

# Nanotechnology Registration in APAC

## Navigating Unknowns to Gain Market Access

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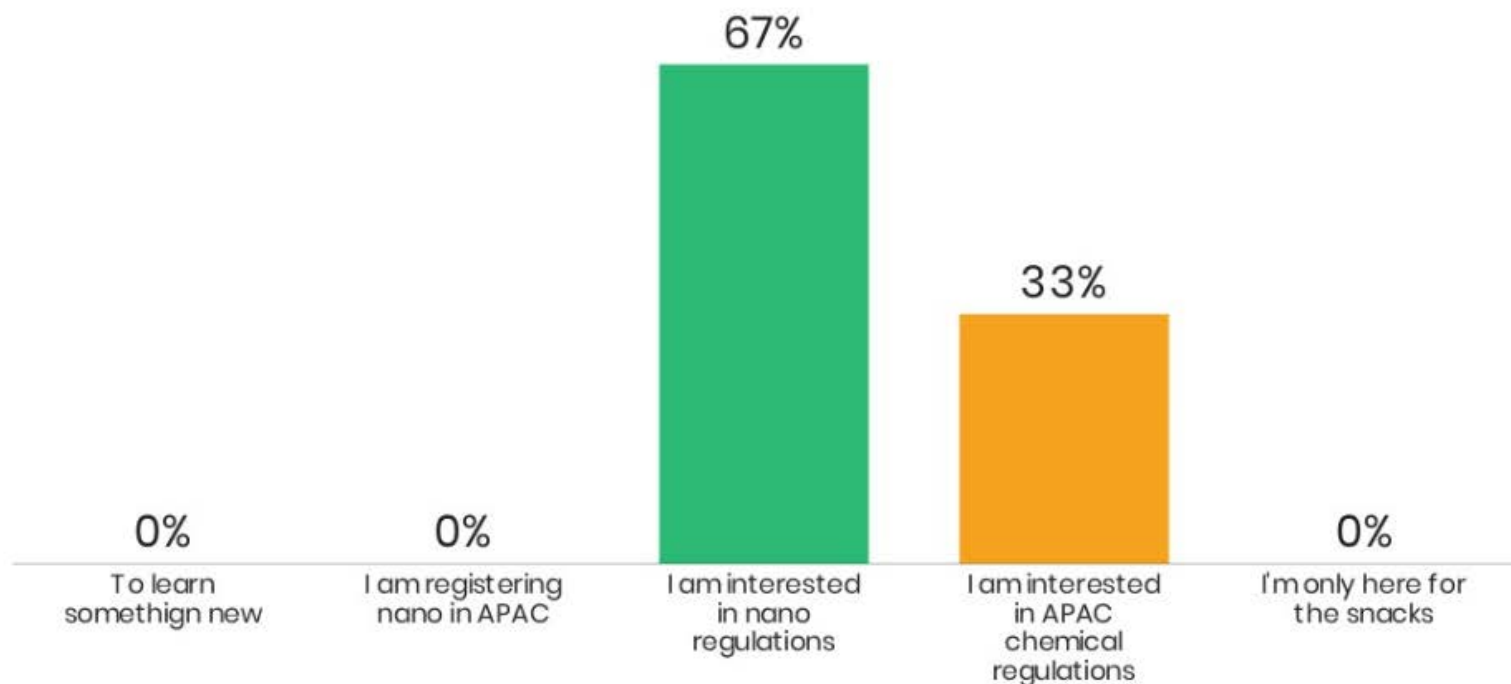
Environmental Resources Management

New York, NY



# Survey Question

## Why are you most interested in this session?



# Background



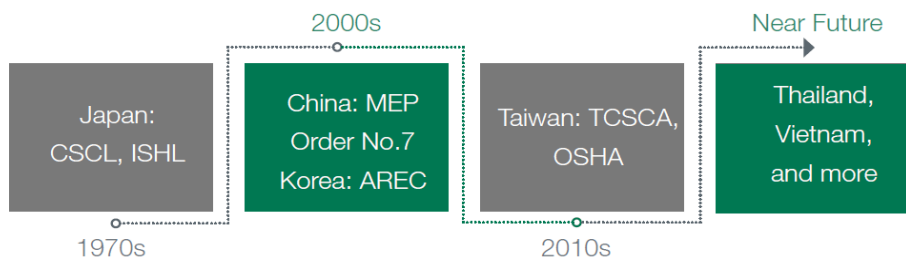
- APAC importance
  - Manufacturers
  - R&D
  - Global economy
  - Emerging markets
  - Business expansion



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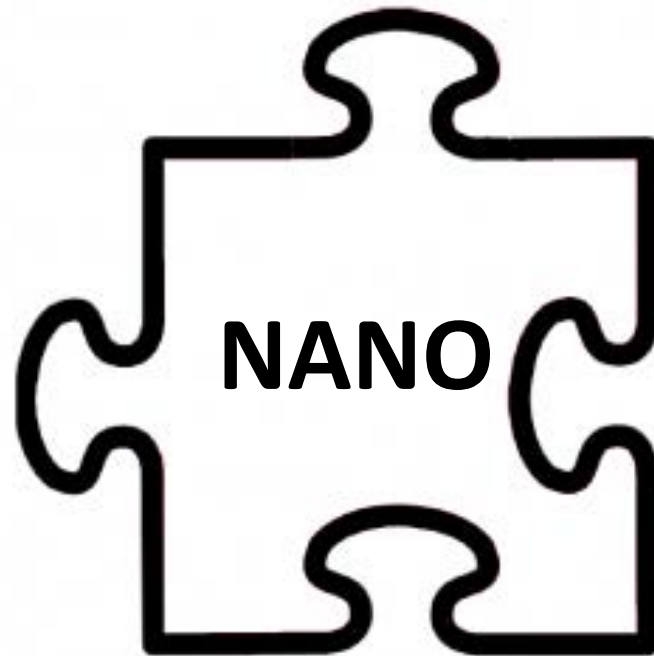


# Major Regulations

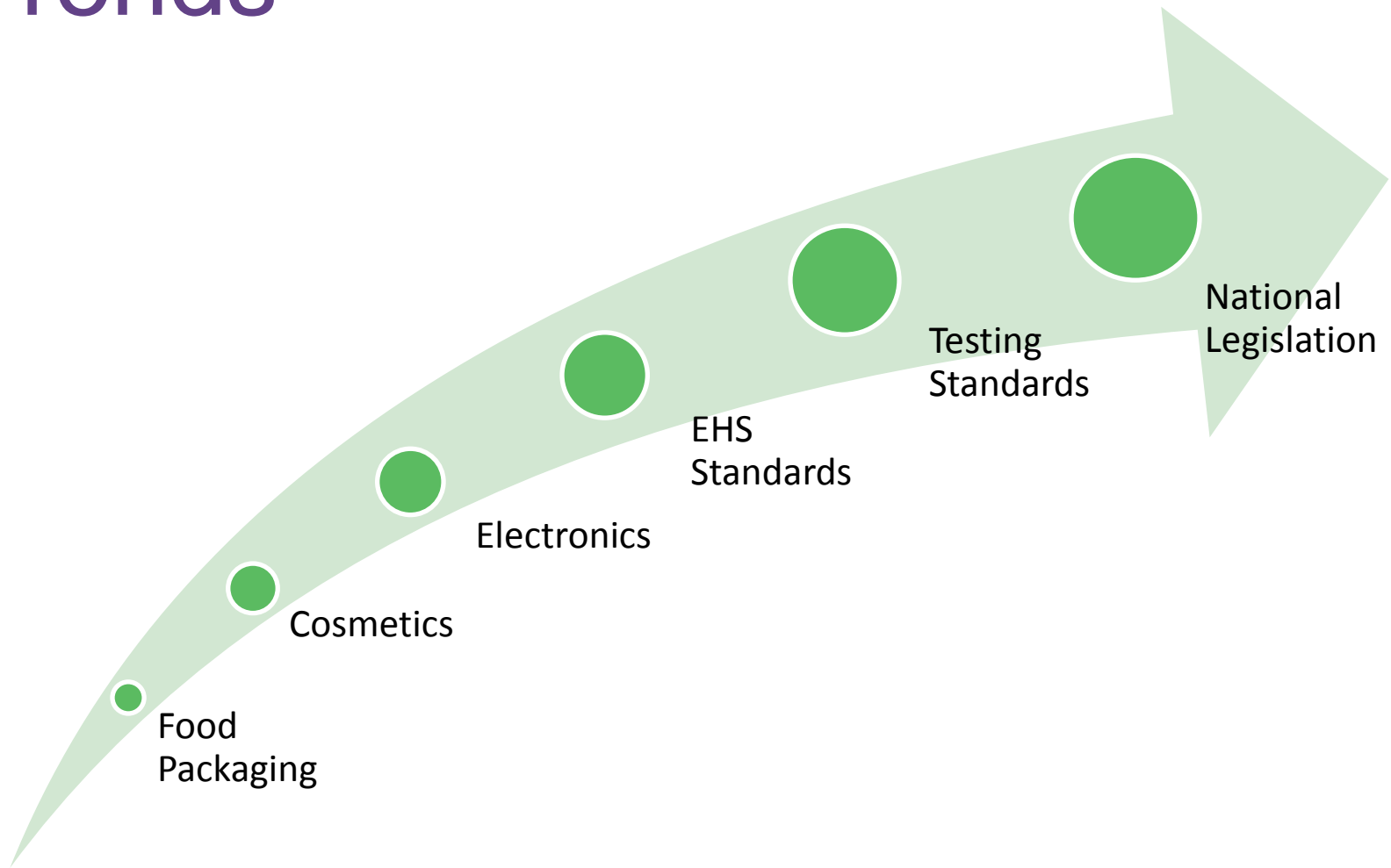


	Japan	China	Korea	Taiwan
New Chemical Registration	<ul style="list-style-type: none"> <li>Chemical Substances Control Law (CSCL)</li> <li>Industrial Safety and Health Law (ISHL)</li> </ul>	Measures on the Environmental Management of New Chemical Substances (MEP Order No.7)	<ul style="list-style-type: none"> <li>Act on Chemical Registration and Evaluation of Chemicals (K-REACH)</li> <li>Occupational Safety and Health Act (OSHA)</li> </ul>	<ul style="list-style-type: none"> <li>Toxic Chemical Substances Control Act (TCSCA)</li> <li>Occupational Safety and Health Act (OSHA)</li> </ul>
Existing Chemical Registration		Regulation on the Safe Management of Hazardous Chemicals (Decree 591): ~3,000 ECs	K-REACH: ~2,000 ECs	TCSCA: total ~500 ECs
Note	Regulations are stable and industry act proactively before regulations are established	MEP Order 7 amendments being finalized	Major amendments on K-REACH (~7,000 ECs expected) and new enactment of Biocide Act (K-BPR) are coming	First batch of existing chemicals required for registration is to be published

# Where Does Nano Fit?

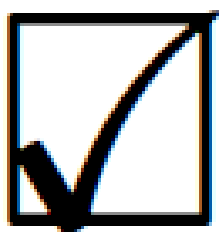


# Trends



# Challenges

## Legislative differences



- Emerging regulations
- Definitions
- Data requirements and quality standards

## Language barriers



- English as a main vs. second language
- Availability and liability of translated documents

## Composition Disclosure



- Ingredient information
- CBI
- Inventory listings

## Authority Communication



- Written vs. oral communication
- Acceptance of waivers or read across data



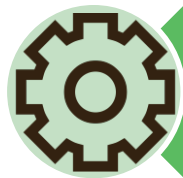
# General Requirements



Understand definitions



Calculate annual volume



Determine use



Identify importers or legal entities





# Case Study

## SCENARIO

- Manufacture a new nanomaterial
- Register globally, including USA and APAC
- Proactive registration

## CHALLENGES

- Definitions, CAS#, CBI
- R&D and commercial uses
- Registration timing

## SOLUTIONS

- Phased approach to registration using local experts throughout the process
- Understanding registration nuances per country

## LESSONS

- Understand product definition and uses
- Communicate with the authorities



# United States vs EU

	United States	European Union
Definition	<p>Under TSCA a nanomaterial is a chemical substances that have structures with dimensions at the nanoscale - approximately 1-100 (nm)</p>	<p>Under REACH a nanomaterial is a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.</p>
Reference	<ul style="list-style-type: none"> <li>• PMN</li> <li>• SNUR (40 CFR 721)</li> <li>• Information gathering (40 CFR 704)</li> </ul>	<ul style="list-style-type: none"> <li>• Recommendation on the definition of a nanomaterial (2011/696/EU)</li> <li>• REACH (EC 1907/2006)</li> <li>• CLP (EC 1272/2008)</li> </ul>
Approach	<ul style="list-style-type: none"> <li>• Nano scale = larger forms</li> <li>• Read across accepted</li> </ul>	<ul style="list-style-type: none"> <li>• Nano is considered it's own entity</li> <li>• Read across only when appropriate</li> </ul>

# Japan

## ISHL

- Main regulation for occupational health including exposure to hazardous chemical
- Addresses new chemical notification, prohibition/restriction, risk assessment, and GHS
- Allows for Small Volume Exemption of 100 kg/y

## CSCL

- Main regulation for chemical management
- Addresses new chemical notification, annual reporting, and prohibition/restriction
- Exemptions available
  - Small Volume Exemption 1 t/y
  - Low Volume Exemption 10 t/y

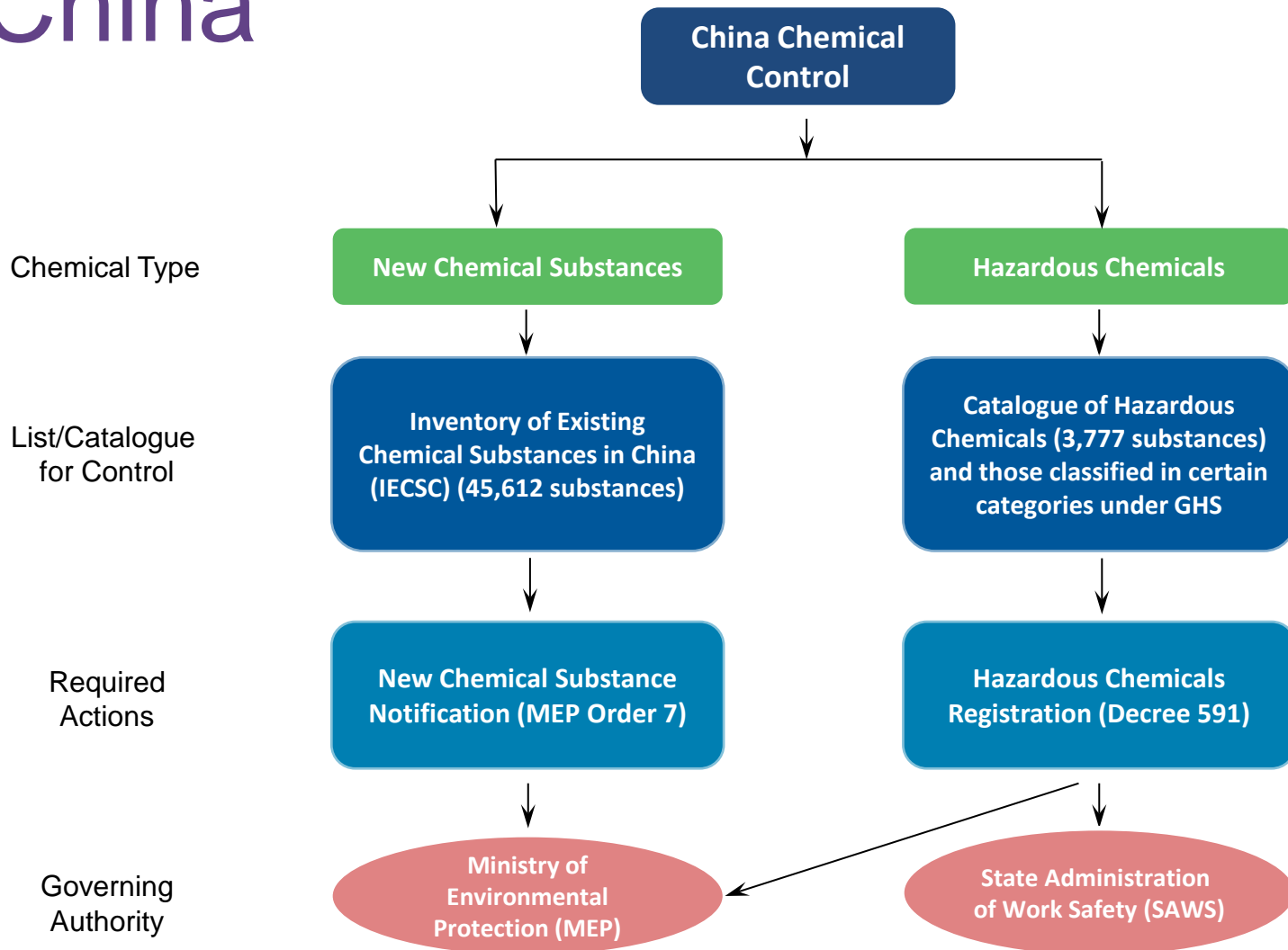


# Japan

<b>Definition</b>	“Nanomaterial” refers to, among solid materials manufactured using elements, etc. as a raw material, a nano-object with at least one of the three dimensions of approximately 1 – 100nm and a nano-structured material composed of nano-objects (including matter composed of aggregated/ agglomerated nano-objects).
<b>Reference</b>	Notice on Precautionary Measures for Prevention of Exposure etc. to Nanomaterials (31 March 2009) Updated 28 <sup>th</sup> Nov 2014 for respiratory PPE – does not influence the definition of a nanomaterial
<b>Approach</b>	<ul style="list-style-type: none"><li>• Review by local chemical expert to determine if the substance is existing</li><li>• Consultation with the authorities</li></ul>



# China



# China

<b>Definition</b>	Nanomaterials are the material which has a structure in the three-dimensional space in at least one dimension in the nanometer scale (from 1 -100 nm range of geometric dimensions), or constituted by the nanostructure unit and a material with special properties.
<b>Reference</b>	GB/T 19619-2004: (Terminology for nano materials) GB/T 33715-2017 Nanotechnologies—Health and safety practices in occupational settings relevant to nanotechnologies, published on May 12, 2017, will come into force on December 1, 2017.
<b>Approach</b>	<ol style="list-style-type: none"><li>1. IECSC check (public and confidential)</li><li>2. Notification based on use and volume<ul style="list-style-type: none"><li>• Testing is required on the physical form stated in the notification application</li></ul></li><li>3. Import</li></ol>



# Taiwan

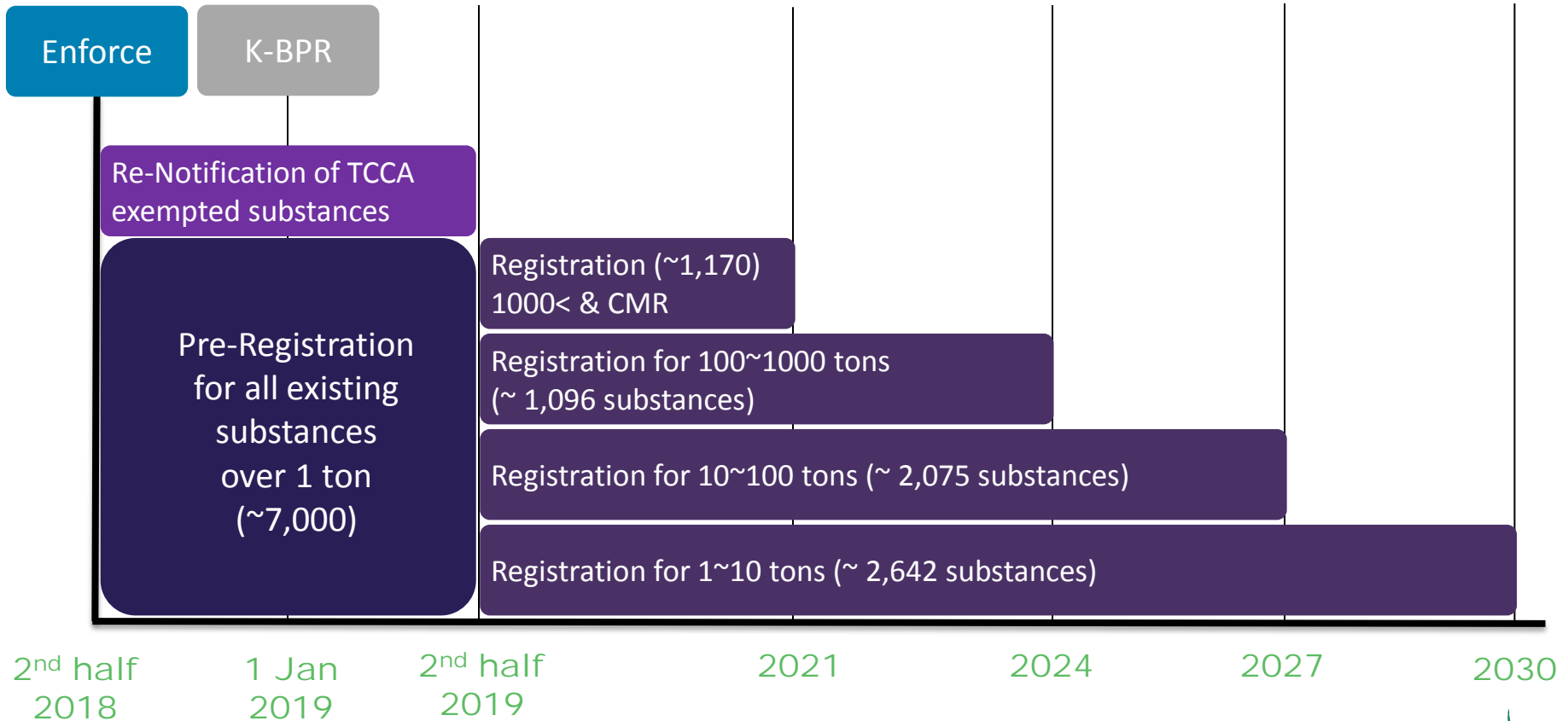
Authority	Substance	Registration Requirements	Who	When
TCSCA (Registration target: new & existing chemicals)	<b>New Chemical</b>	<ul style="list-style-type: none"> <li>➤ Standard registration</li> <li>➤ Simplified registration</li> <li>➤ Small-quantity registration (depending on chemical type, tonnage and uses)</li> </ul>	Importer/ Manufacturer in Taiwan	90 days prior to import/manufacture;
	<b>Existing Chemical</b>	<ul style="list-style-type: none"> <li>➤ Phase I registration: all existing substances(<math>\geq 0.1</math>t/y);</li> <li>➤ Phase II Standard registration: designated existing substances announced by EPA</li> </ul>	Importer/ Manufacturer in Taiwan	<ul style="list-style-type: none"> <li>• Phase I: 2015/09/01 - 2016/03/31</li> <li>• Late Phase I (after 2016/04/01): 90 days after 1<sup>st</sup> manufactured/ Imported volume reaches 0.1 t/yr</li> <li>• Phase II: to be announced by EPA before the end of 2017</li> </ul>
OSHA (Registration target: new chemicals)	<b>New Chemical</b>	<ul style="list-style-type: none"> <li>➤ Standard registration</li> <li>➤ Simplified registration</li> <li>➤ Small-quantity registration (depending on chemical type, volume and uses)</li> </ul>	Importer/ Manufacturer in Taiwan	Before import/manufacture
	<b>Existing Chemical</b>	<ul style="list-style-type: none"> <li>➤ Reporting: priority management chemicals</li> <li>➤ Apply permit: controlled chemicals</li> </ul>	Importer/ Manufacturer/ Supplier / Employer in Taiwan	Reporting: annually Permit: before handling

# Taiwan

<b>Definition</b>	<p>Nanomaterials are not defined as an individual category with specific tonnage bands, once the substance is defined as a nanomaterial, a specific nanomaterial application form/testing report should be fulfilled and submitted.</p> <ul style="list-style-type: none"><li>• Food packaging and food substances (FDA)</li><li>• Cosmetics (FDA)</li><li>• Exposure and control (IOSH)</li></ul>
<b>Reference</b>	<ul style="list-style-type: none"><li>• Regulation of New and Existing Chemical Substances Registration (EPA)</li><li>• Regulations on New Chemical Substances Registration (MOL)</li><li>• Taiwan Nanotechnology EHS Database</li><li>• nanoMark product certification (TANIDA)</li></ul>
<b>Approach</b>	<p>Notified as Taiwan was building the inventory – this is a strategic approach in understanding the regulatory landscape of emerging markets</p>



# Republic of South Korea



# Republic of South Korea

<b>Definition</b>	<ul style="list-style-type: none"><li>• K-BPR Article 2(Definitions) - translation<ul style="list-style-type: none"><li>• A substance satisfying one of below conditions is considered as “Nanomaterial”<ul style="list-style-type: none"><li>• Substance with more than 50% of particles having one dimensional size between 1-100nm</li><li>• Single walled carbon nanotubes, graphene flake or fullerene with one dimensional size less than or equal to 1 nm</li></ul></li></ul></li></ul>
<b>Reference</b>	<ul style="list-style-type: none"><li>• South Korea Act on Registration and Evaluation of Chemicals of Korea (K-REACH)</li><li>• South Korea Act on Chemical Consumer Products and Biocides (K-BPR)</li></ul>
<b>Approach</b>	<ul style="list-style-type: none"><li>• Register chemical substance based on volumes, end use, end users</li></ul>



# Other

- **Australia**

- Australia's regulatory framework for enabling technologies is made up of federal and state regulatory agencies. Coordination of the Australian Government regulators and related policy, research and funding agencies is carried out through the Health, Safety and the Environment Working Group. The regulatory roles fall to the differing agencies depending on the end-use of the enabling technology. Some technologies require approval from more than one agency.

- **India**

- While India ranks third in the number of global research publications in nano, with focus by the Department of Science and Technology, there is a lack of focus on risk analysis and regulation.



# Emerging Markets

## Thailand

- Notification on the List of Hazardous Substances (No. 2) B.E. 2558 (2015) addressed 10 hazard properties and tonnage requiring notification
- Currently collecting hazardous chemical information to establish a national inventory
- The schedule and requirements for registration are not yet outlined

## Vietnam

- Article 44 regulation establishes registration requirements, however a national inventory is required
- Disclosed a draft national inventory in 2016
- Registration requirements will be provided in an official publication

## Indonesia

- Chemical management regulation No. 74/2001 is currently under revision
- Revised requirements have not yet been disclosed



# Technical Strategies

## Definitions

- Understand the definitions of nanotechnology under different regulations and standards

## Substance Identity

- Identify functions, uses, and components of the substances

## Data Needs

- Obtain all testing data based on submission requirements



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# Organizational Strategies

## Inventory Awareness

- Obtain substance use details
- Monitor volumes

## Jurisdictional Understanding

- Identify specific regulations
- Determine nuances when deal with the authorities

## Staffing

- Engage local experts and staff to assist with compliance

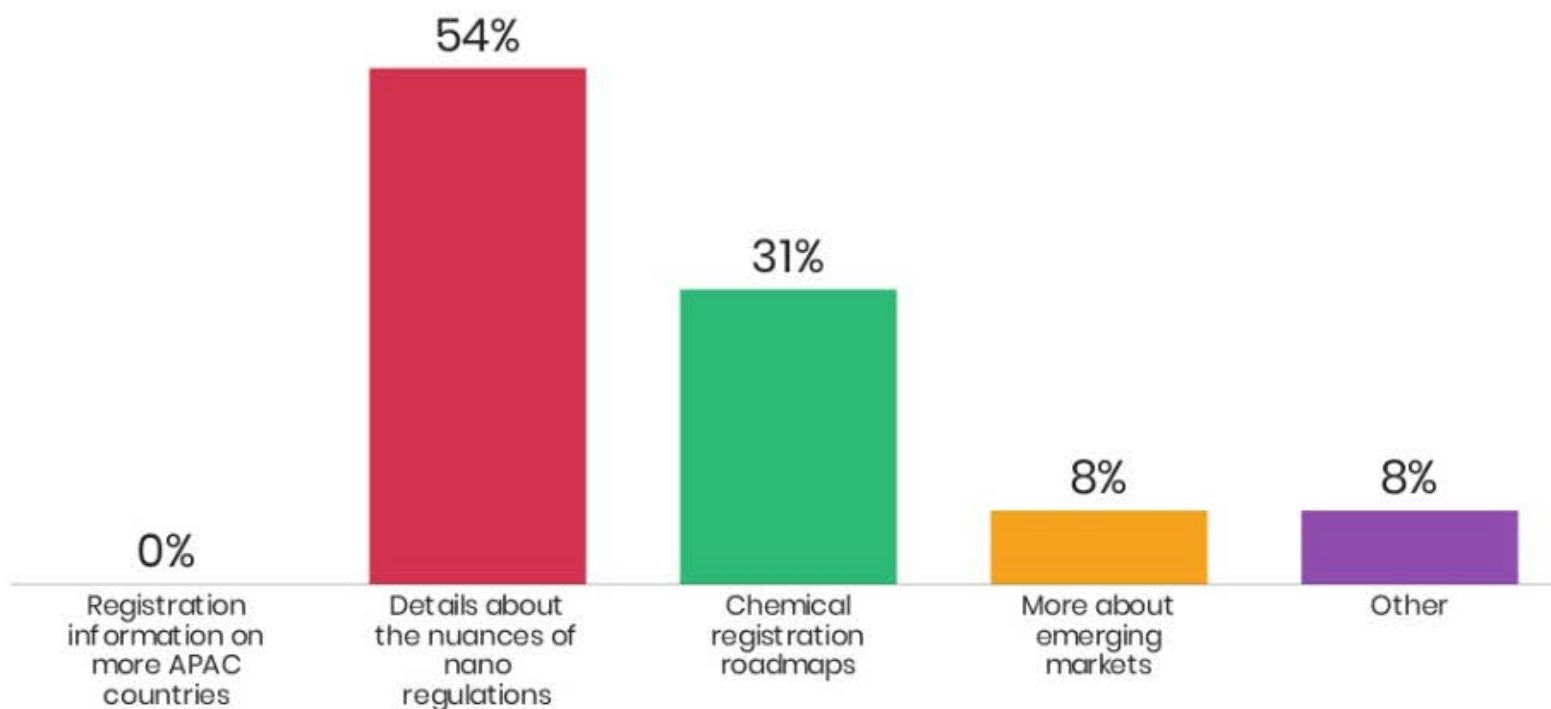


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# Survey Question

## What do you want more of?



# Thank You!

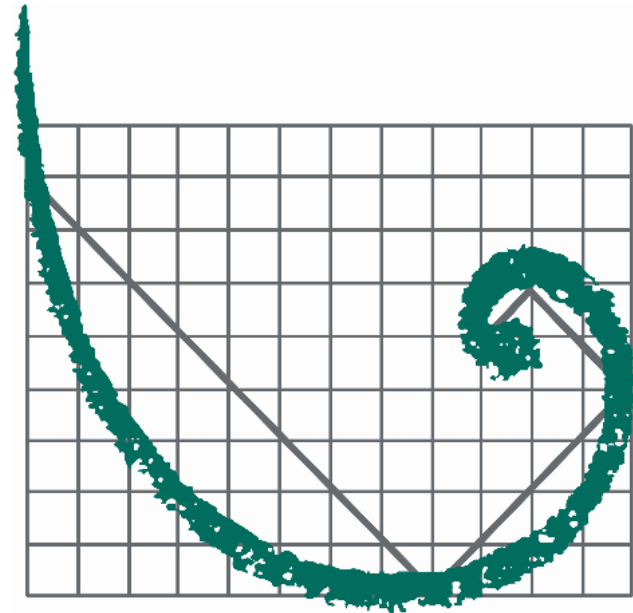
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