Nanotechnology: Safety and Risk Governance in Indonesia

National Workshop on Strengthening R&D Management Capacity of Researcher and Research Management of R&D Institute in the Area of Nanotechnology
26-27 June 2013
Jakarta Indonesia

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LIPI 2013
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INTRODUCTION

- Process Safety Management is the application of management principles and systems to the identification, understanding, and control of hazardous materials to protect employees, facility assets and environment. [Sandia national laboratories]

- Risk governance is management of uncertainty related activities by society itself and implementation of a new technology in a sustainable way (public acceptance)[Austrian academy of sciences]

- Today’s nanotechnology, i.e. the planned manipulation of materials and properties on a nanoscale, exploits the interaction of three technological streams[1]: 1. new and improved control of the size and manipulation of nanoscale building blocks 2. new and improved characterization of materials on a nanoscale (e.g., spatial resolution, chemical sensitivity) 3. new and improved understanding of the relationships between nanostructure and properties and how these can be engineered.

- As a consequence of their small sizes, nanoparticles exhibit different physiochemical properties compared to their respective bulk materials. These include changes in optical properties, material strength, conductivity and the surface-to-volume ratio of the nanoparticles[2].

- A key issue regarding nanotechnology is how best to protect human health, safety, and the environment as nanoscale materials and products are researched, developed, manufactured, used, and discarded. While the rapidly emerging field of nanotechnology is believed by many to offer significant economic and societal benefits, some research results have raised concerns about the potential adverse environmental, health, and safety (EHS) implications of nanoscale materials[3].

- Some have described nanotechnology as a two-edged sword. On the one hand, some are concerned that nanoscale particles may enter and accumulate in vital organs, such as the lungs and brains, potentially causing harm or death to humans and animals, and that the diffusion of nanoscale particles in the environment might harm ecosystems. On the other hand, some believe that nanotechnology has the potential to deliver important EHS benefits such as reducing energy consumption, pollution, and greenhouse gas emissions; remediating environmental damage; curing, managing, or preventing diseases; and offering new safety-enhancing materials that are stronger, self-repairing, and able to adapt to provide protection[3].
BASIC PRINCIPLES OF NANOTECHNOLOGY

- Nanomaterials can be produced using two building strategies, either a “top-down” or a “bottom-up” approach [4,5]

- In the top-down approach, nanomaterials are created by breaking up bulk materials using means such as milling to reduce the size of a complex object to the point where this scale reduction begins to alter the very principles it is based upon.

- The bottom-up approach is radically different, since it involves the building of nanomaterials from individual atoms or molecules that have the capacity to self-assemble like crystal growth.
Bottom-up approach

Schematic outline of sol-gel process and comparison of colloidal and polymeric routes[6]
Nanotechnology derived products[2].

- (a) Nanoparticle: A discrete entity that has all three dimensions in the nanoscale.
- (b) Nanotube: A discrete hollow fibre entity which has two dimensions in the nanoscale.
- (c) Nanosheet: Nano-object with one external dimension in the nanoscale.
Illustration of the increase in surface area with smaller particle size[2].

- (a) A solid cube with 1 cm on each side has 6 cm² of surface area.
- (b) Volume of 1 cm³ filled with cubes with 1 mm on a side has a total surface area of 60 cm².
- (c) Volume of 1 cm³ filled with cubes with 1 nm on a side has a total surface area of 60,000,000 cm².
Application of Nanotechnology[7]

Convergence of scientific disciplines (chemistry, biology, electronics, physics, engineering etc.) is leading to a multiplication of applications in materials manufacturing, computer chips, pharmaceuticals, healthcare, life-science and medical diagnosis, energy, food, cosmetic, biotechnology, Space exploration, security and so on.

- Projected contribution of nanotechnology to the US economy, 2015[28]
Ministry of Research and Technology of Indonesia (Ristek) take a certain attitude toward the new global nanotechnology development by giving guidance in certain activity with a great theme: Research and development on science and technology with sub theme development on Nano Science and Technology [8,9]. The activity has been issued from 2005 to 2009. The content of the document is:

Objective;
Research Development of Nanoscience and Nanotechnology Program has some objective;
- Strengthening and developing researcher ability in framework of mastering Nanoscience and technology.
- Giving focus direction on developing research activity based on natural resources.
- Giving synergy upon national researcher’s ability.

Target
All the activity of Nano science and technology programs are focusing to support the achievement of:
- Capability of fulfilling society need at large by nanotechnology.
- Capability of fulfilling products at domestic and international market.
- Optimal natural resources management.
- Achievement of nano science and nanotechnology in national scale.
- Arrangement of nano science and nanotechnology development policy in national scale.
Roadmap nanotechnologies with supply technology approach[9].

![Diagram of nanotechnology roadmap](image-url)
Platform of nanotechnology Ministry of Research and Technology Republic of Indonesia[8,9]

- Nanotechnology development and world nanotechnology product market
- University
- Industrial society
- Profession society (MNI)
- R&D institutes

- Human and natural resources, industry, facilities

- Roadmap of nanosciences and nanotechnology

- Formulation of policy implementation

- Indonesia national needs
  - 6 research focuses

- Research collaboration
- Nanotool, modelling, engineering
- Nanomaterial
  - Nanocomposite
  - Bionanomaterial
  - Nanoelectronic
  - Nanocoating
  - Nanomagnet
  - Nanosensor

- Patent, semimanufacture, nanotechnology-based tools
Schematic of Nanotechnology Development in Indonesia[8,10]
Strategy to Socialize Nanotechnology in Indonesia[8,10]
Indonesian Policy for Nanotechnology

New Policy/New Program/Initiative/ Funding for nanotech in each ministry

Ministry of Research and Technology (since 2005) [11]
- Initiation for Center of excellence for Nanotechnology (2011)
- Research grant for development and implementation nanotechnology for supporting national industry (2010-2011)

Ministry of Industry (since 2008) [12]
- Agency for Industrial Research and Development decree No.06/BPPI.2/SK/1/2010 regarding Nanotechnology Roadmap for supporting national industry (Textile & Ceramics, Foods, Chemical and Polymer Industry (2008-2010)
- Study on assessment of incentive program for national industry which apply nanotechnology (2010)
- Development of human resources through PhD program and allocation of research grant for development and implementation of nanotechnology for supporting industry (2008-2011)
Nanoparticles and the Environment

The possible routes for nanoparticles exposure to the environment range over the whole lifecycle of products and applications that contain engineered nanoparticles[7]:

- Discharge / leakage during production / transport and storage of intermediate and finished products,
- Discharge / leakage from waste,
- Release of particles during use of the products,
- Diffusion, transport and transformation in air, soil and water.
The emphasis on what kind of risks is a key to be considered in applied nanotechnology and will depend on the perspective of the particular organisation involved in nanotechnologies. To name just a few[7]:

- business risks involved with marketing of nanotechnology enabled products,
- risks related to the protection of intellectual property,
- political risks regarding the impact on the economical development of countries and regions,
- risks regarding privacy when miniature sensors become ubiquitous,
- environmental risks from the release of nanoparticles into the environment,
- safety risks from nanoparticles for workers and consumers,
- futuristic risks like human enhancement and self replications of nano machines.
For a successful risk management of nanotechnologies from Allianz Center for Technology perspective, the following framework is needed[7]:

- sufficient funding of independent research on nanotechnology related risks with active steering by governments,
- transparency about and open access to the results of research activities,
- ongoing dialogue between insurers and commercial and industrial clients,
- international standards and nomenclature,
- adequate regulation of risk issues,
- a global risk governance approach.
Nanotechnology and industrial insurance: Managing Chances and risks

Looking at possible risk scenarios related to nanotechnologies, the following basic features can be distinguished[7]:

- an increasingly high number of persons will be exposed to engineered nanoparticles,
- potential harmful effects will evolve over longer periods of time,
- a high number of companies from various branches of industry could be involved,
- in individual cases it will be difficult to establish a causal relationship between action or omission of a company and the resulting damage, injury or financial loss,
- potential loss scenarios resemble major product liability cases from the past
- occupational exposure is a main concern.
There is currently no comprehensive guidance developed particularly for the safety assessment of nanomaterials in food. A difficulty in giving detailed specific risk assessment guidance in the area is the lack of sufficient data and information which would allow for a comprehensive understanding of potential hazards of nanomaterials[27].

World Health Organization (WHO) commented that as for all new materials used in food and food processing, the potential health and environmental risks of nanoscale materials need to be assessed before they are introduced into food[14].

The experts recommended the Food and Agricultural Organization,(FAO)/WHO should encourage the innovative and interdisciplinary research that may lead to novel risk assessment strategies for the application of nanotechnologies in food[15].

European Food Safety Authority ,EFSA is of the view that given the novelty of nanotechnology, the safety of possible food and feed applications needs to be assessed and a need for risk assessment is expected in the context of 1) the authorisation of regulated substances; 2) the presence of nanoparticles as contaminants in food and feed; and 3) replies to general request such as whether the application of nanotechnologies in food and production leads to changes in nutritional value or bioavailability[16].

Nanoparticles may enter the food chain undetected, accumulate within tissues and organs, and can be taken up by individual cells[4].

There is also concern that the introduction into food of nanoparticles designed to carry dietary supplements could also lead to introduction of foreign substances into the bloodstream Risk assessment paradigm was considered applicable for nanomaterials and has to be performed on a case-by-case basis. Current toxicity-testing approaches used for conventional materials were a suitable starting point for risk assessment of nanomaterials[3,13].

At present, there is no tenable evidence that food or food contact materials derived from nanotechnology is any safer or more dangerous than their conventional counterparts. No general conclusion can be made on the safety of nanofood and food contact materials incorporated with nanomaterials[13].
Much of the current information on the occupational health effects (inhalation, dermal, and ingestion) of nanoparticles has been limited to animal studies. Inhalation may be the greatest health risk. Some of these studies have shown that nanoparticles:

- can penetrate across cell membranes (because of their size)
- may be more biologically active, because of their size-to-surface-area ratio
- may be more toxic than larger sized particles of the same material
- have a greater surface area compared to its weight
- can stay airborne longer
- can change properties
- can persist in tissue and create the potential for delayed toxicity
- exhibit new properties of the same material (e.g. gold is red in color at the nanoscale level)
RISK ASSESSMENT OF NANOMATERIALS IN PHARMACEUTICALS

- Some nanoscale particles may have the potential to penetrate the blood-brain barrier, a structure that protects the brain from harmful substances in the blood but also hinders the delivery of therapeutic agents. The characteristics of certain nanoscale materials may allow pharmaceuticals to be developed to purposefully and beneficially cross this barrier and deliver medicine directly to the brain to treat, for example, a brain tumor[18].
- Some critics are concerned, however, that nanoscale particles might unintentionally pass through the blood-brain barrier causing harm to humans and animals[19].
- Such risk of exposure may arise from the use of nano-sized pesticides and veterinary medicines, contact of food with nanoparticulate-based coatings during preparation or processing, or potential migration of nanoparticles from food packaging[3,13].
RISK ASSESSMENT OF NANOMATERIALS IN ENVIRONMENT

- Nanoscale silver is highly effective as an antibacterial agent in wound dressings, clothing, and washing machines, but some have expressed concerns that widespread dispersion of nanoscale silver in the environment could kill microbes that are vital to waste water treatment plants and to ecosystems. Some beneficial bacteria, for example, break down organic matter, remove nitrogen from water, aid in animal digestion, protect against fungal infestations, and even aid some animals in defense against predators[20].

- Certain nanoscale materials are highly chemically reactive due to their high surface-to-volume ratio[21]. This is a property that might be positively exploited in catalysis, treatment of groundwater contamination, and site remediation. This property also is being explored for use in protective masks and clothing as a defense against chemical and biological agents. However, some research results indicate that the reactivity of some nanoparticles potentially can result in cell damage in animals[22].

- Carbon nanotubes (CNTs) have potential uses in a wide range of applications (e.g., materials, batteries, memory devices, electronic displays, transparent conductors, sensors, medical imaging). However, some scientists have expressed concerns that some CNTs exhibit properties similar to asbestos fibers and might become lodged in organs (e.g., lungs, kidneys, livers), harming humans and animals[23].

- These nano-sized materials may interact with proteins and other compounds nearby and act as carriers of these substances into different biological tissues.
REDUCING THE RISK FOR OCCUPATIONAL EXPOSURE[17]

General
Nanotechnology applications that may pose the greatest risk may include:
- Generating nanoparticles in the gas phase
- Aerosolizing nanoparticles
- Utilizing nanoparticles as a powder and/or liquid
- Cutting and grinding
- Pouring and/or mixing (including lab instruments that mix/agitate)
- Cleaning up spills
- Injecting with a needle
- Performing maintenance (or other activities) on laboratory equipment that has come into contact with nanoparticles

Other factors involved:
- Quantity
- Degree of containment
- Flammability/Combustibility
- Potential for nanoparticles to become airborne
- Duration of job task
Engineering controls used in nanotechnology applications are likely to be similar to those that are currently used in controlling aerosols (gases, dusts, chemical vapors, etc.) found in other laboratory applications and/or processes. Such controls may include:

- Local exhaust ventilation (LEV)
- Filtration
Administrative, or Work Practices

Good work practices involving nanoparticles should include, but are not limited to, awareness of the following practices:

- Develop a site-specific standard operating procedure (SOP) for work involving nanoparticles
- Minimize the potential for inhalation exposure and skin contact
- Practice good personal hygiene (e.g. hand washing, etc.)
- Utilize appropriate procedures when utilizing laboratory equipment
- Follow the manufacturer, or vendor, instructions for the use or handling of nanoparticles
- Handle, store, and transport nanoparticles (in liquid or powder state) in a closed, sealed and labeled container
- Review manufacturer supplied Material Safety Data Sheet (MSDS) for specific safety and health information
- Utilize wet-wiping methods to clean up work areas using a solvent expected to solubilize the nanoparticle in use
- Limit material quantity to what is needed
- Review the elements of this written program
Selection & Use of Personal Protective Equipment (PPE)

- **Gloves**: Personnel should wear polymer gloves (e.g. nitrile) when handling nanomaterials. Wearing two layers of gloves may be a best practice until more is known on nanoparticle penetration through glove materials and skin.

- **Respirators**: The particle size of the nanoparticle should be evaluated in determining the appropriate respirator (penetrating particle size of the respirator).

- **Masks**: Dust masks (and surgical masks) should not be used for protection from nanoparticles.
CONCLUSION AND RECOMMENDATION

- The terminology used in nanotechnologies is very broad. No uniform language or set of definitions exist[7],
- Nanotechnologies cover a very broad field with far from uniform risk characteristics[7],
- Furthermore, if all nanoscale materials are compared to all non-nanoscale materials, it is not apparent that the nanoscale materials as a group would have more inherent hazard[13].
- No data on genotoxicity, or on possible carcinogenesis and teratogenicity, is available for nanoparticles yet[24,25].
- In face of the novelty of the nanoparticles, conventional knowledge about health effects of chemical and materials, which is based on their chemical and physical properties, may not be applicable when dealing with nanoproducts[26].
- Independent research into the risks of nanoparticles, exposure routes and the effects on humans and the environment[7].
- Strengthening the evidence base and allowing public access to the results. Transparency will be a key factor for adequate risk management and public trust[7],
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Thank you for your kind attention
International Workshop on Nanotechnology (IWON) 2013

- Organized by Centre for Science & Technology of Non-Aligned and Other Developing Countries (NAM S&T Centre), Indonesia Ministry of State for Research and Technology (MSRT), Indonesian Institute of Sciences (LIPI), Indonesian Society for Nanotechnology (MNI) and Indonesia Chemical Society (HKI)
- Conducted on **2-4 October 2013 at Puspiptek, Serpong**, Tangerang Selatan, Indonesia
- Important Dates:
  - 2 June 2013 Call for Papers International Workshop on Nanotechnology
  - 20 July 2013 Deadline of Abstract Submission
  - 29 July 2013 Notification of Abstract Acceptance
  - 7 September 2013 Deadline of Full Paper Submission
  - 14 September 2013 Deadline of Registration and Payment
  - 2-4 October 2013 Main Event (Workshop)
- Detailed information and online registration:
  - Email: iwon@nano.or.id or iwon2013@gmail.com