



Scope of CSCL risk assessments and CSCL risk assessment scheme

CSCL OVERVIEW

2016

CSCCL objectives

- ◆ To **prevent environmental pollution** caused by chemical substances that can impair human health or damage 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 assessments

Chemical substances	Industrially manufactured chemical compounds ✖
Exposure pathways	Via the environment
Hazard end points	Long-term effects
Usage categories	Usage categories covered by the law

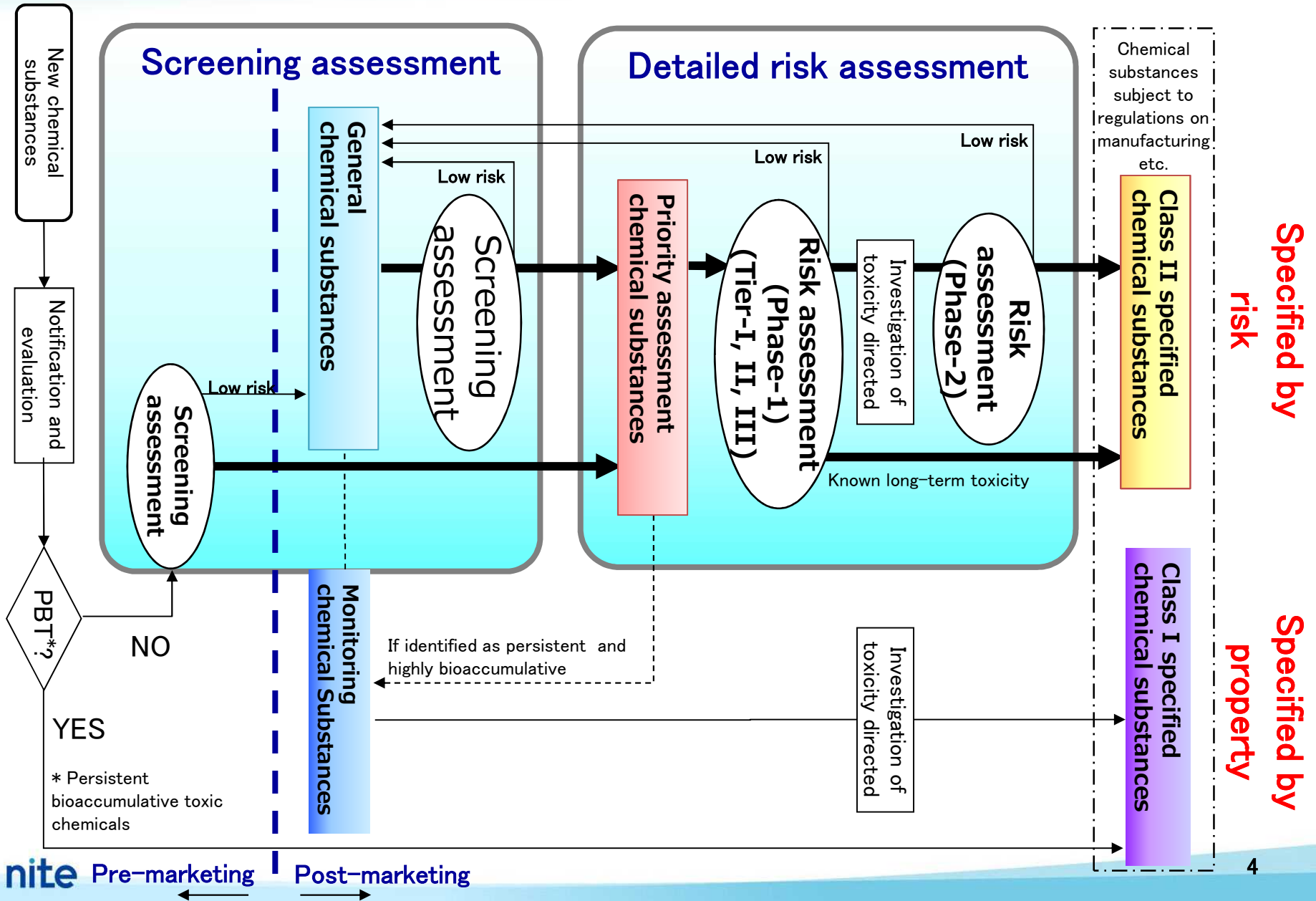
CSCCL: Chemical Substances Control Law

✖ Article 2 of the CSCCL defines chemical compounds. ²

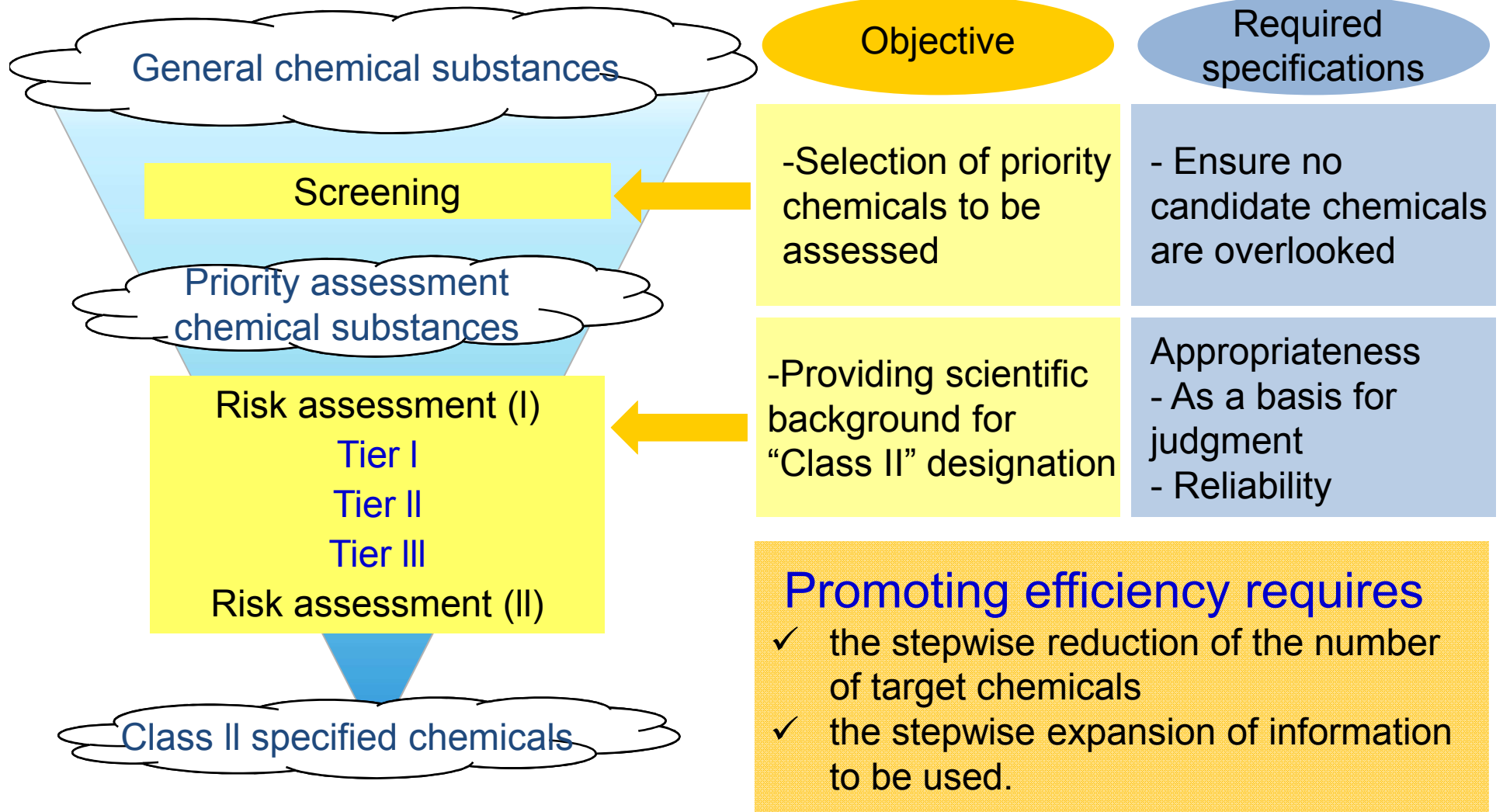
Outside the scope of CSCL risk assessment

- ✓ **Substances not defined as “artificial chemicals” by law**
 - From natural sources such as volcanoes and food
- ✓ **Exposure pathways that are not “via the environment”**
 - Indoor exposure
 - Workplace exposure
 - Direct exposure while using consumer products, etc.
- ✓ **Hazardous properties that can be expected to have “long-term effects”**
 - Acute toxicity (human health)
 - Irritation, sensitization, etc.
- ✓ **Exposure other than “usage categories covered by other laws”**
 - Exposure from usage 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 that are not related to “manufacturing etc.”**
 - Accidental release
 - Emission sources in foreign countries

CSCCL risk assessment scheme



Multi-step assessment



Information to be used in each step

Risk assessment steps		Hazard		Exposure								
		Screening	Long-term	Usage amount	Usage amount details	Degradability	Degradability (half-life)	Bioaccumulation	Physical chemical properties	P R T R	Monitoring	Individual handling information
Screening		●	○	●		○						
R A (I)	Tier I	●	○		●	○		●	●			
	Tier II	●	○		●		●	●	●	○	○	
	Tier III	●	○		●		●	●	●	○	○	●
Risk assessment (II)			●		●		●	●	●	○	○	●

Government order to collect data on long-term effects on humans and the environment



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

Screening and risk assessment

	Screening	Risk assessment
Target chemicals	<ul style="list-style-type: none"> • General chemical substances (reported to the government) 	<ul style="list-style-type: none"> • Priority assessment chemical substances (PACSS)
Purpose	<ul style="list-style-type: none"> • Identification of PACSS 	<ul style="list-style-type: none"> • Focusing on Class II candidates
Required specifications	<ul style="list-style-type: none"> • Conservative assessment 	<ul style="list-style-type: none"> • Appropriateness • Reliability
Number of chemicals (as of FY2015)	<ul style="list-style-type: none"> • 11,904 chemicals (28,409 reports) 	<ul style="list-style-type: none"> • 163 chemicals (2,178 reports)
Annual report requirements	<ul style="list-style-type: none"> • Chemical identity (MITI No., CAS No. (if available)) • Volume manufactured, imported (previous fiscal year) • Usage category and shipped volume 	<ul style="list-style-type: none"> • Chemical identity (MITI No., CAS No. (if available)) • Volume manufactured, imported (previous fiscal year) • Usage category (detailed) and shipped volume • Place of production and use
Threshold	<ul style="list-style-type: none"> • 1 ton/year • >10% in mixture 	<ul style="list-style-type: none"> • 1 ton/year • >1% in mixture
Assessment units	<ul style="list-style-type: none"> • CAS No. • MITI No. • Former Type II & III monitoring chemicals 	<ul style="list-style-type: none"> • PACS registration number



CACL screening approach and results

SCREENING ASSESSMENT

Screening

- STEP 1: Classification of exposure
 - Annual report (manufacture, import, usage category)
 - Emission factor table

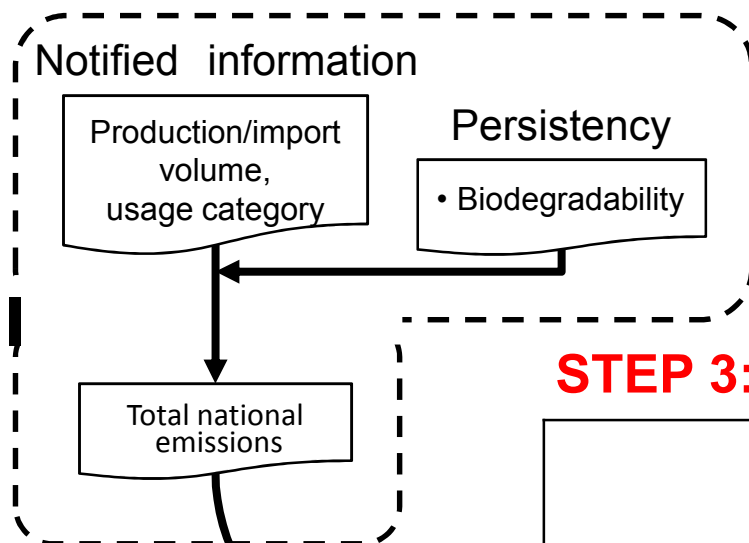
- STEP 2: Classification of hazard
 - Data gap survey
 - Reliability evaluation

- STEP 3: Creation of prioritization matrix

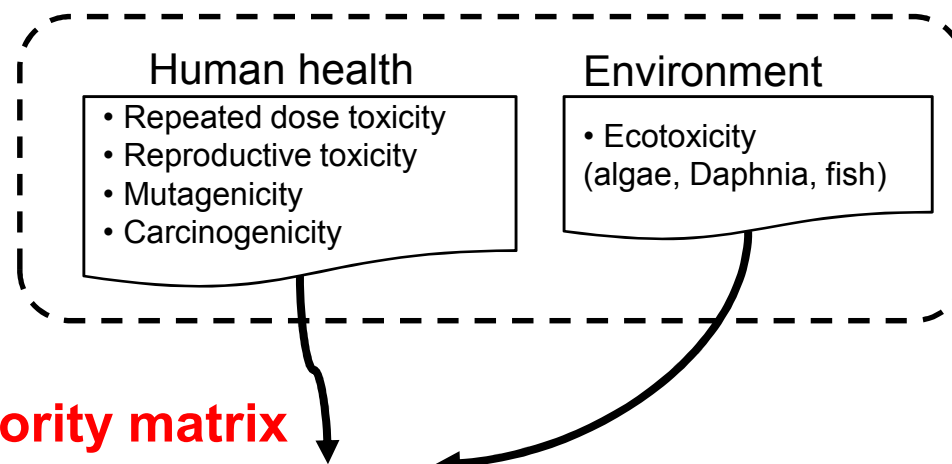
Designation of priority assessment chemical substances

Screening characteristics

STEP 1: Classification of exposure



STEP 2: Classification of hazard



STEP 3: Priority matrix

		Hazard class				
		1	2	3	4	N/A
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	
	N/A	Out of classification				

H: High
M: Medium
L: Low

STEP 1:

Classification of exposure

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

Total amount of environmental release
= Emissions from production stage (A)
+ Emissions from usage stage (B)

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

B = \sum (Quantity of shipment for each
usage category (reported) x
emission factors for each usage
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 formulas for emission amount estimation

[Code of reporter, etc. or reference code of reporter, 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

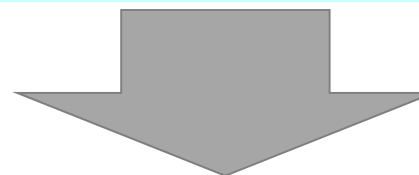
Quantity of shipment (t)	Shipment-related use no.
<input type="text"/>	Specific use () _____
<input type="text"/>	Specific use () _____
<input type="text"/>	Specific use () _____
<input type="text"/>	Specific use () _____

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

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

U_a = Quantity of shipment for each **u**sage category
 x Emission factor to **a**ir for each usage category

U_w = Quantity of shipment for each **u**sage category
 x Emission factor to **w**ater for each usage category



Total nationwide emission amount for **human health** assessment = $\sum_{\text{Business}} \{ (M_a + M_w) + \sum_{\text{Use}} (U_a + U_w) \}$

Total nationwide emission amount for **environment** assessment (only for surface water)
 = $\sum_{\text{Business}} \{ M_w + \sum_{\text{Use}} (U_w) \}$

STEP 2: Classification of hazard

- human health -

Severe ← Hazard class → Moderate

Hazard item	1	2	3	4	Out of class
General toxicity		$D \leq 0.005$ GHS class 1	$0.005 < D \leq 0.05$ GHS class 2	$0.05 < D \leq 0.5$	$D > 0.5$
Reproductive/ developmental toxicity		$D \leq 0.005$	$0.005 < D \leq 0.05$	$0.05 < D \leq 0.5$	$D > 0.5$
Mutagenicity	GHS class 1A	- GHS class 1B, 2 - "Highly positive" in the CSCL - "Class 1" of PRTR - Positive with unknown strength	- Positive* ¹ in all mutagenicity tests in the CSCL	- Positive* ¹ in any mutagenicity test in the CSCL	- Out of GHS class - Negative in all mutagenicity tests in 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 for 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	$\text{PNEC} \leq 0.001$	$0.001 < \text{PNEC} \leq 0.01$	$0.01 < \text{PNEC} \leq 0.1$	$0.1 < \text{PNEC} \leq 1$	$\text{PNEC} > 1$
GHS	Chronic toxicity Class 1	Chronic toxicity Class 2	Chronic toxicity Class 3 using acute toxicity	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

		Hazard class Severe ↔ Moderate				
		1	2	3	4	N/A
Exposure class High ↑ ↓ Low	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 class				

Environment

		Hazard class Severe ↔ Moderate				
		1	2	3	4	N/A
Exposure class High ↑ ↓ Low	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 class				

High

Medium/Low

Further review

Out of classification

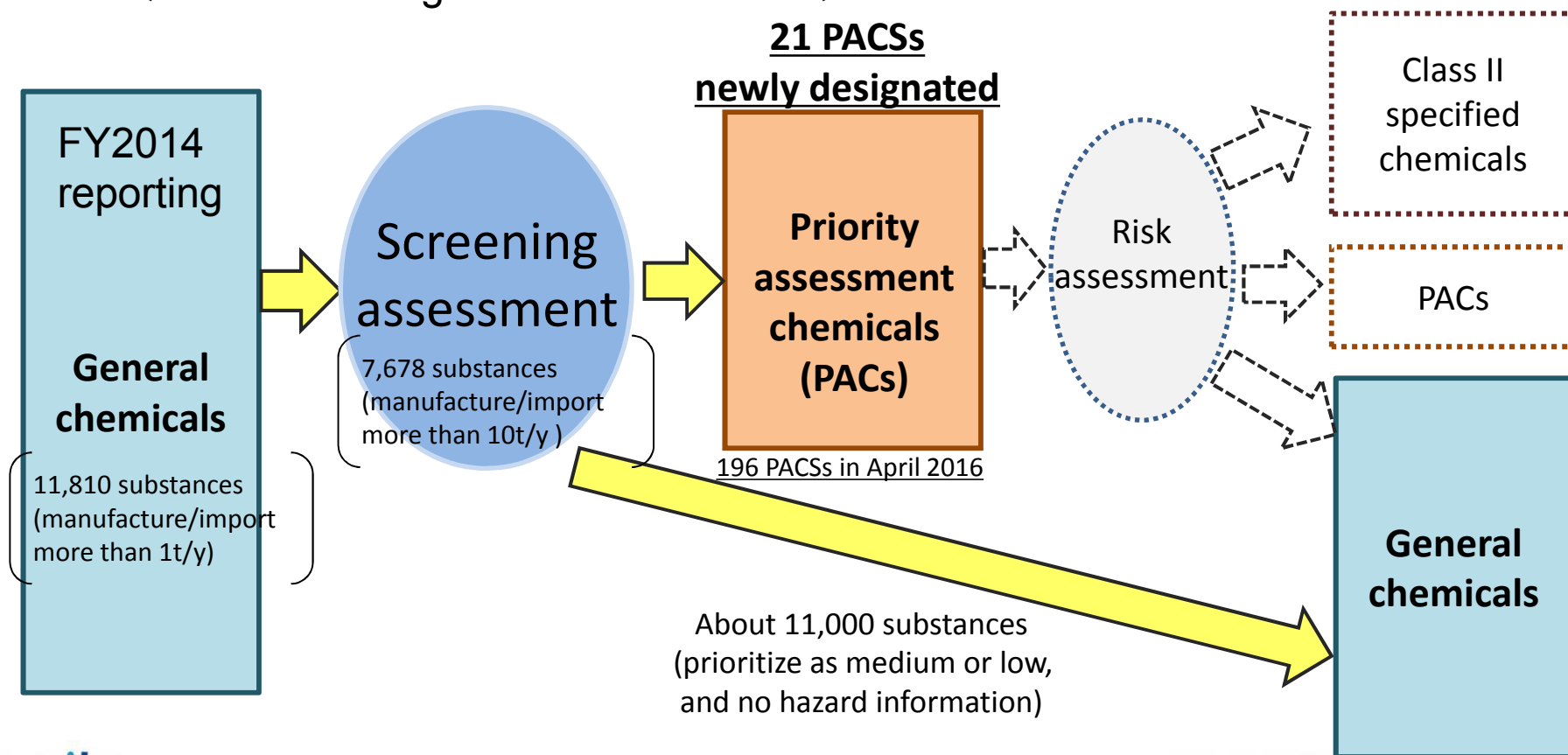
Designated by government as PACSS

Remain as general chemical substances

FY2015 screening assessment results

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

<2015 screening assessment results>





Stepwise CSCL risk assessments for PACS

RISK ASSESSMENT

About PACSs

(Priority Assessment Chemical Substances)

Definition

Chemical substances that are found to **require priority assessments** because of the likelihood that they **may impair** human health or damage the inhabitation and/or growth of flora and fauna in the human living environment through environmental pollution.

(Since risks are initially unclear, assessments must be made)

Overview

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

CSCCL risk assessment system

Report system for manufactured quantity, etc. is a means of exposure assessment

Reports of manufactured quantity, etc.

Name
Material name

<u>Manufacture</u>	<u>Pref.</u>	<u>Qty</u>
ABC		**t
ABC		**t

<u>Shipment</u>	<u>Pref.</u>	<u>Use</u>	<u>Qty</u>
ABC	XX-X		**t
DEF	XX-X		**t
ABC	XX-X		**t

Information used for hazard evaluation by government

Example:

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

Hazard level is assessed to a certain degree by reports and evaluations, etc.

Exposure assessment

Hazard assessment

Amount of exposure

Hazard assessment value

Risk assessment

Methods used to assess efficiently

Our approach combines a stepwise reduction in the number of assessed chemicals with a stepwise expansion of information to be used

Assessment step	Outline	Number of chemicals	Information to be used	Output
<p>Risk assessment (Phase I)</p> <p>Tier - I</p> <p>Tier - II</p> <p>Tier - III</p> <p>Risk assessment (Phase II)</p>	<p>A minimum amount of common information is used to determine the priority of Phase II assessment or hazard information request.</p>			Priority list
	<p>Detailed assessment using publically available information.</p>			Assessment reports
	<p>Newly obtained exposure information is used to review the assessment result.</p>			Assessment reports
	<p>Newly obtained toxicity test result is used instead of existing long-term toxicity information.</p>			Assessment reports

Usable notification information

Report of the Manufactured quantity, etc. of Priority Assessment Chemical Substances

1. Name and Address

2. Manufacture, Imported and Shipped Quantity
 (1) Name etc. of Chemical Substance
 [Material Name]

[Material Management No.] -

[Official Gazette Ref. No.] -

...

3. Manufacture etc. of Chemical Substance

(1) Name of manufacturing business firm and its location

(2) Manufactured quantity by prefecture or imported quantity by country/region for the relevant chemical substance

Prefecture code	Manufactured quantity (t)	Country/region code	Imported quantity (t)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

(3) Shipped quantity by prefecture (or country/region)

Prefecture code	Use code	Shipped quantity (t)
<input type="text"/>	<input type="text"/> - <input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/> - <input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/> - <input type="text"/>	<input type="text"/>

Business Operator A
 Business Operator B
 Business Operator C

For each manufacturer/importer, for each substance

Manufactured quantity by manufacturing location

Shipped quantity by prefecture and by use

If emission factor is available

Released quantity can be estimated

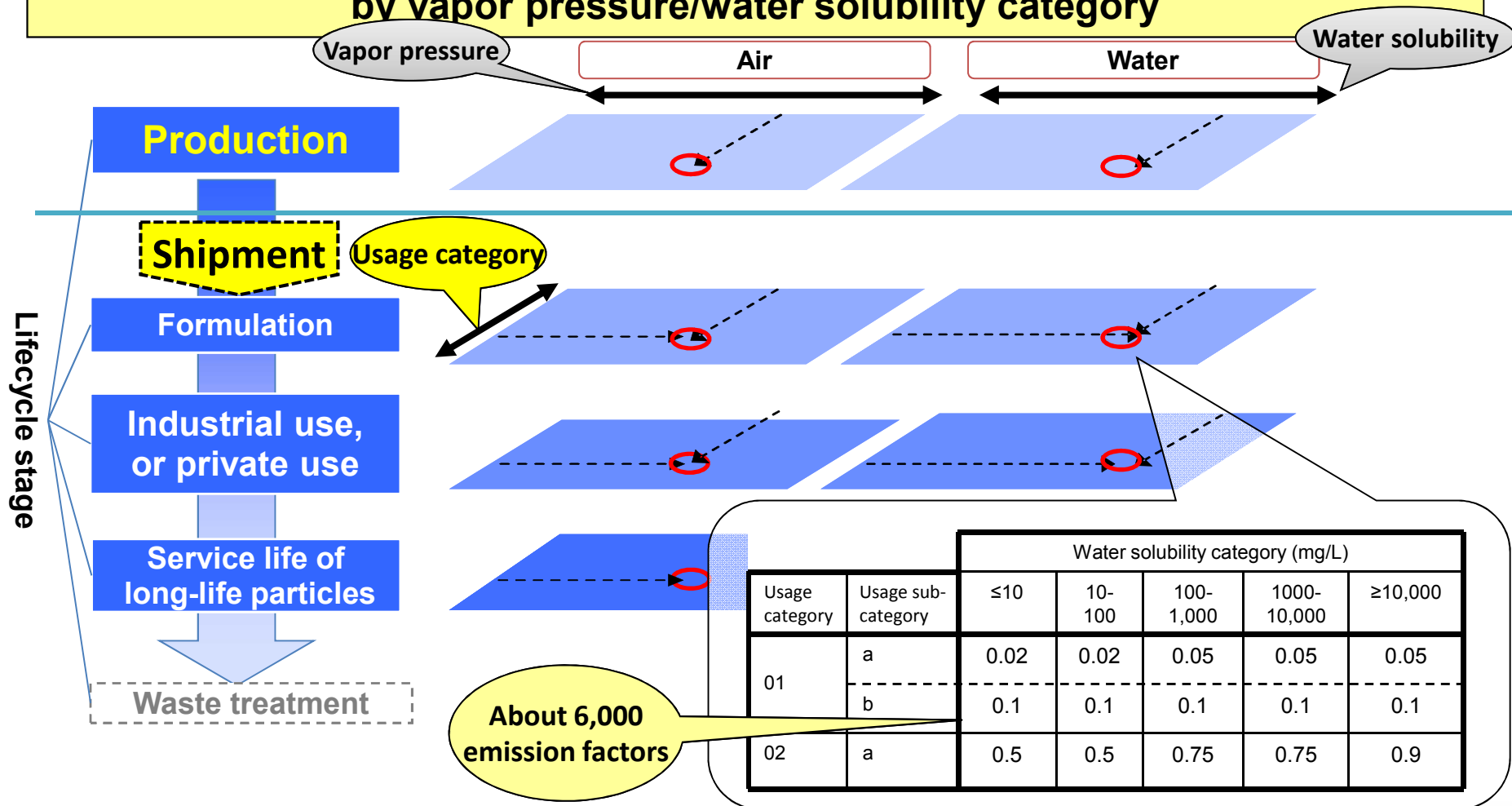
$$\text{Released qty} = \text{Handled qty} \times \text{Emission factor}$$

Have it selectable from reported information

For each usage

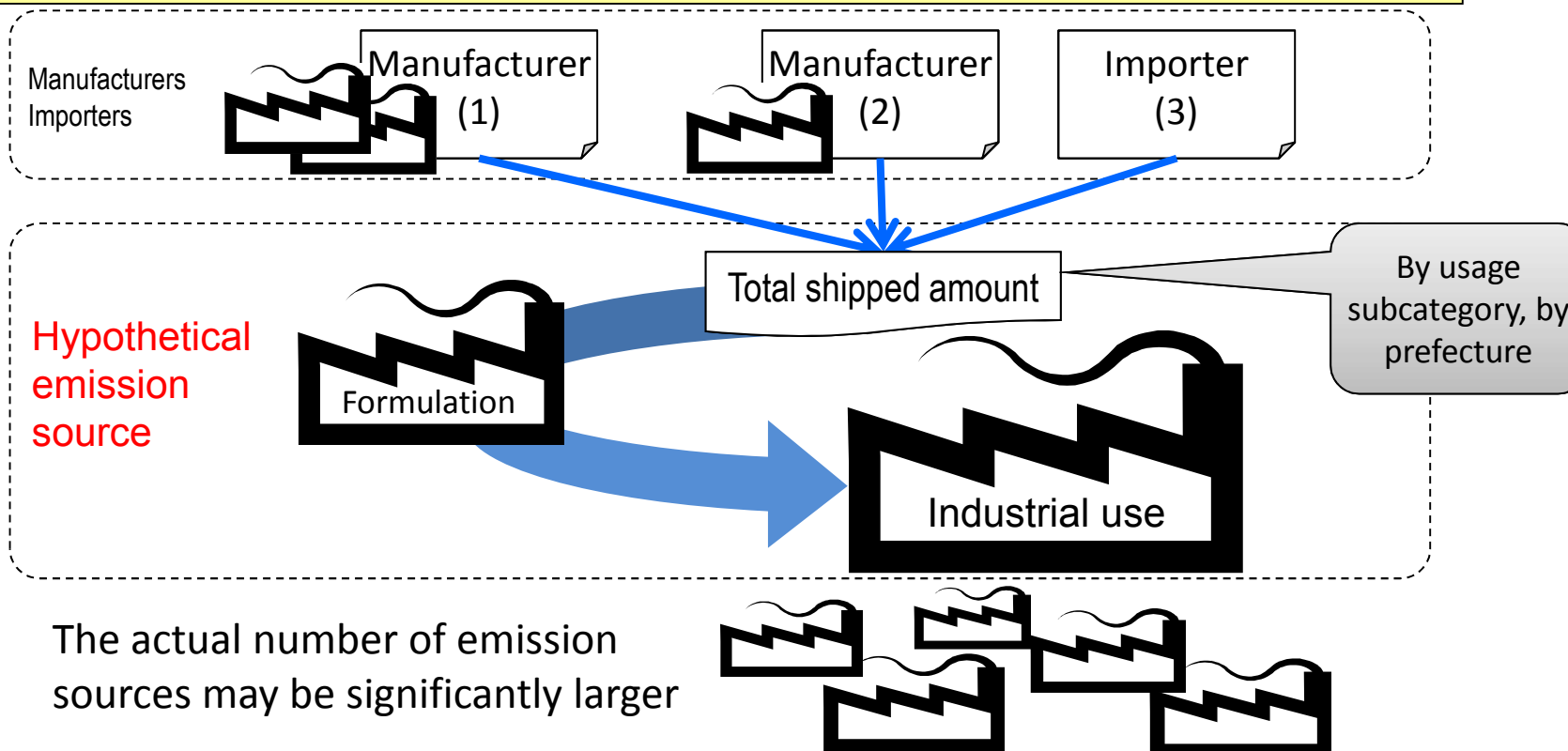
Emission factors

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



“Hypothetical emission source” concept

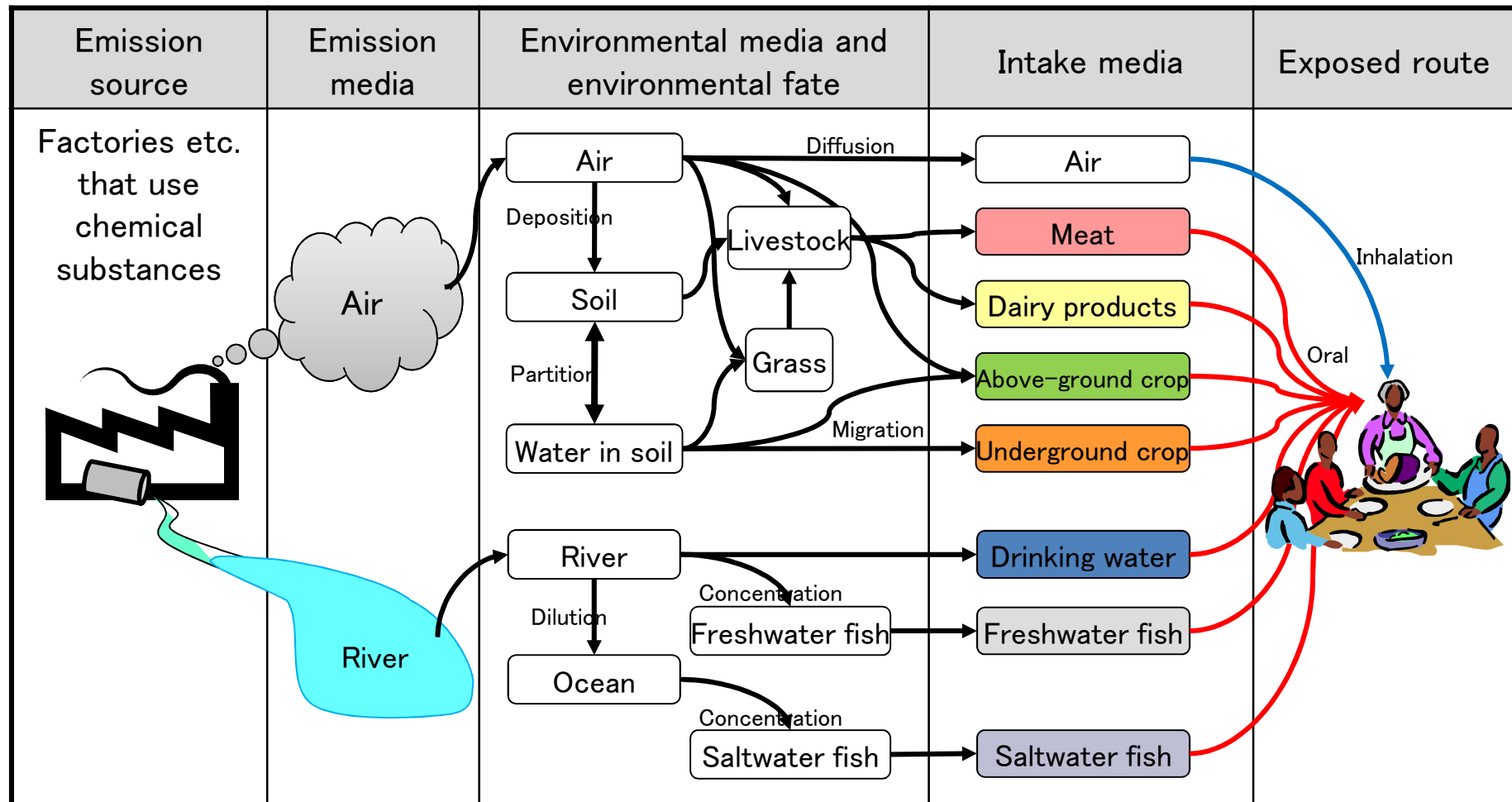
Method for using available information to judge the necessity of next-step assessments while avoiding underestimations



Concept whereby, when no actual emission source information exists, a “hypothetical emission source” is situated nearby and assumptions are made using reported information, such as manufactured quantity
(Because the quantity released from actual emission sources becomes smaller than the quantity released from hypothetical emission sources) [UNCLEAR]

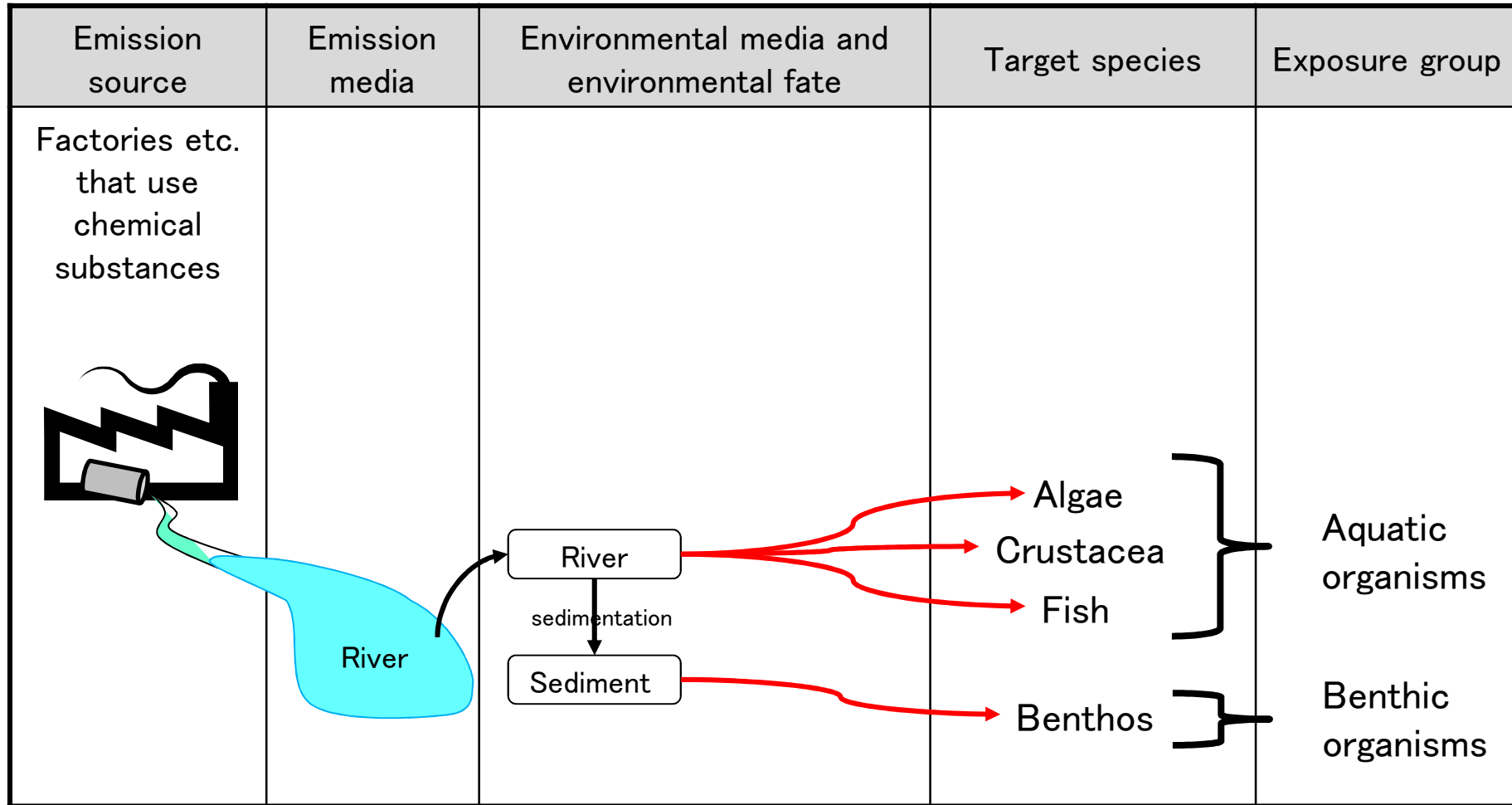
Target of risk assessment

- Environmental pathways of human exposure -

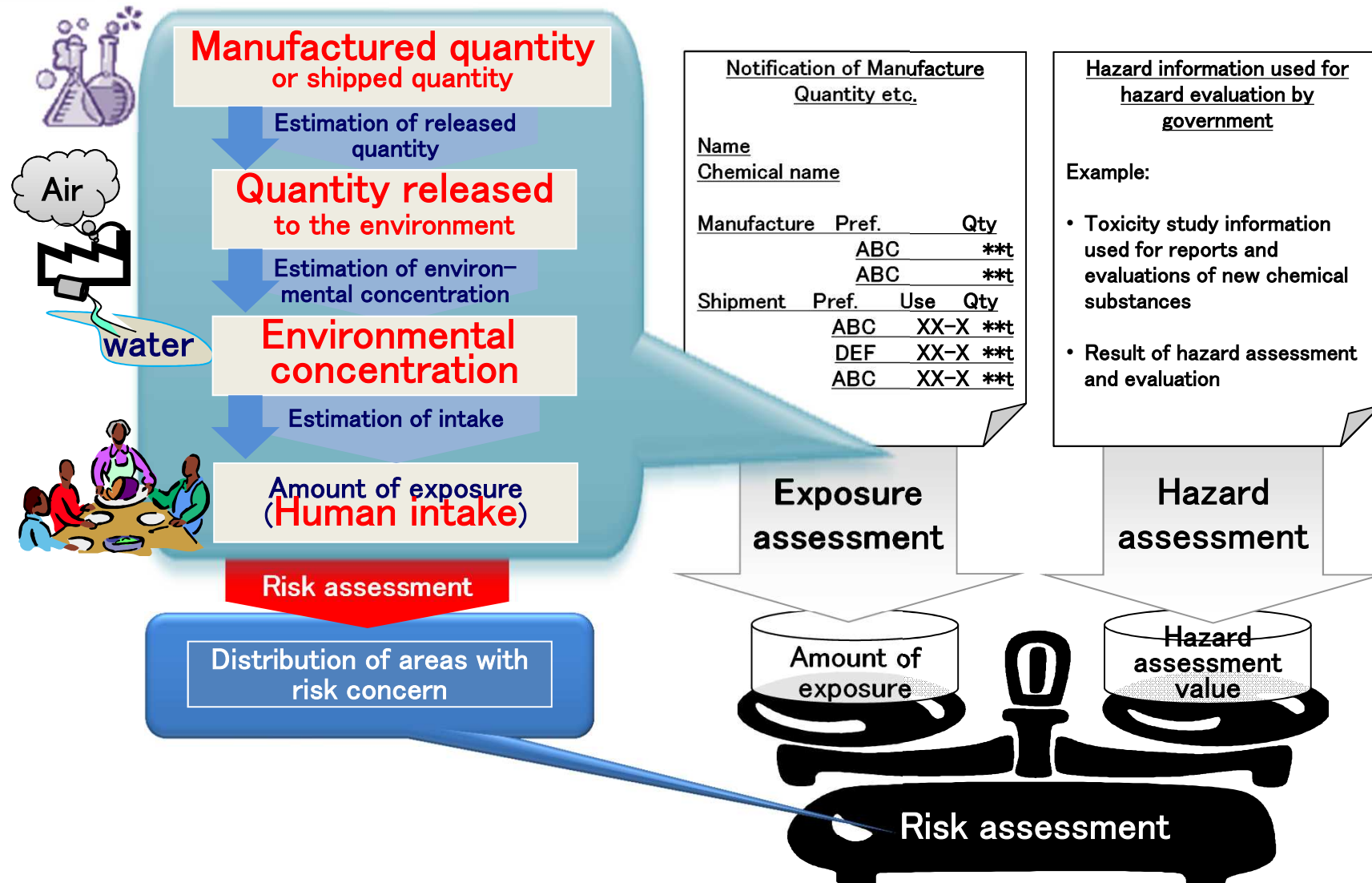


Target of risk assessment

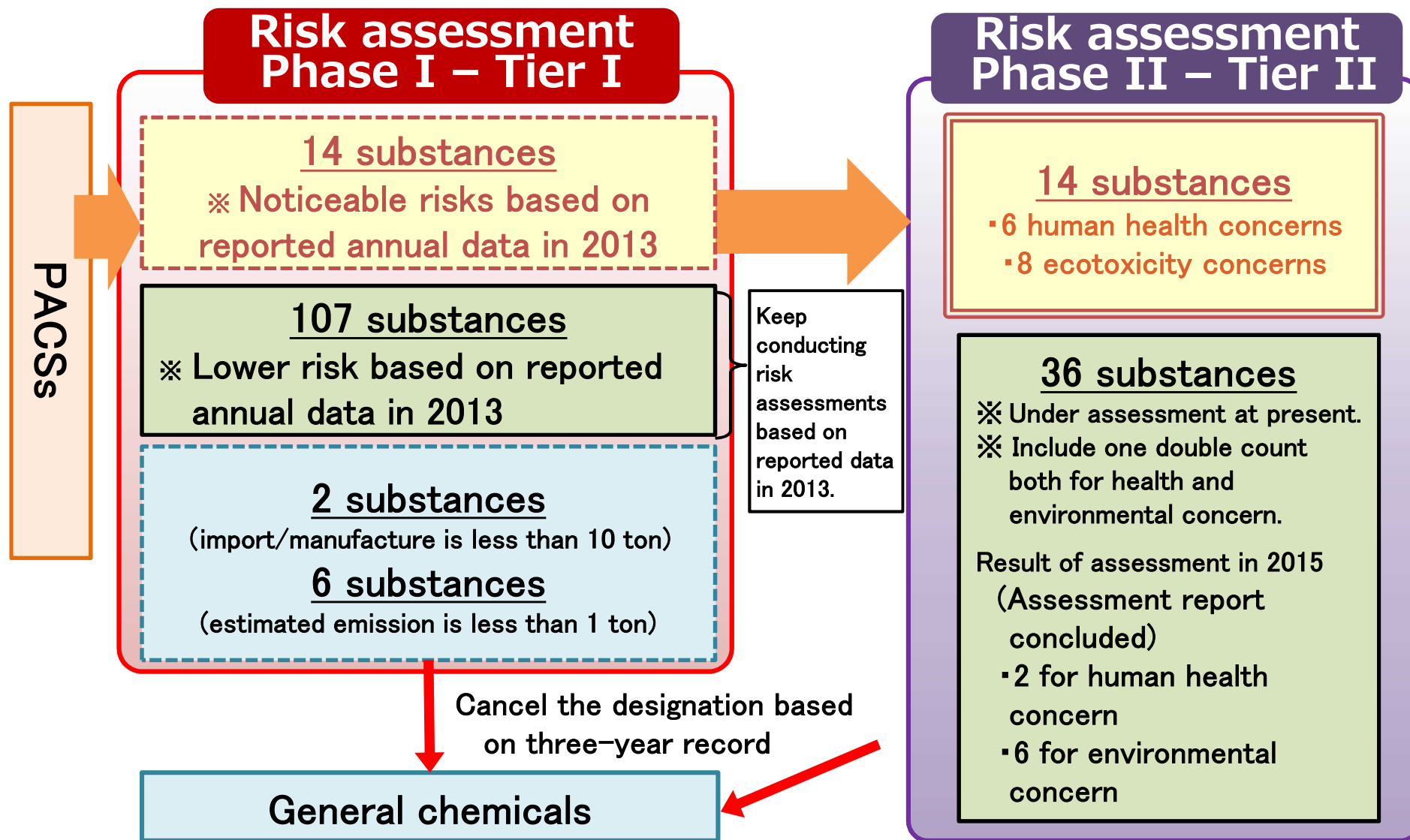
- Ecological effect -



Risk assessment under the CSCL



Current status of risk assessment (FY2015)



References

- Technical guidance documents for PACS risk assessments (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