

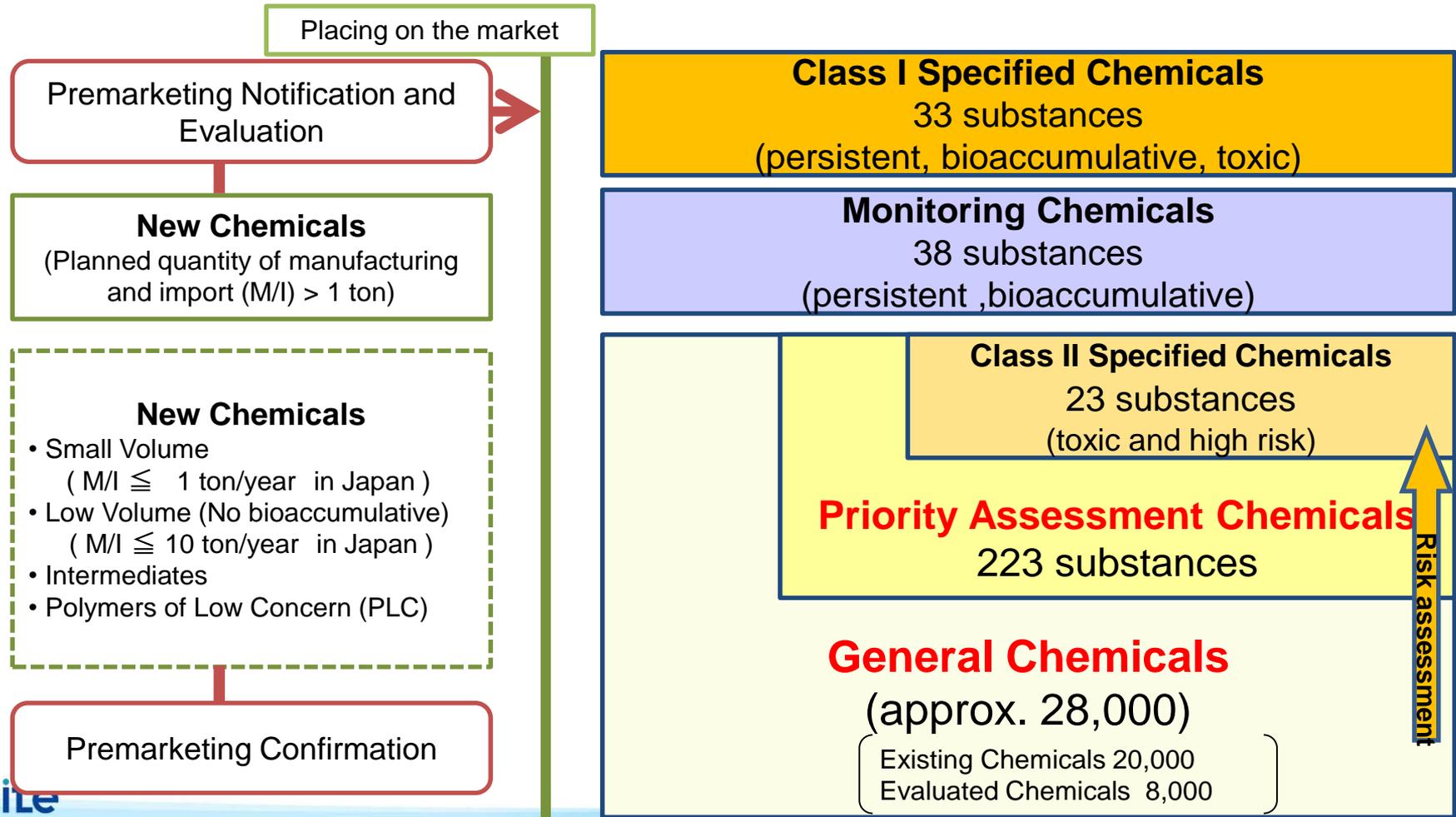
Risk assessment under CSCL in detail

7th November, 2019

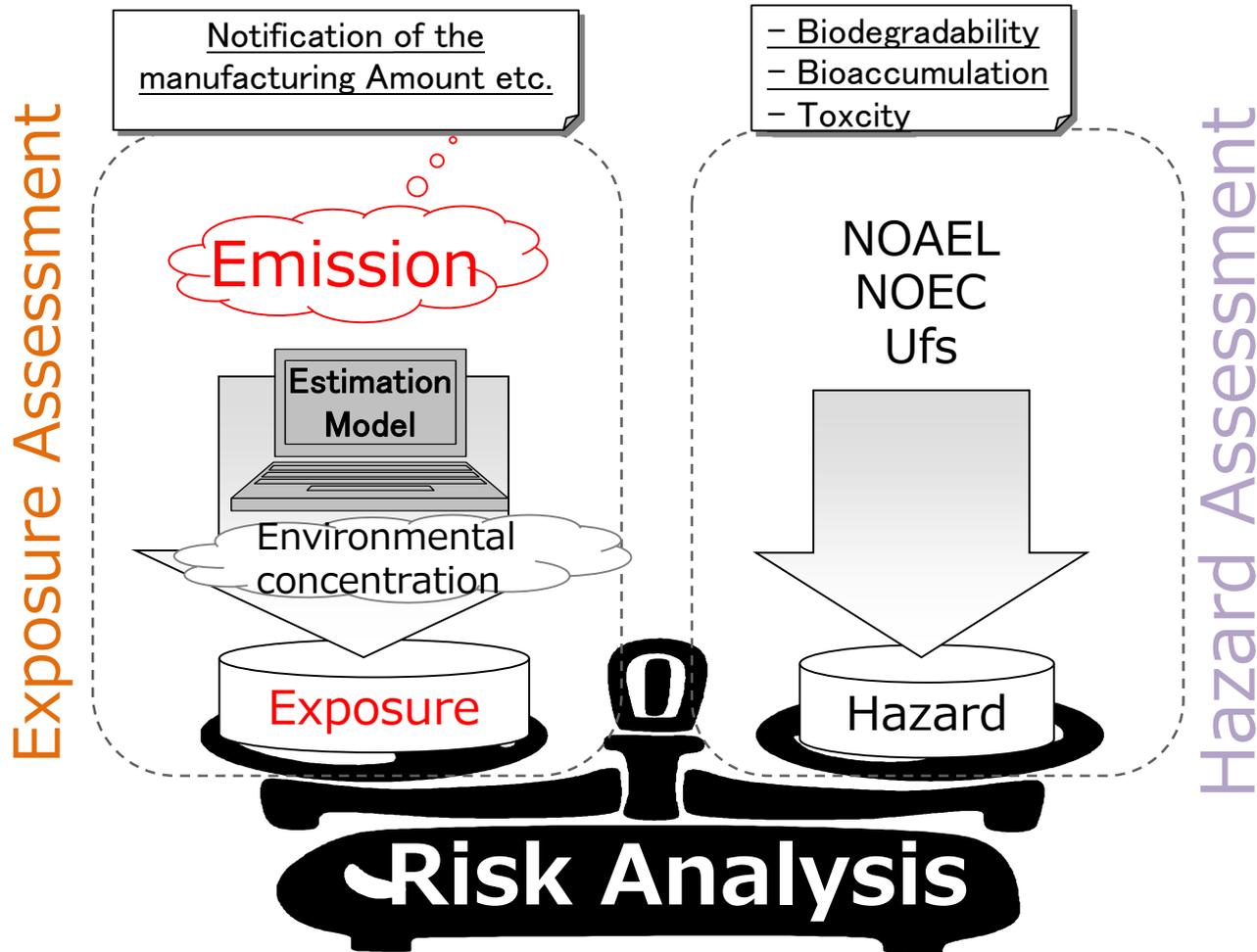
Chemical Management Center,
National Institute of Technology and Evaluation (NITE)

Overview of CSCL

- ✓ The government conducts risk assessment in two phases, both before and after placing the substance on the market.
- ✓ Based on the result of risk assessment, the government may take measures to control risks associated with the chemical.



The picture of Risk Assessment



Toxicity for Human Health Assessments

■ Human Health

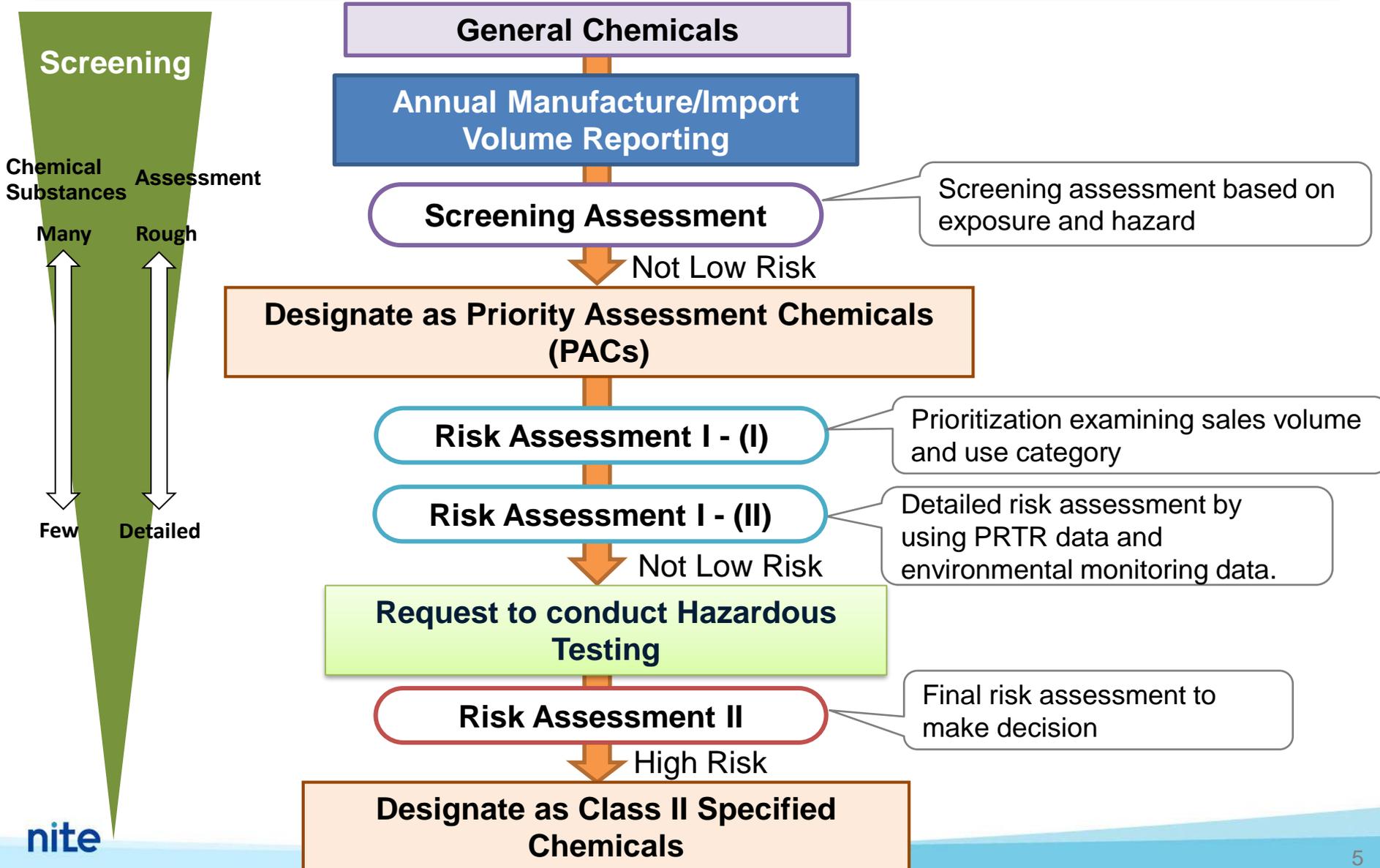
- Genetic toxicity
- Developmental and Reproductive
- Mutagenicity
- Carcinogenicity etc.

■ Ecosystem

- Algae acute/chronic toxicity
- Daphnia acute/chronic toxicity
- Fish acute/chronic toxicity etc.

Flow of Risk Assessment of General Chemicals

✓ The government conducts risk assessment on general chemicals in a step by step manner as follows: (This flow was introduced in the latest revision of CSCL in 2011.)



Screening Assessment using priority matrix

Regarding General Chemicals,

- ✓ Setting exposure class(size of estimated emission amount) and hazard class (strength of Hazard)
- ✓ Conducting Screening Assessment using the following priority matrix

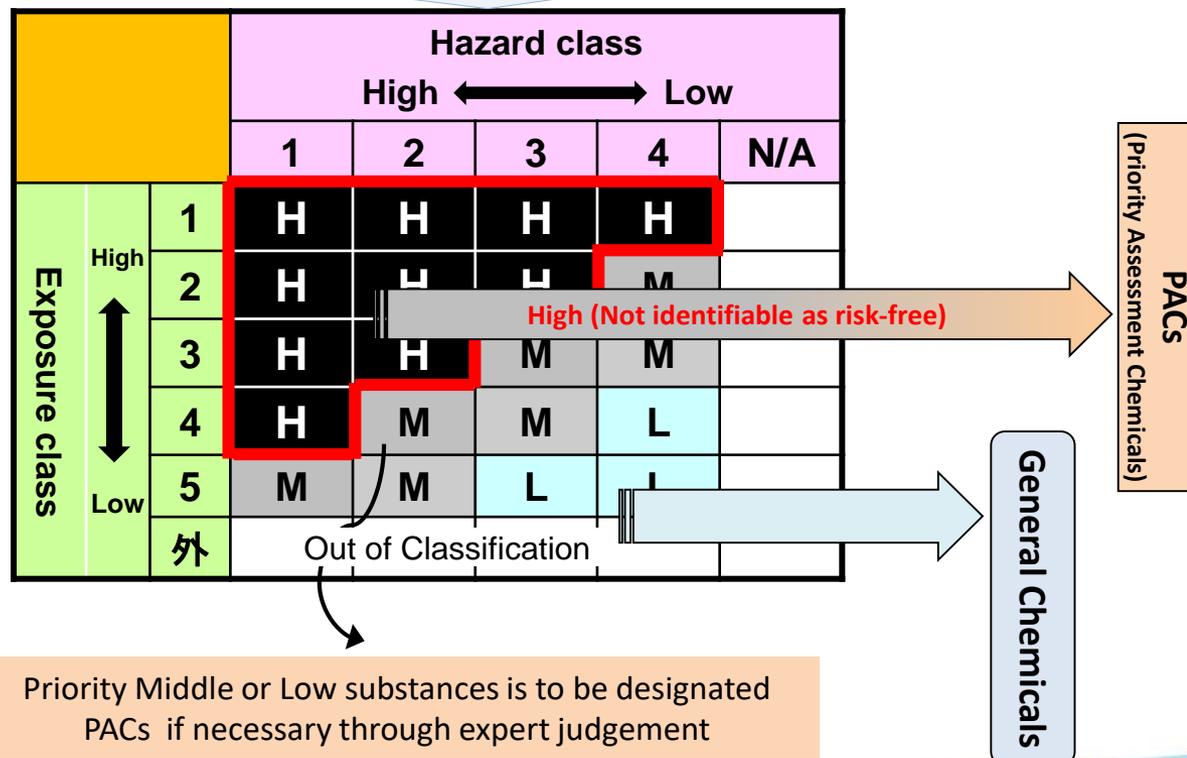
Setting hazard class through hazard data notified or reported, etc. under CSCL on,
【Human health】 general toxicity, Repeated Dose Toxicity, Reproductive Toxicity, Mutagenicity, Carcinogenicity
【Ecosystem】 Eco-toxicity (Algae, Daphnia, fish)

【Total estimated emission amount to environment】

Setting exposure class by calculating total estimated emission amount to environment from (updated every year)

- ✓ notified information on manufactured /imported amount
- ✓ result of Judgment result on non-/readily-degradable

Exposure Class	Total estimated emission amount to environment
Class1	over 10,000 t
Class2	1,000 – 10,000 t
Class3	100 – 1000 t
Class4	10 – 100 t
Class5	1–10 t
Out of class	Less than 1t

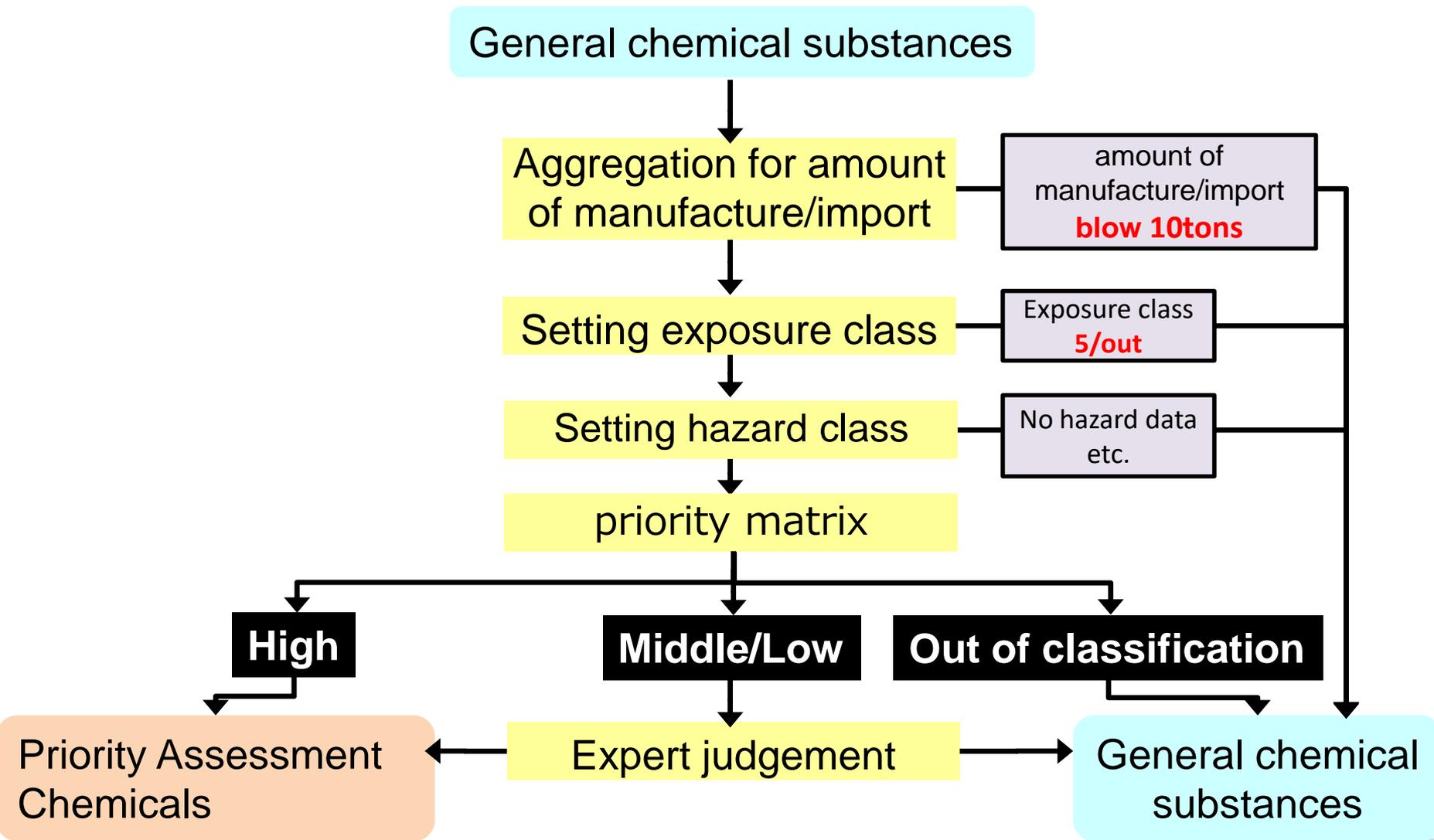


Priority matrix (Eco)

		Hazard class				classification
		1	2	3	4	
		$PNEC \leq 0.001$	$0.001 < PNEC \leq 0.01$	$0.01 < PNEC \leq 0.1$	$0.1 < PNEC \leq 1$	$PNEC > 1$
		Algae Acute toxicity ≤ 2 Daphnia Acute toxicity(amines) ≤ 10 Daphnia Acute toxicity(non-amines) ≤ 1 Fish Acute toxicity ≤ 10 Chronic toxicity ≤ 0.1	Algae Acute toxicity > 2 Daphnia Acute toxicity(amines) > 10 Daphnia Acute toxicity(non-amines) > 1 Fish Acute toxicity > 10 Chronic toxicity > 0.1			Judgement standard of Class III monitoring chemical substances
		(Chronic 1) Chronic toxicity ≤ 0.1	(Chronic) $0.1 < \text{Chronic toxicity} \leq 1$	—	Other	3 kinds of chronic toxicity
		(Chronic 1) If not readily degradable or $BCF \geq 500 (\log Kow \geq 4)$, Chronic toxicity ≤ 0.1 Acute toxicity(missing chronic toxicity) ≤ 1	(Chronic 2) If not readily degradable or $BCF \geq 500 (\log Kow \geq 4)$, $0.1 < \text{Chronic toxicity} \leq 1$ $1 < \text{Acute toxicity(missing chronic toxicity)} \leq 10$	(Chronic 3) If not readily degradable or $BCF \geq 500 (\log Kow \geq 4)$, $10 < \text{Acute toxicity(missing chronic toxicity)} \leq 100$	Other	<3 kinds of chronic toxicity
Exposure class	1	over 10000 tons	High	High	High	High
	2	1000-10000 tons	High	High	High	Middle
	3	100-1000 tons	High	High	Middle	Low
	4	10-100 tons	High	Middle	Low	Low
	5	1-10 tons	Middle	Low	Low	Low
	クラス外	below 1 ton				

The classification of Chronic aquatic toxicity(except readily degradable) for GHS

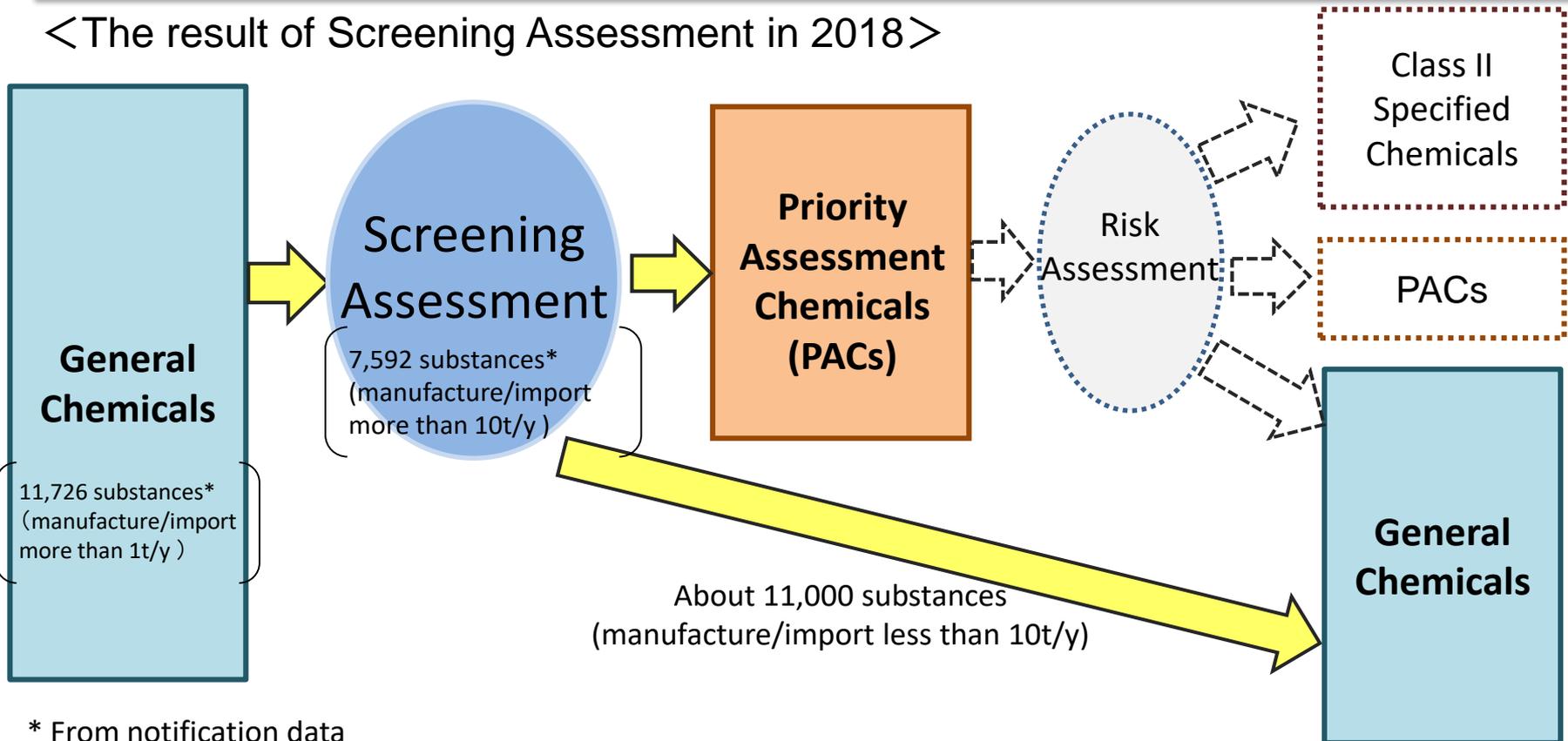
Screening Assessment Flow



Current Situation of Screening Assessment

- The government has conducted screening assessment for general chemicals every year since 2012.
- The number of PACs reached 223 in April 2019.

<The result of Screening Assessment in 2018>



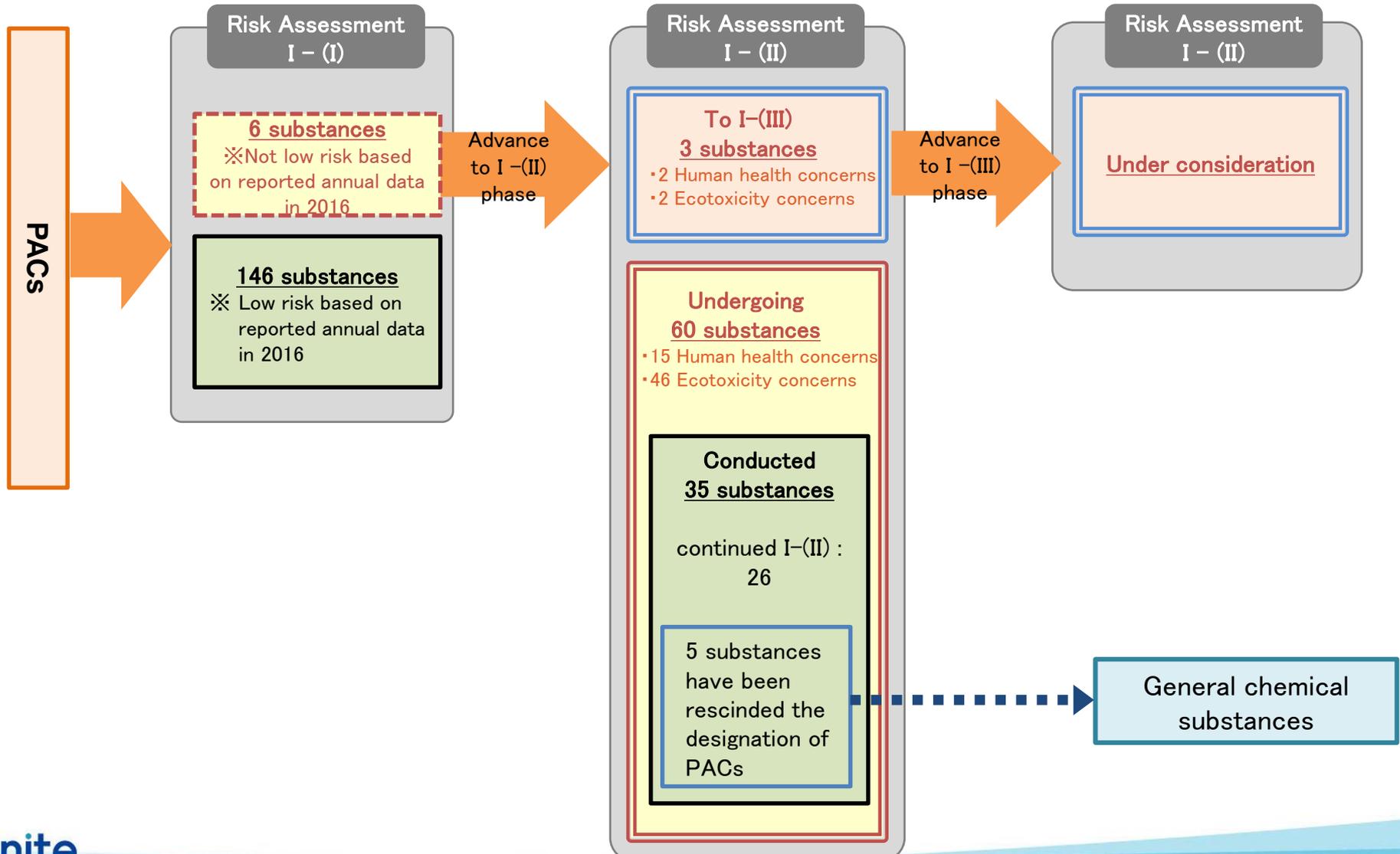
* From notification data in 2016

Detailed Risk Assessment

Phase	Hazard data	Exposure data
Risk Assessment I-(I)	<ul style="list-style-type: none"> ▪ Request for hazardous properties ▪ Report of hazardous properties 	<ul style="list-style-type: none"> ▪ Detailed use categories ▪ PRTR data
Risk Assessment I-(II)	<ul style="list-style-type: none"> ▪ Request for hazardous properties ▪ Report of hazardous properties 	<ul style="list-style-type: none"> ▪ Monitoring data ▪ PRTR data ▪ Examination of estimated emission
Risk Assessment I-(III)	<ul style="list-style-type: none"> ▪ Request for hazardous properties ▪ Report of hazardous properties ▪ Information of handling condition ▪ Additional monitoring data <p>Using such information above, conduct risk assessment precisely</p>	

Current Status of Risk Assessment of PACs

<Current Status of Risk Assessment of PACs in 2018>



Schedule for detailed Risk Assessment

year	No	Chemical Substance Name	Reason for inclusion	Retry
2019	3	n-Hexane	Eco	
	36	Ethylenediaminetetraacetic acid	Eco	
	41	Tetraethylthiuram disulfide (synonym: Disulfiram)	Eco	
	42	N,N'-Ethylenebis(thiocarbamoylthiozinc) bis(N,N-dimethyldithiocarbamate) (synonym: Polycarbamate)	Eco	
	99	N,N-Dimethylpropane-1,3-diyl diamine	Eco	
	129	1,3-Diisocyanato(methyl)benzene	Human Health	
	152	Sodium salts of 2,2',2''-nitrilotriacetic acid	Eco	
	39	Acrylonitrile	Human Health	○
2020	11	1,2-Dichloroethane	Human Health	
	46	Toluene	Human Health	
	166	Salt of hexadecyl(trimethyl)ammonium	Eco	
	167	Salt of didecyl(dimethyl)ammonium	Eco	
	171	Alkanol(C=10-16) (only the substances that contain any of C=11-14 components)	Eco	
	174	[(3-Alkanamido(C=8,10,12,14,16,18, normal chain)propyl)(dimethyl)ammonio]acetate or (Z)-[[3-(octadec-9-enamido)propyl](dimethyl)ammonio]acetate	Eco	
	71	[3-(2-Ethylhexyloxy)propylamine]triphenylboron	Eco	○
	89	Hydrogen peroxide	Eco	○
	94	Acrylic acid	Eco	○
153	N-[3-(Dimethylamino)propyl]stearamide	Eco	○	
2021	17	Tetramethylammonium hydroxide	Human Health	
	142	Copper(I) thiocyanate	Eco	
	164	Alkan-1-amine(C=8,10,12,14,16,18, normal chain), (Z)-Octadec-9-en-1-amine or (9Z,12Z)-Octadeca-9,12-dien-1-amine	Eco	
	172	Sodium salt of saturated fatty acid(C=8-18, normal chain) or unsaturated fatty acid(C=16-18, normal chain)	Eco	
	173	N,N-Bis(2-hydroxyethyl)alkanamide(C=8,10,12,14,16,18, normal chain), (Z)-N,N-bis(2-hydroxyethyl)octadec-9-enamide or (9Z,12Z)-N,N-bis(2-hydroxyethyl)octadeca-9,12-dienamide	Eco	
	175	Sodium alkenesulfonate(C=14-16) or sodium hydroxyalkanesulfonate(C=14-16)	Eco	
	182	2,2-Dibromo-2-cyanoacetamide	Eco	
	217(123)	(1-Hydroxyethane-1,1-diyl)diphosphonic acid or its potassium or sodium salt	Eco	
	19	Ethylene oxide	Human Health	○
	158	2-sec-Butylphenyl N-methylcarbamate (synonym: Fenobucarb or BPMC)	Eco	○

Thank you for your cooperation