LEMBAGA ILMU PENGETAHUAN INDONESIA
*(INDONESIAN INSTITUTE OF SCIENCES)*

LIPI

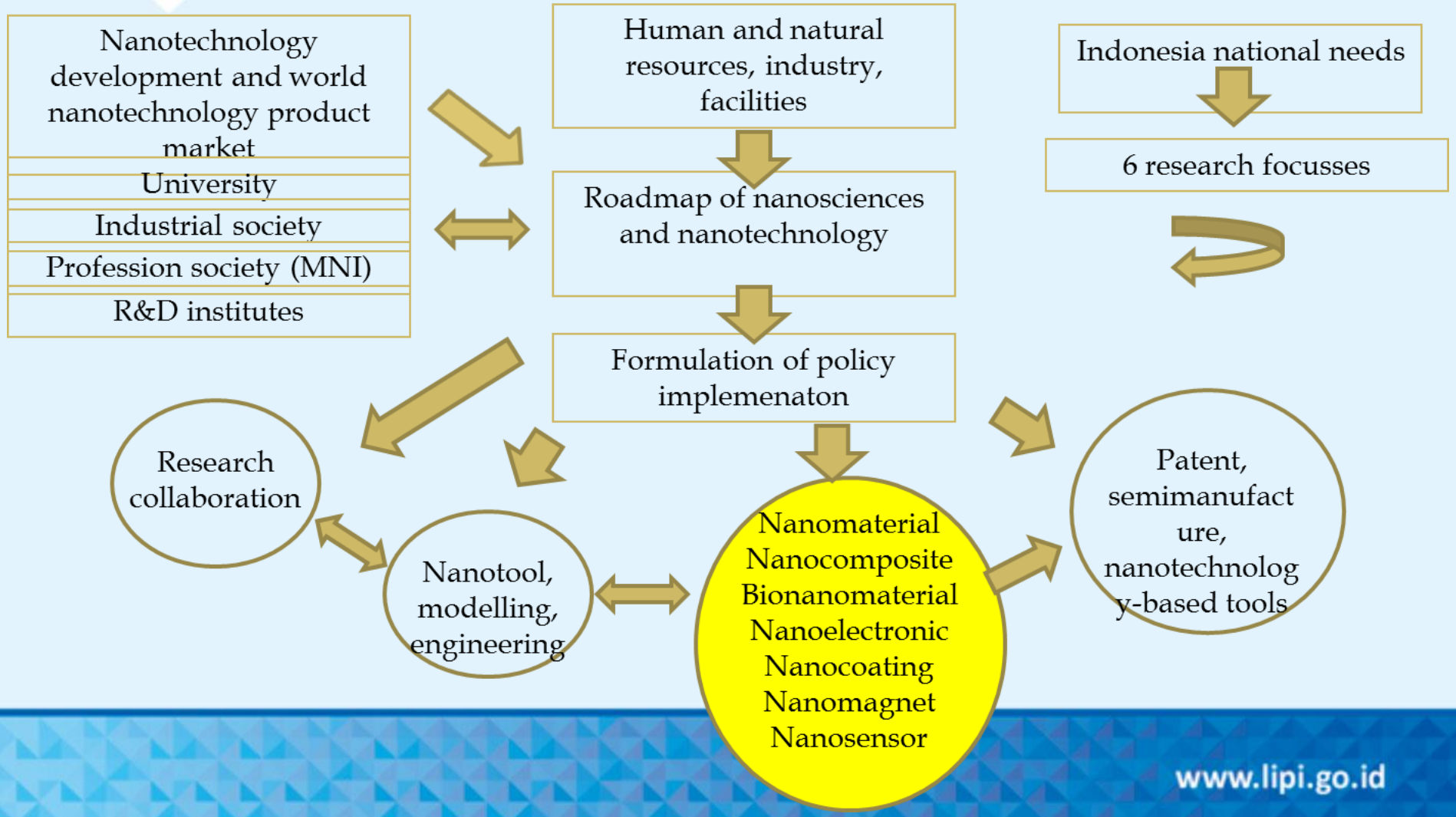
# Development of National Nanotechnology Standards for Safe Consumer Products

Agus Haryono

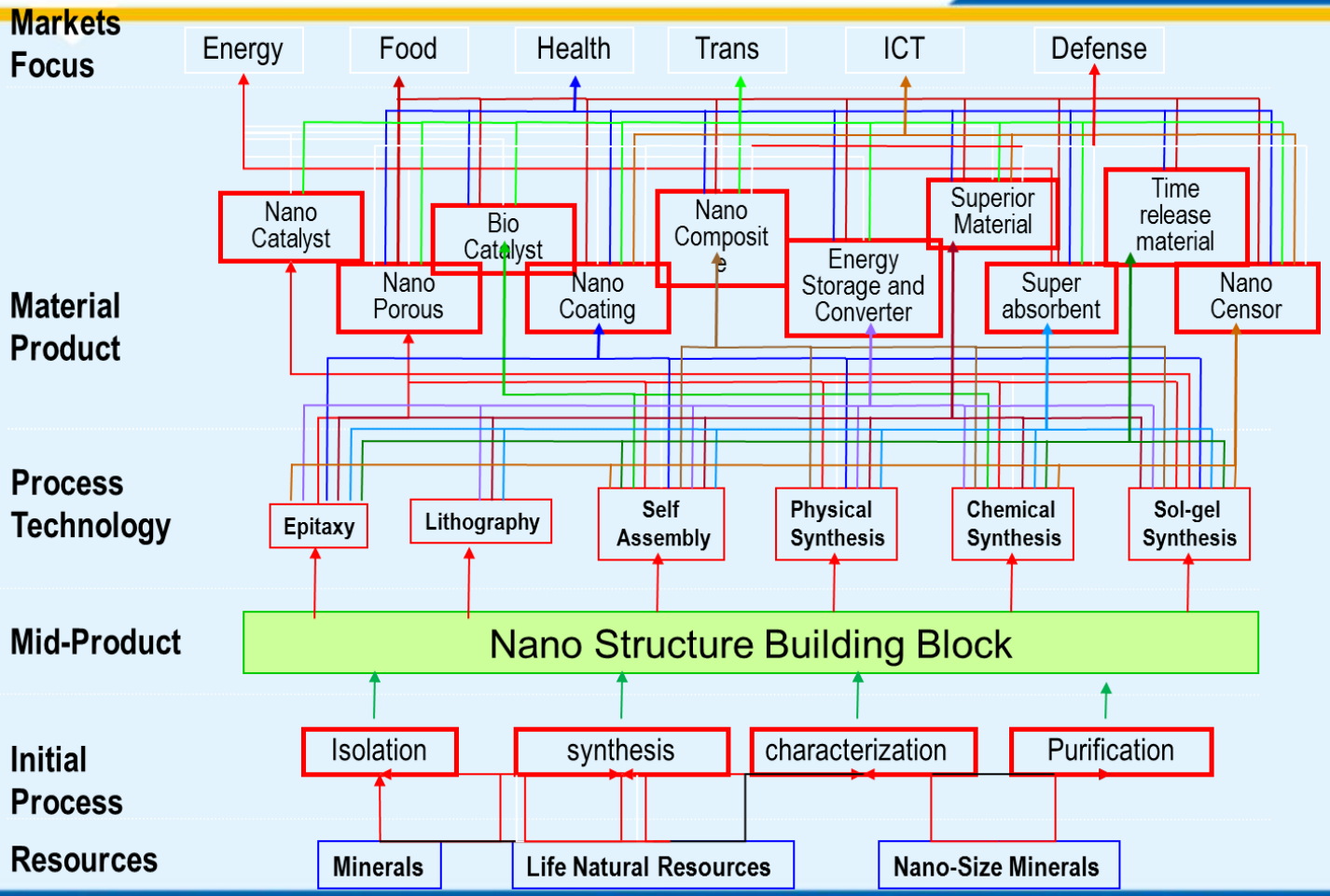
Research Center for Chemistry

Indonesian Institute of Sciences (LIPI)

# Research Based Nanotechnology Indonesia Roadmap



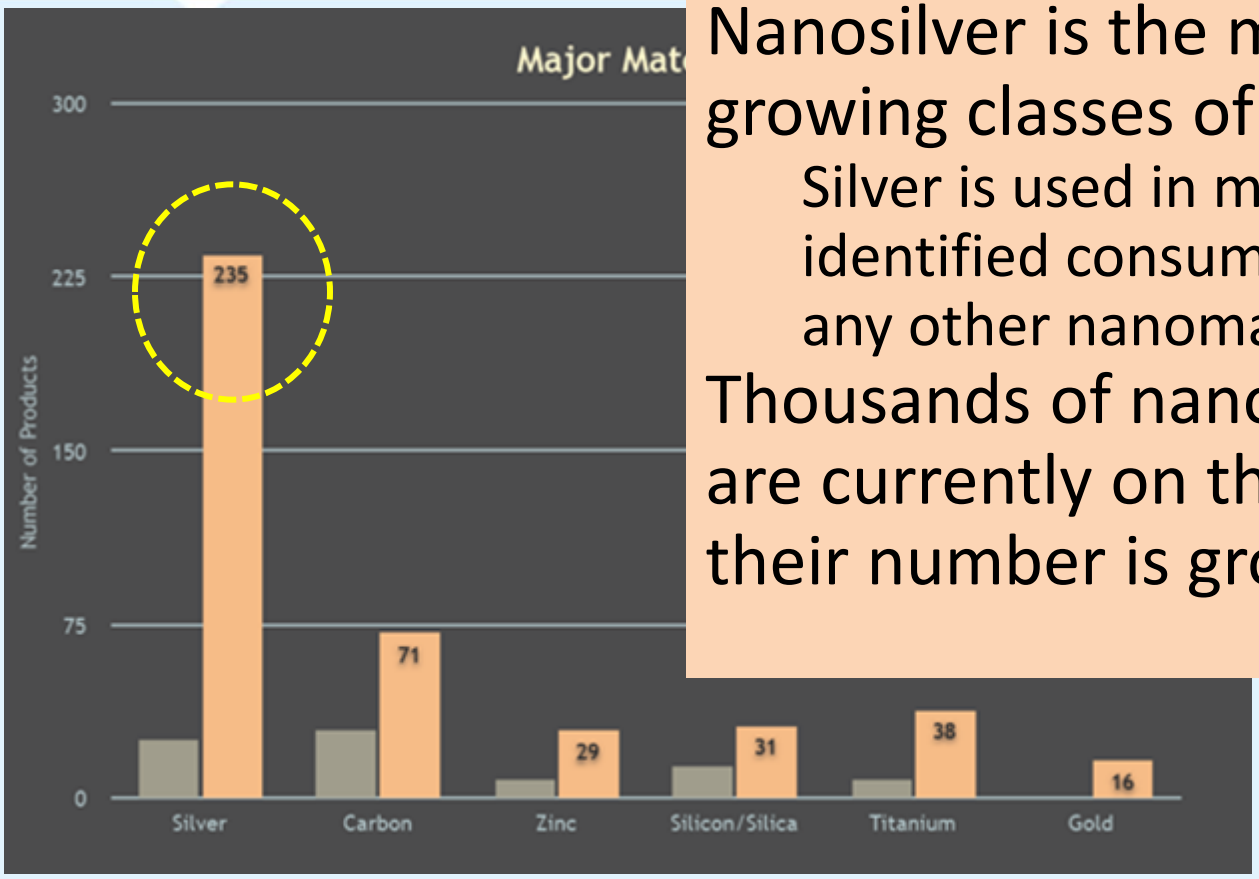
# Technology push Roadmap



# Nanomaterials

- Ubiquitous in nature (smoke, dust)
- Human exposure and accommodation nothing new
- We cannot assume that nanomaterials are the same as their bulk counterpart...but also cannot assume that they are more toxic.
- Every particle should be tested on a case-by-case basis.

# Nanoproduct in the Market



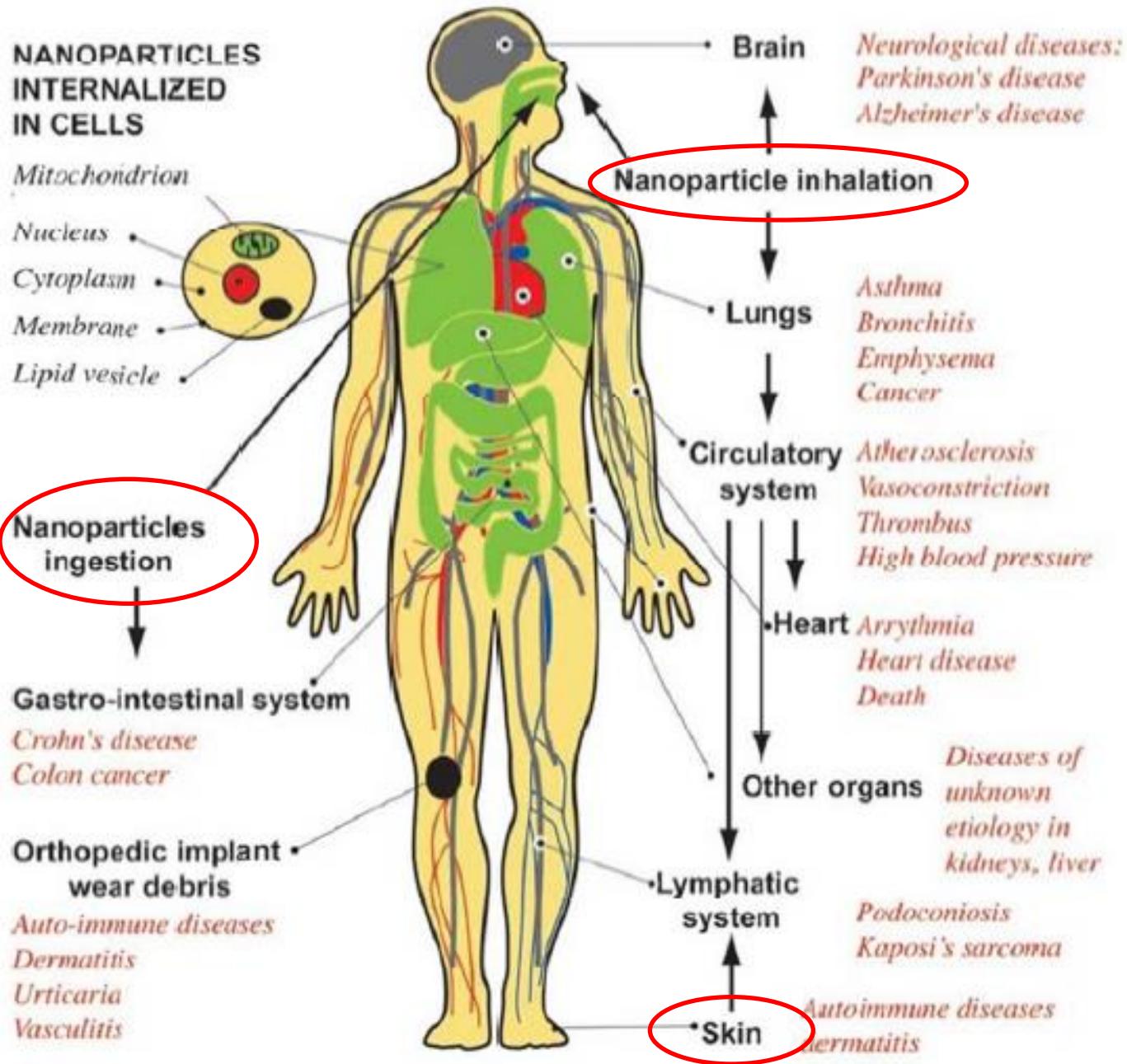

Nanosilver is the most rapidly growing classes of nanoproducts

- Silver is used in more manufacturer identified consumer products than any other nanomaterial

Thousands of nanosilver products are currently on the market, and their number is growing rapidly

# DISEASES ASSOCIATED TO NANOPARTICLE EXPOSURE

C. Buzea, I. Pacheco, & K. Robbie, Nanomaterials and nanoparticles: Sources and toxicity, Biointerphases 2 (2007) MR17-MR71




LIPI

# Exposure of Nanoparticles

www.lipi.go.id

**TABLE 1.** Summary of Selected Cytotoxicity Date for Gold Nanoparticles, 2004–2007

| author | size (nm) | shape | surface group | cell line | toxicity results |
|---|---|---|---|---|---|
| Shukla[29] | 3.5 ± 0.7 | sphere | lysine, poly(L-lysine) | RAW264.7 mouse macrophage cells | 85% cell viability after being exposed to 100 μM gold nanoparticles for 72 h |
| Connor[30] | 4, 12, 18 | sphere | citrate, cysteine, glucose, biotin, CTAB | K562 human leukemia | none of the spherical nanoparticles were toxic at the micromolar ranges used |
| Goodman[33] | 2 | sphere | quaternary ammonium, carboxylic acid | COS-1 mammalian cells, mammalian red blood cells, *Escherichia coli* | cationic nanoparticles were found to be much more toxic than anionic particles of the same size |
| Niidome[35] | 65 ± 5 × 11 ± 1 | rod | CTAB, PEG | HeLa cells | 80% cell death with 0.05 mM CTAB-coated nanorods, only 10% cell death at 0.5 mM PEG-coated nanorods |
| Huff[36] | | rod | CTAB | human tumor KB cells | gold nanoparticles were rapidly taken into the cells and formed permanent aggregates, but the cells remained healthy |
| Patra[41] | 33 | sphere | CTAB, citrate | BHK21 baby hamster kidney cells, Hep2G human liver carcinoma cells, A549 human carcinoma lung cells | nontoxic to BHK21 and HepG2 cells, but toxic to A549 cells |
| Takahashi[37] | 65 × 11 | rod | phosphatidyl-choline | HeLa cells | phosphatidylcholine-modified gold nanorods were much less toxic than CTAB-coated nanorods |
| Khan[39] | 18 | sphere | citrate | HeLa cells | gold nanoparticles did not cause significant gene-expression patterns or cyotoxicity even though they were internalized in the cells. |

# Nanogold Toxicity Study

# Safety of Nanomaterials

- Are nanomaterials safe for food applications?
- Will the use of nanomaterials be accepted by public?
- What are the potential environmental and society impacts of nanomaterials in foods?

| | |
|---|---|
| Healthcare | Wounds dressings, textiles, antiseptics, hospital beds and furniture |
| Home consumer products | Fabric conditioners, baby bottles, food storage containers and salad bowls, kitchen cutting boards, vacuum cleaners, disposable curtains and blinds, tableware, independent Living Aids - bathroom products, furniture (chairs), kitchen gadgets and bath accessories, dishwashers, refrigerators and washing machines, toilet tank levers, sink stoppers, toilet seats, pillows and mattresses, food storage containers, other containers, ice cube trays and other plastic kitchenware, hair and other brushes, hair straighteners, combs, rollers, shower caps.<br><br>Toothpaste, cosmetic deodorants, toothbrushes, tissue paper, epilators, electric shavers<br><br>Pet shampoos, feeders and waters, litter pans, pet bedding and shelter, paper, pens and pencils, ATM buttons, remote control, handrails (buses), computer keyboards, hand dryers, wireless voice communicators with badge and the sleeves, yoga mats, coatings for use on laptop computers, calculators, sheet protectors, name badges and holders, shop ticket holders, media storage products, laminating film, report covers and project folders, photo holders, diaries and agendas, office accessories, transparency film, collapsible coolers |

Consumer products using nano silver

# Consumer products using nano silver

| | |
|---|---|
| Clothing and fabrics | Baby clothes, underwear, socks, footwear, various fabrics and vinyls, bath towels, quilts, sleeping bags, bed linens, pillows, quilts, mattress protectors and towels |
| Food | Packaging, nanobiotic poultry production |
| Construction | Powder coating (door knobs), wall paints, air conditioning, epoxy resin floor, PVC wall cladding, antimicrobial flooring, metal suspended ceiling systems, window blinds and shading systems, shelving systems, decorative wood laminates, electrical wiring accessories, notile panels (alternative to standard tiling), hygienic laminated surfaces, wallpaper, borders and murals, carpet and carpet underlay, seals (door for cooler doors and freezer cells, tank lids, mixers and (bread) kneading machines, hospital doors, vibrating screens/vibrosieves in the pharmaceutical industry |
| Disinfectants | Agricultural disinfectants, industrial disinfectants, aquaculture disinfectants, pool disinfectants |

# nano silver in Food Production chain

| Chain phase | Application | Nanotechnology | Function |
|---|---|---|---|
| Processing of food | Food preparation equipment | Incorporated nanosized silver particles | Anti-bacterial coating of food handling devices |
| Conservation | Refrigerators<br>Storage containers | Incorporated nanosized silver particles | Anti-bacterial coating of storage devices |
| | Food products | Nanosized silver sprays | Antibacterial action |
| | Packaging materials | Incorporation of active nanosilver particles | Oxygen scavenging, prevention of growth of bacteria |
| Food consumption | Supplements | Colloidal metal nanoparticles | Claimed to enhance desirable uptake |

# Potential human exposure to nano silver

| Category | Sub category | Exposure route | Potential Exposure* |
|---|---|---|---|
| Food and beverages | Cleaning | Inhalation/ dermal | High |
| | Cooking utensils, coatings | Dermal | Low |
| | Storage | Dermal | Low |
| | Supplements | Oral | High |
| Personal care and cosmetics | Skin care | Dermal | High |
| | Oral hygiene | Oral | High |
| | Cleaning | Dermal | High |
| | Hair care | Dermal | Low? |
| | Baby care | Dermal | High? |
| | Wound dressings | Dermal | High |
| | Over the counter products | Dermal? | High? |
| Textile and shoes | Clothing | Dermal | ? |
| | Other textiles | Dermal | ? |
| | Toys | Dermal/ Oral | ? |

# CASE: Samsung Washer

- “Nano Technology…when converted to such a level a material may take on new properties and functions…Silver Nano ions easily penetrate cells of microorganisms … sterilize over 650 types of bacteria and serve a better world up to you in style.” (www.samsung.com)
- The EPA informed Samsung that the silver ion generating washing machine is subject to registration under FIFRA as a pesticide.
- It does not represent an action to regulate nanotechnology…we have not yet received any information that suggests that this product involves the use of nanomaterial.”

# Case: cosmetic

- “Harnesses the dramatic anti-oxidant power of Fullerene C60, preventing environmental damage to the skin’s DNA” (zelens.com)

# Case: Air Purifier

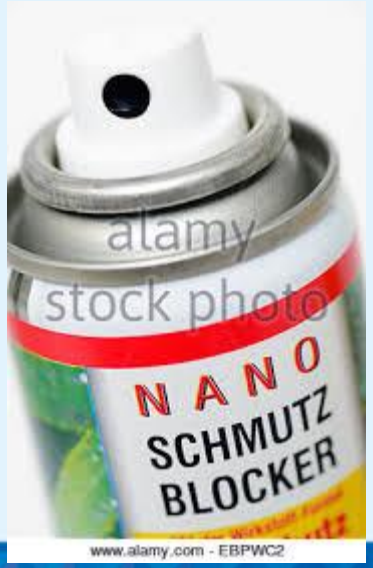
NanoBreeze Air Purifier.

A UV tube is wrapped in fiberglass coated by a layer of titanium dioxide crystals at 40 nanometers diameter.

The tube charges the crystals to create “powerful oxidizing agents” that destroy airborne germs and pollutants over the tube's surface.

# Case: Magic Nano (Germany, 2006)

- ✓Bathroom aerosol spray caused pulmonary edema in 80 users
- ✓No nanomaterials in the product
- ✓Reportedly no problems from pump spray version
- ✓Investigated by the Federal Institute for Risk Assessment
- ✓“There is strong toxicity-based evidence that aerosol surface area is an appropriate metric for low solubility particles.”

# Some Concerns in the application of nanotechnology

- National Standard for advanced materials.
- Environmental problem.
- Possible toxicity to human and biota
- Nanomaterial has different treatment between nanomaterials and advanced materials.
- Government support all of the process.

# Standard

**2 TYPES OF STANDARDS:**

1. Metrological standards: length, mass, time, quantity of matter – primary and secondary standards

2. Written standards

# Written Standards

Written Standards provide agreed ways of:

1. Naming, describing and specifying things
2. Measuring and testing things
3. Managing things e.g. quality and environmental management: ISO 9001 and ISO 14000
4. Reporting things as in e.g. proposed ISO 26000 (Social Responsibility)

To:

1. support commercialisation and market development
2. provide a basis for procurement based on technical requirements and quality/environmental management
3. support appropriate legislation/regulation

# VOLUNTARY STANDARDS

**Can be *NORMATIVE*, defining what MUST be done in e.g. a specific test method, or *INFORMATIVE*, providing information only.**

**Standards are *VOLUNTARY* unless called in a contract or regulation.**

**Standards provide a means of "validated quantification" → certification**

# Why Standard for Nanotechnology

Standards will help to ensure that nanotechnology is developed and commercialised in an open, safe and responsible manner by supporting:

1. safety testing, legislation and regulation
2. worker, public and environmental safety
3. commercialisation and procurement
4. patenting and IPR
5. communication about the benefits, opportunities and potential problems associated with nanotechnologies

# Nanotechnology Standards

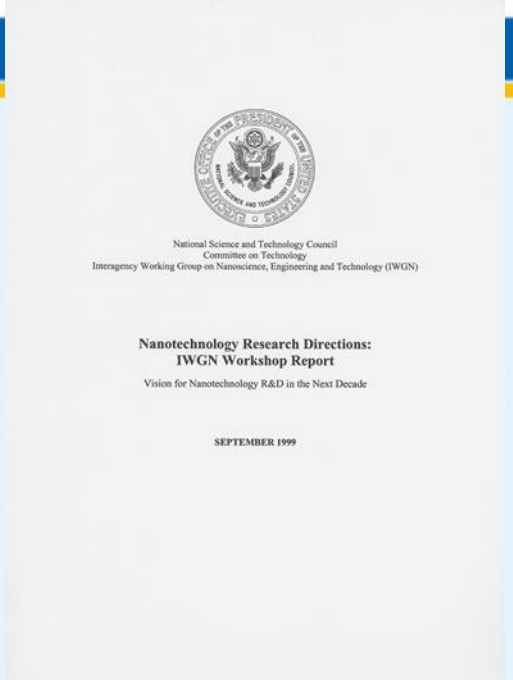
providing agreed ways of:

1. Naming, describing and specifying nanomaterials
2. Measuring and testing nanomaterials
3. Health and environmental safety testing, risk assessment and risk management of nanomaterials

# Nano-standards

"Nanotechnolgy will only become a coherent field of endeavour through the confluence of three important technological streams:

1. New and improved control of the size and manipulation of nanoscale building blocks;
2. New and improved characterization (spatial resolution, chemical sensitivity, etc) of materials at the nanoscale;
3. New and improved understanding of the relationship between nanostructure and properties and how these can be engineered"


National Science and Technology Council
Committee on Technology
Interagency Working Group on Nanoscience, Engineering and Technology (IWGN)

Nanotechnology Research Directions:
IWGN Workshop Report

Vision for Nanotechnology R&D in the Next Decade

SEPTEMBER 1999

**Do not forget safety and consumer acceptance**

# Needs of Standardization

1. To support commercialisation and market development

2. To provide a basis for procurement – technical/quality/environmental management

3. To support appropriate legislation/regulation

# History of Nano Standardization

- 12/03: - **China** establishes United Working Group for Nanomaterials standardization

  - UK proposes CEN/BTWG to develop strategy for European standardization in nanotechnologies.
- 05/04: **UK** establishes NTI/1 national committee
- 11/04: **Japan** establishes study group for nanotech. standardization
- 12/04: China publishes 7 national nanotech standards
- 01/05: UK submits proposal for an ISO committee
- 04/05: - China implements published nanotech standards

- 2011: Indonesia established TC nanotechnology

# International Standard for Nano

- 06/05: - **ISO confirms establishment of TC 229** – UK secretariat & chair.
  11/05: - Inaugural meeting of ISO TC 229 in London.
  - CEN establishes CEN/TC 352 – Nanotechnologies – UK Chair & Secretariat
- 01/06: UK submits first NWIP to TC 229 – **vocabulary for nanoparticles**
- 03/06: IEC receives proposal for new TC for Nanotechnologies
- 04/06: 1st meeting of CEN/TC 352 (agreed to collaborate closely with ISO/TC 229)
- 05/06: IEC agrees to establish TC 113 in the field of nanotechnologies - issue of coordination with ISO/TC 229
- 06/06: 2nd meeting of ISO/TC 229, Tokyo
- 12/06: 3rd meeting of ISO/TC 229, Seoul
- 06/07: 4th meeting of ISO/TC 229, Berlin
- 12/07: 5th meeting of ISO/TC 229, Singapore (jointly with IEC/TC 113)

# ISO TC 229 has adopted:

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

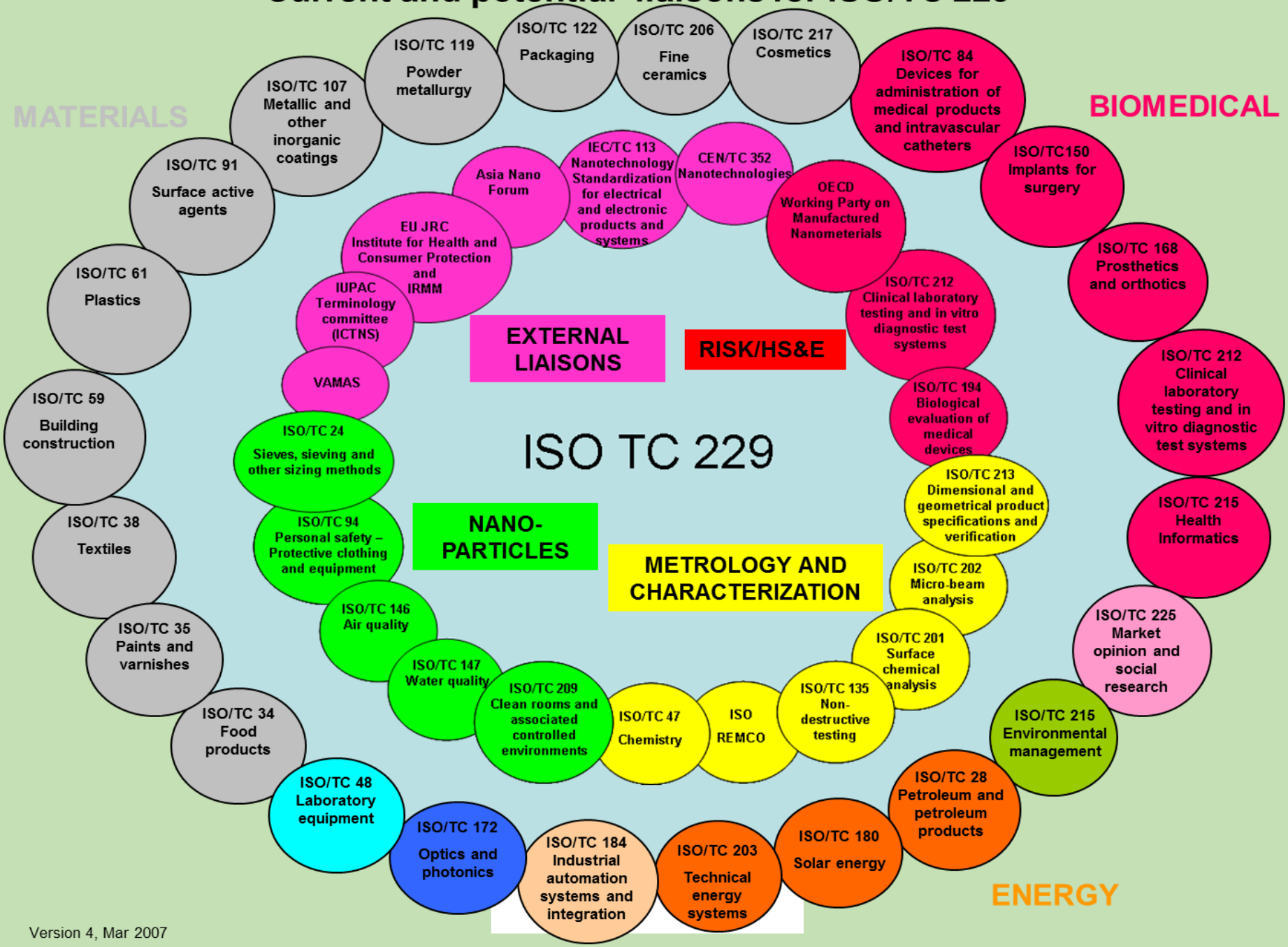
1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, **below 100 nanometres** in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications;
2. Utilizing the properties of nanoscale materials that differ from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

# Task for TC Nanotechnology:

Developed Standard for:

1. terminology and nomenclature;
2. metrology and instrumentation, including specifications for reference materials;
3. test methodologies;
4. modelling and simulation; and
5. **science-based health, safety, and environmental practices**.

# Current and potential liaisons for ISO/TC 229




Version 4, Mar 2007

# Several ISO TC Nano

- 34 - **Food and food products**
- 94 - **Personal safety** – protective equipment
- 122 - **Packaging**
- 146 - **Air quality** (New TR published 2007: Workplace Atmospheres - Ultrafine, nanoparticle and nano-structured aerosols - Inhalation exposure characterization and assessment)
- 147 - **Water quality**
- 150 - **Implants for surgery**
- 194 - **Biological evaluation** of medical devices
- 207/SC 5 - **Environmental management** – life cycle assessment
- 217- **Cosmetics**
- TMB Working Group on Risk Management (Risk Terminology defined in ISO/IEC Guides 51 & 73)

# Important to develop standard

1. **Test methods** to detect and identify nanoparticles, and to characterize nanoscale materials and devices.
2. **Protocols for bio- and eco-toxicity testing**, including protocols to evaluate effects of short term and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanomaterials and nanoscale devices.
3. **Protocols for whole life cycle assessment** of nanoscale materials, devices and products.
4. **Risk assessment tools** relevant to the field of nanotechnologies.
5. **Protocols for containment, trapping and destruction** of nanoparticles and nanoscale entities.
6. **Occupational health protocols** relevant to nanotechnologies, in particular for industries dealing with nanoparticles and nanoscale devices.

# Standardization in Indonesia

- National Standardization Agency (BSN) established in 1997
- Standar Nasional Indonesia (SNI)
- Technical Committee 07-03 for Nanotechnology was established on 2011, and work until now.

# Nano-Standard in Indonesia

| | SNI | |
|---|---|---|
| 1 | SNI ISO 29701:2011 | Endotoxyn test in nanomaterial sample (in vitro)- Limulus amebocyte lysate Test (LAL) |
| 2 | SNI ISO/TR 11360:2011 | **Nanotechnology: Classification and Category of Nanomaterial** |
| 3 | SNI ISO/TS 10867:2011 | Nanotechnology: Characterization of single wall carbon nanotube by using photoluminescence Near Infrared spectroscopy |
| 4 | SNI ISO/TS 27687:2011 | Nanotechnology: Term and definition of nano-objects – nanoparticle, nanofiber and nanorod |
| 5 | SNI ISO/TS 80004-1:2011 | Nanotechnology – Vocabulary: Part 1: Main term |
| 6 | SNI ISO/TS 80004-3:2011 | Nanotechnology – Vocabulary: Part 3: Carbon nano- Object |

# Nano-Standard in Indonesia

| | SNI | |
|---|---|---|
| 7 | SNI ISO/TS 12805:2013 | Nanotechnology: Material specification – Guideline to determine nano-object specification |
| 8 | SNI ISO/TS 80004-4:2013 | Nanotechnology: Vocabulary – Part 4: Nano Structure Material |
| 9 | SNI ISO/TS 80004-5:2013 | Nanotechnology: Vocabulary – Part 5: Relation between nanomaterial and biology |
| 10 | SNI ISO/TS 80004-7:2013 | Nanotechnology: Vocabulary – Part 7: Diagnostic and therapy for health treatment |
| 11 | SNI ISO/TS 11931:2015 | Nanotechnology – Nanoscale Calcium Carbonate in powder form: characteristic and measurement |
| 12 | SNI ISO/TS 11937:2015 | Nanotechnology – Nanoscale Titanium Dioxide in powder form: characteristic and measurement |

# Summary

- Nanomaterial has been developed and commercialized in many applications of consumer products. Therefore, we need to develop standard for nanomaterial in order to protect human health and environment.
- Nanosafety standard is important to be developed as well as development of nanotechnology applications in many fields.
- Networking among Asia Pacific countries is also important