Risk Assessment of Chemical Substances in Japan

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1. Overview of Regulation under Chemical Substances Control Law in Japan

Chemical Substances Control Law (April 1, 2011～)

Existing Chemical Substances

New Chemical Substances			
> 1 ton/year	≤ 1 ton/year	Specified Cases (*e.g.,*intermediates)	Polymers of Low Concern

General Chemical Substances

Evaluation of PBT*

Prior verification and monitoring

Determination by available knowledge, the state of its manufacture, import, etc.

Determination by available knowledge, the state of its manufacture, import, etc.

Monitoring Chemical Substances

Priority Assessment Chemical Substances

if necessary

Instruction to report the state of handling

if necessary

Order to investigate long-term toxicity

if necessary

Instruction to report the state of handling

if necessary

Order to Investigate long-term toxicity

Class I Specified Chemical Substances

Class II Specified Chemical Substances

*P:Persistent
B:Bioaccumulation
T:Toxicity

Obligatory reporting of hazard information obtained by business

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Shift to Risk-based Chemical Management

Risk = Hazard × Amount of Exposure

Hazard : Potential adverse effects of chemicals for human health and the environment

Amount of Exposure : Potential amount of chemicals which may expose human and ecosystem
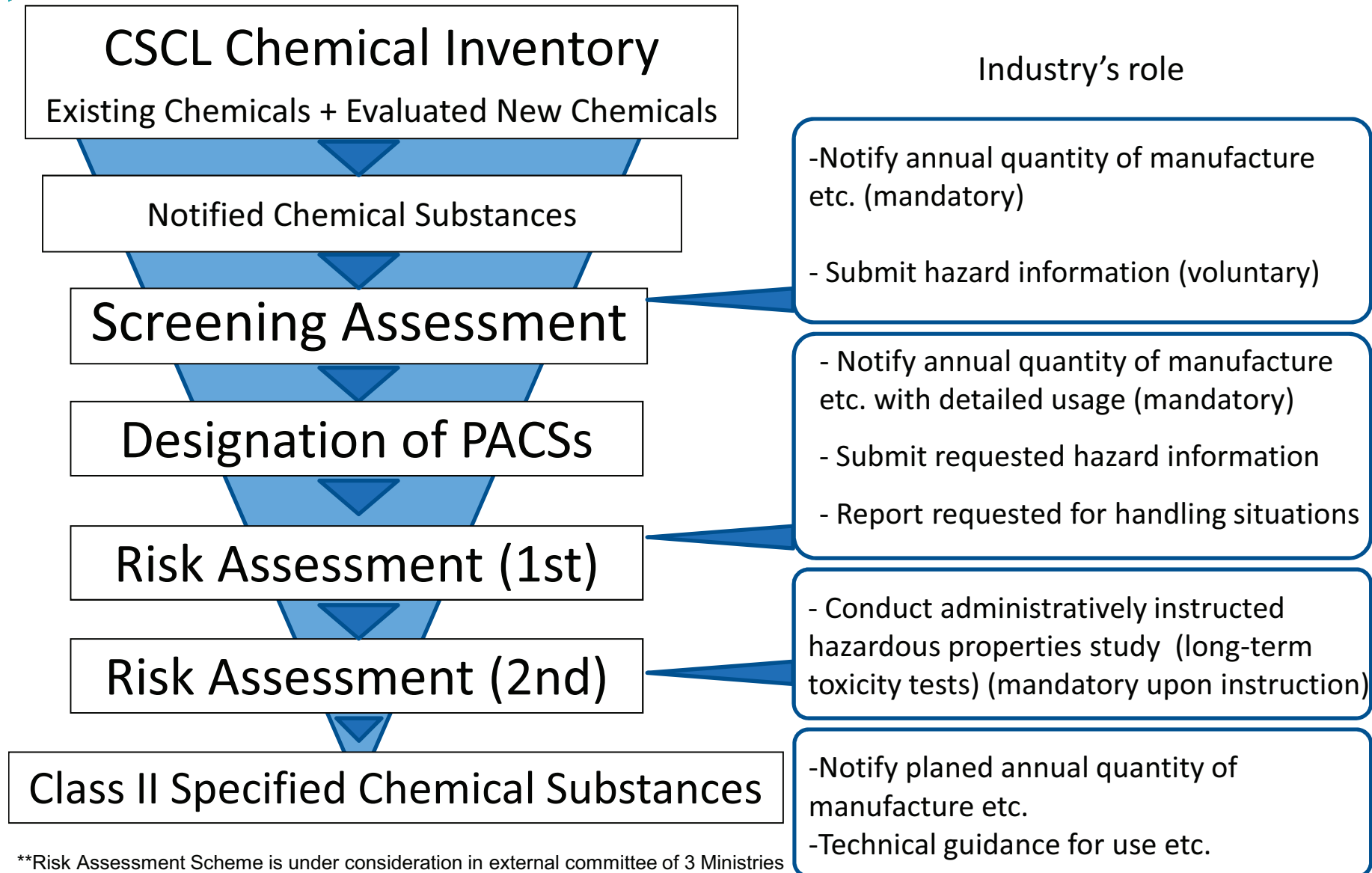
Before the Amendment of Law in 2009

Regulations are mainly based on **hazards of chemicals**

After the Amendment of Law

Regulations shall be mainly based on **risks of chemicals**

Step-wise Risk Assessment

CSCL Chemical Inventory

Existing Chemicals + Evaluated New Chemicals

Notified Chemical Substances

Screening Assessment

Designation of PACSs

Risk Assessment (1st)

Risk Assessment (2nd)

Class II Specified Chemical Substances

Industry's role

-Notify annual quantity of manufacture etc. (mandatory)

- Submit hazard information (voluntary)

- Notify annual quantity of manufacture etc. with detailed usage (mandatory)

- Submit requested hazard information

- Report requested for handling situations

- Conduct administratively instructed hazardous properties study (long-term toxicity tests) (mandatory upon instruction)

-Notify planed annual quantity of manufacture etc.
-Technical guidance for use etc.

**Risk Assessment Scheme is under consideration in external committee of 3 Ministries

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2. Screening Assessment

Screening Assessment

STEP1 : Classification of Exposure

Notified Information : Annual Quantity of Manufacture etc. / Use category

▼

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

▼

Apply Threshold*

▼

Emission Factor Table

▼

Estimation of Environmental Release

▼

Classification of Exposure

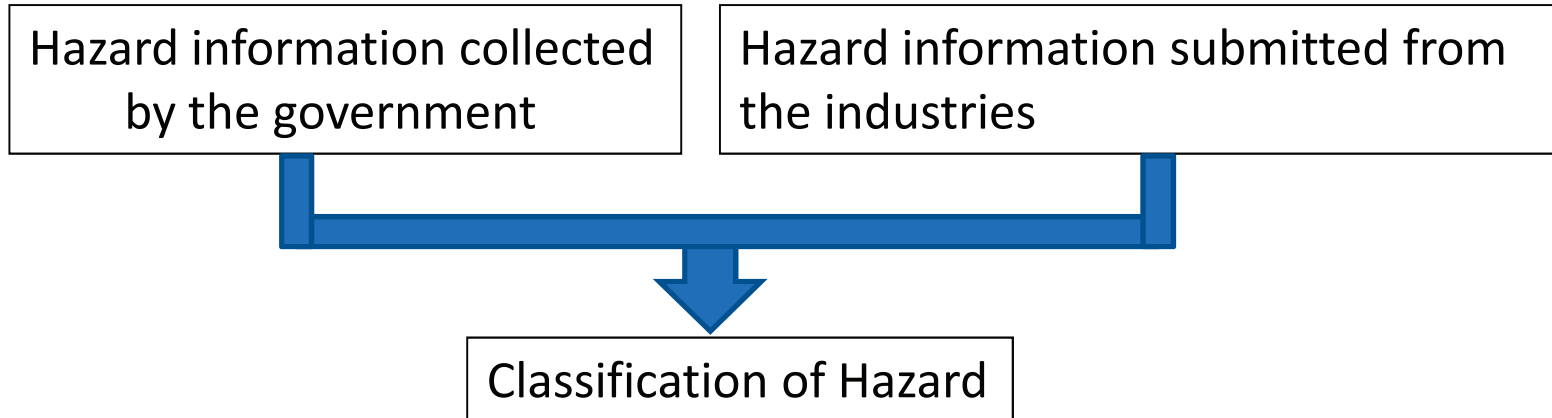| Exposure Class	Total national emissions (tons)
Class1	Over 10,000
Class2	1,000 – 10,000
Class3	100 – 1000
Class4	10 – 100
Class5	1-10

*Threshold for risk assessment:
 Total annual quantity of manufacture etc. is less than 10t/year

Screening Assessment

STEP2 : Classification of Hazard

Hazard information collected by the government	Hazard information submitted from the industries

Classification of Hazard

	Class1	Class2	Class3	Class4
Repeated Dose Toxicity		●		
Carcinogenicity	N o d a t a a v a i l a b l e			
Mutagenicity		No data available		
Reproductive Toxicity			●	

Hazard Class

CSCL Screening Scale
(based on GHS, previous CSCL rule etc.)

If no data available, default class (class 2) will be applied for Repeated Dose Toxicity and Mutagenicity.

(default class will not be applied for carcinogenicity and reproductive toxicity)

*We do not consider that "No data" means "Not hazardous"

The Highest Class in the four categories will be chosen as Hazard Class

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Screening Assessment

STEP2 : Classification of Hazard

Details of Hazard Classes (human health)

	Class1	Class2	Class3	Class4
Repeated Dose Toxicity	N/A	HAV(*)$\leq$0.005	$0.005 <$ HAV ≤ 0.05	$0.05 <$ HAV ≤ 0.5
Carcinogenicity	IARC1 etc	IARC 2A, 2B etc	N/A	N/A
Mutagenicity	GHS1A	GHS 1B, CSCL Strongly Positive	CSCL Dual Positive (**)	CSCL Single Positive (**)
Reproductive Toxicity	N/A	HAV$\leq$0.005	$0.005 <$ HAV ≤ 0.05	$0.05 <$ HAV ≤ 0.5

(*) HAV = Hazard Assessment Value (see next page)
(**) CSCL requires Ames test and Chromosomal aberration test for new chemicals

Screening Assessment

STEP2 : Classification of Hazard

Details of Hazard Classes (human health, cont'd)

- Determination of Hazard Assessment Value
  - HAV = NOAEL etc / Uncertainty Factors (UFs)
  - UFs
    - Inter-Species Difference …   10
    - Intra-Species Difference …   10
    - Use of LO(A)EL…   10
    - Severity of Effect…   1~10
    - Length of Study
      - Less than 90 days…   6
      - Less than 1 year…   2

Screening Assessment

STEP2 : Classification of Hazard

Details of Hazard Classes (environment)

	Class1	Class2	Class3	Class4
Eco-toxicity test	PNEC ≤0.001	0.001< PNEC ≤0.01	0.01< PNEC ≤0.1	0.1< PNEC≤1

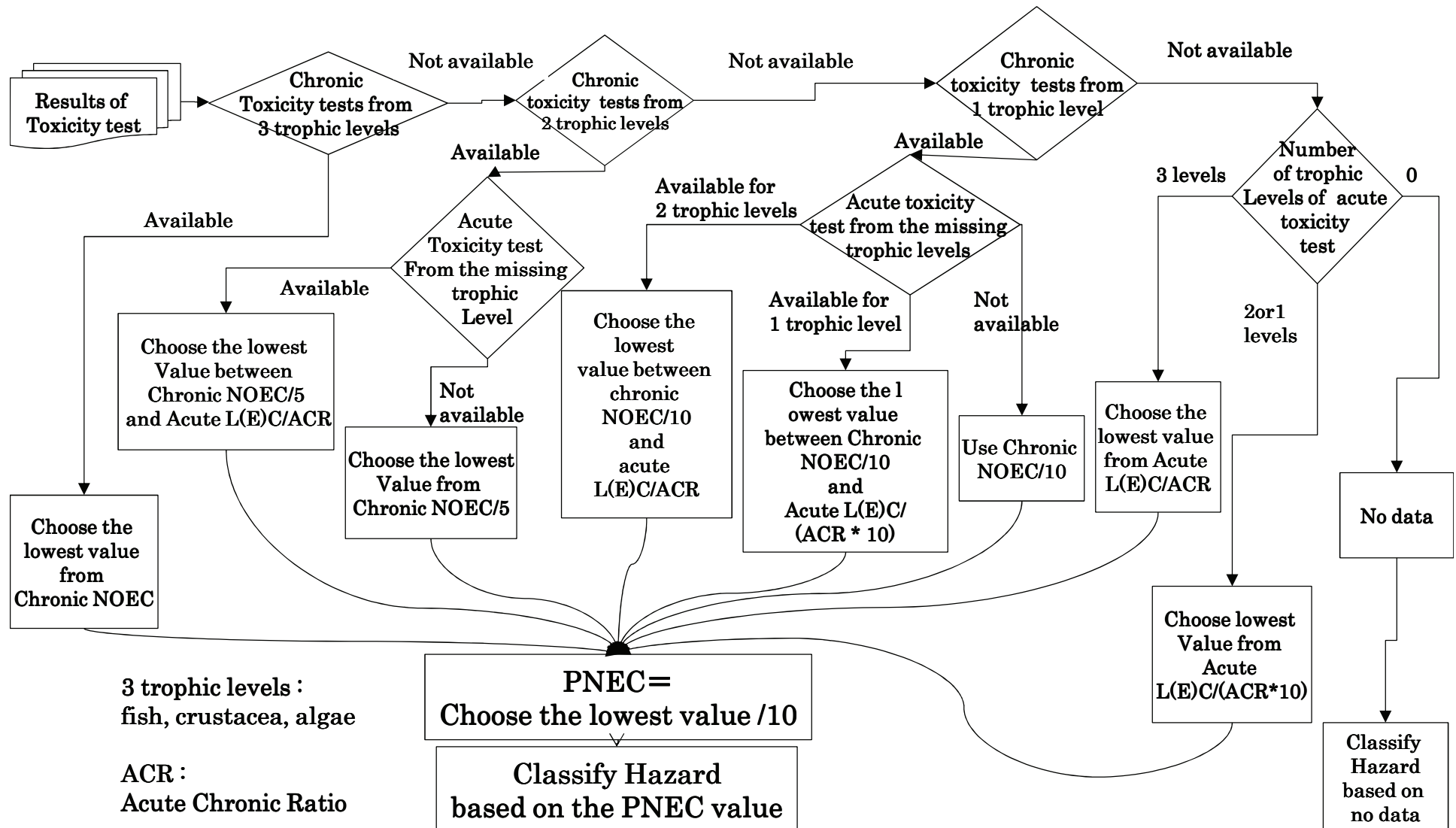PNEC： Predicted No-Effect Concentration (mg/L)
　　　　　　　＝Lowest toxicity value/the product of UF
　　　　　　　＝Deemed chronic toxicity value/10

If no data available, default class (class 1) will likely be applied

Screening Assessment

Flow of Classification of Hazard for Eco-system

Results of Toxicity test → **Chronic Toxicity tests from 3 trophic levels**

- Not available → **Chronic toxicity tests from 2 trophic levels**
- Not available → **Chronic toxicity tests from 1 trophic level**
- Not available → **Number of trophic Levels of acute toxicity test**

Chronic Toxicity tests from 3 trophic levels
- Available → Choose the lowest value from Chronic NOEC

Chronic toxicity tests from 2 trophic levels
- Available → **Acute Toxicity test From the missing trophic Level**
  - Available → Choose the lowest Value between Chronic NOEC/5 and Acute L(E)C/ACR
  - Not available → Choose the lowest Value from Chronic NOEC/5

Chronic toxicity tests from 1 trophic level
- Available → **Acute toxicity test from the missing trophic levels**
  - Available for 2 trophic levels → Choose the lowest value between chronic NOEC/10 and acute L(E)C/ACR
  - Available for 1 trophic level → Choose the lowest value between Chronic NOEC/10 and Acute L(E)C/(ACR * 10)
  - Not available → Use Chronic NOEC/10

Number of trophic Levels of acute toxicity test
- 3 levels → Choose the lowest value from Acute L(E)C/ACR
- 2or1 levels → Choose lowest Value from Acute L(E)C/(ACR*10)
- 0 → No data → Classify Hazard based on no data

PNEC= Choose the lowest value /10

Classify Hazard based on the PNEC value

3 trophic levels：
fish, crustacea, algae

ACR：
Acute Chronic Ratio

Screening Assessment

STEP3 : Classification of Exposure

Use Category Table

Use Category code (♯)	Use Category	Sub Use Category code	Sub Use Category
01	Intermediates	a	Synthetic raw materials, polymerization raw materials, prepolymers
		b	Polymerization initiators
		z	Others
	Solvents		
02	Solvents for paints, varnishes, coatings, printing inks, copying and biocidal products	a	Solvents for paints, solvent diluents
		b	Solvents for paint removers,
		c	Solvents for varnishes
		d	Solvents for coatings, solvents for resist inks
		e	Solvents for printing inks, solvents for electronic devices, solvents for inks and ink detergents
		f	Solvents for biocidal products
		z	Others
03	Solvents for adhesives, pressure sensitive adhesives and sealants	a	Solvents for adhesives, solvents for pressure sensitive adhesives
		b	Solvents for adhesive removers, solvents for paste removers
		c	Solvents for adhesion
		d	Solvents for sealants
		z	Others

Use Categories (50 categories) are used for general chemical substances

Sub Use Categories (about 280 categories) are used for PACSs , Monitoring Chemical Substances and Class II Specified Chemical Substances.

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Screening Assessment

-Based on the notified annual quantity of manufacture etc., the government estimates the amount of environmental release.
- Emission factors for each use category are determined by the government based on surveys and information from the industry, etc.

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

<B> = Σ {quantity of shipment for each use category (notified)

x emission factors for each use category}

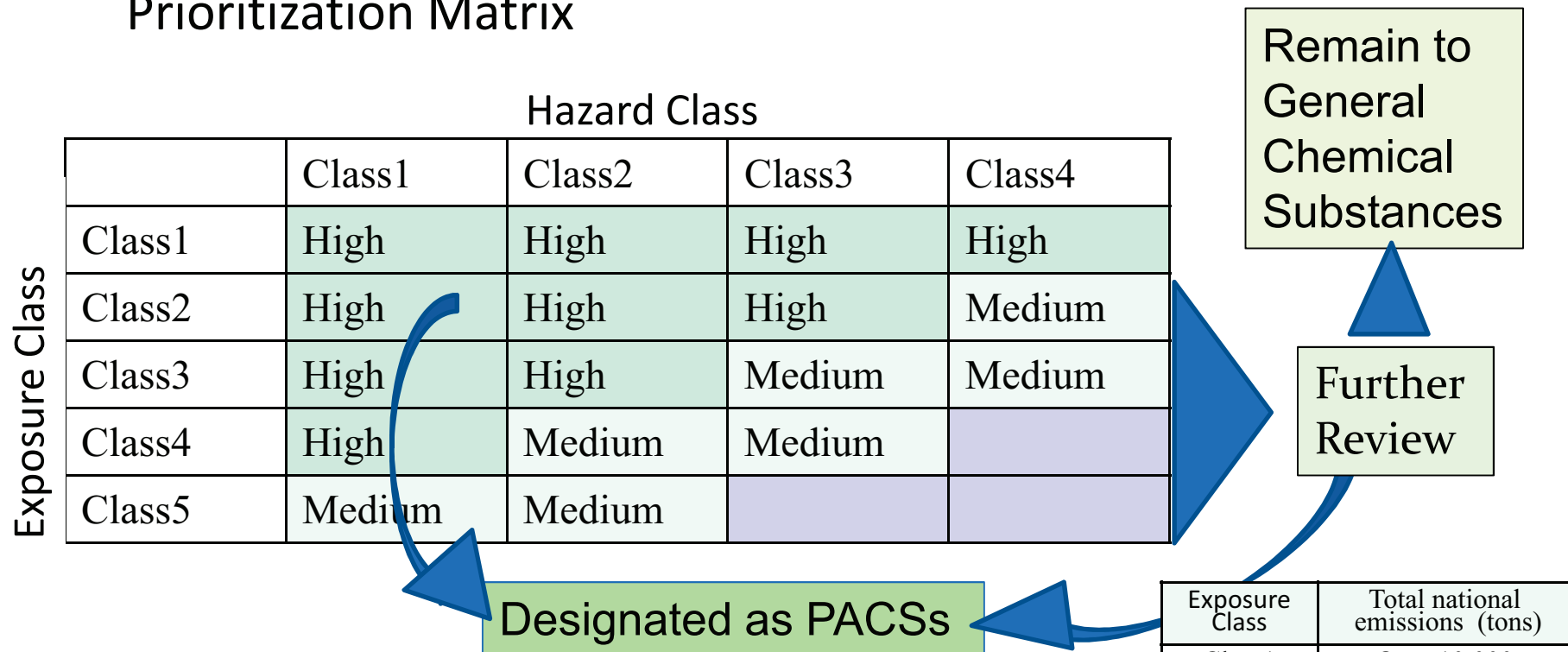Table of emission factors for each use category used in screening assessment

Use Category code (#)	Use Category	general substances		polymers	
		Air	Water	Air	Water
01	Intermediates	0.001	0.0003	0.0001	0.0001
02	Solvents for paints, varnishes, coatings, printing inks and biocidal products	0.3	0.00008	–	–
03	Solvents for adhesives, pressure sensitive adhesives and sealants	0.4	0.0002	–	–
04	Solvents for cleaning and degreasing metals	0.2	0.00008	–	–
05	Solevents for cleaning fablics《laundry, dry cleaning industry》	0.02	0.0001	–	–
06	Solvents for cleaning others	0.06	0.0003	–	–
07	Solvents for chemical manufacture and processing	0.02	0.0007	–	–
08	Solvents for aerosol	1	0	–	–
09	Other solvents	1	0	–	–
10	Chemical process regulators	0.0004	0.0003	0.000005	0.0002

*We classify exposure based on emissions of "Air+Water" for Human Health, "Water" for Eco-system

Screening Assessment

STEP4 : Prioritization

Prioritization Matrix

Hazard Class

	Class1	Class2	Class3	Class4
Class1	High	High	High	High
Class2	High	High	High	Medium
Class3	High	High	Medium	Medium
Class4	High	Medium	Medium	
Class5	Medium	Medium		

Exposure Class

Remain to General Chemical Substances

Further Review

Designated as PACSs

Exposure Class	Total national emissions (tons)
Class1	Over 10,000
Class2	1,000 – 10,000
Class3	100 – 1000
Class4	10 – 100
Class5	1-10

NOTE:

-Threshold value for risk assessment will be applied

-Opportunities are given to industry for submission of hazard information before designation of PACSs

-Similar methodology is adopted for eco-toxicity.

-List of PACSs will be reconsidered based on annual reporting and new hazard information.

3.   Result of the first Screening Assessment

Result of the first Screening Assessment

- As of April 1, 2010, 1070 type II monitoring substances and 276 type III monitoring substances have been designated.

- Threshold(*) are applied for the assessment

- 447 type II monitoring substances and 166 type III monitoring substances were assessed.

  (*) Threshold of the assessment : 10,000kg per year of manufacturing and import

Result of the first Screening Assessment (cont'd)

- Total 88 substances are selected for PACSs
  - 68 substances are selected for risks to human health
    - 1,2-dichloroethane, 1,4-dioxane, 1,3-butadiene, etc.
  - 13 substances are selected for risks to eco-system
    - 4,4'-(Propane-2,2-diyl)diphenol, 1,2,4-Trimethylbenzene etc.
  - 7 substances are selected for both risks
    - hydrazine, chloroform, bromomethane, etc.
- List of all PACSs are available at
  - http://www.meti.go.jp/policy/chemical_management/english/files/PACSs-list.pdf

4. Procedure after designation of PACSs *(under discussion)*

Procedure after designation of PACSs *(under discussion)*

Priority Assessment Chemical Substances

Notification of Quantity, etc. of Manufacture (Article 9)
Reporting of Hazardous Properties (Article 41)

Preparation for Assessment

Total annual quantity of manufacture etc. is less than 10t

Assessment I

Hazard Assessment I | Count of Quantity of Manufacture etc. | Exposure Assessment I

Addition and Inspection of Hazardous Properties

Estimation of Environmental Release

Hazard Assessment

Exposure Assessment

Prioritization

· Total annual quantity of exposure is less than 1t
· When Assessment II isn't done

Rescission of Designation as a PACS (Article 11)

Monitoring of Quantity, etc. of Manufacture

<More than past three years>
Total annual quantity of manufacture etc. is less than 10t
or
Total annual quantity of exposure is less than 1t

★ : Hearing of Opinion of Councils (Article 56)

Requesting of Hazardous Properties Study (Article 10(1))   Reporting of Hazardous Properties (Article 41)

Carry out Assessment II in consideration of priority and collection situation of hazardous properties

Hearing of Opinion of Councils about Designation of a Class II specified Chemical Substance (Article 2(3))

Assessment II

Rescission of Designation as a PACS (Article 11)

Hazard Assessment II

Exposure Assessment II

Investigation of Hazardous Properties | Investigation of monitoring data (mainly on existing data) | Investigation of PRTR data | Inspection of presumed amount of environmental release

Hazard Assessment | Exposure Assessment based on monitoring data | Exposure Assessment based on PRTR data | Exposure Assessment based on notified data

Risk Characterization

Requesting of Hazardous Properties Study (Article 10(1))   Reporting of Hazardous Properties (Article 41)
Requesting of Report on the Status of Handling (Article 42)   Voluntary Report on the Status of Handling
Additional Monitoring etc.

Hearing of Opinion of Councils about Designation of a Class II specified Chemical Substance (Article 2(3))

Assessment III
Assessment II based on more correct data

Rescission of Designation as a PACS (Article 11)

Instruction of Hazardous Properties Study (Article 10(2))

Hearing of Opinion of Councils about Designation of a Class II specified Chemical Substance (Article 2(3))

Second Risk Assessment
Assessment III based on hazardous properties study

Rescission of Designation as a PACS (Article 11)

Class II Specified Chemical Substances

General Chemical Substances

Summary

Under CSCL, amended in 2009, stepwise risk assessment started. So far, methods for screening assessment was established and initial batch of chemicals have been screened. Development of methods for further risk assessment is underway.

Once a substance is designated as a PACS, non-mandatory request for hazard and exposure information will be made to manufacturers and importers.

First risk assessment will be done using these data, and decisions will be made whether to issue a mandatory instruction for hazard testing.

The methods for these assessments are under discussion at the joint council of three relevant ministries (Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment).