2016 International Symposium of
Environmental Health

Risk Assessment Scheme Under CSCL

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Contents

1. Overview of Chemical Substances Control Law (CSCL)

2. Screening assessment

3. Risk assessment

The scope of risk assessment and risk assessment scheme under CSCL

OVERVIEW OF CSCL

Objectives of CSCL

- To **prevent environmental pollution** caused by chemical substances that pose a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna.
- To implement necessary regulations with respect to **the manufacture, import, use, etc. of chemical substances**

Scope of risk assessment

Chemical substances	**Industrially manufactured chemical compounds※**
Exposure pathways	**Via the environment**
Hazard end points	Long term effects
Use categories	Use categories covered by the law

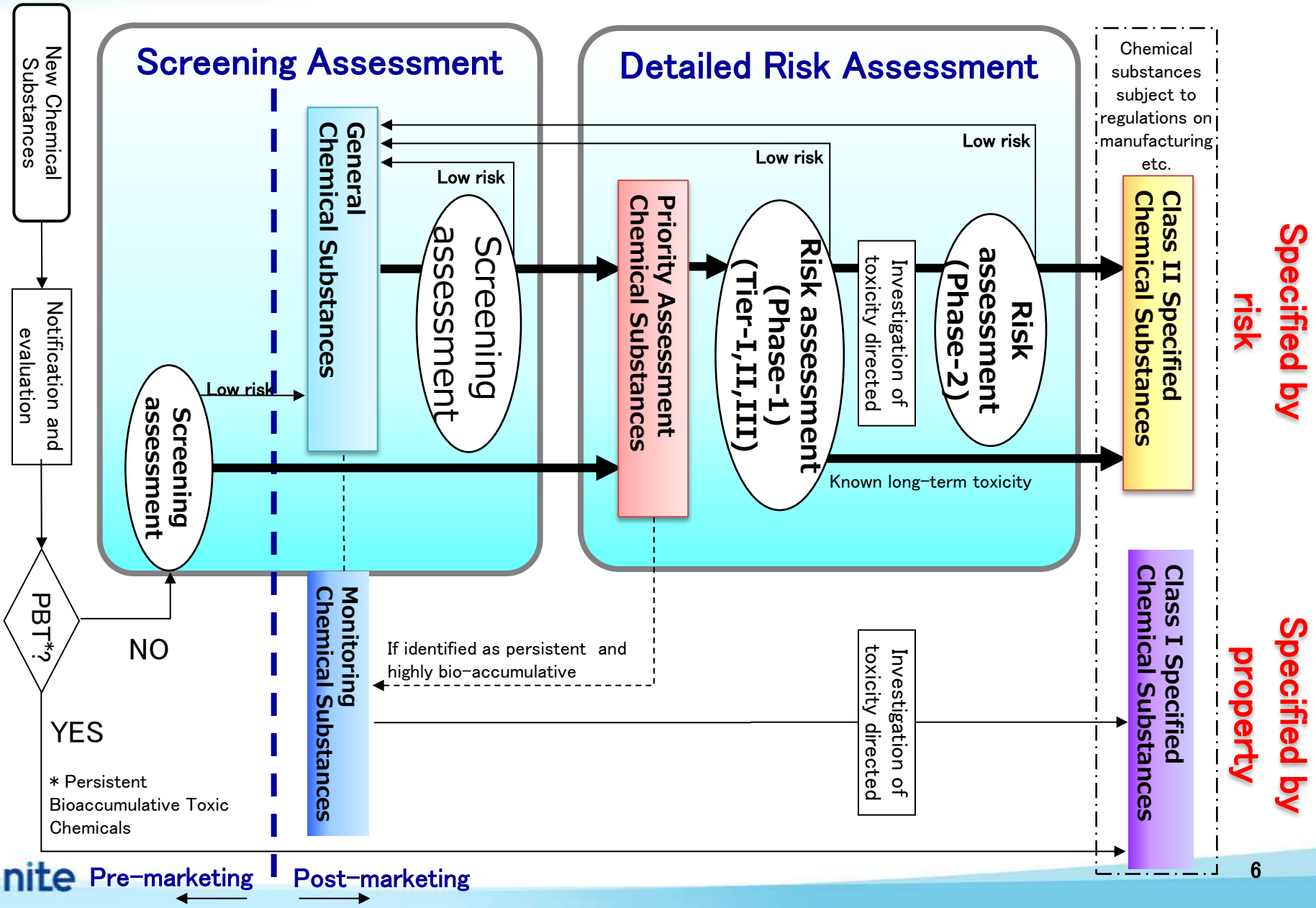
CSCL: Chemical Substances Control Law

※Article 2 of the CSCL defines chemical compounds.

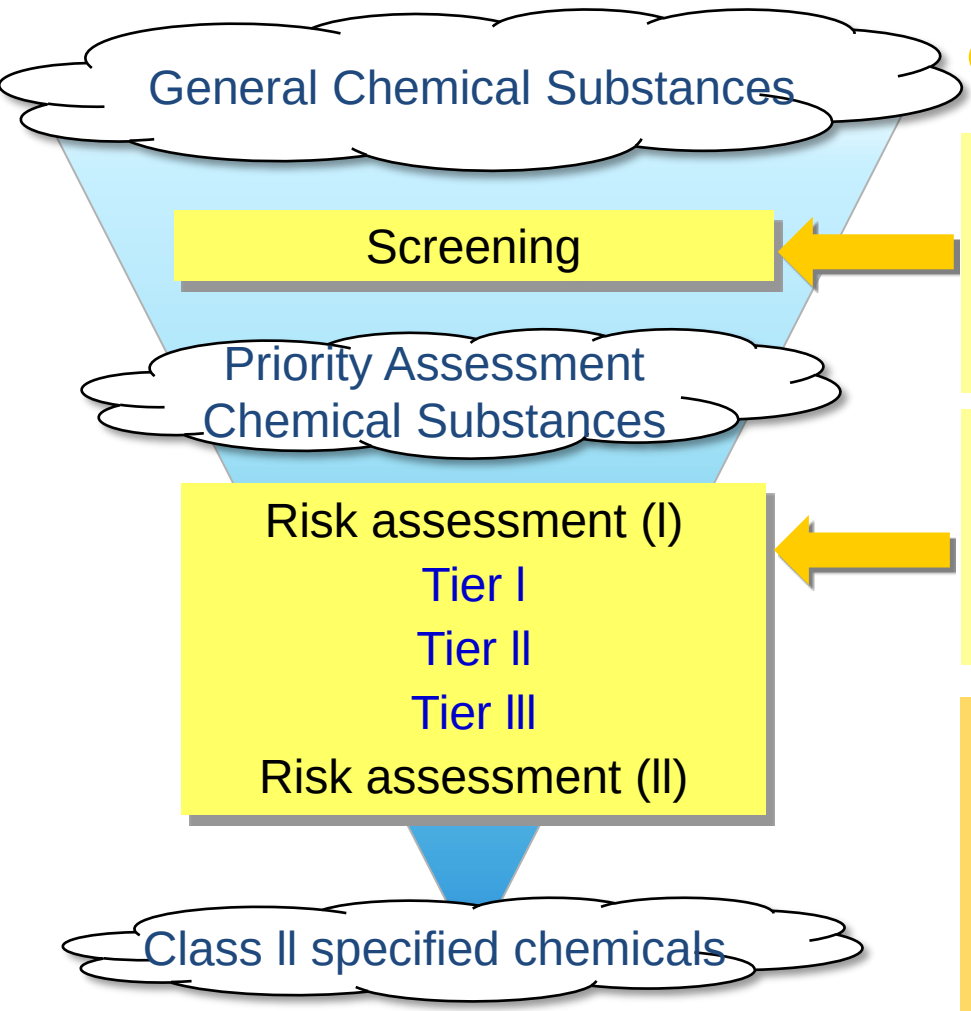
Out of the scope of CSCL risk assessment

- ✓ **Not "chemical substance" defined by the law**
  - **Natural sources such as volcano and food**
- ✓ **Exposure pathway except "via the environment"**
  - **Indoor exposure**
  - **Work place exposure**
  - **Direct exposure while using consumer products**
- ✓ **Hazard property expect "long term effect"**
  - **Acute toxicity (human health)**
  - **Irritation, sensitization etc.**
- ✓ **Exposure except "use categories covered by the law"**
  - **Exposure from use categories regulated by other laws such as the food sanitation law, the pesticide control law, the fertilizer control law and the pharmaceutical affairs law.**
- ✓ **Emission sources, which are not "manufacturing etc."**
  - **Accidental release**
  - **Emission sources in foreign countries**

Risk Assessment Scheme under the CSCL



Multiple step assessment



Objective	Required spec
-Selection of chemicals to be assessed in priority	- Not to miss any candidate chemicals
-Providing scientific background to designate “class II”	Appropriateness - As a basis of judgment - Reliability

To be efficient

- ✓ the stepwise reduction of the number of target chemicals
- ✓ the stepwise expansion of information to be used.

Information to be used in each step

Risk Assessment Steps		Hazard		Exposure									
		Screening	Long term	Use amount	Detail use amount	Degradability	Degradability (Half life)	Bioaccumulation	Physical chemical property	P R T R	Monitoring	Individual handling information
Screening		●	○	●		○						
RA (I)	Tier I	●	○		●	○		●	●			
	Tier II	●	○		●		●	●	●	○	○	
	Tier III	●	○		●		●	●	●	○	○	●
Government order to collect data on long term effect to humans and the environment												
Risk assessment (II)			●		●		●	●	●	○	○	●

Exposure evaluation

Rough

Detailed

Hazard evaluation in detail

REDs are newly added to the previous step. ●or● : Essential, ○or○ : Use if available.

Screening and Risk Assessment

	Screening	Risk Assessment
Target Chemicals	•General Chemical Substances (Notified to government)	•Priority Assessment Chemical Substances (PACSs)
Purpose	•Identification of PACSs	•Focusing of class II candidate
Required Spec	•Conservative assessment	•Appropriateness •Reliability
Number of chemicals (as of FY2015)	**•11,904 Chemicals** (28,409 reports)	**•163 Chemicals** (2,178 reports)
Annual report Requirements	•Chemical identity (MITI No., CAS No.(if available)) •Volume manufactured, imported (previous fiscal year) •Use category and shipped volume	•Chemical identity (MITI No., CAS No.(if available)) •Volume manufactured, imported(previous fiscal year) **•Use category (detailed)** and shipped volume **•Place of production and use**
Threshold	•1 ton/year •>10% in mixture	•1 ton/year •>1% in mixture
Assessment unit	**•CAS Number** •MITI Number • Former Type II & III monitoring chemicals	• **Registration Number of PACSs**

The CSCL screening approach and results

SCREENING ASSESSMENT

Screening

- STEP1 : Classification of Exposure
  - Annual Report (Manufacture, Import, Use category)
  - Emission Factor Table
- STEP2 : Classification of Hazard
  - Data Gap Survey
  - Reliability Evaluation
- STEP3 : Prioritization Matrix

Designation of Priority Assessment Chemical Substances

Characteristics of Screening

STEP 1 Classification of Exposure

Notified Information

- Production/import volume, Use category
- Persistency
  - Biodegradability

Total national emissions

STEP 2 Classification of Hazard

Human health

- Repeated Dose Toxicity
- Reproductive Toxicity
- Mutagenicity
- Carcinogenicity

Environment

- Ecotoxicity (Algae, Daphnia, fish)

STEP 3 Priority Matrix

Exposure Class \ Hazard Class	1	2	3	4	N/A
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	
N/A	Out of Classification				

H: High
M: Medium
L: Low

STEP 1
Classification of Exposure

Sum up the amounts reported by all notifiers and assign the total to the following equation

Total amount of environmental release
= Emissions from production stage 〈A〉
+ Emissions from using stage 〈B〉

A = Quantity of manufacture (notified) x emission factors of production stage

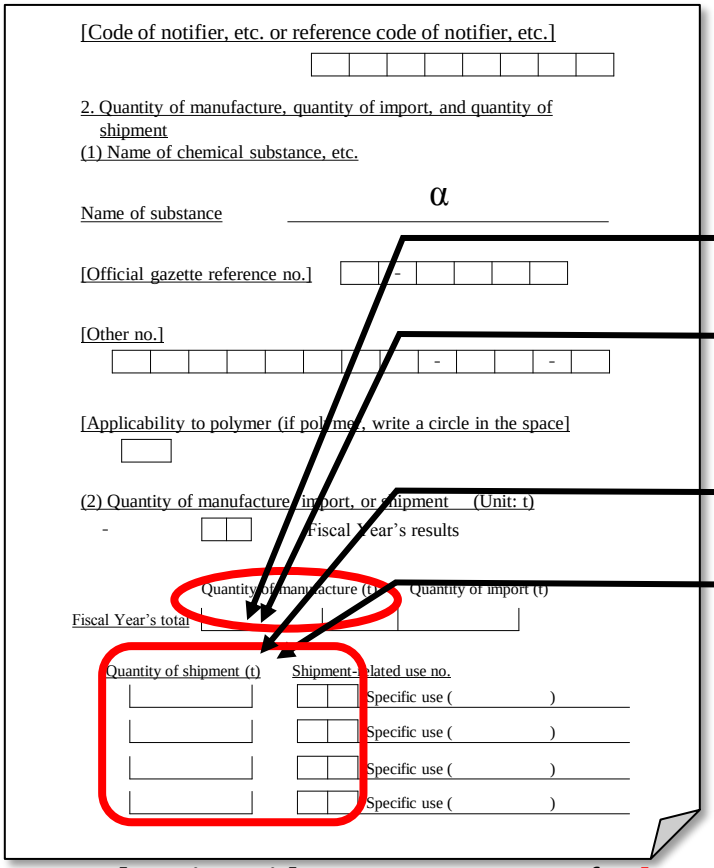
$$\Sigma$$

B = $$\Sigma$$ (Quantity of shipment for each use category (notified) x emission factors by each use category)

Use to assign exposure class

Exposure class	
1	> 10,000 t
2	1,000 – 10,000 t
3	100 – 1,000 t
4	10 – 100 t
5	1 – 10 t
N/A	<1 t

Math formula for emission amount estimation


[Code of notifier, etc. or reference code of notifier, etc.]

2. Quantity of manufacture, quantity of import, and quantity of shipment
(1) Name of chemical substance, etc.

Name of substance α

[Official gazette reference no.]

[Other no.]

[Applicability to polymer (if polymer, write a circle in the space]

(2) Quantity of manufacture, import, or shipment (Unit: t)

- Fiscal Year's results

	Quantity of manufacture (t)	Quantity of import (t)
Fiscal Year's total		

Quantity of shipment (t)	Shipment-related use no.	
		Specific use ( )
		Specific use ( )
		Specific use ( )
		Specific use ( )

Ma = Quantity of **m**anufacture
x Emission factor to **a**ir of production stage

Mw = Quantity of **m**anufacture
x Emission factor to **w**ater of production stage

Ua = Quantity of shipment for each **u**se category
x Emission factor to **a**ir for each use category

Uw = Quantity of shipment for each **u**se category
x Emission factor to **w**ater for each use category

Total nationwide emission amount for **human health** assessment $= \sum_{\text{Business}} \{(Ma + Mw) + \sum_{\text{Use}} (Ua + Uw)\}$

Total nationwide emission amount for **environment** assessment (only for surface water)

$= \sum_{\text{Business}} \{ Mw + \sum_{\text{Use}} (Uw)\}$

STEP 2 Classification of Hazard - human health -

Severe ← Hazard class → Moderate

Hazard item	1	2	3	4	Out of class
General toxicity		D ≤ 0.005 GHS class 1	0.005< D ≤0.05 GHS class 2	0.05< D ≤0.5	D > 0.5
Reproductive/ developmental toxicity		D ≤ 0.005	0.005 < D ≤ 0.05	0.05 < D ≤ 0.5	D > 0.5
Mutagenicity	GHS class 1A	- GHS class 1B, 2 - "Highly positive" of the CSCL - "Class 1" of PRTR - Positive with unknown strength	- Positive*1 in all mutagenicity tests of the CSCL	- Positive*1 in any of the mutagenicity tests of the CSCL	- Out of GHS class - Negative in all mutagenicity tests of the CSCL - Negative in in vivo test*2
Carcinogenicity	GHS class 1A	GHS class 1B, 2			Out of GHS class

D: Hazard assessment value (HAV)
= NOEL, etc. / Uncertainty factor (mg/kg/day)

*1: Except slightly or highly positive cases
*2: Individually determine if positive in in vitro tests

STEP 2 Classification of Hazard
- environment -

Severe ← Hazard class → Moderate

	1	2	3	4	N/A
Criterion	PNEC ≤0.001	0.001< PNEC ≤0.01	0.01< PNEC ≤0.1	0.1< PNEC ≤1	PNEC > 1
GHS	Chronic toxicity class 1		Chronic toxicity class 2	Chronic toxicity class 3 using acute toxicity	Out of class

PNEC: Predicted no-effect concentration (mg/L)
= Minimum toxicity value / Uncertainty factor
= Deemed chronic toxicity value / 10

STEP 3 Priority Matrix

Human health

Exposure class	Hazard class: Severe ⟷ Moderate				
	1	2	**3**	4	N/A
1 (High)	**H**	**H**	**H**	**H**	
2	**H**	**H**	**H**	**M**	
3	**H**	**H**	**M**	**M**	
4	**H**	**M**	**M**	**L**	
5 (Low)	**M**	**M**	**L**	**L**	
N/A	Out of class				

The Environment

Exposure class	Hazard class: Severe ⟷ Moderate				
	1	2	3	**4**	N/A
1 (High)	**H**	**H**	**H**	**H**	
2	**H**	**H**	**H**	**M**	
3	**H**	**H**	**M**	**M**	
4	**H**	**M**	**M**	**L**	
5 (Low)	**M**	**M**	**L**	**L**	
N/A	Out of class				

High → **Designated by Government as PACSs**

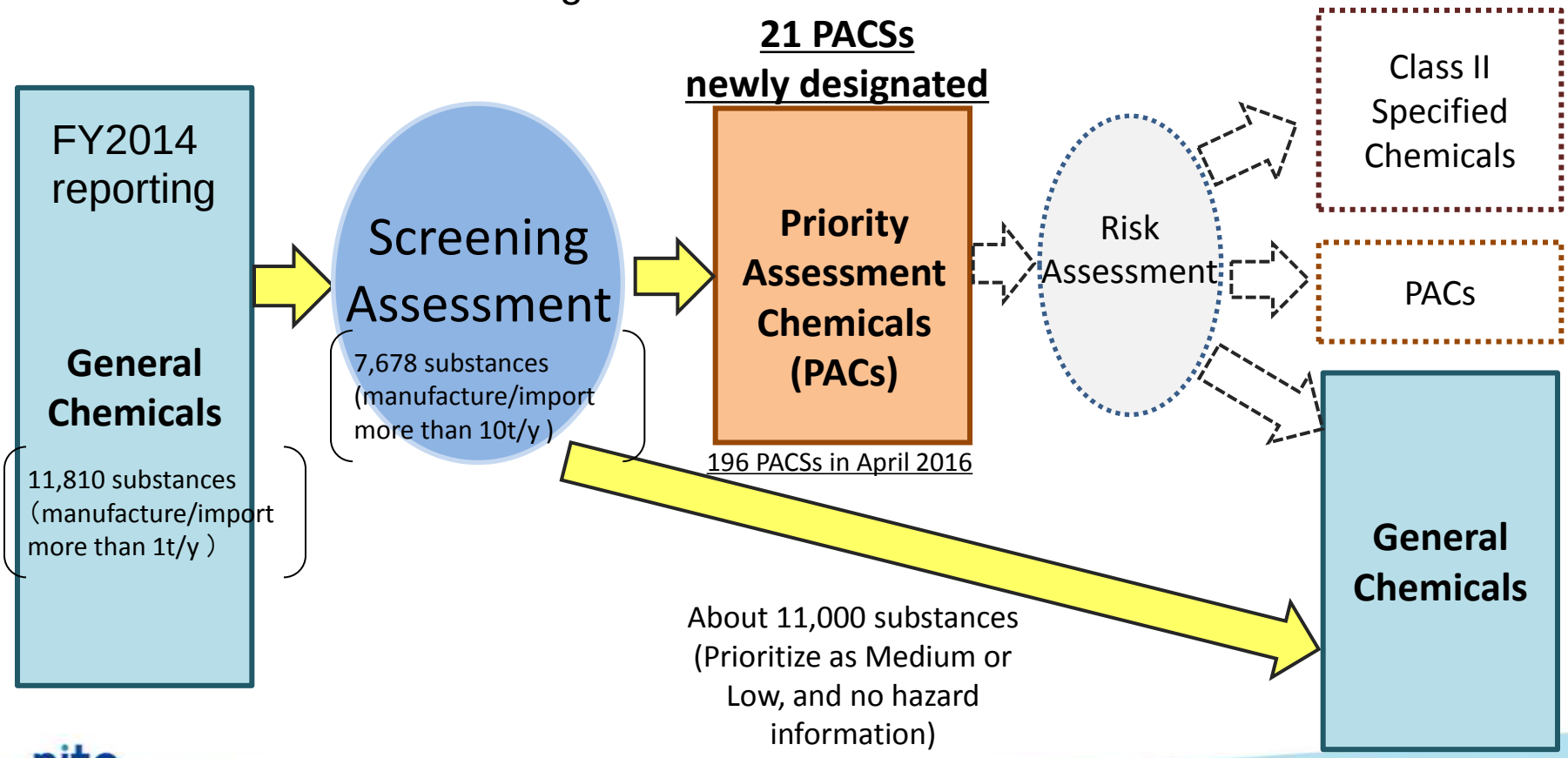
Medium/Low → **Further Review**

Out of Classification → Remain to General Chemical Substances

FY2015 Screening Assessment Result

- The government has conducted screening assessment for general chemicals every year since 2012.
- The number of PACs reached 196 in April 2016.

＜The result of Screening Assessment in 2015＞



The CSCL step-by-step risk assessment for PACS

RISK ASSESSMENT

About of PACSs
(Priority Assessment Chemical Substances)

Definitions

Chemical substances that are found to **require priority assessment** because of the likelihood that such **chemical substances may present risks** of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment through environmental pollution.

(**Not clear whether the risk is low**)

Overview

- There are **196** PACSs (April, 2016).
- **Annual reports** of manufacture/import volume and usage is mandatory. (≥ 1 ton per year)
- **Risk assessment** based on annual notification are conducted.
- The manufactures/importers may be requested **additional toxicity information** if necessary.

System of CSCL for Risk Assessment

Notification system for manufacture quantity etc. is the means of exposure assessment

Notification of Manufacture Quantity etc.

Name
Material name

Manufacture	Pref.	Qty
	ABC	**t
	ABC	**t

Shipment	Pref.	Use	Qty
	ABC	XX-X	**t
	DEF	XX-X	**t
	ABC	XX-X	**t

Hazard information used for hazard evaluation by government

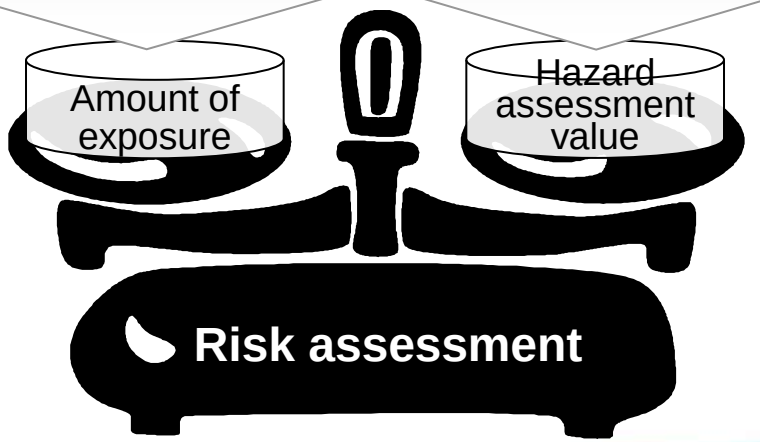
Example:

- Toxicity study information used for notification and evaluation of new chemical substances
- Result of hazard assessment and evaluation

Hazard level is assessed to a certain degree by notification and evaluation, etc.

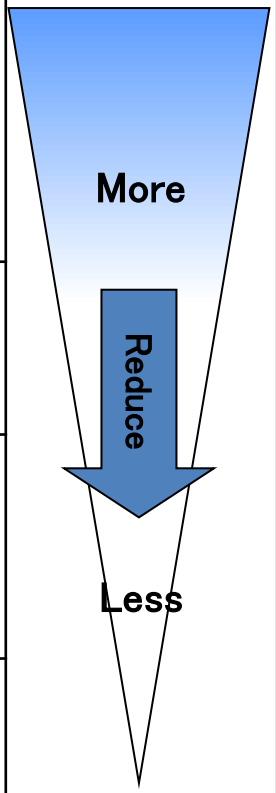
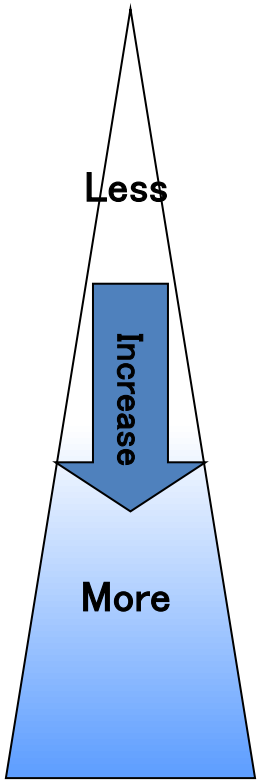
Exposure assessment

Hazard assessment

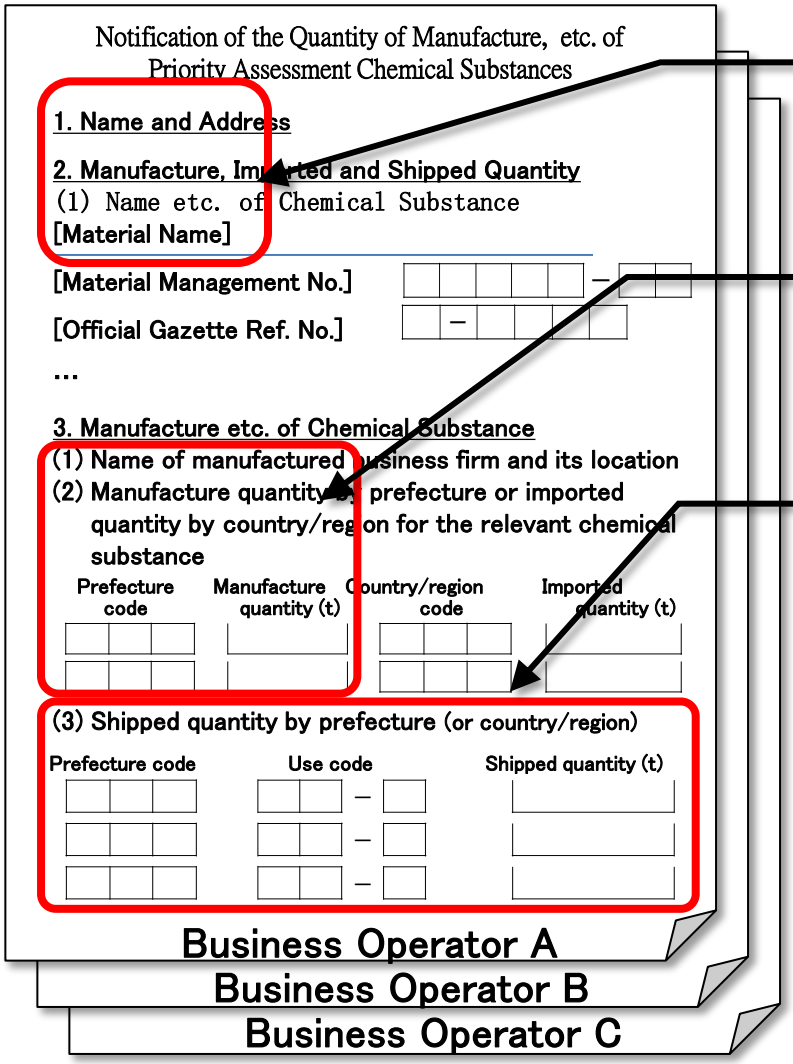


Methods to efficiently assess

The approach consists of the stepwise reduction of the number of assessment chemicals and the stepwise expansion of information to be used

Assessment step	Outline	Number of chemicals	Information to be used	Output
Risk assessment (Phase-1) Tier- I	Common and minimum information is used to determine the priority of assessment phase-2 or hazard information request.			Priority List
Tier- II	Detailed assessment using publically available information.			Assessment Reports
Tier- III	Newly obtained exposure information is used to review the assessment result.			
Risk assessment (Phase-2)	Newly obtained toxicity test result is used in stead of existing long term tox info.			Assessment Reports

Usable Information in Notification



For each manufacturer/importer, for each substance

Manufacture quantity by manufacturing location

Shipped quantity by prefecture and by use

If emission factor is available

Released quantity can be estimated

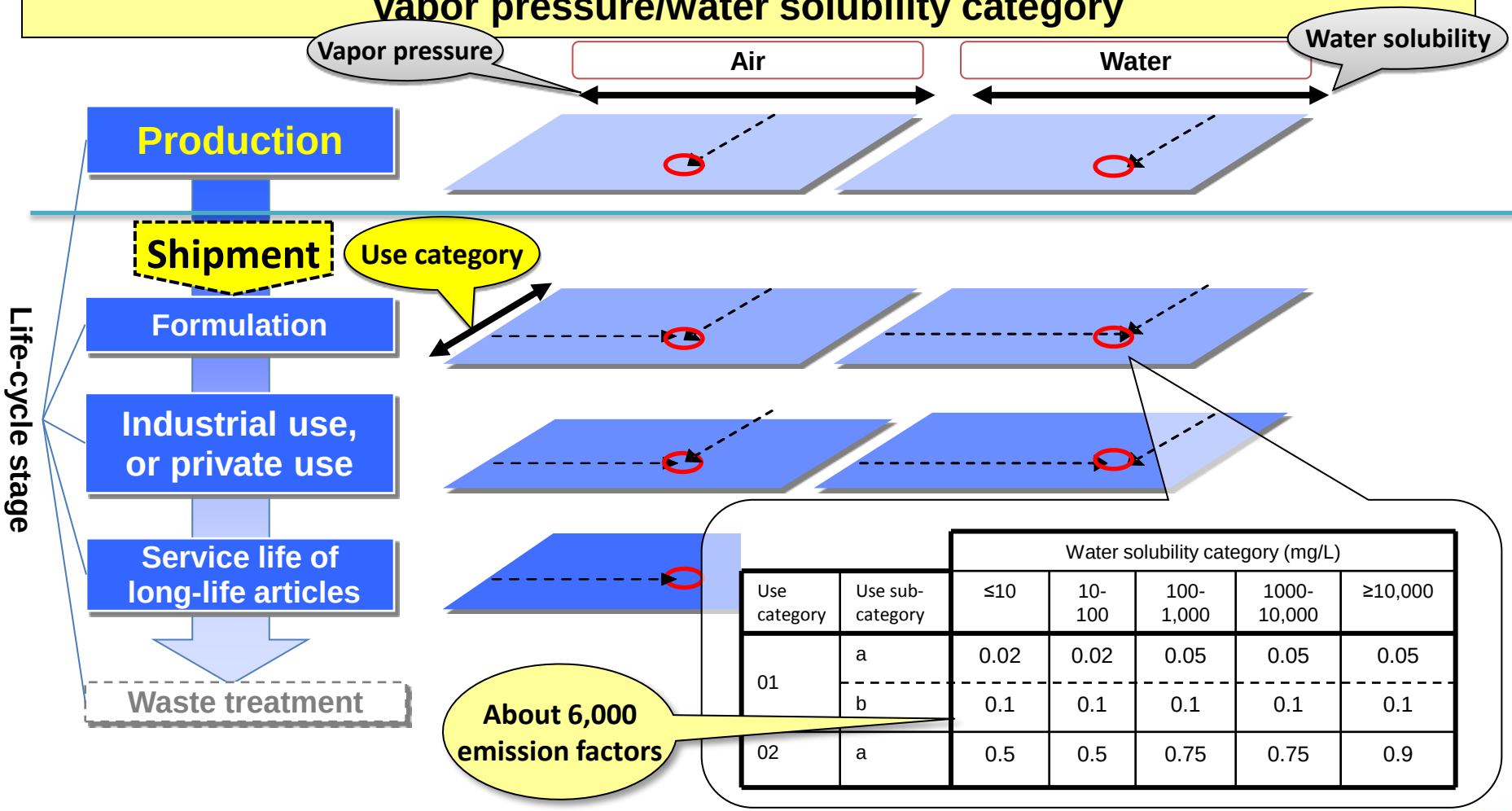
Released qty = Handled qty × Emission factor

Have it selectable from notified information

For each use

Image of Emission Factors

Emission factors are specified by life-cycle stage (manufacturing, post-shipping), by medium released into (air, water), by use subcategory, and by vapor pressure/water solubility category

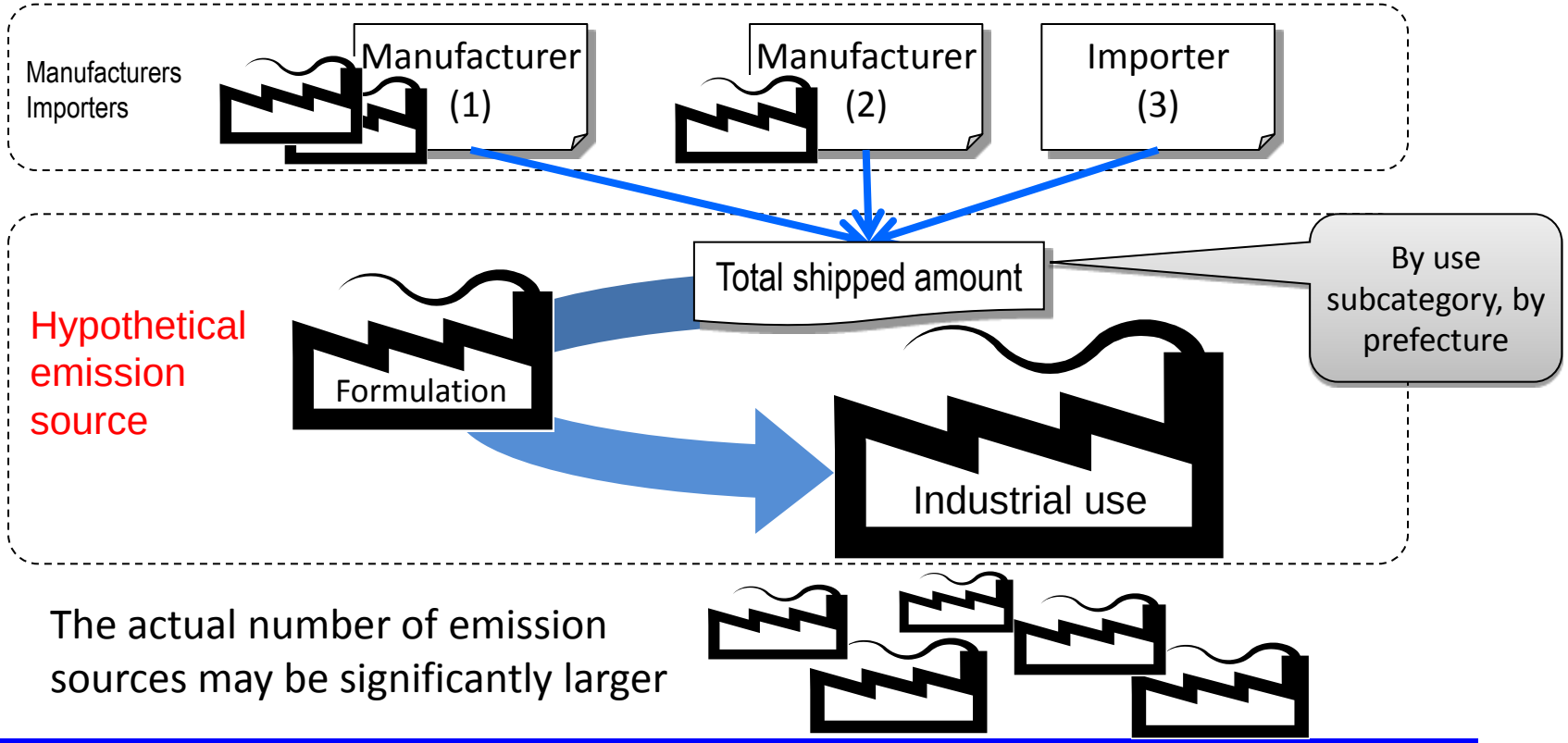


Use category	Use sub-category	Water solubility category (mg/L) ≤10	10-100	100-1,000	1000-10,000	≥10,000
01	a	0.02	0.02	0.05	0.05	0.05
	b	0.1	0.1	0.1	0.1	0.1
02	a	0.5	0.5	0.75	0.75	0.9

http://www.meti.go.jp/policy/chemical_management/english/cscl/ra_emissionfactor-v03_131101.html

Concept of "Hypothetical Emission Source"

Means to use available information for judging the necessity of the next-step assessment with avoiding underestimation



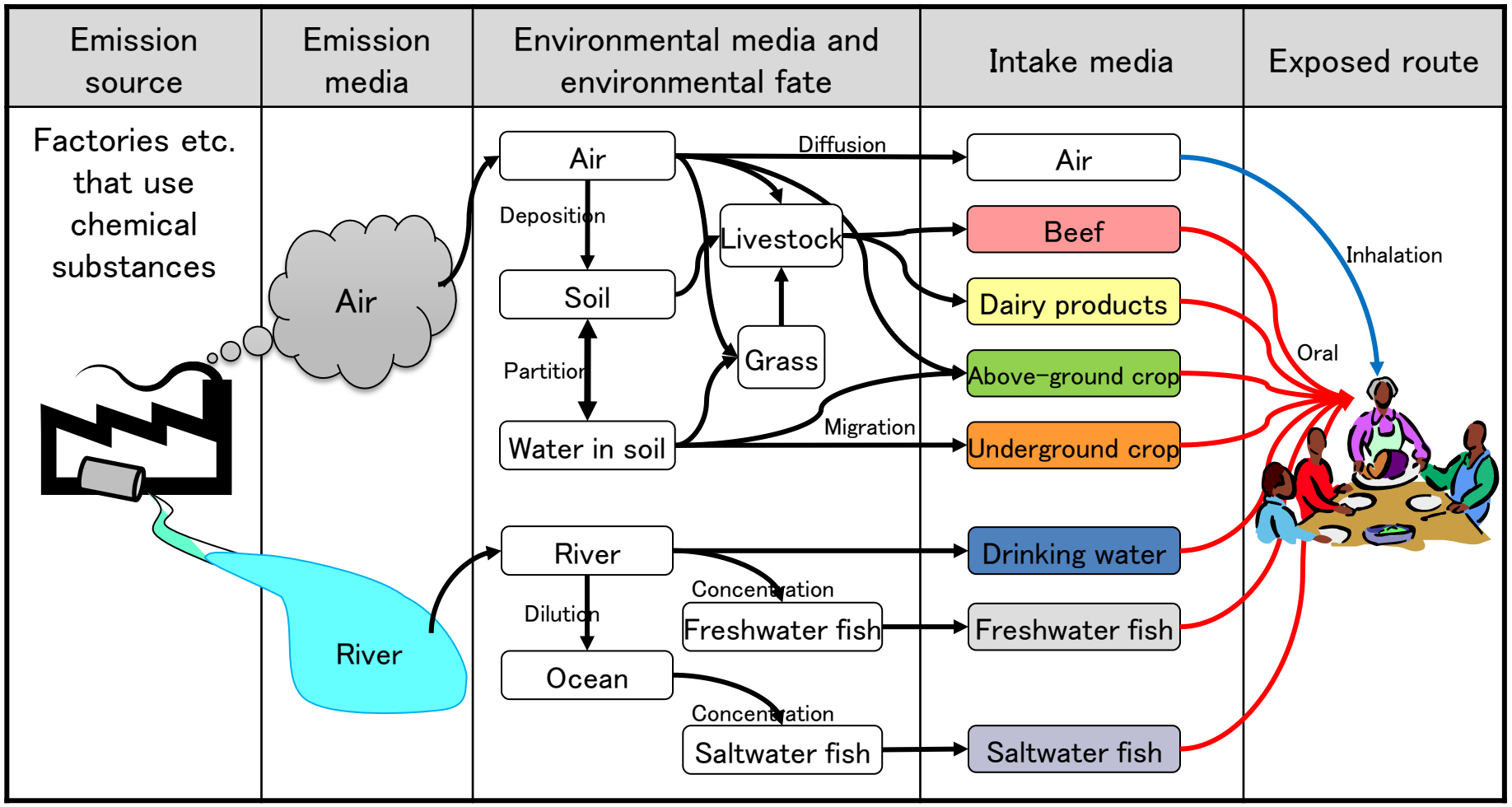
The actual number of emission sources may be significantly larger

Concept where no risk is concerned for actual emission sources if there is no risk concerned for places near "hypothetical emission sources" assumed using notified information such as manufactured quantity

(Because the quantity released from actual emission source becomes smaller than the quantity released from hypothetical emission sources)

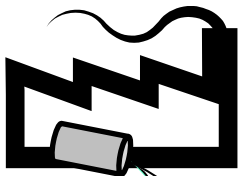
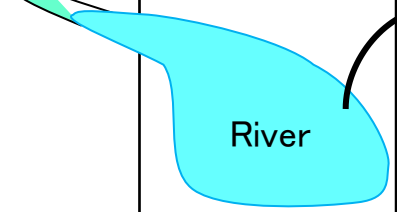
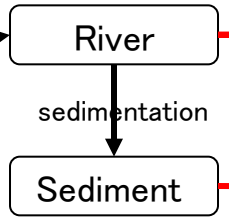
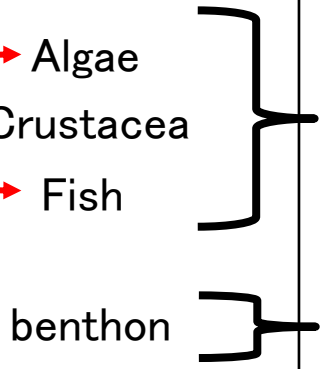
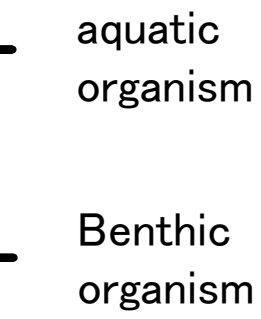
Target of Risk Assessment

- Environmental Pathways of Human Exposure -

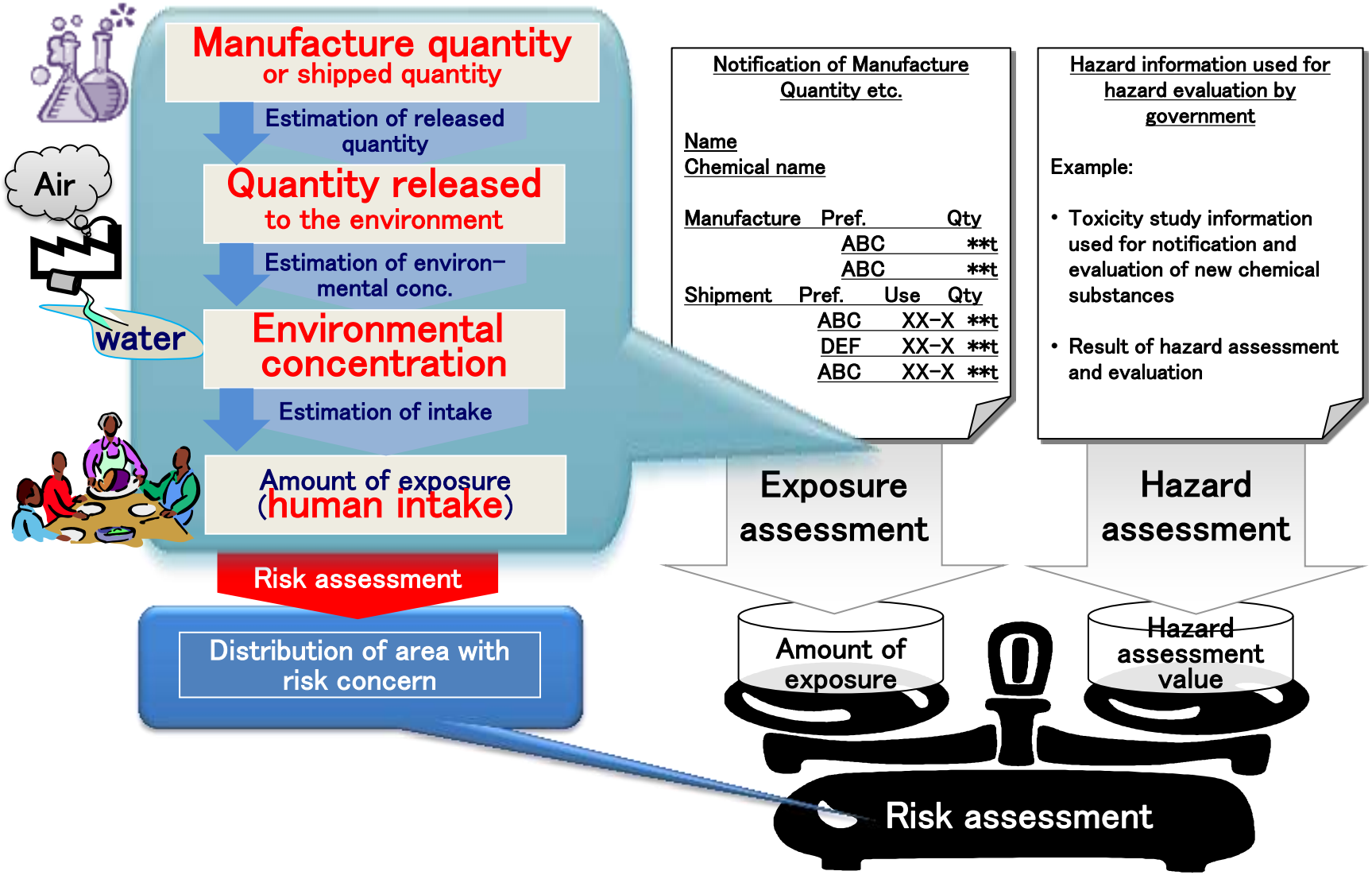


Target of Risk Assessment

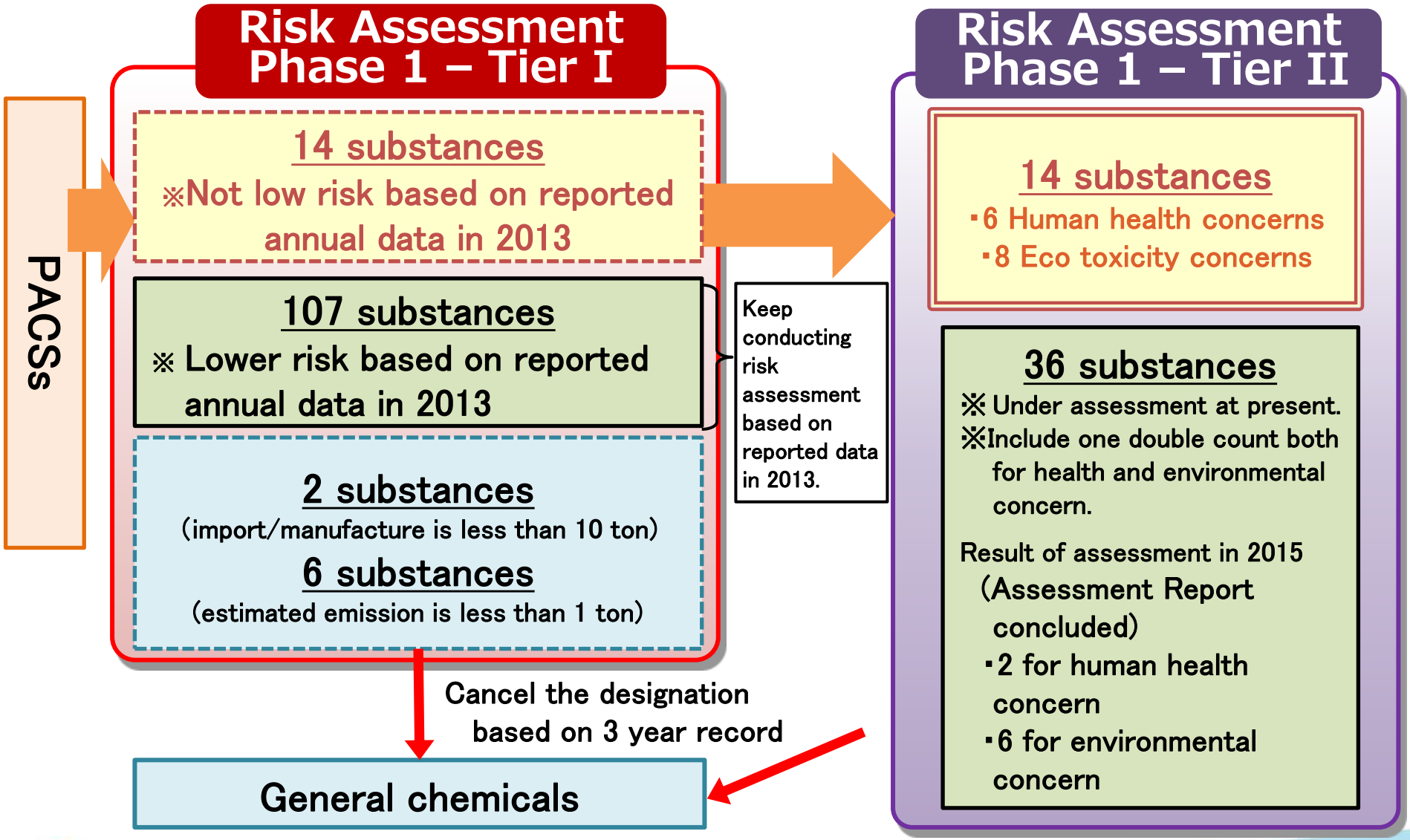
- Ecological Effect -

Emission source	Emission media	Environmental media and environmental fate	Target species	Exposure group
Factories etc. that use chemical substances 				

Risk Assessment under the CSCL



Current status of Risk Assessment (FY2015)



References

- Technical guidance documents for risk assessment of PACS (Japanese only)
  http://www.meti.go.jp/policy/chemical_management/kasinhou/information/ra_1406_tech_guidance.html
- Notification of the Manufacturing Amount, etc. of General Chemical Substances and Priority Assessment Chemical Substances (English)
  http://www.meti.go.jp/policy/chemical_management/english/cscl/files/publications/forimporters/procedure_dec2010.pdf
- Japanese Use Category under amended CSCL (English)
  http://www.meti.go.jp/policy/chemical_management/english/cscl/information.html
- Emission Factor Tables for Risk Assessment Under the CSCL (English)
  http://www.meti.go.jp/policy/chemical_management/kasinhou/information/ra_emissionfactor-v03_131101.html

Thank you for your kind attention!