, Kerala.

Research into water filtration is one of the key flagship activities in Indian nano research with a number of research centers involved. Products are at varying stages of commercialization. ARCI, Hyderabad is field-testing silver nanofilters; IIT, Chennai has developed nanosilver based carbon blocks used in Eureka Phorbes Aquaguard; and Total Gold Nova, Tata Consultancy Services (TCS), Tata Chemicals, and Titan Industries have developed and are marketing a filter impregnated with nanosilver particles, activated silica, and carbon. Other institutes are working on carbon nano filters, nano photocatalysts, nanosilver coated alumina catalysts for water filtration, and nano IronOxide/ mixed oxide for arsenic removal.

International Cooperation

Indian government agencies are involved via the Nanotechnologies Sectional Committee (MTD 33) with the International Organization for Standardization's Technical Committee on Nanotechnologies (ISO/TC 229). International research collaborations are carried out with the EU, China, India, and Russia. These programs seek to promote collaboration between scientists and to establish an electronic archive of nanoscience and nanotechnology publications. Bilateral cooperative arrangements exist with Germany, Italy, and Taiwan, as well as with China, Brazil, and South Africa to fund targeted research on advanced materials, healthcare, clean water, and energy. Since 2006, Annual "Nanotechnology Conclaves" are being conducted with annually changing partners, including the U.S., the UK, Japan, Iran, and South Korea.

India, Brazil, and South Africa, as part of the IBSA trilateral developmental initiative, have also formulated a tri- and bi-lateral collaborative nanotechnology program, which includes research in health, water treatment, and agriculture, as well as education and human resource development. India leads with its flagship project on water purification. It is unclear how far these initiatives progressed.

Nanotechnology Industry in India

The size of the nanotech industry in India is, on a global scale, still relatively small and is chiefly dominated by a few major corporations, including the Reliance, Birla, and Tata conglomerates. The leading sectors in terms of patent filing are healthcare (cancer treatment drugs, medical devices, and gene therapy) and textiles. The textile industry has been quick to adopt nanotechnology to make fabrics more spill- and stain-resistant, anti-static and odor controlling. For instance, in 2008, the Ashima Group exported over one million yards of nano-treated fabric to U.S. retailers, such as Gap and Banana Republic. In 2009, Tata Chemicals launched the "Tata Swach," a water purifier based on rice husk ash impregnated with nano-silver particles, which claims to provide clean drinking water to a family of five for around USD$ 0.50 per month.

Indian companies are starting to develop joint ventures with overseas companies, such as Shasun Pharma, the University of Missouri, and the U.S.-based Nanoparticle Biochem, to work on nanoparticle-based drug treatments of cancer and other medical nano applications. Hysitron Inc., a company providing nanomechanical test instruments for standard laboratory environments, has set up an India R&D centre in Thiruvananthapuram. Reinste Nano Ventures Private Limited has joined with the German Silanotex GmbH to introduce a range of nanosilver products to India, including nanosilver impregnated resins, fleeces, and other fabrics.

Nano risk management and regulation

India has a number of institutions involved in nanotoxicology and other aspects of nano risk assessment (see table 3). Other institutions involved in risk assessment and risk management include the Centre for Occupational and Environmental Health (COEH), the Bureau of Indian Standard's (BIS) sectional committee on nanotechnology (MTD 33), the Central Food Technology Research Institute (CFTRI), the National Environmental Engineering Research Institute (NEERI), the National Chemical Laboratory (NCL), the National Institute of Oceanography (NIO), the Technology Information, Forecasting and Assessment Council (TIFAC), and the Indian Council of Agricultural Research (ICAR).

Currently, India has only a loose framework of legislation through which nanotechnological risks could be addressed, but none of these do so explicitly. Independent commentators have suggested that the present legal regime is insufficient to deal with the potentially detrimental effects nanotechnologies may have on health and environment. In 2010, NanoMission announced the creation of a task force to investigate a Nanotechnology Regulatory Board. Others have identified the lack of coordination among a multitude of government departments as a key issue in dealing with risk identification and management. For instance, the DST, whilst the coordinating body for major government programs on science and technology, does not have a mandate to address risk governance. One major category of risk-related areas comes under the responsibility of Ministry of Environment and Forest (MoEF), but none of the acts or legislation of MOEF have explicitly identified nanoparticles as a hazard.

Public engagement and Civil Society Response

Public engagement activities on nanotechnology by the government have been limited, and the public debate on nanomaterial safety is muted. A number of scientists have demanded that regulatory issues be addressed, and the Energy and Resource Institute (TERI), an independent non-profit research institute, is conducting a project on "Capability, Governance and Nanotechnology Developments: A Focus on India." TERI has organized a "National Conference on Nanotechnology and Regulatory Issues." While TERI is recommending the application of the precautionary principle to nanotechnology regulation, it also claims that no new laws on nanotechnology were needed but recommended amendments to relevant existing legislation.

TABLE 3: NANOTOXICOLOGICAL RESEARCH INSTITUTIONS IN INDIA

Institute	Focus
Indian Institute of Toxicology Research (IITR)	• the development and validation of methods for nanomaterial toxicology • in vitro and in vivo toxicity of nanoparticles used in consumer products and therapeutics • eco-toxicity of certain nanostructured polymers, metals, and metal oxides • efficacy and safety of nano-based herbal products • guidelines for the safe handling of nanomaterials
National Institute of Pharmaceutical Education and Research (NIPER)	• test the toxicity of newly developed drugs based on nanotechnologies and • hosts the Centre for Pharmaceutical Nanotechnology • regulatory guidelines for approving nanotechnology based drugs • protocols and guidelines for toxicity testing • software to analyse links between nanomaterial properties and physiological responses
Indian Institute of Chemical Technology (IICT)	• nano science research protocols, • in vivo and in vitro toxicology studies
Indian Council of Medical Research (ICMR)	• formulates, coordinates, and promotes nanomaterial safety-related biomedical research • nanomaterial safety studies • home to the National Institute of Occupational Health (NIOH)
Central Drug Research Institute (CDRI)	• nanotoxicological studies
Bureau of Indian Standard Committee MTD33	• fund toxicology studies on various nanomaterials

PAKISTAN

Pakistan, with approximately 180 million inhabitants, is the sixth most populous country on earth. Its economy is semi-industrialized but is considered to have considerable potential. Nanotechnology research and development received government encouragement between 2003 and 2008 with the establishment of the National Commission on Nanoscience and Technology (NCNST).

While there has been a gap of five years, in early 2013, the Chairman of the Pakistan Council for Science and Technology (PCST) announced that a nanotechnology initiative will again be launched under the National Nano-Technology by a reviving of the National Commission of Nano-Science and Technology.

The following research institutes are in involved in nanotechnology research: the Pakistan Institute of Nuclear Science and Technology (PINSTECH), COMSATS Institute of Information Technology (CIIT), National Institute of Biotechnology and Genetic Engineering (NIBGE), Quaid-i-Azam University, Pakistan Institute of Engineering and Applied Sciences (PIEAS), GIK Institute of Engineering Sciences and Technology (GIKI), and Pakistan Council of Scientific and Industrial Research (PCSIR). A number of other universities (International Islamic University, Punjab University, and the private Preston University) are offering M.S. courses or undergraduate courses in nanotechnology and have also established active research groups.

Pakistan has also promoted international collaborations to conduct cooperative research work among the ESCAP member countries, i.e. countries in the Asia-Pacific Region, in the field of nanotechnology.

SRI LANKA

Sri Lanka is an island off the southern coast of the Indian subcontinent. It has over 20 million inhabitants and a tropical climate.

The Sri Lankan government is implementing a National Nanotechnology Initiative via the National Nanotechnology Board. The initiative aims to address economic and social challenges in areas such as health and medicine, electronics, energy and environment, advanced materials, and ICT. A draft National Nanotechnology Policy has been completed. Significantly, the fifth objective of this policy is to "establish a regulatory framework for promotion of nanotechnology to suit the needs of our society and industry while paying attention to ethical, environmental and safety aspects with regular monitoring, evaluation and public debate."

In 2008, Sri Lanka established the Sri Lanka Institute of Nanotechnology (SLINTEC) within a public-private partnership framework that also includes the commercial production facility NANCO Ltd. The concept of public/private partnership is a key plank of the proposed National Nanotechnology Policy.

Research activities at SLINTEC, and by extension in Sri Lanka, focus on technologies that will solve such problems as food security, safe drinking water, healthcare, and sustainable economic development. Research areas include in agriculture: advanced plant nutrients, nano-fertilizer, targeted plant nutrient release, integrated plant nutrient systems, and targeted release of pesticides, as well as water purification through research into various nanomaterials, development of nano-membranes, electrochemical methods for water purification, and developing sensors for testing water quality. Exploration of titanium processing, as well as the development of smart textiles via nano coating and nano fibers in addition to efficient textile processes to save water, energy, and chemicals are further key research areas. The five industry partners are Brandix Lanka (textiles), Dialog Telecoms (sustainable energy sources), Haleys (agriculture), Loadstar (nanomaterials), and MAS Holdings (textiles). In 2010, SLINTEC acquired five international patents for carbon nanotubes, nanofertiliser, and nano rubber with a view to commercialize these. A pilot plant to test commercial production of nano titanium dioxide (TiO2) to be used as paint pigment and a cosmetic ingredient is expected to start operation in June of 2013.

While nanotechnology regulation and public debate are part of the National Nanotechnology Policy, the steering committee for the policy neither contains representation of civil society groups nor were any included as recipients of the draft document. A project “developing a regulatory framework for nanotechnology related activities in Sri Lanka,” and funded by the International Development Research Centre (IDRC) is currently underway. As part of the project, a regional Dialogue on Nanotechnology Developments in South Asia - Stakeholder Perspectives was held in September 2012. Other activities include increasing public awareness of nanotechnology for high school students. The project places great emphasis on the potential benefits of nanotechnology but says virtually nothing regarding risks.

NEPAL[2]

Nepal, with approximately 27 million inhabitants, is one of the least developed countries in the South Asia region. It is sandwiched between India and China, Asia’s two fastest growing economies. Notwithstanding these circumstances, Nepalese research institutions are working on establishing nanotechnology programs, including training, and are encouraging international collaboration, despite a lack of well-developed infrastructure for research and development in nanotechnology.

Research in nanotechnology in Nepal focuses on carbon nanotubes, reinforcement of plastics, bionanomaterials, tissue engineering applications, anti-microbial

2 Pers comm. Ram Charitra Sah, CEPHED, Nepal in association with Dr. Rameshwar Adhikari, Central Department of Chemistry, Tribhuwan University, Nepal (2013).

nanoparticles and drugs, nanomedicine for Ayurvedic medicines, and applications of 1D, 2D and 3D nanoparticles.

For instance, overseas trained researchers and scientists are conducting work in the area of polymer based nanotechnology at the Central Department of Chemistry, Tribhuvan University. Additionally, several Masters of Science dissertations have been completed in this area by the department, as well as three PhD studies related to nanochemistry. There are also limited research activities in the Central Department of Physics, Tribhuvan University, Kathmandu, and the School of Sciences, Kathmandu University, Kavre.

Nanotechnology is also progressively being incorporated into science bachelor and other masters level curricula. There is also an initiative to extend this into school level science courses. To further this, protocols for nanotechnology experiments in university curricula are being developed, and teacher training programs are being arranged. A regular Summer School in Materials Science in Kathmandu for graduate students and young scientists aims to strengthen capacity in nanoscience and nanotechnology in Nepal.

In December 2012, the "First International Conference on Infectious Diseases and Nanomedicine" was held in Kathmandu. The conference was followed by a short course on tropical diseases and recent trends in nanomedicine. One of the main aims of the conference was to encourage networking of scientists and young researchers from South Asian Countries with the rest of the world and to promote education and research in microbiology, drug delivery, and nanomedicine in Nepal. Other conferences included POLYCHAR, the 19 World Forum on Advanced Materials, 2011, and the

Kathmandu Symposia on Advanced Materials 2012, and these had significant nanotechnology content.

The advancement of nanotechnology and its potential impact on Nepalese society has, as of yet, not been explored. The Nepalese NGO, the Center for Public Health and Environmental Development (CEPHED), is well aware of the issues of public health and the environment in relation to nanotechnology, is advocating safety related issues, and is trying to initiate a dialogue with individual experts, scientists, and research institutes. There is no nano specific regulation in Nepal.

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BANGLADESH

Bangladesh has no established governmental nanotechnology program; however, the Materials Science Division of the Atomic Energy Centre in Dhaka is carrying out some research relating to the synthesis of nanoparticles by chemical methods (e.g., silver, iron oxide, and various ceramic oxide nanoparticles) and its application in composite materials. Research collaborations are encouraged; for instance, in 2011, Bangladesh had research collaborations with 11 countries.

Other nascent nanotechnology activities include the establishment of the Bangladesh Nanotechnology Society, a non-profit organization which aims to encourage scientific research and business development for the benefit of society. In September 2012, an international workshop on nanotechnology, "Nanotechnology and its prospects in Bangladesh," proposed the development of a Nanotechnology Roadmap with goals and objectives in line with the Vision 2021 of the government. There are currently no guidelines or regulations on nanotechnology in Bangladesh

The Environment and Social Development Organization (ESDO) has released an awareness fact sheet outlining positive, as well as negative, aspects of nanotechnology. The National Institute of Biotechnology (NIB) and Bangladesh Atomic Energy Commission (BAEC) are planning together with Dhaka University and the Bangladesh University of Engineering and Technology (BUET) a public dialogue on nanotechnology in the near future.[3]

3 Pers. Comm. ESDO 2013

CONTINENTAL SOUTH EAST ASIA

Continental South East Asia consists of Thailand, Vietnam, Laos, Cambodia, and Burma and is situated east of the Indian Subcontinent and south of China. Thailand and Vietnam have a developing nanotechnology industry and research community, while Laos, Cambodia, and Burma will not be covered here, as they have no nanotechnology industry or research capabilities.

VIETNAM

Vietnam has a population of about 86 million people with one third of the population being between 10-24 years old.

The Vietnamese government believes that nanotechnology is a key area of science that will create new industries and high-tech products. The key institutions involved in nanotechnology policy and research are the Ministry of Science and Technology, the Vietnamese Academy of Science and Technology, and the Ministry of Education and Training. The Ministry of Science and Technology (MoST) is the main R&D policy making organization in Vietnam and is responsible for establishing the national plan of science and technology development and for the allocation of funds for national priority programs and national key laboratories.

The Vietnamese Academy of Science and Technology (VAST) is the largest science and technology research centre in Vietnam, established in 1975, consists of 19 research institutes and more than 20 spin-off enterprises, and employs more than 25000 researchers. It is actively involved in nanotechnology research and also sponsors and organizes international workshops and conferences. The Ministry of Education and Training (MoET) is responsible for education policy and for managing the system of universities in Vietnam, including Hanoi National University, Hanoi University of Technology, and National University in Ho Chi Minh City.

The Ho Chi Minh National Universities Laboratory for Nanotechnology, for instance, established in 2006, offers a range of undergraduate and post graduate courses in nanotechnology. Its recent research activities have focused on LED lights, RFID cards, nanowire chips, and solar cells.

Vietnam has a number of R&D facilities with a focus on environmental applications, such as efficient lighting (LED and solar cell) and water treatment. Nanomaterial research includes developing materials for lighting, solar applications, photocatalytics, and cancer treatment applications; composite materials using carbon nanotubes and others; metal nanoparticles (copper, silver) for agriculture application as pesticides; and Quantum Dots. There are a number of private enterprises in Vietnam focusing on nanotechnology, e.g., SHTP Labs.

Vietnam National University has cooperative ties with many universities, research institutes, and laboratories in various areas of nanotechnology and these include joint research projects, joint training programs, and student and staff exchanges. Vietnam and the EU collaborate through the Centre National de Recherche Scientifique (CNRS), France. Vietnam does not appear to have any nano specific regulation. However, the National Institute of Labor Protection (NILP) does mention nanotechnology on its website. It is unclear whether any toxicology or other risk assessment activities are carried out.

THAILAND

Thailand, with a population of about 64 million people, can be considered a newly industrialized country. It is a very popular tourist destination, the number one exporter of rice in the world, and exports textile, footwear, fishery products, rubber, jewelry, cars, computers, and electronic appliances.

Research and Development

Thailand's involvement in nanotechnology received official government support with the founding of the National Nanotechnology Center (NANOTEC) in 2003, an autonomous agency under the umbrella of the National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology. NANOTEC serves as a national research and development center and as a funding agency to support universities and other research institutes. NANOTEC consists of 11 central laboratories that cover nano delivery system; nanomolecular target discovery; nano-cosmeceuticals; nano safety and risk assessment; nanomolecular sensoring; organic nanomaterials; hybrid nanostructures and nanocomposites; nanomaterials for energy and catalysis; nanoscale simulation; bi-components; a spinning fiber pilot plant; and testing and service. Flagship projects focus on health and the environment: drug delivery systems; water treatment and remediation; food processing and storage; disease screening, diagnosis, and health monitoring; vector and pest detection/ control (e.g., nano coated anti malaria mosquito nets); energy and production, conversion and storage; nanocatalysts for agricultural wastes; agricultural productivity enhancement; and textiles. NANOTEC has also initiated a training program for South-East Asian countries in nanotechnology and nano-safety. The National Nanotechnology Strategic Plan (2007 – 2013) and a Nanotechnology Roadmap established a government framework for sustainable nanotechnology development in Thailand.

Nanotechnology Industry

There are a number of nanotechnology products available in Thailand, including nanocomposite food packaging, nanoclay membranes for water treatment, and curcuminiod nanoliposome face cream. Researchers at Chiang Mai University have modified local rice varieties to develop a variant that grows throughout the year by applying nanotechnology. This particular nanotechnology technique involves the perforation of the wall and membrane of a rice cell through a particle beam for introducing one nitrogen atom into the cell, which triggers the rearrangement of DNA of rice. Novel techniques applying nanotechnology could contribute to improving the current situation which, in several parts of the globe, is alarming.

Nano risk management and regulation

The National Health Commission Office of Thailand (NHC) acts as a central facilitator for nano safety issues in Thailand. The legal infrastructure that deals with nanotechnology in Thailand consists of the Hazardous Substance Act, the Enhancement and Conservation of National Environmental Quality Act, and the Labor Protection Act. In 2012, Thailand established a Nanosafety and Ethics Strategic Plan (2012-2016) which aims to

- foster knowledge about safety and ethics for nanotechnology and nanoproducts
- develop and reinforce legal mechanisms
- strengthen and encourage public participation

Activities included public hearings (mid 2010 to early 2012), training (at the regional level) for science teachers in high schools, Nanowatcher network, etc. The website, "Safe Nano," is an on-line publication (knownano.org), part of the Nanosafety Information Center of Thailand (NICT), and a collaborative effort of Chulalongkorn University and NANOTEC. "Knownano.org (also accessible through nonano.org - pun intended) is designed to be a nanosafety one-stop site for Thai-speaking clients .....from lay people ...to scientists, entrepreneurs, ...as well as people who want to find out about upcoming local, regional and international meetings related to the safety of nanotechnology and manufactured nanomaterials." In 2011, the National Nanotechnology Centre also established NanoQ, a certification mark that indicates that the product in question is nano-enabled; a Nano safety label is being planned for 2016.

Internationally, Thailand is participating in working parties of international organizations such as OECD and ISO TC 229.

Nanotechnology education

In terms of graduate education, a number of universities are offering undergraduate, Masters, and PhD Programs, such as Chulalongkorn University, Centre for Innovative Nanotechnology (http://www.nano.chula.ac.th/) - Bachelor Degree in Engineering (Nano-Engineering), Mahidol University - Center of Nanoscience and Nanotechnology (http://www.sc.mahidol.ac.th/research/nano.htm) - Master Program, Center of Excellence in Nanotechnology at AIT (http://www.faculty.ait.ac.th/joy/new/) - Masters and PhD program, and College of Nanotechnology at KMITL(BioNEDD - http://bionedd.org/) - Bachelor Degree in Engineering (Nano-materials), M.Sc. and PhD.

NORTH ASIA

The Northeast Asian countries discussed here comprise China, Japan, South Korea, and Taiwan.

CHINA

China is one of the leading nations in nanotechnology. At least 50 universities, 20 government institutes, and over 1000 enterprises are engaged in research in all areas of nanotechnology. Numerous conferences and networking events, many of a global nature, occur every year. In order to advance their strategic position globally, China has also pursued a strategy of extensive patenting and building nanotechnology infrastructure with a view to attract foreign venture capital and has built global alliances. It has also established a number of institutions focusing on commercializing nanotechnology inventions, including the Tianjin Nanotech Industrialization Base (2000), Nanopolis Suzhou (2010), and NERCN (2003). For instance, the Nanopolis Suzhou, launched in 2010, has apparently attracted more than 2,700 nanotech-related experts, entrepreneurs, and engineers and incubated more than 100 nanotechnology companies. Nanopolis Suzhou focuses on the areas of micro-manufacturing and nano-manufacturing technologies, nanomedicine, and energy and clean technologies.

Research and development

China organizes its science and technology program around five year plans. The 11th Five-Year Plan (2007-2012) emphasized innovative technologies, including the development of new materials for information, biological, and aerospace industries and the commercializing of nanotechnology. The current Medium to Long-term Plan 2006-2020, a follow-up to the last Five-Year Plan, aims to provide sustained technology innovation with the goal of becoming a global leader in science and technology research. In this context, nanotechnology development is given the highest priority status, focusing on nanomaterials and devices, design and manufacturing technology, nanoscale complementary metal-oxide semiconductor devices, nano drug carriers, energy conversion and environmental purification materials, and information storage materials.

A number of Chinese agencies have a role in regulating nanotechnology, including the Ministry of Environmental Protection (MEP), State Administration of Work Safety (SAWS), State Food and Drug Administration (SFDA), and Standardization Administration of China (SAC). In 2010, China updated its chemical regulation to bring it in line with REACH; while this does not include nanotechnology specific regulations, it implies that should Europe move in that direction, so might China. However, as enforcement is the responsibility of local and regional governments, successful implementation may be difficult. Medical device regulation was already amended in 2006 to take into account nanoscale biomaterials and silver, requiring manufacturers or importers to provide more detailed pre-market approval information.

The National Steering Committee for Nanoscience and Nanotechnology (NSCNN), established in 2000, coordinates and streamlines all national research activities and consists of the Ministry of Science and Technology (MOST), the Chinese Academy of Sciences (CAS), National Natural Science Foundation (NSFC), the National Development and Reform Commission (NDRC), the Ministry of Education (MOE), and the Chinese Academy of Engineering (CAE). Other regulatory bodies, such as health, environment, and worker safety ministries, are excluded since the steering committee's prime aims are commercialization.

There are three national nanotechnology centers in China: the National Nano Science Centre, Beijing, the National Centre for Promoting and Developing Nanotechnology, and the National Nano-Commercialization Base, Tianjin, as well as 22 local and university centers. Undergraduate and postgraduate courses with an emphasis on nanotechnology are available at a number of universities.

Nano risk management and regulation

As early as 2001, the Chinese Academy of Sciences began studying the environmental and toxicological impacts of nanomaterials, and today over 30 research organizations are involved in this type of research.

Additionally, the China Nanosafety Lab within the National Center for Nanoscience and Technology (NCNST) believes that drafting a regulatory framework for research and industrial activities on nanotechnology is a priority for the Centre. A number of specific regulations are already in place, including amendments to the medical devices regulation to reclassify them as Class III devices (and thus subject to a more detailed registration requirement). By 2010, ten books on nano EHS issues had also been published, focusing on nanotoxicology, biological effects, and the safe application of various nanomaterials. A database on nanomaterial safety issues had also been developed. The National Network and Communication on the Health and Environmental Impact of Nanomaterials not only focuses on EHS issue but also aims to address ethics and communication.

International Cooperation

China is an active participant in the OECD Working Party on manufactured nanomaterials and is also very active in nanotechnology standardisation, having published a number of standards, mainly in regards to measurement, characterization, and terminology of nanomaterials. The National Nanotechnology Standardization Technical Committee (NSTC) and the Technical Committee 279, a nanomaterial specific sub-committee under the Standardization Administration of China (SAC), reviews all standards, and the latter also develops test protocols. The core standards research groups include micro-fabrication, nano-metrology, health, safety and the environment, nano-indentation testing, and scanning probing microscopy. Seventeen of the published standards are considered voluntary but are treated as de facto mandatory.

Public Engagement

Public perception in China is "shaped around the narrative of sustaining and increasing national economic well-being, the prospective assumption of global leadership in cutting-edge technologies and science, and improving the quality of life for Chinese citizens." Nanotechnology is additionally framed in a nationalist context and divergences from either narrative are swiftly suppressed. Furthermore, the view in the relevant Chinese institutions is that public consultation may result in the public forming 'wrong' ideas about the potential riskiness of nanotechnology and hence consultation is best avoided; however, 'educating' the public so that they do not develop misconception is considered a good idea.

JAPAN[4]

Japan is one of the global leaders in nanotechnology research, development, and product innovation. Since the 1980s, the Japanese government has continuously made R&D investment in nanotechnology and materials.

Research and Development

The Science and Technology Basic Plan (currently in its 4th incarnation) is the principal vehicle of nanotechnology promotion in Japan. Key research areas supported by the Japanese government include nanomaterials, nano electronics, nano biotechnology and biomaterials, and technology fundamentals. The previous plan also included a section on "public confidence and engagement," which was supposed to promote responsible actions in terms of ethical, legal, and societal issues and aimed to reinforce the concept of accountability and public relations of

4 Prepared by Dr. Rye Senjen, IPEN and Takeshi Yasuma , CACP - Japan

science and technology activities. Interestingly, this strategy also included research on the social acceptance of nanotechnology.

The most recent plan, post the 2011 tsunami disaster, shifted its aim to the promotion of "green innovation and life innovation," i.e healthcare services, while clearly identifying nanotechnology as key building blocks of science and technology. The plan also places emphasis on renewal and regeneration as a response to dealing with large-scale disasters.

In Japan, the promotion of and advancements in nanotechnology are under the responsibility of the Ministry of Education, Culture, Sports, Science & Technology (MEXT), and regulation of nanoscale materials is primarily the responsibility of three ministries: Ministry of Economy Trade and Industry (METI), Ministry of Environment (MoE), and Ministry of Health, Labor and Welfare (MHLW). Together these ministries are responsible for human health and environment, worker safety, drug safety, and food safety. Japan has a number of key research institutes, including the National Institute of Advanced Industrial Science and Technology (AIST) and one of its departments, the Research Institute of Science for Safety and Sustainability (RISS). AIST is Japan's largest public research institute and is focused on nanotechnology applications as well as risk management methods.

Japan has many leading nanotechnology laboratories at various universities, including Keio University, the University of Tokyo, Tokyo Institute of Technology, Chiba University, Kyoto University, Osaka University, Osaka Institute of Technology, Shinshu University, Tohoku University, and Hokkaido University. Nanotechnology is taught at the undergraduate and post graduate levels, and universities have a variety of international links and collaborations. Large companies, such as Hitachi, NEC, NTT, Sony, etc., with their private research laboratories also invest heavily in nanotechnologies.

Japan participates actively in the work of OECD Working party on nanomaterials, as well as ISO TC 229 (in particular as the convener of the Working Group on Measurement and Characterization- WG2).

Nano risk management and regulation

Japan has undertaken a number of risk assessment activities, including a 5 year project by METI, and coordinated AIST, focusing on developing toxicity test protocols and risk assessment methodologies for manufactured nanomaterials. In 2011, as the result of a 3 year project on exposure to manufactured nanomaterials in the workplace conducted by the National Institute of Occupational Safety and Health Japan (JNIOSH), reports on the principles of risk assessment, as well as reports on Titanium Dioxide, Fullerene, and Carbon Nanotubes, were published. AIST also provides a Consumer Product Inventory of products claiming nanotechnology content in Japan. Some pages are available in English.

As in most countries, nanomaterials are regulated under existing regulatory frameworks for conventional substances and products, and there are currently no plans by the Japanese authorities to introduce any regulatory changes to account for nanotechnologies. However, manufacturers must notify the regulator about nanomaterials if they are new chemicals under the Chemical Substance Control Law. There is no official definition of nanomaterials in Japan, but for working purposes, it seems that a nanomaterial must have at least one of its dimensions between 1 and 100 nanometers.

In Japan, the Chemical Substance Control Law and the Industrial Safety and Health Law define "existing" chemicals, and all other substances are regarded as new and are required to submit safety data but only if the volume of production or import exceeds a defined threshold. The government has clarified that the Chemical Substance Control Law does not consider shape or size of materials, and consequently, if a chemical has already been registered as an existing material, then the material, even if now available nano sized, is not required to submit new data.

As a response to the 2008 scientific papers on the asbestos-like pathogenicity of carbon nanotubes, the three responsible ministries held a series of review meetings on nano-safety measures and issued a number of reports (in Japanese). The prompt response and clear statement of the precautionary approach of the MHLW Labor Standards was remarkable.

Both the Ministry of Economy, Trade, and Industry (METI) and the Ministry of the Environment (MoE) have established working groups dedicated to nanomaterial safety, resulting in a report, published in 2009, on potential risks in manufacturing nanomaterials. The report included voluntary guidelines for the handling of nanomaterials. The Ministry of Health, Labor, and Welfare (MHLW) has published nanotechnology guidelines relating to workers in general and also guidelines relating to medical practices and pharmaceuticals in particular. The Information Portal for the public engagement of nanotechnology, as part of AIST, functions as a public engagement platform, as well as a convenient access point, for many of the above reports. It also provides information on workshops, meetings, etc.

Public engagement and civil society response

Japanese civil society groups have raised a number of concerns regarding nanotechnology development. One of the key issues is the lack of specific regulation for nanomaterials in Japan, as the regulators do not consider size and shape of materials. Citizens Against Chemicals Pollution (CACP) have recommended establishing a regulatory body for the regulation of both chemicals and nanomaterials, independent from the influence of industries and combining the current functions given to the three ministries. One of the key ministries responsible for nanoregulation, METI, appears closely aligned with MEXT in promoting nanotechnologies as a vehicle for economic growth. AIST, which is the responsibility of METI, is the research institute for nanotechnologies with the largest power, capability, and budget. However, because of the pro-nano stance of METI, there is the potential for a conflict of interest. Despite the rhetoric of public engagement, governmental decision making on nano policies appears to be not particularly transparent to the general public, and no public consultation through the official public comment procedure has been ever taken place. Few civil society groups or NGOs are involved in committees organized by the government, and even if they are involved, member selection criteria are not transparent. As far as it is known, only two NGOs are actually working on nano issues in Japan: Citizens Against Chemicals Pollution (CACP) and Citizen's Science Initiative Japan (CSI).

Overall information available to the general public on nano issues is, however, sparse, especially on nanoregulation and EHS. There is a general lack of media coverage, articles, reports of studies, publications, and books in Japanese on nano issues. Few trade unions are involved in nano issues at the work place, and the voices of the big trade unions appear especially absent.

Citizens Against Chemicals Pollution (CACP)

CACP is the key Japanese NGO involved in raising nanotechnology issues (Japanese website - http://www.ne.jp/asahi/kagaku/pico/). CACP is a Non- Government Organization based in Tokyo and was established in 1997; since then, there has been work on policies and issues related to chemical pollution in humans and the environment. It has been actively involved in the chemicals policies area and commented on REACH and SAICM, as well as Japanese Chemicals Laws. It has also worked on toxic chemicals including mercury, dioxins, endocrine disruptors and pesticides, toxic wastes related to the Basel Convention and ship breaking in South Asia, nanotechnology issues, MCS/EHS, and children's health. CACP is also working on the anti-nuclear power movement in Japan after the Fukushima accident on March 11, 2011.

The mission of CACP is to provide information with the public and take action necessary for protecting human health and environment from harmful chemicals based on Precautionary Principle and Environmental Justice. CACP is a member of IPEN. CACP proposed, in 2008, a comprehensive framework for nanoregulation based on the following basic principles

1. No Data, No Market Principle.
2. No Release into Environment until Safety Confirmation.
3. Precautionary Principle.
4. Burden of Proof of Suppliers.
5. Mandatory Requirements for Data Submission.
6. Mandatory Requirements for Labeling on Products.
7. Public Participation in Decision Making.
8. Access to Information.

CACP's activities on EHS issues relating to nanotechnologies included the launch of web site in Japanese - Issues of Nanotechnology and Social Influence (http://www.ne.jp/asahi/kagaku/pico/nano/nano_master.html). This website addresses EHS issues, as well as raising awareness about nano issues. Other activities include opinion pieces in the national paper, calling for a moratorium at public forums, attending international meetings including IPEN, UNITAR, and SAICM, working with International NGO coalition on the oversight of nanotechnology, reviewing and proposing new chemicals policy law, and attending government committees as observer. CACP also presented nanotechnology issues to members of parliament, lectured on nano issues at seminars, contributed articles to NGO newsletters, published a booklet "Nanotechnology and Nanomaterials: What are the problems?", and finally released "Report of Study on Issues and Safety Management related to Nanotechnology." CACP has also translated over 500 nano-related articles and made these available on the CACP website.

Citizen's Science Initiative Japan (CSI)

CSI is a not- for-profit Organization (NPO) based in Tokyo and established in 2004 working on science and technology for citizens including on Electromagnetic Field, Nanotechnology, Food, Scientific Communication, Low Level Radiation, and Life Enhancement.

Activities of CSI in the nanotechnology area include reviewing literature on nanoregulation, organizing seminars, interviewing scientists, investigating nanoproducts, and publishing results of activities in the monthly report "Science and technology for citizens."

SOUTH KOREA

South Korea is a leading country in the development of nanotechnology. The government plays the key role in the promotion of nanotechnology, especially in terms of infrastructure construction and related education and training programs. Korea plans to increase its nanotechnological principal researchers from 5400 in 2009 to 30000 by 2020. The Ministry of Education, Science and Technology (MEST), the Ministry of Knowledge Economy (MKE), and the Ministry of Environment (MoE) together are responsible for establishing Korea's mid-and long-term nanotechnology strategies.

The Korean Agency for Technology and Standards (KATS) - Materials and Nanotechnology Standards Division actively participates in international and regional standardization organizations such as ISO, IEC, and PASC.

Part of Korea's success can be traced to the drawing up of a series of Nanotechnology Development Plans by the National Science and Technology Council of Korea. The first plan was adopted in 2001 and established a nano R&D-base, the second plan five years later was drawn up in order to establish a nano industrialization-base.

Nano risk management and regulation

The third and current plan focuses on commercialization but with nano safety given a prominent place for the first time. Proposed actions include a nano safety specialist training program, impact assessment and measurement systems for nanomaterial spills, a self-regulating control and report system for nanomaterials, and nano safety governance will be promoted. Additionally, the government will invest in technology for identifying and testing/ evaluating nanomaterials and performing health and environment hazard assessment. Guidelines to the safe handling of manufactured nanomaterials in workplace/ laboratories (published as a national standard) had already been implemented in 2009. The interministerial "National Nano-safety Strategic Plan (2012-2016)" further refines and includes funding for a number of projects on nano safety and regulatory issues. In 2011, the Ministry of Knowledge and Economy (MKE) and the affiliated Korean Agency for Technology and Standards also issued "Guidance on safe management of nanotechnology based product" as a Korean standard and are developing a standard on work exposure, monitoring, and assessment of carbon nanotubes and nanosilver.

The Ministry of Environment (MOE) is developing a voluntary survey on the production and use of nanomaterials to develop an inventory of nanomaterials in the market.

A nano EHS information network will also be built. Core nanotechnologies pursued in the third plan are IT, nanobiotechnology, energy and environment, materials, and manufacture. For instance, nano bio-technology for a healthy life includes nanobased high-tech agriculture, nano wellbeing products (food and household items), and nanomedicine. Energy and environment focuses on battery and fuel technology, lost cost/ high efficacy solar cell technology, water purification, and ultra-low power consumption technology. There is also a focus on nanomaterial technology development as a basis for future industries, such as nanomaterial mass production and nano biomimetics.

Nanotechnology Industry

The number of nanotechnology companies has remarkably increased from early beginnings and is probably now over 200. There are at least 43 universities with nano departments, and National Nano Fabrication Centers were built in five different places. The three plans, amongst other activities, have continually strengthened the R&D network among universities, research centers, and companies.

Key industry players include the Korean conglomerates Samsung and LG which are focusing on technologies related to organic/inorganic nanomaterials, nanodevices, and nanoprocessing for next generation semiconductor and data storage and energy storage. Korean companies have also developed a number of consumer products, especially utilizing nanosilver. Other products include cosmetics, toothpaste, soap, textiles, paint, ceramics, filters, and deodorants.

INSULAR/MARITIME SOUTH EAST ASIA

Maritime South East Asia comprises Malaysia, the Philippines, Indonesia, Singapore, Brunei, and East Timor. The latter two will not be covered here.

INDONESIA

Indonesia is an archipelago consisting of approximately 17508 islands inhabited by about 238 million people. Indonesia is the third most populated country in Asia.

Indonesia's nanotechnology effort officially started in 2006 with the National Nanoscience and Nanotechnology Development Platform. The main government agencies responsible for nanotechnology are the Ministry for Science and Technology (MOST) for national research institutes and universities and the Indonesian Institute of Science (LIPI). Government science and technology priorities are food, Information and Communication Technologies (ICT), alternative renewable energy, transportation management technology, and medicine.

Nanotechnology research in Indonesia is chiefly focused on nanostructured materials; however, the application of nanotechnology to energy, water treatment and remediation, food and agriculture, medicine, and nanobiotechnology are also being increasingly pursued.

The Indonesian Society for Nanotechnology - Masyarakat Nanotechnology Indonesia (MNI) was established in 2005 as a communication forum among government, research institution, university, and industry. A number of Indonesian universities are involved in nanotechnology research and/or education, including the Institute Technology Bandung, the Institute Technology Surabaya, University of Gajahmada, the Indonesian Institute of Science, the National Nuclear Energy Agency for Indonesia, the Aeronautics and Space Agency for the Assessment and Application of Technology, the Mochtar Riady Centre, and the Eijkman Institute.

During 2010, Indonesia invested USD$ 29 million in nanotechnology focused R&D, funding more than 60 research projects. Areas funded included ceramics, textiles, food, energy, and ICT. The MNI worked with the government to help identify the research projects.

While 35% of key industries, such as textiles, ceramics, and chemistry, have applied some form of nanotechnology, Indonesia lacks actual nanotechnology regulation and has only one regulation that relates to the handling of hazardous materials. The extent of public participation in debating nanotechnology and its effect on Indonesian society is unclear.

MALAYSIA

Malaysia comprises Peninsular Malaysia and the Malaysian part of the island of Borneo with a population of about 28.5 million persons.

Malaysia's involvement in nanotechnology started in 2000 with the establishment of a number of nanotechnology research centers at public universities. Malaysia joined the Asia Nano Forum in 2004. The Malaysian government recognized nanotechnology in its Third Industrial Master Plan, which is intended to guide the country between 2005 and 2020. The focus of this plan, apart from nanotechnology, is on biotechnology, advanced manufacturing, advanced materials, ICT, and alternative source of energy, with a view to encourage innovation among local companies and developing new products.

The Malaysian National Nanotechnology Initiative (NNMI), established in 2006, serves as a central coordinating platform for government nanotechnology policy and for the coordination of R&D programs and infrastructure, as well as a liaison point with industries. Associated with the NNMI is NanoMalaysia Berhad, the 'business entity' that commercializes nanotechnology products developed by local R&D institutions with private sector involvement. From 2010, the Malaysian Nanotechnology Directorate (NND) took responsibility for planning, managing, and administration of the NNIM, including the implementation of the Nano Malaysia Program (2011–2015). Part of this program are a number of centers of excellence, including the Centre of Innovative Nanostructures and Nanodevices at the Universiti Teknologi PETRONAS (UTP), the Ibnu Sina Institute for Fundamental Science Studies (IIS) at the University Teknologi Malaysia, the Institute of Microengineering and Nanotechnology (IMEN) at Universiti Kebangsaan Malaysia, MIMOS, and the Institute of Nanoelectronics Engineering at the Universiti Malaysia Perlis (UniMAP). In 2011, there were approximately 150 scientists and more than 300 graduate students directly involved in nanotechnology research in Malaysia. A number of Malaysian universities offer undergraduate and postgraduate degrees with a focus on nanotechnology.

The main areas of nanotechnology-focused research comprise nanoelectronics and computer technology, medicine, aeronautics and space exploration, environment and energy, biotechnology and agriculture, national security, and education. Nanomaterials, nanoelectronics and computer technology, life sciences, and medical research have received the most funding by MOSTI.

In 2011, a Nanotechnology Awareness Seminar/Nanotechnology Carnival (NanoFest 2011) was held in cooperation with the National Science Centre in Kuala Lumpur to increase awareness of nanotechnology. The event emphasized the importance of nanotechnology as an engine of economic growth. A workshop on Safety, Health and Environmental (SHE) Implications of nanotechnology was held at the National Nanotechnology Directorate (NND), MOSTI, also in 2011, with a view to assist in the formulation of the upcoming national safety guidelines. There appears to be no nano specific regulation in Malaysia.

PHILIPPINES

The Philippines are an archipelago of 7107 islands in the Western Pacific Ocean, with a population of more than 92 million people, plus an additional 12 million Filipinos living overseas.

In 2011, the government of the Philippines announced a 10 year strategic plan/ road map for the development of a R&D strategy on nanotechnology covering at least six industrial sectors – the semiconductor, information technology, energy, agriculture, medicine, and environmental protection. Nanotechnology has been identified as one of the priority areas of research identified by the Department of Science and Technology-Philippine Council for Advanced Science and Technology Research and Development (DOST-PCASTRD). PCASTRD's mandate is to develop, integrate, and coordinate national research. Flagship projects include chemical sensors and biosensors based on nanostructured materials for agriculture; food, environment and health monitoring; and nanostructured solar energy devices (e.g., prototypes and local production process technology for portable energy and off-grid application). PCASTRD also provides funds for scholarships and research fellowships. PCASTRD has also proposed to include nanotechnology as part of all science and engineering degrees.

In the area of agriculture, funded nano projects include rapid and early pest and pathogen detection; precision agriculture – monitoring of agricultural growth parameters; and post-harvest quality monitoring, nano-sized feedstock, nano-sized fertilizers/nutrients, and pesticides. Research into nanocomposite films and membranes aims to extend the shelf-life of fresh and processed produce, aid the clarification of juices, and improve whey protein production. Projects concerning nanotechnology for water purification and environmental remediation are also being funded. Seedgrowth, a plant supplement consisting of nano-sized fruit extracts and microorganisms, was developed in the Philippines and apparently reduces the need for chemical fertilizers and increases crop yield. Scientists from DOST have also developed a low-cost water purification system in the form of a ceramic filter coated with silver nanoparticles.

There appears to be no nano specific regulation in the Philippines.

SINGAPORE

Singapore is an island city-state off the southern tip of the Malay Peninsula with about 5 million inhabitants.

The nanotechnology industry is a rapidly growing enterprise in Singapore. Singapore is aiming to become a niche manufacturer of high tech nano enabled products. However, there is no current formal regulation of nanomaterials and their safe handling.

Singapore is actively involved in the Asia Nano Forum (ANF) as well as a participating member in the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) Technical Committees on nanotechnology. Singapore also has a national working group on nanotechnology to monitor the work of the ISO TC 229 and IEC TC 113 on standardization for nanotechnology. Singapore also chairs the standardization working group in the ANF.

Nanotechnology research institutions include the National University's Nanotechnology Initiative (NUSNNI), the Institute of Bioengineering and Nanotechnology (under the umbrella of the Agency for Science, Technology and Research -A*STAR), as well as the Nanyang Technological University's (NTU) Nanocluster. The main focus of many of these research groups is nanomaterial development and application in areas such as nanomedicine and semiconductor device manufacture. NUSNNI also hosts a nanotoxicology research focus group studying health and environmental impacts of gold nanoparticles using animal models but, as of yet, no research into the human health and safety aspect. While the exact number of personnel involved in nanotechnological research, development, and perhaps manufacture is not precisely known, there is also a gap in understanding the occupational health and safety implications of these activities. Specialist degrees in nanoscience and nanotechnology at the undergraduate and postgraduate level are available.

Singapore holds numerous international workshops and conferences on nanotechnology related topics.

In 2010, the Ministry of Manpower and Singapore Economic Development Board commissioned a report to gather information on the profile of usage of nanomaterials and current occupational safety and health practices in the establishment of handling nanomaterials.

Multiple forms of nanomaterials are in use in Singapore. The most commonly used nanomaterials include titanium dioxide, carbon nanotubes, and zinc oxide. Volumes are typically less than one kilogram and come in solid powder or solution form. Organizations using these materials were generally interested in learning more or needed help in defining specific nano safety measures.

TAIWAN

Although Taiwan's status under international law is contested, the Taiwanese state (officially named the Republic of China -ROC) has authority over the islands of Taiwan, Penghu, Matsu, and Kinmen. With a population of over 23 million people, Taiwan is a well-developed market economy and one of the world's principal exporters of electronics and information and telecommunication technology.

The Taiwanese government started to focus on the industrial and commercial development of nanotechnologies as early as 2002 with the National Nanotechnology Programme (NNP). The core objectives of the initial plan were to create innovative applications, improve academic excellence, establish international competitive nanotechnology platforms, and speed up the commercialization.

The objectives of Phase II (2009-2014) of the NNP aim are to further strengthen research and education programs by focusing on the conversion of nanotechnology into products and to continue to promote the commercialization of nanotechnology. Additional to these core objectives, the EPA included a plan towards the development of responsible nanotechnology with an EHS focus.

A number of ministries are involved in environment, health, and safety projects and include the Environmental Protection Administration (EPA), Department of Health (DOH), and Council of Labor Affairs (CLA).

The government has also become aware of the need to improve public support for nanotechnology. Three policy measures, as part of the NNP, specifically address this issue: the NanoMark Certification System, the Nano Education Program, and the National Nanotechnology Standards Council (NSTC). The Phase II plan also places a greater emphasis on materials with the potential for environment benefit while, at the same time, focusing on the ecological impact of nanoparticles, risk assessments, and management. Research is heavily focused on the development of nano-electronic and optoelectronic technology, nanoscale instruments, nanotechnology for energy and environmental applications, and nanoscale biomedical research. The Bureau of Standards, Metrology and Inspection, MOEA, and the Industrial Development Bureau. MOEA, are the main participants in the nanoMark project. The voluntary NanoMark certification system, launched in 2004, aims to lift the credibility of nanoproducts by verifying the claimed functional properties of nanoproducts manufactured by local companies in Taiwan, providing information of certified nanoproducts to the public, and building consumers' acceptance of nanoproducts. The approval process is carried out by the Professional Executing Agency for nanoMark Product Certification System, which is entrusted by BSMI, MOE, via a transparent approach based on the testing results of nano-size and functionality. The possible health and environmental risks are not taken into consideration. There is no public participation.

Cosmetic and pharmaceutical products are not eligible for the NanoMark certification as their associated risks are largely unknown and therefore lack benchmarked categorization. By 2011, a total of 855 products received certification, the most commonly used nanomaterials in these products were titanium dioxide, silicia, nanosilver, and carbon nanotubes.

The Taiwanese EPA is actively involved in nanotechnology research and lists as major achievements in recent years, amongst others, the promotion of an interagency precautionary risk management on nanotechnology and the development of environmental benign nanotechnologies, risk management through the setting of standard operation procedures (SOPs) and safe working guidelines for research laboratories and workplaces, development of measurement and characterization methods for environmental nanomaterials, establishment of a database of exposure and hazard of environmental and workplace nanomaterials, and research the ethical, legal, and societal implications of nanotechnology via a survey of the nanotechnology benefit and risk perception of different stakeholders.

The Council of Labor Affairs (CLA) regulates all chemicals. In 2008, updates to the existing regulations were proposed to ensure that greater information on chemical risks is disclosed by manufacturers and importers, following closely the EU's REACH in approach. Currently, no nano specific regulation exists.

Taiwan has a set of common nanotechnology laboratories spread across Taiwan including the Taipei area (National Taiwan University and Academic Sinica), Hsin-Chu area (Taiwan Silicon Valley including ITRI and the nearby National Tsing Hua University and National Chiao Tung University), Central Taiwan, and South Taiwan. Nanotechnology education is offered at all levels of the education system.

The Taiwanese nanotechnology industry is actively involved in the development of regulation via the Taiwan Nanotechnology Industry Development Association (TANIDA). It was formed in 2004 and has 57 industrial members. It was involved in establishing the Taiwan Nanotechnology Standards Council (TNSC) together with the Bureau of Standards, Measurement and Inspection (BSMI), and ITRI. TNCS also contributes to international standards as a member of ISO TC229.

Few Taiwanese environmental NGOs are involved in assessing nanorisk, partially owing to the lack of reported local cases. Most NGO activities are concerned with conveying potential nanorisks reported by NGOs in other western developed countries. The approach of the Taiwanese government and domestic enterprises towards nanoscience and technology (NS&T) appears more focused on developing nanoproducts or patents and is less concerned with fundamental research and development. The media dialogs and public views on NS&T are therefore overwhelmingly optimistic. The lack of open discussion on nanorisk is worrisome. On January 2013, the NGOs have asked the government to include nanomaterials in the amended Toxic Substances Control Act. The outcome is yet to be determined by the Legislative Yuan (Taiwan Congress).

OCEANIA/SOUTH PACIFIC

In geopolitical terms, Oceania/the South Pacific is the zone of islands that includes Micronesia, Fiji, Polynesian Island Nations, New Zealand, New Guinea and nearby Islands, the Solomon Islands, Australia, Vanuatu, and New Caledonia. In the context of this report, we will only discuss nanotechnology developments in Australia and New Zealand. The region is inhabited by about 36 million people, of which about 22 million live in Australia and just over 4 million in New Zealand.

AUSTRALIA

The Australian government invests considerably into Australian nanotechnology research via the Australian Research Council and the Commonwealth Scientific and Industrial Research Organization (CSIRO); state governments also provide funding. There are 50 Australian companies claiming to be working in 'nanotechnology.'

Nanotechnology is actively perused by a number of Australian universities and undergraduate and postgraduate degree courses are offered widely. The Australian Nanotechnology Network serves as an initiative to bring together key research groups within Australian universities and also sponsors international conferences. Many Australian universities offer nanotechnology specific undergraduate and graduate degrees.

The National Enabling Technologies Strategy – NETS (superseding the National Nanotechnology Strategy), introduced by the Australian Government at the end of 2009, purports to be a comprehensive national framework to guide the safe and responsible development of new technologies. Its goals include a national and collaborative approach among stakeholders on the development of nanotechnologies (including issues related to nanoregulation, EHS, and ELSA), continual review of the regulatory framework by the relevant agencies (National Industrial Chemical Notification and Assessment Scheme (NICNAS), Safe Work Australia, Food Standards Australian New Zealand (FSANZ), Therapeutic Goods Administration (TGA), Department of Environment, Water, Heritage and the Arts, Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education, and Department of Defense) and developing standards and measurements. As part of this strategy, an Enabling Technologies Public Awareness and Community Engagement (PACE) Section and an Enabling Technologies Policy (ETP) Section have been established. The latter coordinates policy and facilitates uptake of enabling technologies, while PACE Section seeks to increase the public's awareness, knowledge, and understanding of enabling technologies, including the risks and the benefits. The goal of NETS is also "to maximize community confidence" and community benefits, promote industry uptake, and increase public engagement.

Nano risk management and regulation

Australia's regulatory system does not specifically regulate nanomaterials. In fact, the 2008 government commissioned the Monash report – "a Review of Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks and the Australian Government Approach to the Responsible Management of Nanotechnology" – came to the conclusion that there was no need for major changes to the regulatory framework; however it did identify certain regulatory gaps:

> *1) Distinction between 'new' or 'existing' substances or products,*
>
> *2) Regulatory triggers based on weight or volume,*
>
> *3) Knowledge of presence or implications of presence of nanomaterials,*
>
> *4) Adequacy of risk assessment protocols and conventional techniques,*
>
> *5) Research and development exemptions,*
>
> *6) Risk assessment processes and protocols reliant on international documents (where specifically applicable to Australian risk assessment processes).*

NICNAS (National Industrial Chemical Notification and Assessment Scheme) is the Australian regulatory authority responsible for industrial chemicals, including nanomaterials. It started consulting stakeholders regarding industrial nanomaterials and published proposed reforms in "Proposal for Regulatory Reform of Industrial Nanomaterials Public Discussion Paper" in 2009. It also established a Nanotechnology Advisory Group (NAG) with a broad group of stakeholders, including a union and an environmental NGO representative to consult with regard to the regulatory reforms proposed. The proposed regulatory reforms will address how to deal with nano-forms of new and existing chemicals. The former may require pre-market assessment, while the later will eventually culminate in mandatory once-off use-specific reporting.

Safe Work Australia has developed a Nanotechnology OHS Program focusing on occupational areas, with a specific focus on the identification of hazards related to nanomaterials, development of exposure measurement capability, and evaluation of the effectiveness of workplace controls for preventing exposure to engineered nanoparticles. It has published a number of guidance documents, information sheets, and research reports, available on its website: http://www.safeworkaustralia.gov.au/sites/swa/whs-information/nanotechnology/pages/nanopublications. Other regulatory agencies, such as the Australian Pesticide and Veterinary Medicines Agency (APVMA), have published fact sheets and are assessing whether data requirements and risk assessment frameworks need to be modified.

Civil society response

Environmental civil society organizations, consumer groups, and unions have taken a keen interest in nanotechnology developments and have publicly expressed safety concerns over nanotechnologies, especially about nanoparticles in consumer products, such as sunscreens and antibacterial products, and potential worker related health risks.

Foremost amongst these is Friends of the Earth Australia (FOE- nano.foe.org.au). FOE Australia started its campaign on nanotechnology in early 2005 in response to the rapid development of the nanotechnology industry with little or no critical debate or regulatory oversight and has consistently called for a moratorium on the research, development, and production of synthetic nanoproducts until regulations are developed to protect the health and safety of workers, the public, and the environment from the impacts of nanotechnology. FOE has produced a number of ground breaking reports on nanotechnology, including on food, cosmetics, nanosilver, and climate.

NEW ZEALAND/AOTEAROA[5]

New Zealand/Aotearoa is an island state of about 4.5 million people in the Southwestern Pacific Ocean. The country is heavily dependent on international trade, especially agricultural products.

There is no large nanotechnology industry in New Zealand per se, and New Zealand is likely to be a net importer of the technology. However, nanotechnology research is being actively pursued, chiefly through the MacDiarmid Institute in Wellington (www.macdiarmid.ac.nz), a research network with researchers and facilities spread around New Zealand universities. The institute specializes in advanced materials and nanotechnology with an emphasis on four themes: nanofabrication and devices, electronic and optical materials, molecular materials, and bionano. It also holds an annual high school student nanotechnology camp. Massey University, Palmerston North offers specific undergraduate and master's degrees in nanotechnology science and engineering; other universities offer the opportunity to work towards a PhD.

5 Prepared with the assistance of Stephanie Howard, Sustainability Council, New Zealand/Aotearoa

Nano risk management and regulation

The key regulatory agencies responsible for nanomaterial regulation are the Ministry of Business, Innovation, and Employment, Medsafe, Ministry of Health, Ministry for the Environment, the Environmental Protection Authority, the Ministry of Consumer Affairs, the New Zealand Customs service, and New Food Safety Authority and Food Standards Australia and New Zealand.

New Zealand has close regulatory ties with Australia, and food standards are jointly regulated. The current conservative government is also attempting to harmonize other regulatory bodies with Australia, but current chemical regulations are substantially different.

In 2006, the New Zealand Ministry of Science, Research and Technology published a nanotechnology roadmap. In this roadmap, the New Zealand government acknowledged that social research is important and that the government should ensure inclusive public engagement to enable communities to contribute to decisions on nanoscience and nanotechnology applications. It also promised appropriate regulatory arrangements to managing nanoscience and nanotechnologies, but little actual public engagement or regulation has materialized, and nano safety currently does not feature on the work program of any government agency.

The government commissioned an independent report on the adequacy of nanotechnology regulation in 2011, but the report contained no firm recommendations on the government's request. The report claimed that no wholesale changes to the New Zealand regulatory system are required but did identify numerous regulatory gaps, including potential issues in the overall regulatory scope, appropriateness of quantity-based triggers and conditions, and nano specific labeling. The idea was that the relevant ministries and agencies would formulate a response plan to the regulatory analysis, but since the release of the report, no further work program in any of the department potentially responsible for nanoregulation has been implemented, with the minor exception of one work stream at the EPA (chemicals regulation), which was underway before the review began.

In terms of workplace safety, no regulation has been implemented, and no workplace monitoring is taking place. Overall, the lack of awareness of nanotechnology-related issues amongst consumers, suppliers, business, and government alike appears considerable.

Civil Society Responses

However, the New Zealand Sustainability Council, an independent non-governmental organization concerned with the realization of a sustainable New Zealand, has taken up nanotechnology as one of its key issues (see http://www.sustainabilitynz.org/category/nanotechnology/).

The EPA requires manufacturers and importers of personal care products to notify it if nanoscale ingredients are present (excluding Titanium Dioxide and Zinc Oxide). However, this requirement appears to be poorly enforced and has resulted in few notifications since its introduction in 2006. The Sustainability Council has worked to ensure proper nanoscale cosmetics regulation, especially in terms of transparency and proper enforcement of the requirement, and this has led to a decision by the Ombudsman supporting notifications being made publicly available to allow consumer choice and the EPA releasing notifications on their website.

In 2011, the Council also urged the EPA to support mandatory labeling and safety testing of nanoscale cosmetic ingredients and review the regulatory definition of the nanoscale to ensure that the risks are properly managed. Mid 2012, in a first step towards regulating the nanoscale ingredient, the EPA has made it compulsory to label nanoscale ingredients in cosmetics. This will bring New Zealand in line with EU labeling requirements; however, the regulation will not come into effect until 2015 to allow for old stock to be sold. In the interim from December 2012, cosmetic products notified as containing nanoscale ingredients will also be publicly listed on the Environmental Protection Authority (EPA) website.

4. RISKS OF NANOTECHNOLOGY TO HUMAN HEALTH AND THE ENVIRONMENT

NANOTECHNOLOGY RISKS NEED TO BE ASSESSED

Traditional chemical management defines the risk posed by a substance as a function of a) the hazard characteristics of a specific substance, and b) the exposure to this substance (i.e., risk = hazard x exposure or R=HxE).

When information is lacking on either one of these two elements (the hazardous property of a substance or the level of human or environmental exposure to it), it creates uncertainty with regard to the risk posed by the substance, as defined in traditional chemical management. When converging scientific information points in the direction of hazardous properties but is insufficient to fully characterize the risk, it is often referred to as potential risks. This section will focus on the hazard characteristics of nanomaterials, while the next will focus on exposure pathways.

Historical evidence supported by scientific findings shows that all new technologies come with risks to human health and the environment, and nanotechnology is no exception. The increasing number of engineered nanomaterials and nanoproducts gives rise to increasing breadth and extent of the potential risks posed to human health and the environment. For example, engineered nanomaterials are of similar size range as exhaustion particles from engines combustion, and certain carbon nanotubes are in many ways similar to asbestos fibres, substances that are known to cause adverse effects to human health, namely, cancer and asbestosis. For the last 15 years, diverse stakeholders, such as non-governmental organizations, environmental activists, consumers, trade unions, and other social actors, have raised questions about the risks posed by nanotechnology and manufactured nanomaterials.

Unfortunately, the responses consistently have been that these risks are largely unknown, that it was too early in the technology to evaluate the risks (let alone implement risk management measures), or even that there were no risks to hu-

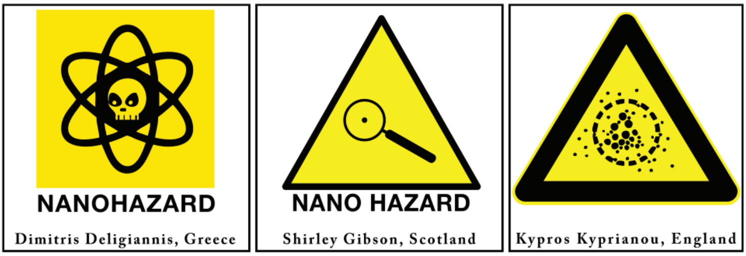


Figure 6. Nanohazard symbol. Winners of the symbol for Nanohazard, called by the ETC Group during the Global Social Forum in Nairobi, 2007.

man health or the environment arising from nanotechnology and manufactured nanomaterials. The uncertainty about nano related risks has not impeded the rapid introduction of nanotechnology products into the market. On the contrary, most nanotechnology policies put in place in the last 10 years have been largely been geared towards accelerating nanotechnology introduction into the markets with only very limited consideration of precautionary approaches to address the potential risks of this emerging technology.

As a result of mounting scientific evidence and sustained activism, a number of countries adopted national strategic frameworks in a (mostly failed) effort to balance the management of uncertain risks without compromising innovation and potential benefits. Examples of countries with such frameworks include the U.S., Germany, the Netherlands, and Australia, just to mention a few. There are an increasing number of ongoing research projects under the auspices of these frameworks to characterize and mitigate these risks.

In the Asia-Pacific Region, the kinds and scale of national strategies that countries have developed vary widely and are largely dependent on the economic position of the country in question (see relevant sections above).

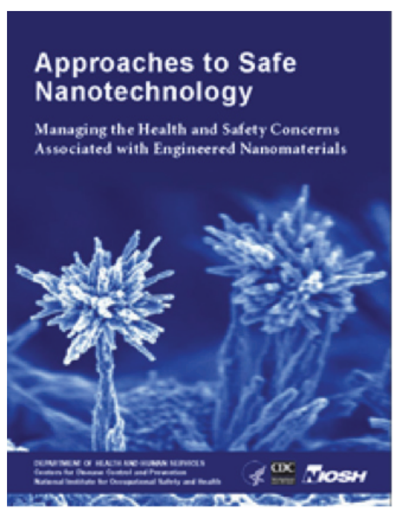


Figure 7. NIOSH (USA)

NANORISK INFORMATION IS INCREASING

An increasing number of databases hosting scientific articles and other forms of data about the health and environmental risks of diverse engineered nanomaterials commonly used in nanoproducts and industrial applications are becoming available. These initiatives aim to, first, collate data on risks of engineered nanomaterials from diverse scientific reports; and, secondly, establish how the accessible data can be applied to understand risks associated with nanotechnology. To this end, several databases on different types of engineered nanomaterials have been developed by various organizations internationally. A few examples are presented to illustrate this point (see Table 3).

The International Council on Nanotechnology (ICON), an institution at Rice University, in Houston, U.S., researches the risks of engineered nanomaterials and hosts a database on the health, safety, and environmental effects of these materials. From 2000 to 2010, the database registered a sustained increase in published articles in the scientific journals dedicated towards understanding the potential risks of engineered nanomaterials to human health and the environment. By 2013, there were 4469 peer reviewed and published scientific articles listed in the ICON EHS database in relation to nanomaterial particle type, hazard, or risk exposure group.[6]

This accumulation of scientific knowledge no longer permits ignoring the reasonable suspicion that various engineered nanomaterials will pose a variety of toxic effects to human health and the environment. Although the overall picture is highly complex owing to the large diversity of engineered nanomaterials and their distinctive forms, the section below presents a few examples to illustrate the potential risks of engineered nanomaterials.

CARBON NANOTUBES

Among others, the potential benefits of carbon nanotubes are often hyperbolically presented in scientific and media reports including the possibility of attaching carbon nanotubes or buckyballs to carcinogenic cells in order to kill them off without side effects, thus transforming cancer into a treatable illness. Consideration of their potential risks is, however, often overlooked. In 2008, Polland and collabora-

6 Elaborated from the ICON database (http://icon.rice.edu/) combining nanomaterial particle type (carbon, metal, organic/polymers, semiconductor, oxide, multiple, or other/unspecified) and hazard or risk exposure group (industrial/research worker, consumers, general population, ecosystem, or other/unspecified) and content emphasis (peer reviewed journal article) and production method (engineered)

tors reported that in the abdominal cavity of mice, carbon nanotubes have similar effects as asbestos fibres and are hence carcinogenic.

Similarly, in 2008, Takagi and collaborators demonstrated that carbon nanotubes produce mesothelioma in mice. Even single-walled carbon nanotubes, which are much more perfect, homogenous, and of higher purity than multi-wall carbon nanotubes, have been shown to cause toxic effects to mice. Chou and co-workers showed that single-walled carbon nanotubes produced granulomas in the lungs of mice. Even protozoa that ingested carbon nanotubes showed higher mortality rates, became paralyzed, or at least had limited mobility according to published findings of Ghanfari and collaborators. Other studies have demonstrated that as the sizes of carbon nanotubes, nanoparticles of black carbon, and other materials decrease, the allergic responses also increase. This research has been acknowledged in recent Occupational Health and Safety (OHS) guidance documents for instance in Britain: "In view of the evidence for lung damage and lack of information on the effects of long-term repeated exposure, a higher level of control is warranted for CNTs and other HARNS (e.g., nanorods, nanowires) . . . HSE's advice is to take a precautionary risk management approach when there is the potential for workers to inhale CNTs and other biopersistent HARNs with (HSE 2013)."

Producers of these materials and some scientists argue that nanotubes are firmly (fixed) embedded in product matrixes and are not, therefore, available for direct exposure, such as the isolated particles tested in the toxicological studies, and are thus less likely to interact with humans or the environment during the application phase of the products. They conclude that these materials pose no risks to the consumers. This, however, is correct only to a certain extent. Carbon nanotubes (and other manufactured nanomaterials) are widely used in many different industries, from cosmetics, automobiles, and cellular batteries to sport clothing and equipment. Each of these products has a distinct life cycle which can ultimately lead to exposure of the environment and/or humans to these materials. For example, the production of carbon nanotubes in industrial settings and their incorporation into products hold a serious possibility for workers to inhale those particles before they are integrated into a matrix.

NANOMATERIAL WASTE MANAGEMENT

Similarly, trash burning of textiles, batteries, and other nanotechnology products can separate carbon nanotubes from the product matrixes, and because they do not break down at temperatures below 850oC, they can survive burning and can then be inhaled or introduced into the food chain. In addition, manufactured nanomaterials can also wear off from products, such as clothing when the garment in which they are embedded wears down, and this can imply direct contact with human skin and hence penetration. These possibilities were considered, analyzed, and reported by Kohler and collaborators in 2008.

The effect that nanomaterials contained in waste may have on the hazardousness of these emissions is largely unknown. However, preliminary evidence by Holder in 2013 suggests nanomaterials may undergo physical or chemical transformations, may catalyze the formation and destruction of other pollutants (e.g., dioxins), and may affect the effectiveness of control technology to remove them, as well as affect their transport and impact in the environment. Vejerano et al. in the same year reported that the total PAH emission factors were on average Ð6 times higher for waste spiked with nanomaterials, e.g., nanoforms of titanium, nickel oxide, silver, cerium, iron oxide, as well as fullerenes and quantum dots versus their bulk counterparts. Chlorinated furans were also formed at elevated concentrations when silver and titanium nanomaterials were part of the waste.

Wastewater treatment plants will be one of the key entry points of nanomaterials into soil (via sludge) and fresh water. Some research on the effect of engineered nanomaterials on wastewater treatment is starting to emerge. Kiser et al. in 2009 collected sewage, biosolids, and liquid effluent from a commercial wastewater reclamation facility using activated sludge process and tertiary filtration treatment and found engineered nano titanium particles in a range of sizes. Furthermore, research by Dobias in 2013 focused on observing the release of silver ions from silver nanoparticles in natural waters under field conditions and found that the particles persisted even after 4 months. The exact nature of the particles is likely

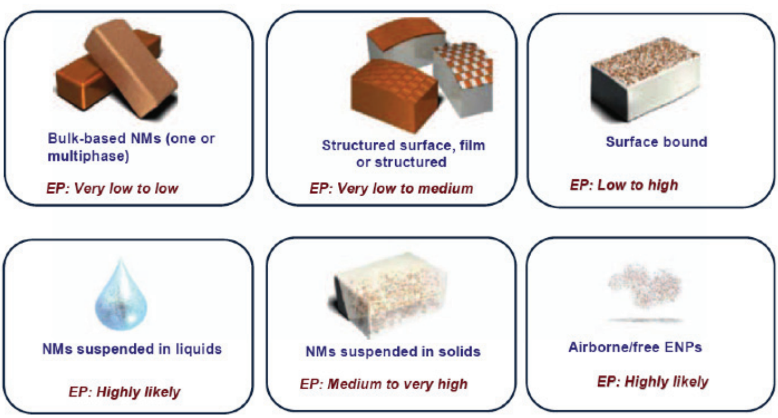


Figure 8. Classification of potential exposure of engineered nanomaterials

Source: Wischers and Musee, 2010

to be crucial however - for example, a polymer coating appeared to affect the fate and behavior of nanomaterials in wastewater treatment plants, with coated silica nanoparticles flocculating more readily than uncoated nano silica.

NANOMATERIALS MAY ENTER THE HUMAN BODY IN A VARIETY OF WAYS

The effect of inhalation of nanomaterials is well documented through the data on ultrafine particles (e.g., dust, carbon black and other pollutants). Choi et al. in 2010 reported that nanomaterials can translocate from the lung into the liver, spleen, heart, and possibly other organs. Also in 2010, Elder et al. reported access via the olfactory bulb. Another potential exposure route in humans is through the skin; in this context, access by fullerenes and quantum dots has been reported, dependent on size and surface coatings by Ryman-Rasmusen et al. Gastro-intestinal assimilation and translocation from there into the blood stream has also been demonstrated. Hillyer reported the accumulation of nanomaterials in low concentrations in the liver, spleen, heart, and the brain as early as 2001. In 2009, Takeda and collaborators demonstrated that titanium dioxide can cause hereditary damage. They also clearly demonstrated the possibility that nanoparticles can cross the placental barrier and cause a reduction in sperm production in the male embryos. Moreover, in terms of genetic effects, Yang and collaborators asserted, in 2009, that silver nanoparticles can interact with genetic material, modifying it and affecting its replication.

As a result of increasing concerns on the potential penetration of engineered nanomaterials from cosmetics to the human skin, in 2010, Wischers and Musee examined the available scientific data on the subject. Their findings were that engineered nanomaterials do penetrate the upper part of healthy skin where they can be visualized but do not penetrate deeper into the viable layers of the epidermis. At the same time, the opening around the hair follicle where sebum is located often acts as a reservoir and engineered nanomaterials accumulate there until they are removed with the sebum flow.

In 2009, Sharma and collaborators reported that nanoparticles of zinc oxide, commonly used for sun blocking in cosmetics, caused damage to the DNA of human epidemic cells that were tested at lower concentrations than is typically used in cosmetics. It also generated oxidative stress responsible for the production of free radicals responsible for causing skin cancer. Furthermore, in another study, Deng and collaborators affirmed that nanoparticles of zinc oxide have the potential to damage and kill brain stem cells of lab mice. It is known that nanoparticles can cross the cell barriers, travelling via the blood or lymphatic system, and even enter into the brain by olfactory nerves, crossing the blood brain barrier, as demonstrated by Oberdorster and colleagues in 2005.

These few examples (selected and presented from a much larger body of evidence) and an increasing body of published scientific evidence points to the likelihood of toxic effects to humans from a number of manufactured nanoparticles. In this context, these risks merit to be addressed further in order to support long-term responsible exploitation of nanotechnology without leaving a legacy of adverse effects to the society.

LACK OF KNOWLEDGE IS HAMPERING ASSESSMENT OF ECOTOXICITY

The toxicity of nanoparticles is not limited to human health but also affects other forms of biological organisms in the environment. A body of evidence shows the increasing accumulation of nanoparticles in ecosystems with potential for transfer to higher organisms through the food chain which may result in exposure of humans through foods, such as fish and vegetables among others. For instance, numerous scientific reports have illustrated the possible toxic effects of engineered nanomaterials to the organisms found in the environment, such as fish, bacteria, earthworms, and snails, among others.

Globally, hundreds of thousands of tons of nanomaterials are being released into the environment throughout the lifecycle of nanomaterial production, use, and disposal, both intentionally and unintentionally. Possible entry routes for nanomaterials into the environment include waste disposal (wastewater treatment, storm water run-off, landfill, and incineration) and unintended release, such as through abrasion and wear as well as emissions from manufacturing and accidental spills. A 2013 study into the global lifecycle of engineered nanomaterials by Keller et al. estimated that, in 2010, 260,000–309,000 tons of nanomaterials ended up in landfills (63–91%), soils (8–28 %), water bodies (0.4–7 %), and the atmosphere (0.1–1.5 %).

Ascertaining the ecotoxicity of nanomaterials and how they are distributed in the environment, as well as the effect they may have on organisms, is currently not only challenging but also beset with limitations due to a lack of suitable monitoring equipment and extensive knowledge gaps. There is currently no environmental monitoring of nanomaterials in the field, but this may change in the near future. In the interim, environmental models of the effect of nanomaterial release into the environment are being calculated and reported. Nano metaloxides have been shown to contaminate soils and enter the food chain via plant uptake. Recent studies by Yin et al. and Colman et al. reported that different plant communities experience reduced growth or biomass after taking up nanosilver from the soil. Soya beans, a major human and animal food source, have been shown by Hernandez et al. in 2013 to absorb and be adversely affected by nano zinc oxide and nano cerium oxide from contaminated soils.

Dimpka et al. in 2012 have shown that nanosilver, nano copper oxide and zinc oxide nanoparticles damage beneficial soil microbes to varying extents depending on the soil type. Exposure to carbon nanoparticles may harm earthworms by slowing population growth, increasing mortality, and damaging tissue (van der Ploeg et al 2010). An often overlooked aspect of environmental contaminants is that they usually exist as part of a complex mixture of chemicals in the environment. The composition of this mixture may increase or decrease the bioavailability of individual components and hence toxicity to organisms. Hartman et al, in 2010 found that the presence of nano titanium dioxides may increase the accumulation of cadmium in carp (Cyprinius carpio).

In 2007, Roberts et al. reported that water fleas (Daphnia magna), which had consumed carbon nanotubes encompassed in lipid, had blocked digestive tracts, and mortality was observed. In 2008, Leroueil and collaborators demonstrated that various organic and inorganic nanoparticles produced imbalances to plants and animals. For example, titanium dioxide, a key ingredient for the cosmetics industry has been reported to have damaged algae and also caused fish to become completely disoriented, according to a research report from Federici and collaborators in 2007.

Within the scientific community, some have advanced the argument that the toxicity demonstrated in vitro does not occur after the same engineered nanomaterials are incorporated into final products. Again, this form of generalization is problematic in light of the diversity in the manner and form in which these materials are incorporated into numerous and diverse products. It is therefore important to distinguish between engineered nanomaterials that are suspended in liquids or solids and those that are firmly integrated into the solid matrix.

WHICH NANOMATERIALS PRESENT THE GREATEST RISK?

Following this classification protocol, the National Institute for Occupational Safety and Health of the United States (NIOSH) has recognized that the engineered nanomaterials that present the most risks are in powders of solid states, dispersed or condensed into powders as they are used in cosmetics for example. The second level of risk is presented by manufactured nanoparticles suspended in liquids, like nanotubes in water. The third level of risks arises from nanoparticles integrated into networks and matrixes, such as thin films. Finally, those posing the least risk are those incorporated into nanostructures, like in metal alloys. This analysis, however, does not fully consider the possibility of transformation and release of the particles at different stages of their life cycle.

The degree of risk is also related to the different possible ways in which nanoparticles interact and enter into the organisms or organs. In general, humans are exposed to engineered nanomaterials either through, ingestion, inhalation, or penetration through the skin. Manufactured nanoparticles can be injected or can dissolve, for example, in the case of implants and medical products. It is also important to consider the possibility of accidents, like fires or explosions, which can also expose unprotected individuals to the risk of engineered nanomaterials, which to date is yet to be studied in great depth to allow any form of generalization of what can cause risk or not.

> The precautionary approach was first formalized in principle 15 of the Rio Declaration on Environment and Development from the 1992 Earth Summit which read: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." This approach gave rise a precautionary principle. This principle does not have a globally agreed formulation but was summarized in 1998, by a meeting of scientists, lawyer, policy makers, and environmentalists as the following: "When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

Finally, although nanotechnology risks are being explored fairly early in their development compared to other technologies, commercialization of product and thus human and environmental exposure is still happening without due consideration for their potential risks.

The available data indicate the diversity of engineered nanomaterials risk profiles to humans and the environment (e.g., while some manufactured nanomaterials show elevated risks, others show low toxicity or no specific risks), but taken together, they point to the critical need to develop a precautionary approach to the development of this technology as part of the regulatory-driven measures..

The precautionary principle in the context of nanotechnology implies that the scientific data should be applied to proactively avoid future adverse effects of engineered nanomaterials to human health and the environment. Producers of

TABLE 3. EXAMPLES OF INSTITUTIONS HOSTING DATABASES USEFUL FOR SUPPORTING RISK ASSESSMENT OF ENGINEERED NANOMATERIALS.

Organization	Host Institution	Activities
Center for the Environmental Implications of NanoTechnology (CEINT)	Duke University http://www.ceint.duke.edu/	Directs and conducts collaborative research studies on behavior of nano-scale materials in complex systems including fate, transport, exposure, and toxicity. The center is involved in developing inventories of key properties of emerging nanomaterials (ENMs) that influence their fate and transport and development of predictive toxicity models.
PEN of Charities	Woodrow Wilson International Centre for Scholars http://www.nanotechproject.org/	The Project on Emerging Nanotechnologies – nanotechnology inventories on the global trend of the type and quantity of manufactured nanomaterials. Most of the information is provided voluntarily by global industries. Silver Nanotechnology Commercial Inventory – database of silver nanotechnology in commercial products
Nanomaterial Stewardship Program (NMSP)	United States Environment Protection Agency (US EPA) http://www.epa.gov/oppt/nano/stewardship.htm	Voluntary testing and inventory development of engineered nanoscale substances manufactured, imported, processed, or used in collaboration with volunteer companies.
International Council on Nanotechnology (ICON)	Non-commercial organization affiliated to the United States National Science Foundation Center for Biological and Environmental Nanotechnology (CBEN), Rice University http://www.icon.rice.edu/	Develops and communicates information on potential environmental and health risks of nanoscience and nanotechnology that would foster risk reduction and maximize socio-economic benefits
Center for Environmental Implications of Nanotechnology (UC-CEIN)	University of California http://www.cein.ucla.edu/	Directs and conducts collaborative research studies on environmental, health, and safety impacts of ENMs and generates data to develop risk-ranking models based on fate, transport, and toxicity. An inventory of data generated that is accessible through journal articles provides information to researchers and scholars on the ENMs toxicology.

nanoproducts may view this as an additional business expense; however, the chilling account of the 14 malevolent technologies described by a report of European Environment Agency of 2001: Late lessons from early warnings: The precautionary principle 1896-2000 provides insights into all that can go wrong in relation to human health and the environment when risks of a given technology are ignored in the commercialization phase or when scientific evidence of risks are ignored by government agencies and corporate entities purely on commercial grounds. For example, if the early warnings given for technologies, such as asbestos, back in 1800s had been carefully considered and addressed, society may have benefited immensely from insights on asbestos as a technology while at the same time avoiding the immense harm asbestos are continuing to inflict. Clearly, society cannot afford such costly oversights, particularly in the context of nanotechnology.

A precautionary approach would ensure that this technology does not leave a legacy of human death, health impairment, and environmental damages. Rather, nanotechnology could provide a unique test platform for how risks of a rapidly emerging technology should be handled proactively to harness its greater good for society.

5. EXPOSURE OF HUMANS TO ENGINEERED NANOMATERIALS AND RISK MANAGEMENT APPROACHES

As indicated above, risk is characterized by the product of hazard and exposure. The aim of chemical risk management is to protect humans from the adverse effects of a given substance. In order to adequately manage the risks of engineered nanomaterials (when they can be) to humans and the environment, it is important to understand how humans and the environment can be exposed to these materials at various stages of their life cycle. It is therefore important to identify the exposure scenarios that may occur during the entire lifecycle of engineered nanomaterials, (e.g., during the production, transportation, storage, use, and disposal phases) so as to support appropriate risk assessment and risk management.

In 2004, a report by the UK Royal Society on Nanosciences and Nanotechnologies voiced concerns about the potential health and environmental risks of engineered

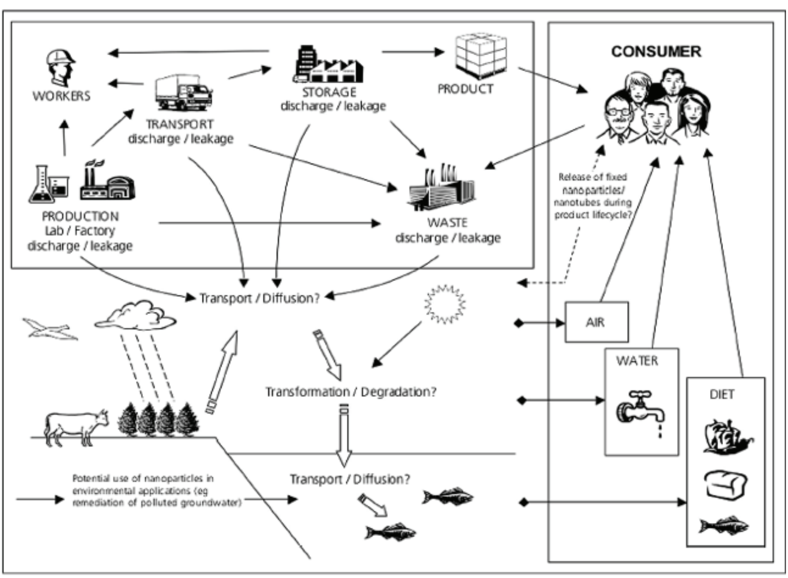


Figure 9. Exposure pathways of nanomaterials

Source: RS&RAE, 2004: 37.

nanomaterials. Figure 9 below illustrates the potential exposure pathways of engineered nanomaterials to the human and environments that were identified in this report.

Workers currently experience the highest degree of exposure to engineered nanomaterials. Workers can be exposed through various operations, such as release of engineered nanomaterials as aerosol in non-closed systems, during the handling of different types of engineered nanomaterials suspended in powders and liquids with no or poor protective equipment, in cleanup operations, during maintenance of equipment and processes used for the production, and finally, when handling waste streams containing engineered nanomaterials (generally called nanowastes).

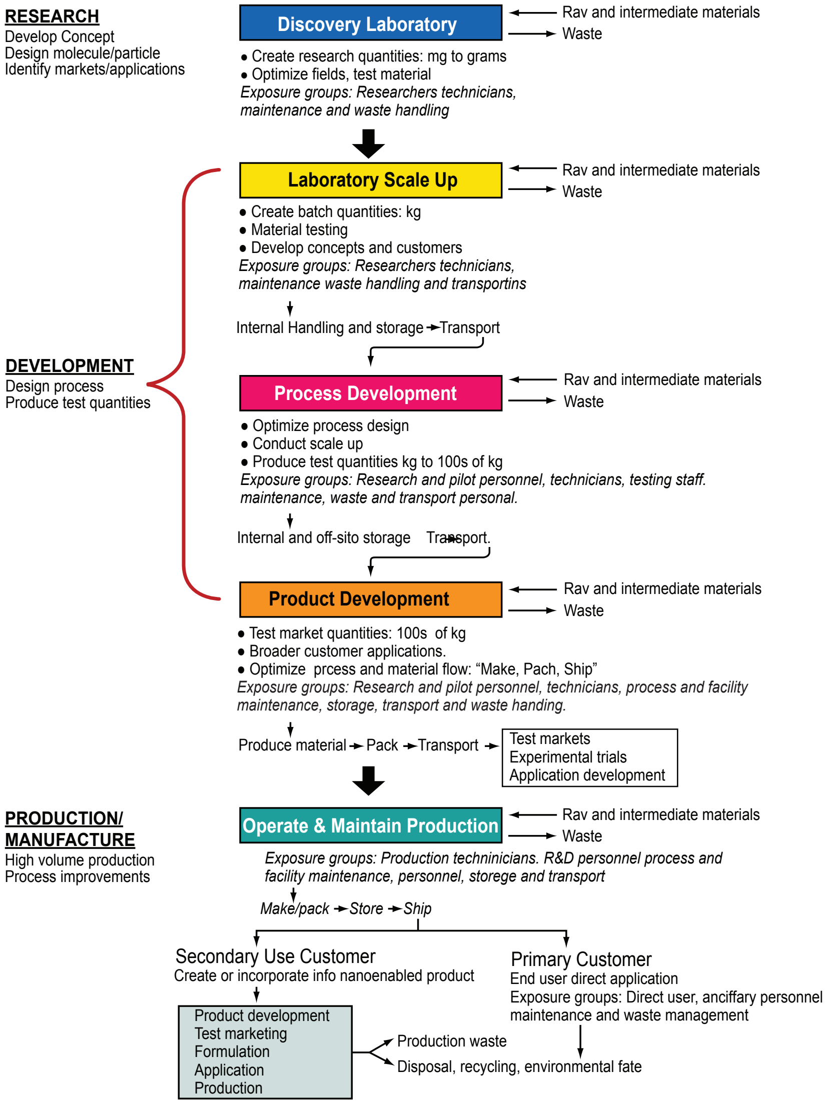
A number of reports highlighted that most engineered nanomaterials are and will continue to be produced mainly by small business. Such small businesses in the Asia-Pacific Region and around the world have a relatively poor record on workers' safety and protection from exposure to harmful chemicals in occupational settings. There is no compelling evidence to date suggesting that the production of engineered nanomaterials will be different or that the protection of the workers will be handled differently.

Furthermore, many developed countries, in light of increasing trends on the relocation of industries owing to increasingly stringent occupational and environmental legislations have 'exported' technologies through foreign direct investment (FDI) platforms, and nanotechnology industries will not be an exception. Therefore, as the number of countries in the Asia-Pacific Region using and/or producing nanotechnology products increases, the issues on occupational exposure, use, and disposal of engineered nanomaterials merit careful consideration to ensure that no adverse effects result from the development of nanotechnology.

Schulte and collaborators from NIOSH presented the diagram below to outline the risks of occupational exposure to nanomaterials. Although the associated risks to the environment and consumer do not appear in the diagram, they can logically be deduced at each stage. For example, all the stages demonstrate the presence of waste, as shown on the far right of the diagram. Such waste will eventually end up in the environment as the final sink. Mechanisms to prevent the release of engineered nanomaterials into the environment are inadequate at the moment as has recently been highlighted by Musee in 2011.

Figure 10 also shows that within every stage humans are subjected to various degrees of exposure and ultimately risk depending on the nature of their occupation. At the research stage, for example, researchers and technicians are exposed to engineered nanomaterials risks, including during the maintenance, waste handling,

Figure 10. Workplaces with potential for occupational exposure to engineered nanoparticles



Note: The diagram illustrates the life cycle of nanomaterial from laboratory research development through product development, use, and disposal. Each step of the life cycle represents opportunities for potential worker exposure to nanoparticles.

Source: Schulte, et al. (2008).

and storage. Nanowaste transporters from the laboratories are likely to be exposed to engineered nanowastes in the waste streams as well.

In the second stage, as Figure 10 illustrates, of large-scale development or production of raw nanomaterials, workers directly involved and exposed include researchers, technicians, pilot personnel, testing staff, facility maintenance crew, and personnel responsible for storing and transporting nanomaterials to industries for incorporation into products, as well as workers handling waste.

The next phase of exposure is during the production stage: manufacturing of intermediates and final products. Nanomaterials are incorporated into various industrial processes, with the final objective of endowing the product either for commercial or utilitarian advantage.

Consumer direct exposure then occurs with the use of nanoproducts. It leads to different degrees of risk depending on the product type and the form as well as route of exposure (e.g., inhalation, ingestion, dermal contact, etc.). The relationship between exposure to nanomaterials and health risks is controlled by multiple factors. These include inherent nanomaterial properties, degree of exposure, environmental conditions, and the use of protective systems, such as clothing and other preventive methods.

The body of evidence pointing to risks associated with exposure to engineered nanomaterials calls for the development and implementation of prudent approaches to control exposure, in particular in occupational settings. In order to deal with engineered nanomaterials proactively, the approaches below should be implemented as part of a precautionary approach to limit exposures and to increase our collective understanding of the potential risks of engineered nanomaterials.

Systematic health surveillance of workers in occupational settings: These should comprise hazard surveillance and medical surveillance as well as transversal health monitoring of workers. In the Asia-Pacific context, because of the limited resources, the governments should institute, as a minimum, a mandatory requirement for industries manufacturing engineered nanomaterials to undertake health monitoring of their workers. This also requires independent bodies to validate the data generated as part of the health surveillance.

Labelling requirement for all nanoproducts: The absence of information relating to the presence of nanomaterials for most nanoproducts in the market today, including in particular in Asia-Pacific, is detrimental to the health and the right to know of workers and consumers. To guarantee the respect of this right to know, all products containing nanomaterials, whether they are manufactured in the Asia-Pacific Region or imported, should be legally required to be adequately labelled. Further information including premarket testing data (in certain jurisdictions, this is regarded as "pre-manufacturing data") demonstrating that the product is not hazardous should be provided along the supply chain. This would allow the development of risk control measures.

Exposure control measures and personal protective equipment: Specific measures should be made mandatory to ensure that workers are not exposed to hazardous materials. Examples of such mechanisms include the use of engineering controls (e.g., exhaust ventilations, process design, design of benign engineered nanomaterials, use of wet chemistry during production, closed systems) and administrative controls in the form of policies that would reduce the exposure of workers to engineered nanomaterials (e.g., good housekeeping practices, systematic scheduling of workers performing tasks in areas of high exposure to limit/minimize the exposures to workers, and also the numbers expose). Moreover, the provision of adequate personal protection equipment (PPE) to workers, such as respirators, gloves, and protective clothing, may also be warranted. It is critical that the provision of PPE is not seen as a substitute for engineering controls but rather as an essential measure in the face of remaining uncertainty relating to the risks of engineered nanomaterials.

6. IMPLICATIONS OF NANOTECHNOLOGIES FOR EMPLOYMENT

The question of impacts on employment has not yet entered into the research agendas on the social implications of nanotechnology. Even though there are currently relatively few products, industries, and workers involved in nanotechnology compared to other industries, it appears clear that this technology is high tech and highly sophisticated, which deepens the trend to reducing workforces and automating the processes of production and services - a trend which began with the microelectronic revolution and resulted in a dramatic reduction of employment in many sectors of the economy.

Nanotechnology products that are already on the market allow us to identify three common characteristics: the products have multiple functions that previously required more than one product (multifunctional), the products remain useful longer, and the products use fewer raw materials. Some products combine two or three of these characteristics. Taken together, this means that manufacturing these products will lead to decreased demand for workers. In addition, these innovations reduce the demand for traditional products that compete with them.

The food industry illustrates the multifunctional aspect of nanotechnology well. Food corporations add vitamins, collagen, photo extracts, and other nano-encapsulated substances to food and drinks. George Weston Foods adds the fatty acid omega-3 to one of the most popular brands of white bread in Australia. The Qinhuangdao Ialji Ring Nano-Product Co. Ltd. enriches its nano-tea with selenium. These are examples of nutraceutical products that simultaneously have aesthetic, nutritional, and medicinal functions, which were previously delivered with different products. CHT Brazil Chemical (Brazil Quimica) produces Nouwell E, a textile fiber that has cosmetic functions, transferring vitamin E to the skin and releasing perfume. The Life Shirt, for example, monitors respiratory and cardiac activity and changes in posture and transfers this information to a portable computer.

These multifunctional products demonstrate a trend of merging productive branches and signify a reconfiguration of current industrial sectors and workforce distribution. It is likely that there will be fewer jobs available and a demand for less specialized employees. The aggregating of functions also brings the centralization of transportation, distribution, marketing, and commercialization, which possibly results in fewer employees in these fields as well.

Many nanotechnology products are used to make goods more durable on the market. EMBRAPA developed digestible films with nanoparticles to cover macadamia nuts to block the entrance of oxygen and water vapour, making the nut last longer. Miller Brewing uses bottles made of a plastic that incorporates nanoparticles of ceramics to establish a barrier which blocks molecules of carbon dioxide from escaping and molecules of oxygen from entering the bottle, keeping the beer fresh and giving it a shelf-life of up to six months. Scientists from companies like Kraft, Bayer, and Kodak are developing a variety of packaging materials that absorb oxygen, detect pathogens in foods, and alert the consumer when the food is spoiled.

By using nanotechnology, companies can produce products that have a longer storage life in supermarkets. This will help companies because it will reduce the amount of products wasted. In addition, the economic activities revolving around transportation, storage, quality assurance, shelf maintenance, and other functions

Figure 11. Telephone Exchange in 1930 and telephone exchange today

will be reduced. With this increase efficiency, fewer workers will be required. What sort of public policy are governments considering to remedy this loss in employment? None thus far.

Other products exploit the advantages of new materials produced by nanotechnology to substitute for other raw materials. Adidas uses carbon nanotubes to produce running shoes with lighter weight traction systems. Easton Sport uses carbon nanotubes to produce bicycle frames. Elko's Invisicion uses the conductive properties of carbon nanotubes in the manufacturing of transparent covers for flat screen (TVs) with OLED light and for solar cellular phones. Nanotubes also could replace the copper wires that transmit electricity, modifying all global commerce.

Braskem produces a resin of polypropylene with added nanoparticles of ceramic that replace metals and other plastics in the automobile and domestic appliances industries.

These changes in the materials used alter the distribution of the workforce among different sectors. Given that the exploitation of raw materials is tied to geographic characteristics, on a national and international level, the changes in demand will bring about a new regional and international distribution of employment opportunities.

7. SAICM IN ASIA-PACIFIC AND INTERNATIONAL NANO GOVERNANCE

SAICM is a voluntary agreement, approved in Dubai, UAE, in February 2006 at the International Conference on Chemicals Management. This strategic approach is composed of a High Political Declaration, an overarching Policy Strategy, and a Global Plan of Action, which all together constitute a framework that pursues the global objective "that chemical substances are produced and used in a way that significantly reduces the impact on the environment and health." SAICM is administered by the United Nations Environmental Program which runs the Secretariat of this agreement with the World Health Organization.

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

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

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

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

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

The report recommends the establishment of cooperation, collaboration, and partnerships (among countries, the public and private sectors, and civil society organizations) for the strengthening of human resources and of institutional capacity.

The report also recommends encouraging dialogue, assisting in training, research, and development, dissemination and sharing of information, and that appropriate means for such activities be provided.

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

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

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

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

The implementation of these activities, together with the guidance document created by UNITAR for developing national nanotechnology policy and programs, can be instrumental in supporting the building of capacity for the safe management of nanotechnologies and nanomaterials in the Global South. Their implementation will, however, require increased political will to address the safe management of nanomaterials, including through adequate funding and multi-stakeholder engagement.

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