Chemical Risk Assessment under the Chemical Substances Control Law in Japan and comparison with REACH

Yusuke Hirai

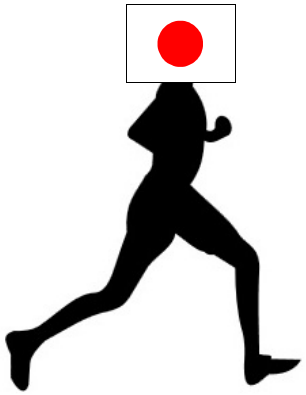
Risk Analysis Division,
Chemical Management Center,
National Institute of Technology and Evaluation, Japan

Outline

- Chemical Substances Control Law (CSCL)* was one round behind
- Major difference between CSCL and REACH
- Step-wise risk assessment under the CSCL
- Screening assessment for general chemical substances
- Risk assessment for Priority Assessment Chemical substances(PACs)
- Current Status

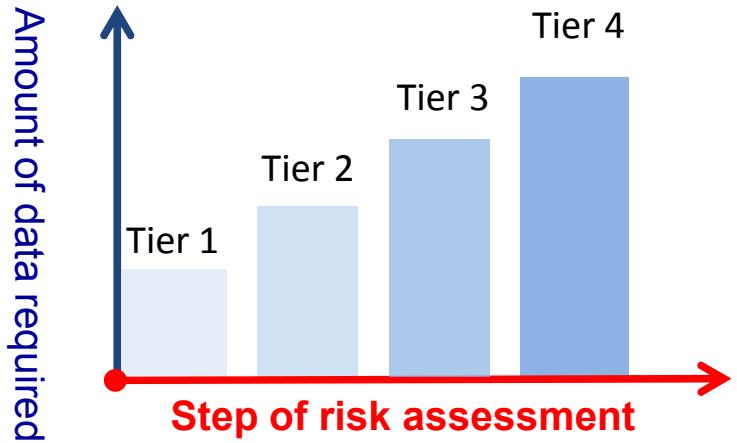
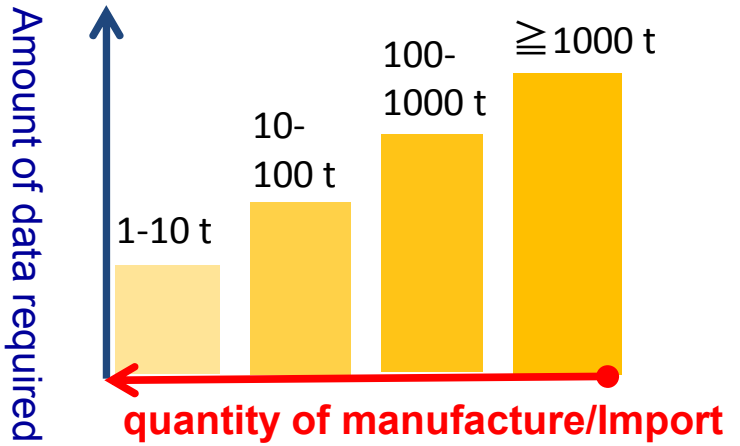
* **C**hemical **S**ubstances **C**ontrol **L**aw(CSCL):
The Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances

CSCL was one round behind



- First runner in the past （CSCL established since 1973）
- Risk assessment for some chemicals (TCE,PCE,TBT etc.) (since 1989)
- Development of risk assessment scheme (from 2001 to 2006)
  - ✓ *150 Initial risk assessment documents by NITE/CERI*
  - ✓ *27 Risk assessment documents by AIST*
- TGD(draft) for risk assessment under CSCL by NITE (from 2006-2010)
- Latest amendment on 2009, implementation on 2011
  - ✓ *Management based on "Risk"*
  - ✓ *Scope all the existing chemicals*
  - ✓ *Prioritization led approach*

What is difference?

CSCL	REACH
Prioritization led approach	**No-data, no-market** approach
Risk assessment **by the government** (Approx. 30 staffs)	Risk assessment **by the industry** and Substance Evaluation **by the Member States**
	

Implementation Time line

The WSSD 2020 goal to minimize significant risk

CSCL

All chemicals

Number of chemicals

Prioritization by the government

Regulations

REACH

All chemicals

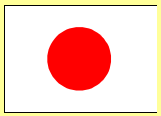
Risk assessment by the industry

CoRAP by the Member states

Restriction
Authorization

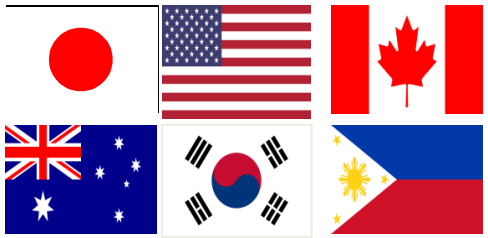
Chemicals in products are also regulated

The Target of Risk assessment

CSCL 	REACH 
Humans via the environment	Humans via the environment
Ecosystem	Ecosystem
~~Workers~~	Workers
~~Consumers~~	Consumers
~~Food additives, the fertilizer~~	~~Food additives, the fertilizer~~
~~medicine, cosmetics~~	~~medicine, cosmetics~~
~~Pesticides~~	~~Pesticides~~
Biocides (exclude hygiene)	~~Biocides~~

Regulatory approach in APEC region

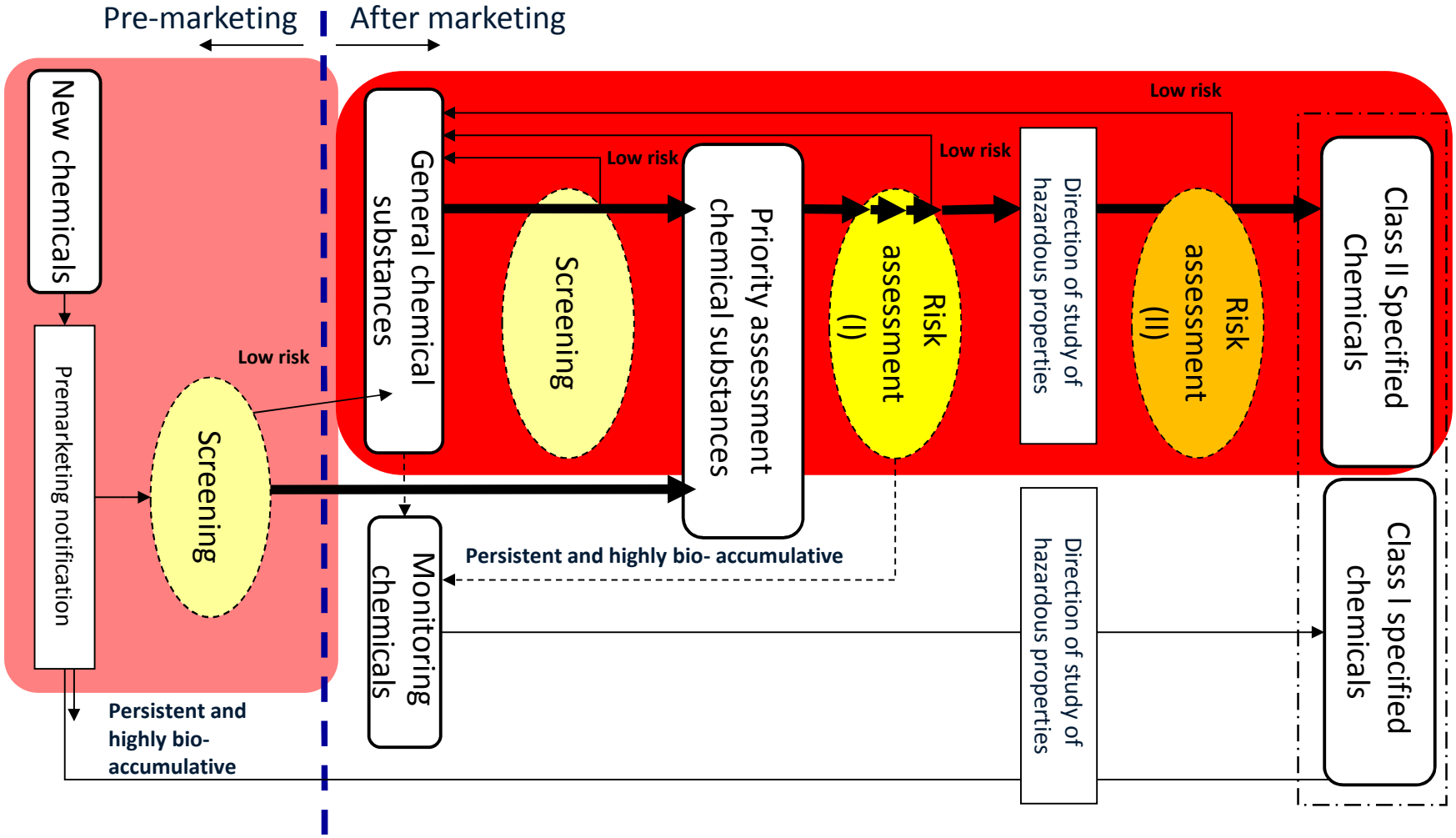
Conductor of Risk Assessment	
Government	Business
	

Scope of Risk Assessment		
All Chemicals (Existing & New Chemicals)		New Chemicals only
Prioritization	***No-data, no-market***	
		

Modified ERIA(2011) Study on the Economic Impact of Chemicals Management in ASEAN and East-Asia

Step-wise risk assessment under the CSCL

Step-wise risk assessment



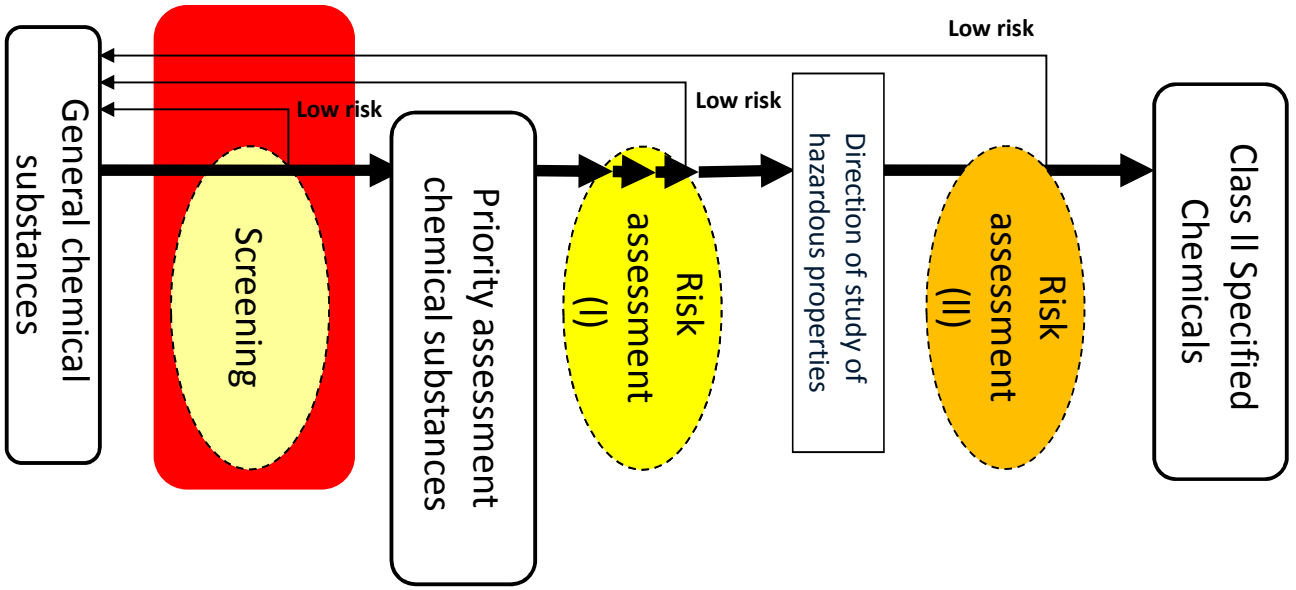
Detailed data is used in higher tier

nite National Institute of Technology and Evaluation　化学物質管理センター

		General chemicals	Priority Assessment Chemicals			
		Screening	Risk Assessment(RA) Ⅰ			RAⅡ
		Tier 0	Tier 1	Tier 2	Tier 3	Tier 4
Toxicity	Screening test	○	●	●	●	×
	Long term test	○	○	○	○	●
P	Degradability	○	○	●	●	●
B	Bioaccumulation	×	○	●	●	●
Physical chemical property		×	○	●	●	●
Exposure	Production volume	●	●	●	●	●
	Use Category & volume	●	●	●	●	●
	Sub use category & volume	×	●	●	●	●
	PRTR	○	×	○	○	○
	Monitoring	△	△	○	○	○
	handling situation	×	×	×	○	○

●：Essential, ○：Use if available, △：Pending, ×：No required

Screening assessment for General chemical substances



Scoring approach is used

Information for CSCL screening

Persistency

- Biodegradability

Human health

- Repeated Dose Toxicity
- Reproductive Toxicity
- Mutagenicity
- Carcinogenicity

Environment

- Ecotoxicity (Algae, Daphnia, fish)

Notified Information

Production/import volume,
Use category

Emission in Japan (Estimated)

Exposure class	Hazard class 1	2	3	4	Not classified
1	H	H	H	H	
2	H	H	H	M	
3	H	H	M	M	
4	H	M	M	L	
5	M	M	L	L	
Not classified	Out of classification				

H: High
M: Medium
L: Low

Exposure Class based on total emissions

Receive the submitted information (Annual Quantity of Manufacture, etc. / Use category)

Aggregate the data for target chemical substances of each assessment using MITI number or CAS number

Apply threshold（less than 10ton/y)

Exclude from priority setting

Multiply Emission Factor

Estimation of Environmental Release (Total national emissions(tons/y)

		Classification of Exposure
Exposure class	1	Over 10,000 ton
	2	1,000 – ＜10,000 ton
	3	100 – ＜1000 ton
	4	10 – ＜100 ton
	5	1-＜10 ton
	Not Classified	＜1 ton

Hazard Class

If no data available, default class (class 2) will be applied

Hazard information collected by the government

Hazard information submitted from the industries

Classification of Hazard

	Class1	Class2	Class3	Class4	Not Classified
Repeated Dose Toxicity	✕	●			
Carcinogenicity	No data available				
Mutagenicity		No data available			
Reproduction Toxicity			●		

Priority “High” goes to next tier

Prioritization Matrix		Hazard class				
		1	2	3	4	Not classified
Exposure class	1	H	H	H	H	
	2	H	H	H	M	
	3	H	H	M	M	
	4	H	M	M	L	
	5	M	M	L	L	
	Not classified	Out of classification				

Apply threshold
（less than 10ton/y)

High

Medium/Low

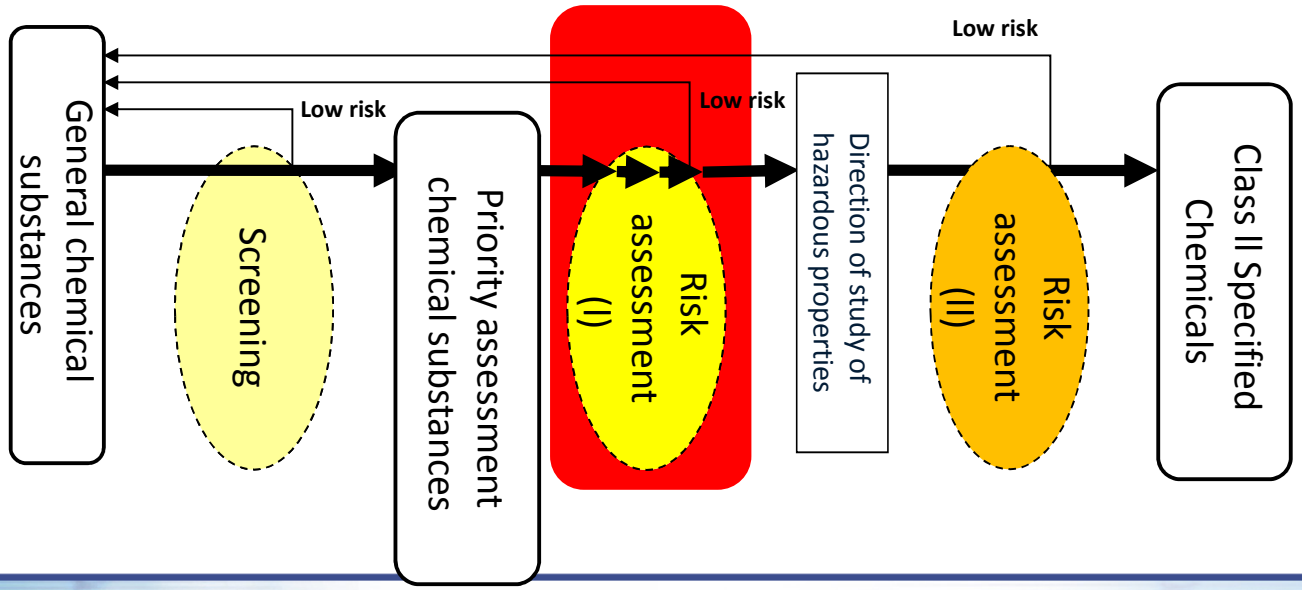
No need for assessment

Further Review

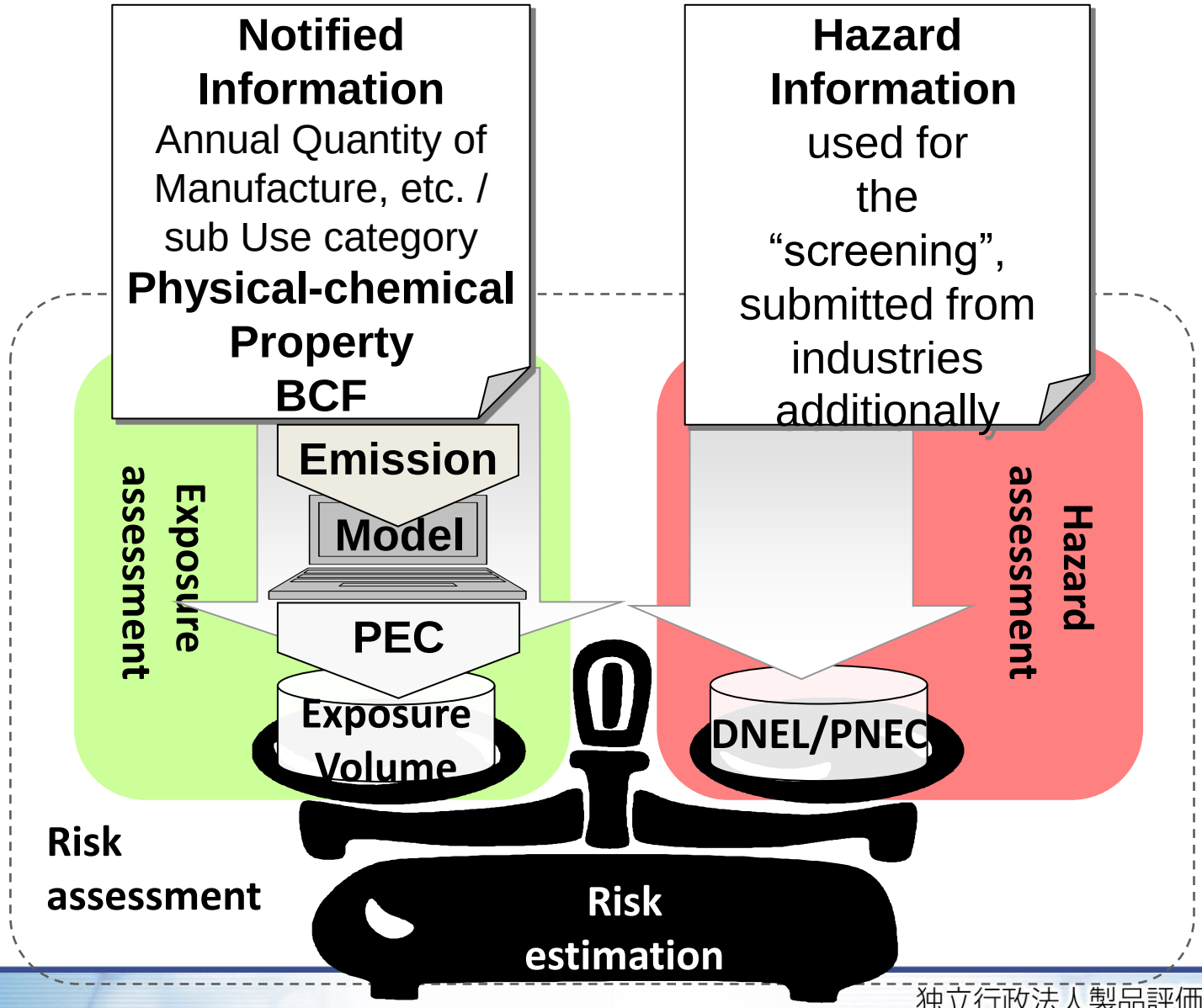
Designated by Government as PACSs

Remain to General Chemical Substances

Risk assessment Ⅰ for Priority Assessment Chemical substances(PACs)



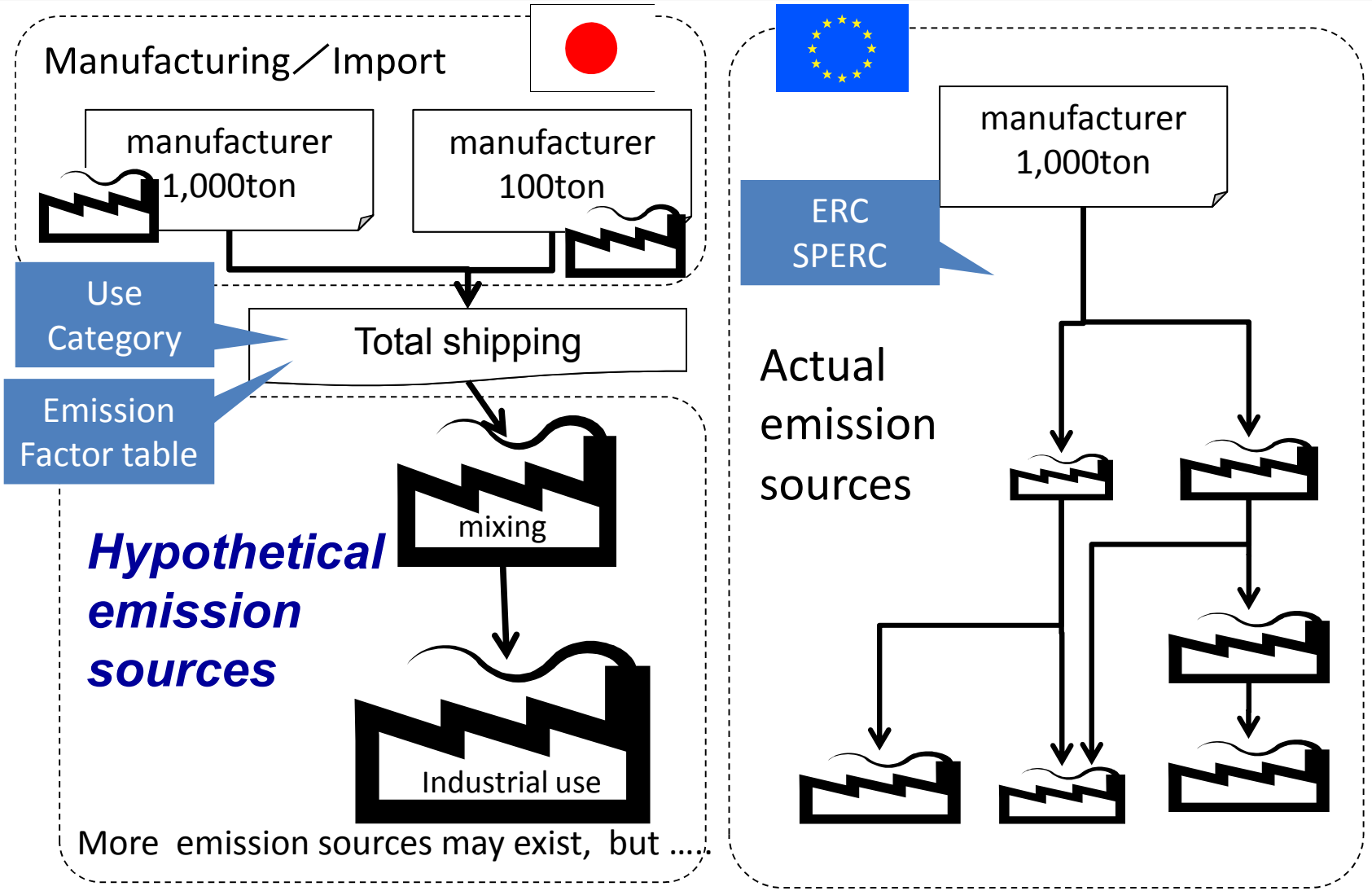
Exposure assessment is Unique



Exposure scenario

Source	Scenario	Lifecycle stage
Point source	**Hypothetical emission sources**	Production/ formulation/industrial use
Non point source	Down the drain (ex. For cleaner products)	Private use
	For air fresheners, biocidal products	
	For fuel, fuel additives	
	For Antifoulants	Service life

Hypothetical emission sources



Current Status

FY2010	FY2011	FY2012	FY2013～
1st Screening on Jan.	1st RA Ⅰ Tier1	2nd RA Ⅰ Tier1	Launch of 1st RA Ⅰ Tier2
1,400 chemicals (before amendment)	88 PACs	87－x PACs	x PACs
	2nd Screening on Jan.	2nd RA Ⅰ Tier1	
	700 chemicals (precedence group)	8 PACs	3rd RA Ⅰ Tier1
	8,000 ? Chemicals (all chemicals ?)	3rd Screening on summer	? PACs

Thank you for your attention !!

Acknowledgement

Takashi Fukushima (METI, Japan)
Yuko　Nakagiri（METI, Japan)
Tomohiro Tsunemi (METI, Japan)
Mariko Murata (NITE, Japan)
&
Wataru Naito (AIST, Japan)

If you would like to know more detailed information about this topics or other topics, please contact me.

hirai-yusuke@nite.go.jp