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# Risk assessment and safety compliance of nanotechnology-based products – Regulatory mechanisms, guidelines and good practices

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National Nanotechnology Center (NANOTECH)  
National Science and Technology Development Agency (NSTDA)  
THAILAND

**International Conference on Nanotechnology for Safe and Sustainable Development  
&**

**Consultative Meeting on Proposed ASEAN Nanosafety Networking Platform**

2-4 May 2017

Putrajaya, MALAYSIA

# Nanoproducts in Thailand...



**Nano**



# Guidance for Industry on Nano Health Products

**FDA Thailand, Ministry of Public Health**

สำนักงานคณะกรรมการอาหารและยา กระทรวงสาธารณสุข



2016

แนวปฏิบัติ  
สำหรับผู้ประกอบการ  
ผลิตภัณฑ์สุขภาพนาโน



สำนักงานคณะกรรมการอาหารและยา  
กระทรวงสาธารณสุข

จัดทำโดย : คณะทำงานพัฒนาและกำหนดแนวทางการกำกับดูแลประสิทธิภาพ  
และความปลอดภัยของผลิตภัณฑ์สุขภาพนาโน

The guidance document contains 4 chapters:

- Chapter 1** Application of nanomaterials and nanotechnology in health products
- Chapter 2** Safety of nanomaterials and nano health products
- Chapter 3** International regulation of nano health products
- Chapter 4** Guidance on registration of nano health products in Thailand

# Seven industrial standardization manuals related to nanotechnology (2016)



มาตรฐานอุตสาหกรรมด้านนาโนเทคโนโลยีร่วมกับ สมอ. ประกาศในราชกิจจานุเบกษาแล้ว 7 ฉบับ

Part 1: Guidance on specifying manufactured nanomaterials

Part 2: Guidance on physico-chemical characterization for specifying manufactured nanomaterials

Part 3: Guidance on safe handling and disposal of nanomaterials

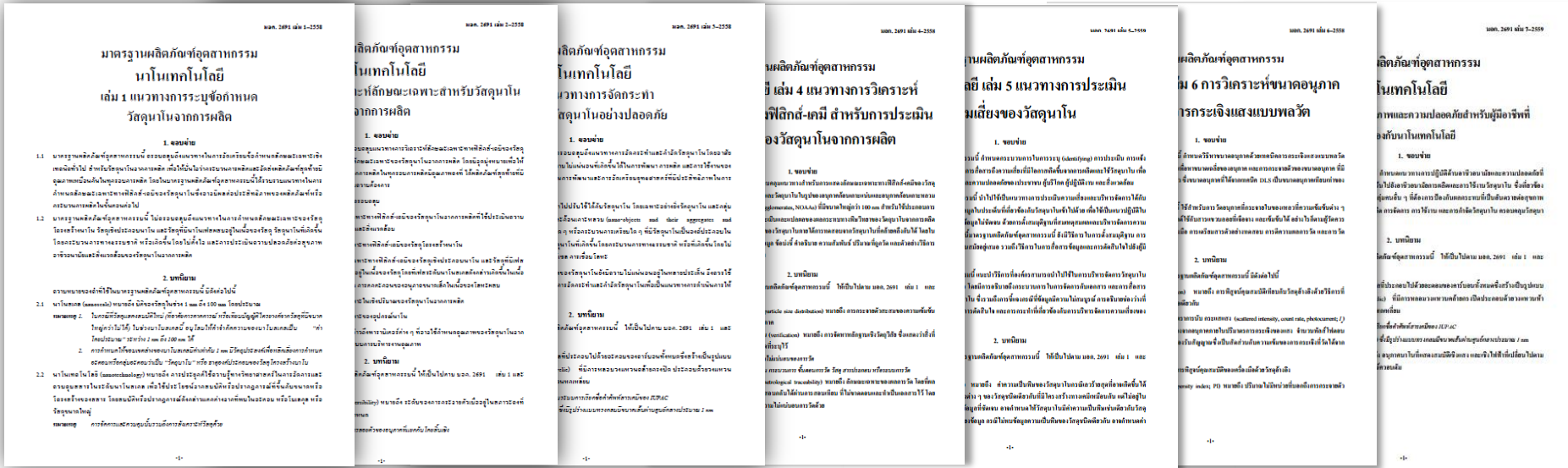
Part 4: Guidance on physico-chemical characterization for toxicologic assessment of manufactured nanomaterials

Part 5: Guidance on nanomaterial risk evaluation

Part 6: Particle size analysis using dynamic light scattering

Part 7: Health and safety practices in occupational setting relevant to nanomaterials

## Collaboration between “Thai Industrial Standards Institute (TISI) and NANOTEC”



# Labeling of Nanoproducts (NanoQ)



**NanoQ** is a certified mark for nanoproducts which are certified by the Nanotechnology Association of Thailand.



## Motivation to have Nano Q

- ☑ **Increase public trust:** Facilitate healthy development of nanotechnology
- ☑ **Protect consumer:** Avoid waste money
- ☑ **Protect good companies:** Eliminate unfair competitions between good & bad products
- ☑ **Facilitate trade:** Stimulate economic growth

## Current product groups eligible for NanoQ

1. Textiles
2. Coating and paints
3. Ceramics
4. Household plastic

## Steps to obtaining NanoQ

1. File a request with supporting documents
2. Submit nanoproducs sample to technical committee of the Nanotechnology Association of Thailand
3. The sample will be analyzed by certified testing laboratories
4. Factory visit will be carried out to ensure occupational and environmental safety related to manufacturing process of the nanoproducs

**\*\* Investigation checklist is applied according to the Guidance from “Industrial standardization manuals related to nanotechnology” \*\***

5. Consideration and approval process

Seven industrial standardization manuals related to nanotechnology (2016)



มาตรฐานอุตสาหกรรมด้านนาโนเทคโนโลยีรวมกัน สผ. ประกาศในราชกิจจานุเบกษาแล้ว 7 ฉบับ

- Part 1: Guidance on specifying manufactured nanomaterials
- Part 2: Guidance on material characterization for specifying manufactured nanomaterials
- Part 3: Guidance on safe handling and disposal of nanomaterials
- Part 4: Guidance on physio-chemical characterization for toxicologic assessment of manufactured nanomaterials
- Part 5: Guidance on nanomaterial risk evaluation
- Part 6: Particle size analysis using dynamic light scattering
- Part 7: Health and safety practices in occupational setting relevant to nanomaterials

Collaboration between “Thai Industrial Standards Institute (TISI) and NANOTEC”



# Labeling of Nanoproducts (NanoQ)



## Products certified by NanoQ

- 1) Coating materials inside the ambulance
- 2) Nanoproducts used for coating hospital's walls
- 3) Water storage tank
- 4) Bed net
- 5) Multi-purpose coating materials



✚ The aseptic ambulance of Supremeproducts Co.,Ltd has received the first NanoQ label in Thailand.



**NETTO**

Super Premium Quality

**MOSQUITO NET**  
**NANO TECH**

20 WASHES

NANO TECHNOLOGY WATER REPELLENT ANTI-LV

This Product is co-developed by the National Nano-Technology Center, National Science and Technology Development Agency (NSTDA).  
Patent Registration Number : 1100200009

# Testing Services

-- Infrastructure and Activities --



# National Advanced Nano-characterization Center (NANC)

ศูนย์วิเคราะห์ทดสอบทางนาโนเทคโนโลยีขั้นสูง

(2016)



Research & Development



Lab Continual Improvement



Standards & Regulations



**Location:** Innovation Center 2 (INC2) Tower C, 4<sup>th</sup> and 5<sup>th</sup> floor  
Thailand Science Park, Pathum Thani, Thailand



- ➔ Develop and improve sample characterization techniques
- ➔ Investigations on toxicological effects using *in vitro* and *in vivo* models
- ➔ Contract and collaborative researches



- ➔ Inter Lab comparison (National and International)
- ➔ Support technical information for Nano Q certification
- ➔ Cooperate with national organizations (TISI, Thai FDA, NIMT, etc.) to develop guidance related to nanotechnology for industries



- ➔ One-stop testing service for industries
- ➔ In-house testing service
- ➔ Technical consultation by experts
- ➔ Technical training and workshop

# NANOTEC Characterization Facility: National Advanced Nano-characterization Center

## Nanostructure and Mechanical Characterization



## Nano Stability Analysis



## Nanoscale Identification and Analysis



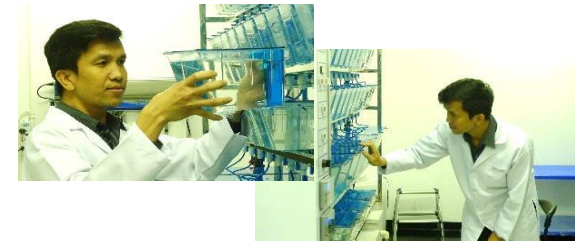
## Chemical Identification



## Nano-biomolecular Analysis



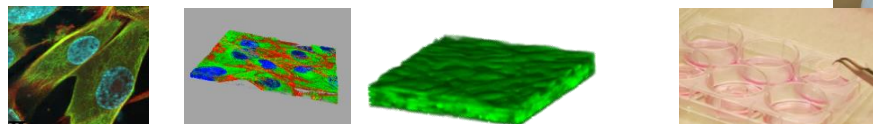
## In vivo Nanotoxicology Analysis



## Integrative Microbiology and Nanosafety Analysis



## Cell Culture and Tissue Engineering & Nanomaterial Exposure and Monitoring





**Particle size analysis –  
Dynamic Light Scattering (DLS)**

**ISO 22412: 2008**



**Particle size analysis –  
Image analysis by Scanning Electron  
Microscope (SEM)**

**ISO 13322-1: 2014**



**Measurement of  
antibacterial activity for  
non-porous materials**

**ISO 22196: 2011**



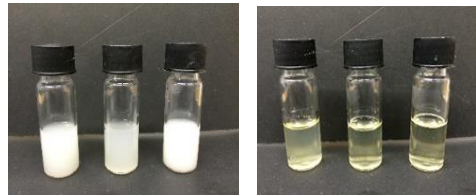
- NANC supports and promotes manufacturer's capabilities to compete in national and international markets.
- Scientific-based characterizations and toxicological testing can facilitate the manufacturers' selection of raw materials during R&D process in order to develop safe and high-quality products.
- Provide testing services for nanoproduct samples submitted for NanoQ.

## Nanoproducts in our focus

- Health and Cosmetic Manufacturers  
(Health and Cosmetic products)
- Food and Agricultural Manufacturers  
(Agricultural products, Processed foods, Food packages)
- Post-petrochemical Manufacturers  
(Textiles, Plastic beads, Synthetic rubbers, Glue, and Coating chemicals)

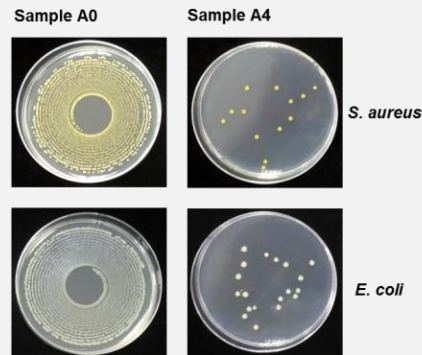
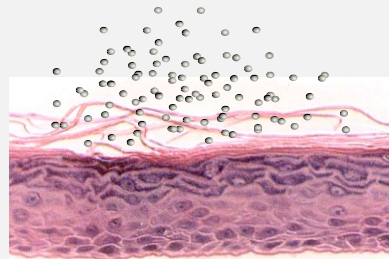


# Research and testing services



## Testing of the products and raw materials

- Physical/chemical characterizations
- Release and sustainability (ASTM F619-03)
- Skin irritation (OECD TG439)
- Phototoxicity (OECD 432)
- Antibacterial tests  
(ISO 22196, JIS Z 2801, AATCC 100, JIS L 1902, etc.)

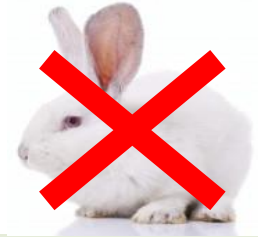


# Thailand's Status related to Toxicological Testing

-- Regulatory context and our good practices--

## New European directive 2010/63/EU on the protection of animals used for scientific purposes

firmly support 3Rs principle : Reduction / Refinement / Replacement



## EU Cosmetic Products Regulation (EC) No1223/2009

*As of 11 July 2013*

- Prohibits the testing of finished cosmetic products and cosmetic ingredients on animals (**testing ban**)
- Prohibits the marketing in the European Community, of finished cosmetic products and ingredients included in cosmetic products that were tested on animals (**marketing ban**)

Exceptions for repeated dose toxicity, reproductive toxicity, and toxicokinetics

## ASEAN Cosmetic Directive and Thailand's status

The need for alternatives to animals used in toxicity testing was recognized by **Thailand** with the ASEAN MOU signing in 2015 to adopt the directives for non-animal testing of Cosmetics. **The aim of this MOU signing is to harmonize with international acceptance practices especially the EU.**



# Animal test

## Acute Dermal Irritation-Corrosion Test (OECD TG 404)



## Acute Eye Irritation/Corrosion (OECD TG 405)

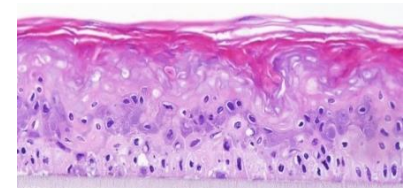


# Non-Animal test

## Skin corrosion (OECD TG 431) Skin irritation (OECD TG 439)



THE EUROPEAN UNION REFERENCE LABORATORY  
FOR ALTERNATIVES TO ANIMAL TESTING

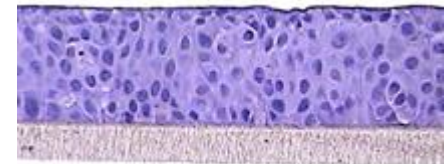


Reconstructed human  
Epidermis (RhE)

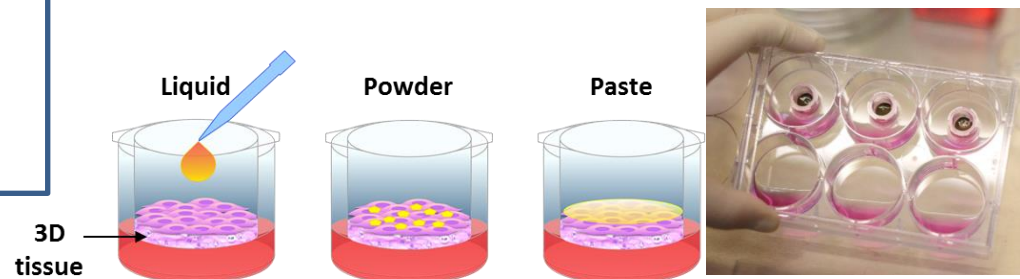
## Eye irritation or serious eye damage (OECD TG 492)



THE EUROPEAN UNION REFERENCE LABORATORY  
FOR ALTERNATIVES TO ANIMAL TESTING



Reconstructed human  
Cornea-like Epithelium  
(RhCE)



## Alternative methods:

Method	International Guideline
<i>In vitro</i> <b>skin corrosion</b> : Transcutaneous electrical resistance test method	OECD TG 430 (2015)
<i>In vitro</i> <b>skin corrosion</b> : Reconstructed human epidermis (RhE) test method	OECD TG 431 (2015)
<i>In vitro</i> <b>skin Irritation</b> : Reconstructed human epidermis test method	OECD TG 439 (2015)
<i>In vitro</i> membrane barrier test method for <b>skin corrosion</b>	OECD TG 435 (2015)
<i>In vitro</i> 3T3 NRU <b>phototoxicity</b> test	OECD TG 432 (2004)
<i>In chemico</i> <b>skin sensitization</b> : Direct peptide reactivity assay (DPRA)	OECD TG 442C (2015)
<i>In vitro</i> <b>skin sensitization</b> : ARE-Nrf-2 luciferase test method	OECD TG 442D (2015)
<i>In vitro</i> mammalian cell <b>micronucleus</b> test	OECD TG 487 (2014)
<i>In vitro</i> mammalian cell <b>gene mutation</b> test using the thymidine kinase gene	OECD TG 490 (2015)
Short time exposure <i>in vitro</i> test method for identifying i) Chemicals including serious <b>eye damage</b> and ii) Chemicals not requiring classification for <b>eye irritation</b> or <b>serious eye damage</b>	OECD TG 492 (2015)

# The 1<sup>st</sup> Thailand Meeting on Alternatives to Animal Testing



Co-organized by 3 institutes under the Ministry of Science and Technology

- Thailand Center of Excellence for Life Sciences (TCELS)
- National Nanotechnology Center (NANOTEC)
- Thailand Institute of Scientific and Technological Research (TISTR)



- **Part I: New Paradigm and Alternative Methods in Skin Irritation Testing**  
(12 July 2016 at Century Park Hotel Bangkok)
- **Part II: Understanding and Acceptance of Alternative Methods**  
(24-25 August 2016 at Century Park Hotel Bangkok)





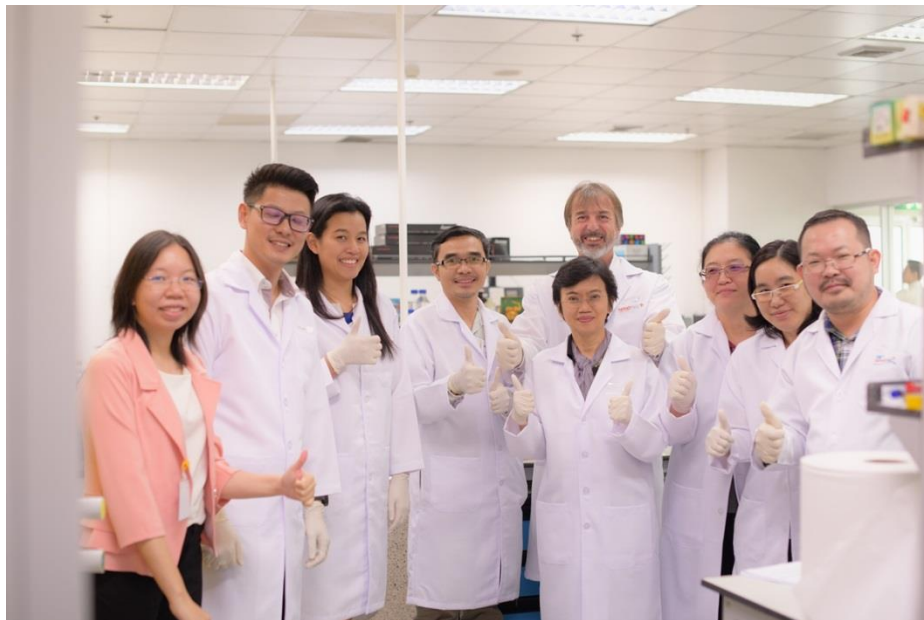
## Closed Session Workshop

### "Alternative Methods with Training on Skin Irritation Test According to OECD TG439"

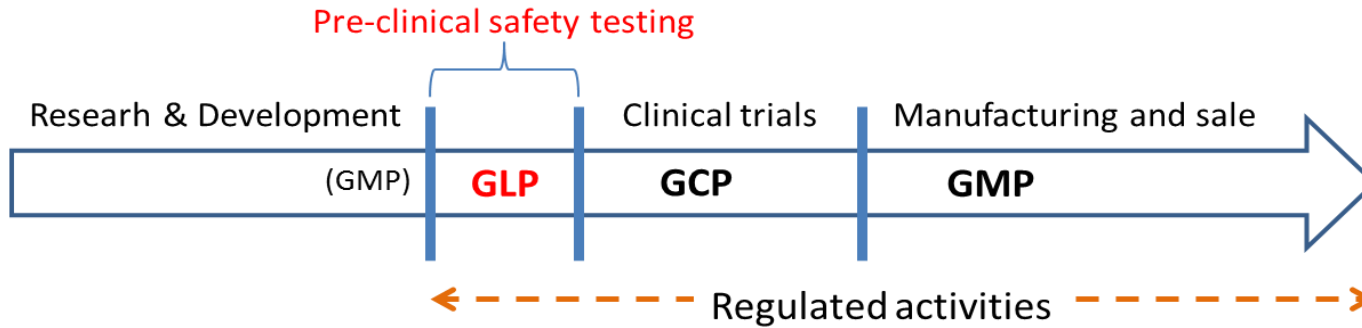
13 – 14 July, 2016



NANOTECH, Innovation Cluster II Building, Thailand Science Park, Pathum Thani

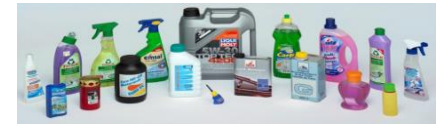


# OECD-GLP Certified Laboratories



## Products

- Pharmaceuticals
- Cosmetics
- Veterinary drugs
- Food additives
- Household chemicals



## Collaborative networks

- Department of Medical Sciences, Ministry of Public Health
- Thailand Center of Excellence for Life Sciences
- National Nanotechnology Center, NSTDA
- Thailand Institute of Scientific and Technological Research
- Chulabhorn Research Institute
- Universities



# The 1st Meeting on Pre-clinical study collaborative network hosted by Department of Medical Sciences, Ministry of Public Health



The goal of the meeting aim to look at the possibility of setting up the Pre-clinical study collaborative network in Thailand with partnership from leading research agencies/institutions in the field of toxicology such as MOPH, NANOTEC, TCELS, CRI, Chulalongkorn University and Mahidol University. The meeting allows for each partner to share information related to *in vitro* and *in vivo* facilities and available methods for testing service in order to pool resources of the network. The meeting also aimed to push forward the idea of OECD-GLP (Good Laboratory Practice) for pre-clinical testing laboratories in Thailand.

# Thank you for your attention!



A Driving Force for  
National Science and Technology Capability

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THAILAND

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