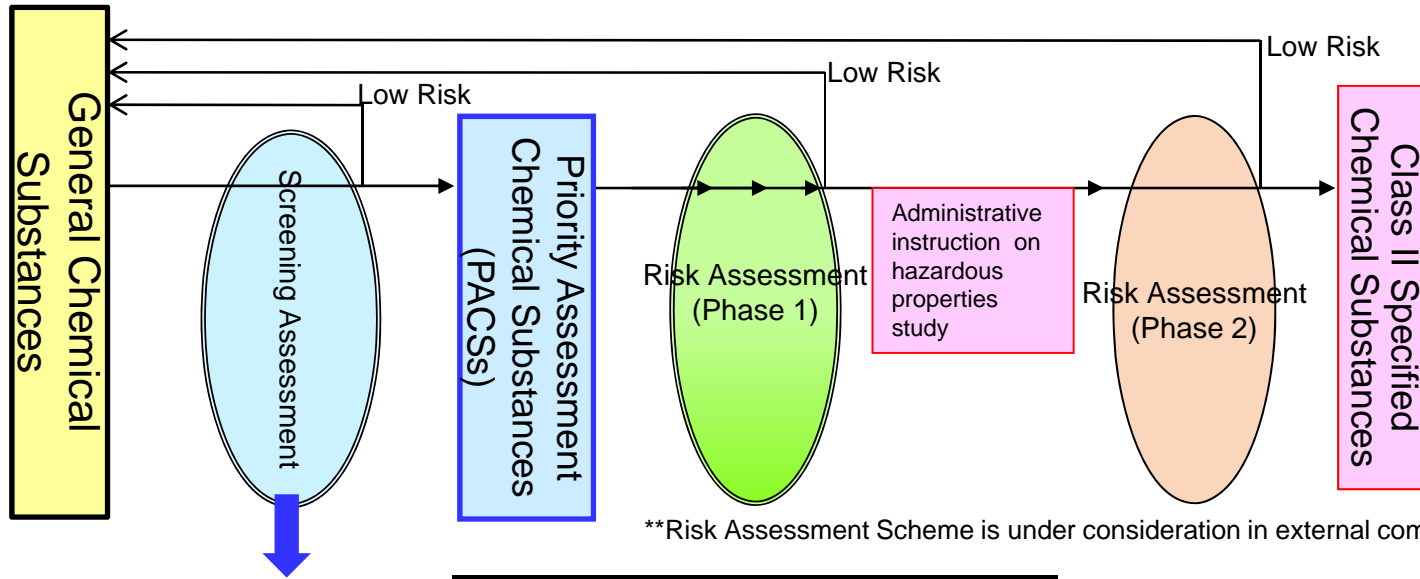


Screening Assessment under amended Chemical Substances Control Law

April 2011

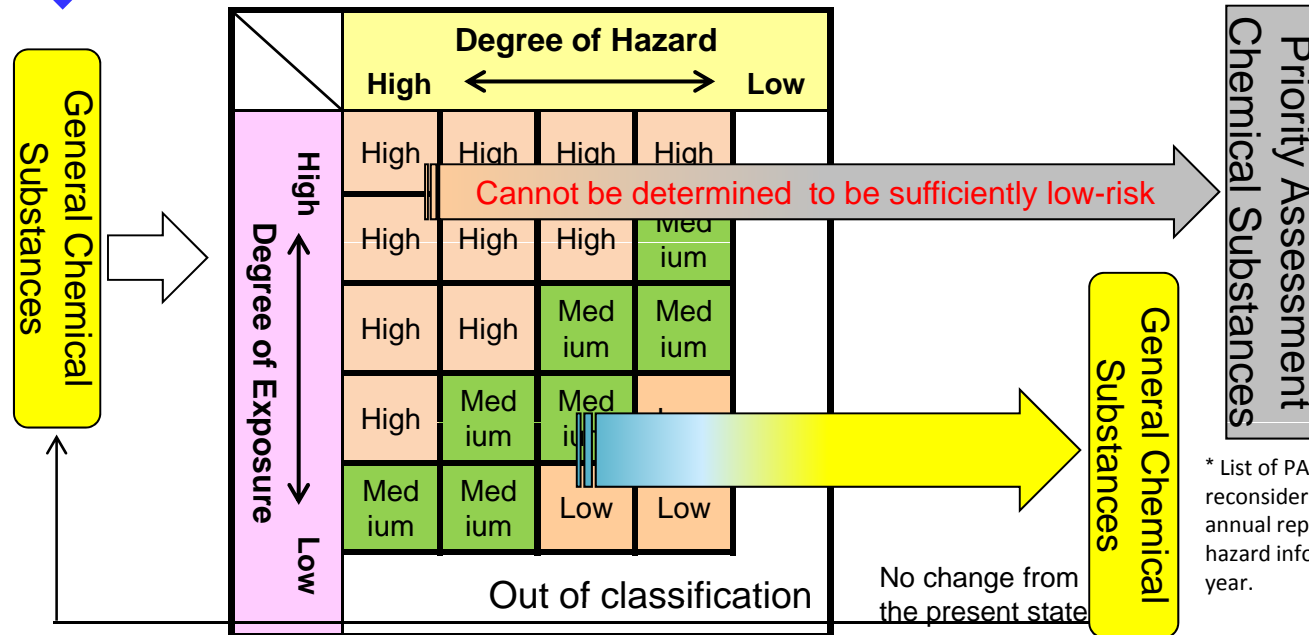
Chemical Safety Office, Chemical Management Policy Division,
Manufacturing Industries Bureau
Ministry of Economy, Trade and Industry

Screening Assessment and Risk Assessment Scheme



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

(Detailed Screening Assessment Scheme)



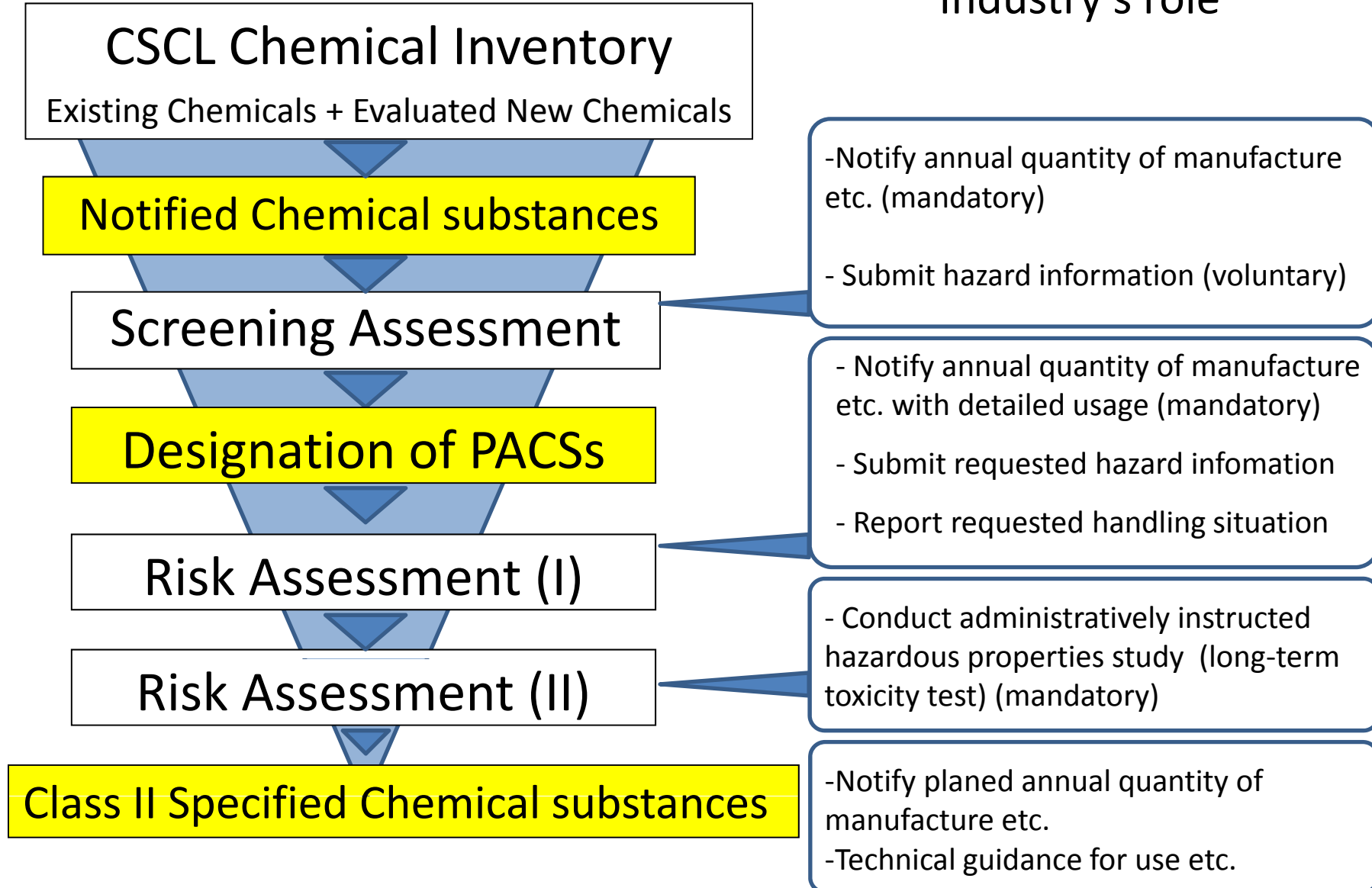
* List of PACSs will be reconsidered based on annual reporting and new hazard information every year.

$$\boxed{\text{Risk}} = \boxed{\text{Hazard}} \times \boxed{\text{Environmental Release (Exposure)}}$$

Step-wise Risk Assessment

Assessment process

Industry's role



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

Screening Assessment

STEP1 : Classification of Exposure

Notified 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*

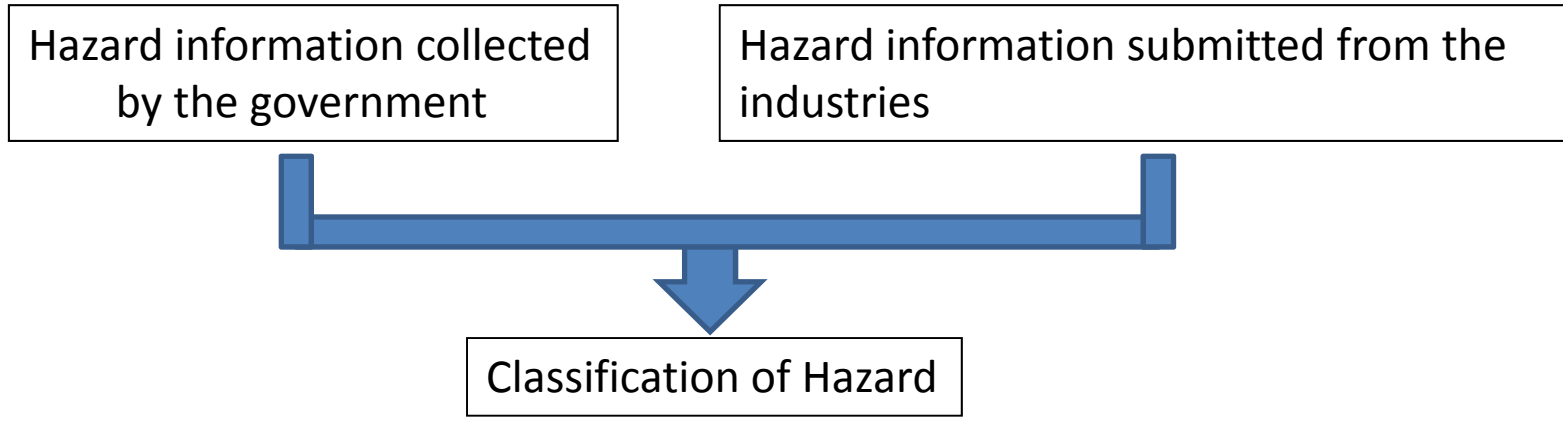
Emission Factor Table

Estimation of Environmental Release

Classification of Exposure

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

STEP2 : Classification of Hazard



	Class1	Class2	Class3	Class4
Repeated Dose Toxicity		●		
Carcinogenicity	No data available			
Mutagenicity		No data available		
Reproduction Toxicity			●	

C_SCL screening Scale
(based on GHS, previous C_SCL rule etc.)

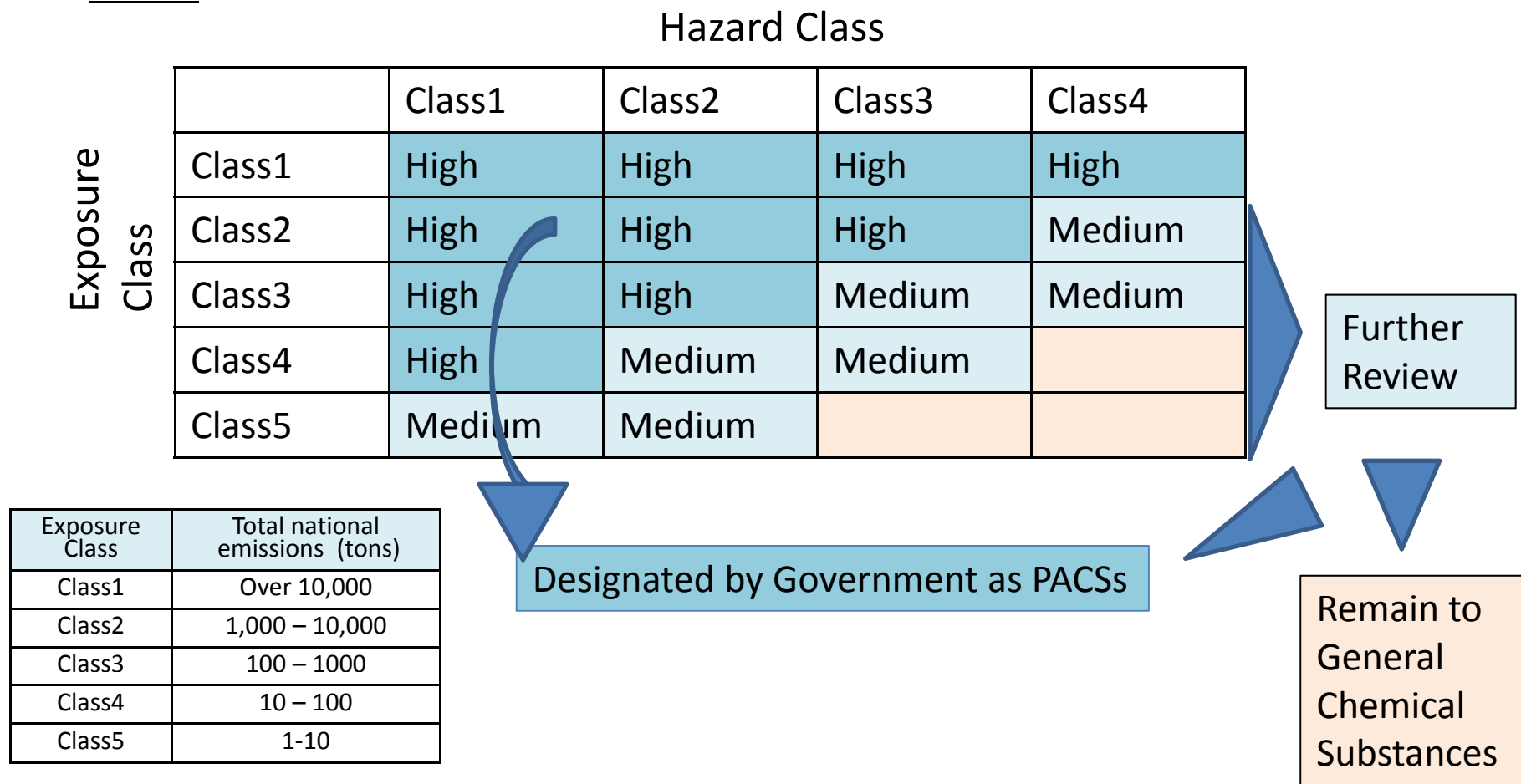
If no data available, default class (class 2) will likely be applied for Repeated Dose Toxicity and Mutagenicity.
(default class will not be applied for carcinogenicity and reproductive toxicity)

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

Hazard Class

Highest Class in the four categories will be chosen

STEP3 : Prioritization Matrix



NOTE:

- Threshold value for risk assessment will be applied
- Opportunities for industry to submit hazard information are given before designation of PACSs
- Similar methodology is adopted to eco-toxicity.
- List of PACSs will be reconsidered based on annual reporting and new hazard information. 6

Use Category Table

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

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 and sub use categories (about 280 categories) are established for Priority Assessment Chemical Substances , Monitoring Chemical Substances and Class II Specified Chemical Substances.

Estimation of Environmental Release

- 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.

**Total amount of environmental release =
emissions from production stage <A> + emissions from using stage **

<A> = quantity of manufacture (notified) × emission factors of production stage

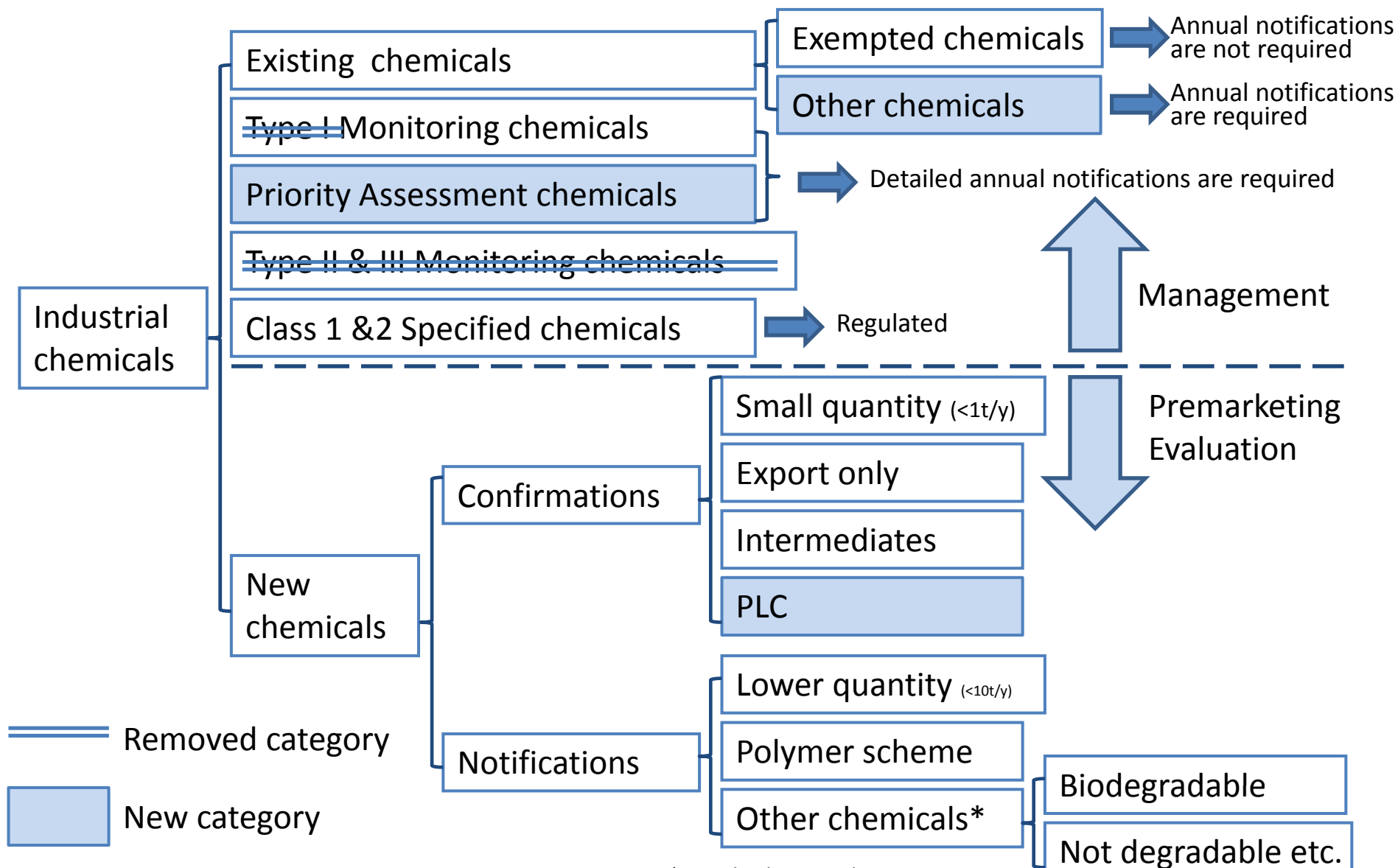
 = Σ {quantity of shipment for each use category (notified)
× emission factors for each use category}

Table of emission factor 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	Solvents for cleaning fabrics (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

Chemical categories under amended CSCL



*It can be designated PACSs or Monitoring chemicals according to the result of evaluation