Outline and Recent Progress of Chemical Substances Control Law (CSCL)

5 November 2015

Takashi Fukushima

Deputy Director General, Chemical Management Center

National Institute of Technology and Evaluation (NITE)

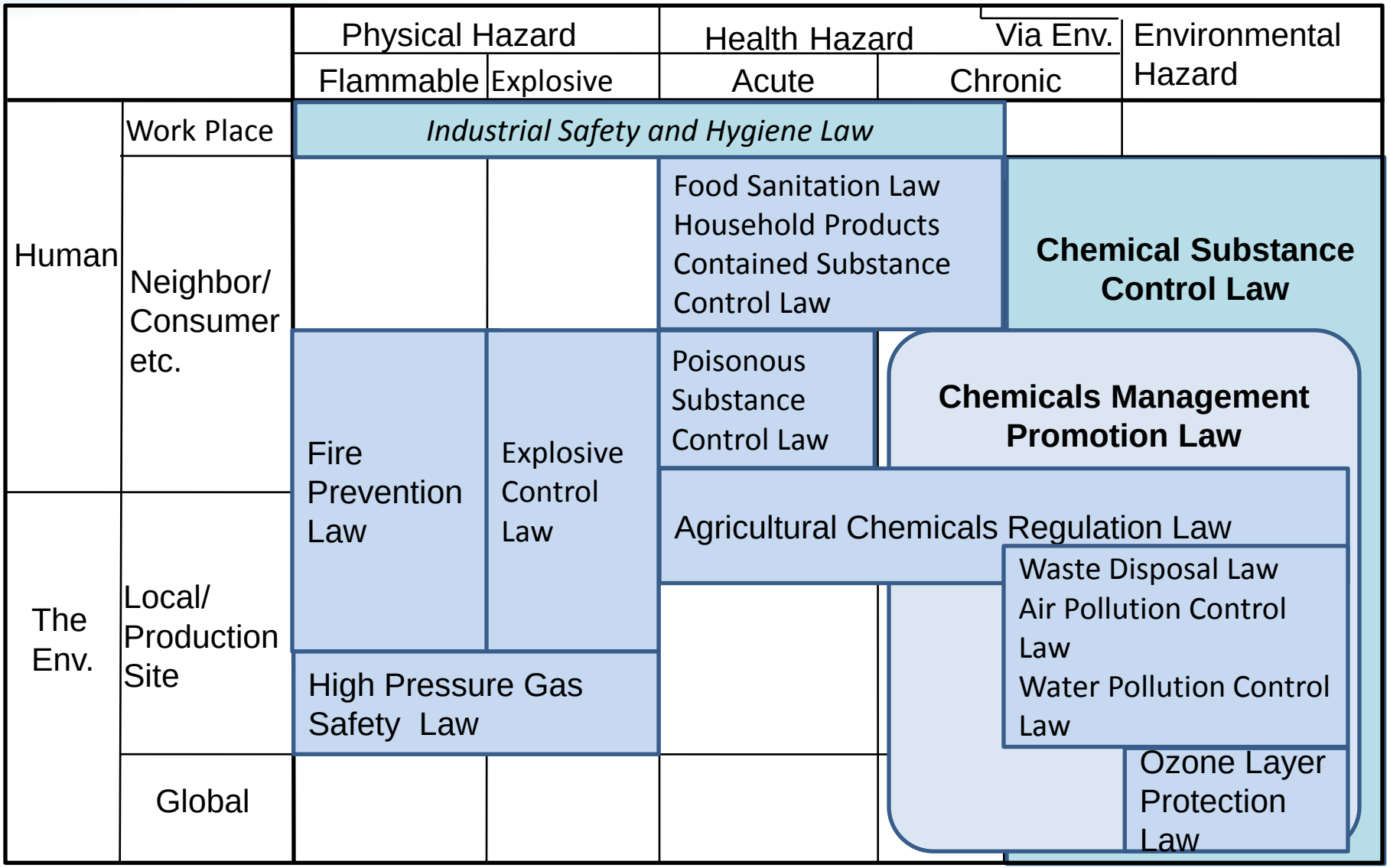
nite

SAHTECH 財團法人 安全衛生技術中心
SAFETY AND HEALTH TECHNOLOGY CENTER

Contents

1. Outline of CSCL

Outline of Chemical Regulation in Japan



What is CSCL in brief

"Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc." is known as "Chemical Substances Control Law (CSCL)"

- Pollution control laws were developed in early 60's.
- PCB contamination case in 1968 triggered the discussion to manage industrial chemicals.
- Implemented in 1973 as a central law to manage industrial chemicals.
- Introduction of new chemical notification scheme and ban of PBT chemicals such as PCB
- Amendments - 1986, 2003 and 2009

Year	Main Points of amendment
1986	Introduction of Class 2 specified chemicals Expansion of dataset for new chemicals (human toxicity)
2003	Expansion of objective of the law to protect ecosystem Expansion of dataset for new chemicals (eco-toxicity)
2009	Introduction of comprehensive assessment of existing chemicals

Purpose and Scope of CSCL

Purpose

- To prevent environmental pollution caused by chemical substances that pose a risk of impairing human health and interfere with the inhabitation and growth of flora and fauna.

Scope

- Chemical substances

  Chemical compounds created by causing chemical reactions.
- Industrial chemicals

  Chemicals that are subject to other laws such as medicine and pesticides are out of scope of CSCL

Outline

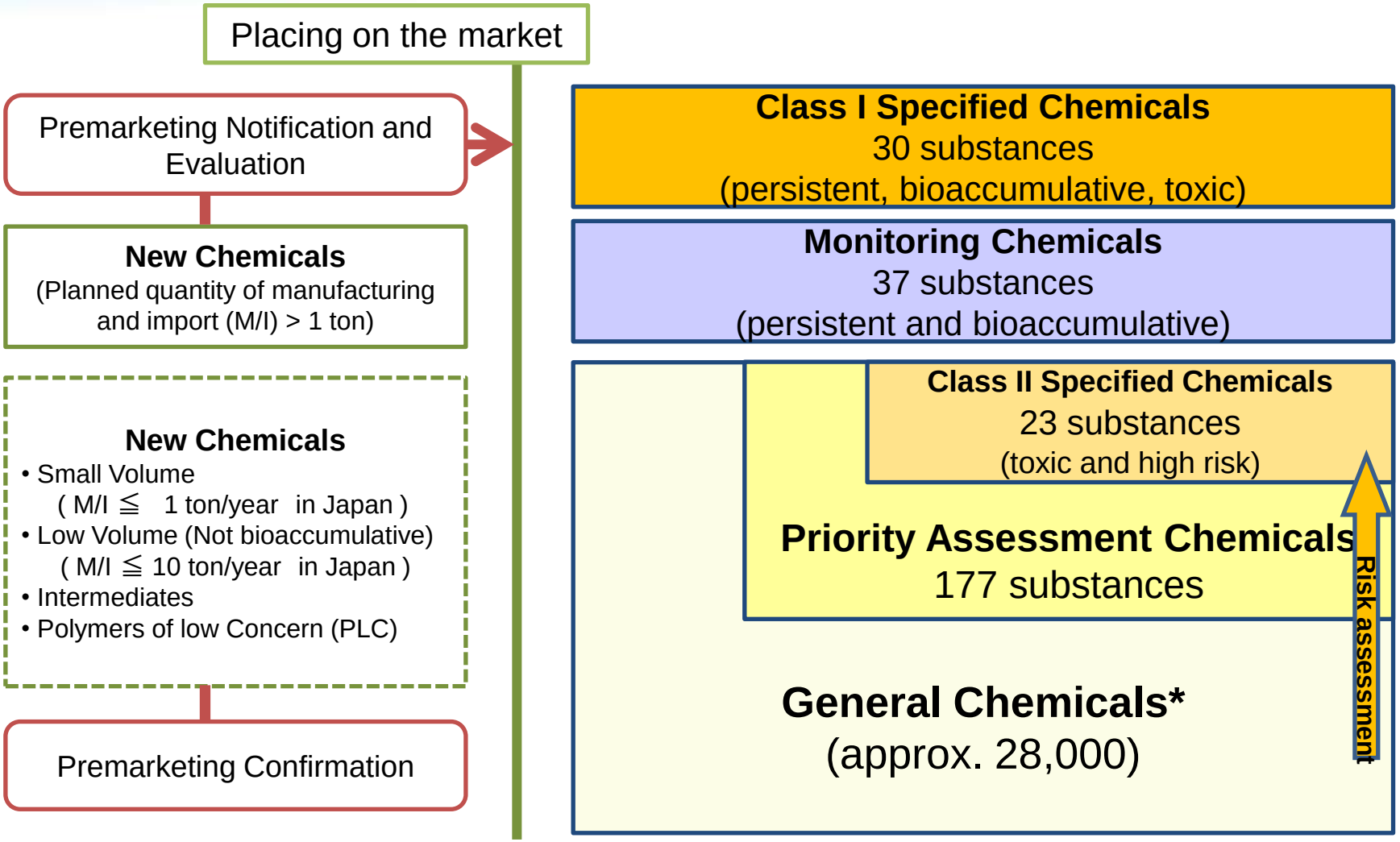
- New Chemicals

  Notification and evaluation by the government are required before manufacture/import.
- Existing Chemicals

  Annual report of manufacture/import volume and use is necessary. The government has been conducting risk assessment based on this annual report and can ask additional toxicity information to the industries if necessary.
- Management of certain chemicals

  Substantial ban of Class 1 specified chemicals (PBTs) etc.

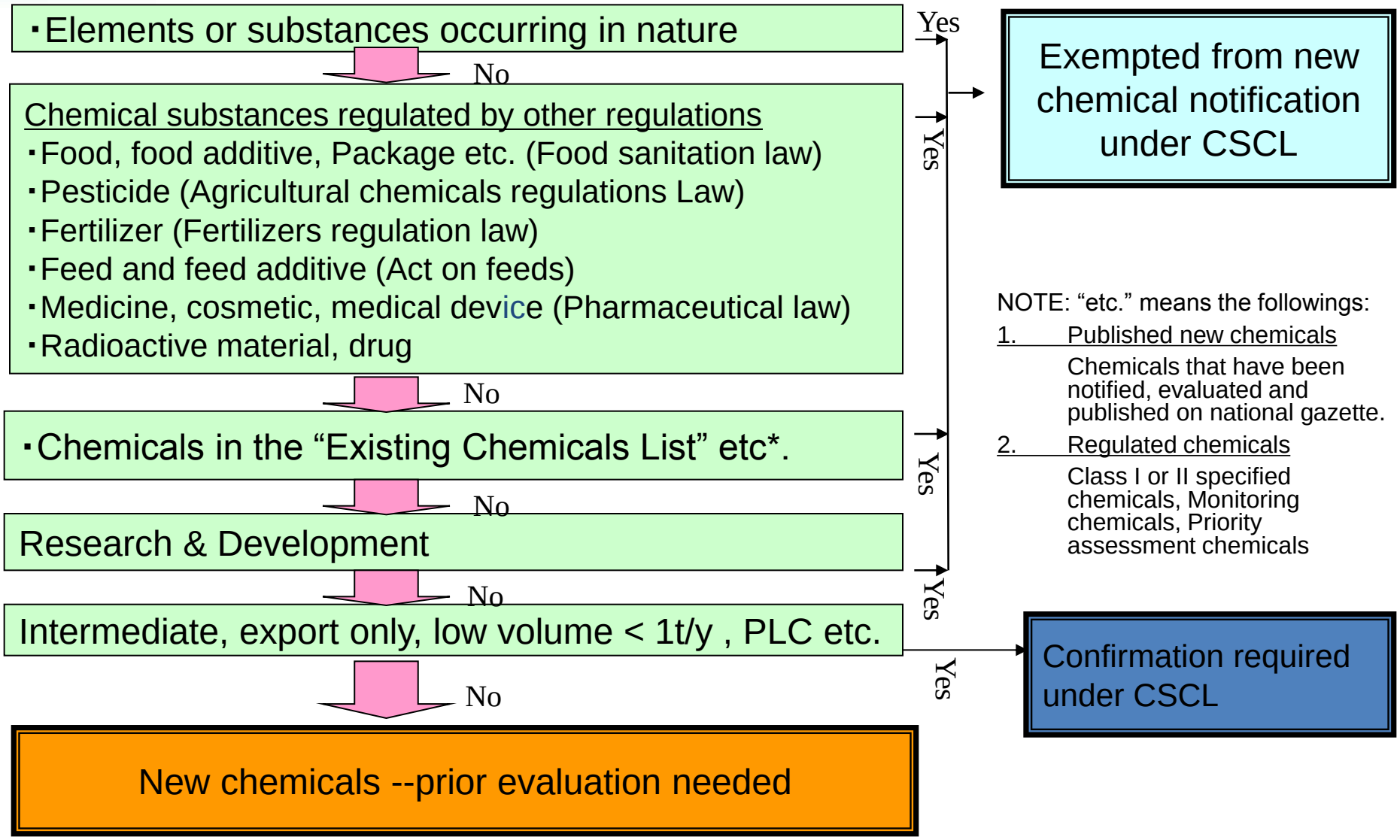
Overview of CSCL



NOTE: “General Chemicals”=“Existing chemical” + “Published new chemicals”
+ “Former Type 2 & Type 3 monitoring” – “Class 1, Class2, monitoring & PACSs”

2. New Chemical Notification

Scope of New Chemical Notification



NOTE: “etc.” means the followings:

1. Published new chemicals
   Chemicals that have been notified, evaluated and published on national gazette.
2. Regulated chemicals
   Class I or II specified chemicals, Monitoring chemicals, Priority assessment chemicals

Pre-marketing Notification vs. Confirmations

Pre-marketing Notification	
Normal Notification	➢ Basic dataset required *(Biodegradation, Bioaccumulation, Toxicity, Eco-toxicity) ➢ No volume limit of manufacture/import ➢ Chemical name will be published in National Gazette
Law Volume Notification	➢ Limited dataset (Biodegradation & Bioaccumulation) ➢ Volume limit (Up to 10 ton/year, all Japan) ➢ Confirmation required (Annual) ➢ No publication in National Gazette
Confirmations	
Small Volume	➢ Confirmation required (Annual)
PLC	➢ PLC Confirmation required (Test result of “Polymer flow scheme” required) ➢ No publication in National Gazette
Intermediate	➢ One time confirmation ➢ Applicable in the same company ➢ Detail documentation required
Closed System	➢ One time confirmation ➢ Detail documentation required
Export Only	➢ One time confirmation ➢ Limited export destinations ➢ Detail documentation required
Small Volume Intermediate/Export only	➢ One time confirmation ➢ Documentation requirement is reduced

Required Tests for New Chemical Notification

Required test	OECD TG
Biodegradation test	TG301C
Partition coefficient test	TG107, TG117
BCF test (if Log Pow>3.5)	TG305
Ames test	TG471
Chromosomal aberration test	TG473
28days repeated dose toxicity test	TG407
Acute fish toxicity test	TG203
Acute daphnia immobilization test	TG202
Algae growth inhibition test	TG201

If biodegradable and degradation products are not identified.

Less than 10 tons

If degradation products are identified, tests of the products are required.

NOTE: Certain flexibility may be applied.
Other methods for BCF assessment are applicable.

New approaches to bioaccumulation assessment

1. Bioaccumulation Assessment by using QSAR and Read-across

A chemical can be considered not highly bioaccumulative if the chemical fulfils the following conditions:

(1) Chemical A is similar in structure to Chemical B (specifically as follows):

i) Chemical A has the same basic skeleton as Chemical B and chemical A's structure is partially changed from compound B, or

ii) Chemical A is an isomer of Chemical B.

(2) Measured BCF (bio-concentration factor) of chemical B < 500.

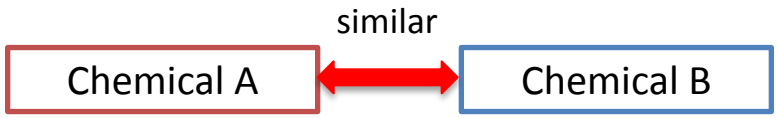
(3) Bioaccumulation of chemical A is estimated in a rational way to be almost the same as or lower than chemical B based on their chemical structure. (specifically as follows)

i) Calculated BCF by using QSAR of chemical A is almost the same as or lower than measured and calculated BCF of chemical B.

ii) Two or more similar chemical B have measured BCF <100.

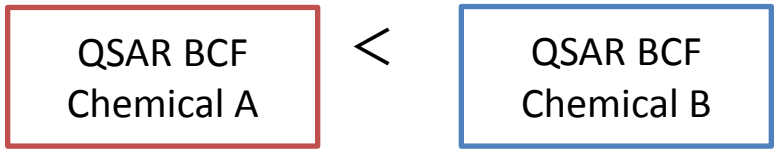
Case 1

(1) Chemical Structure



(2) Measured BCF

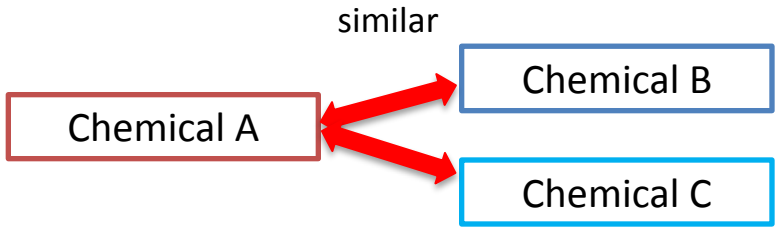
(3) Calculated BCF by using QSAR



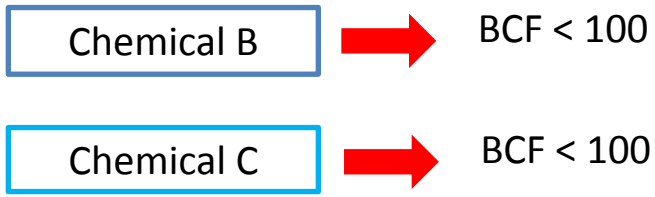
※ Recommended QSAR model is either BCFBAF (EPI SUITE) or BCF base-line model (OASIS Catalogic).

Case 2

(1) Chemical Structure



(2) Measured BCF



※ Measured BCF data of previously assessed new chemicals are available on NITE's website in September 2014 in order to facilitate the above approach.

2. Bioaccumulation Assessment Based on the Comparison of Hydrophilicity (Polarity) by HPLC

A chemical can be considered not highly bioaccumulative if the chemical fulfils the following conditions:

(1) Chemical A is similar in structure to chemical B. (specifically as follows):

i) Chemical A has the same basic skeleton as Chemical B and chemical A's structure is partially changed from compound B, or

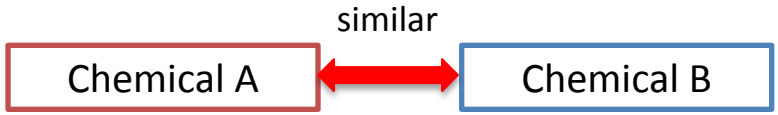
ii) Chemical A is an isomer of Chemical B.

(2) Measured BCF of chemical B is < 500.

(3) It is observed that chemical A is more hydrophilic (polar) than chemical B by reversed-phase HPLC.

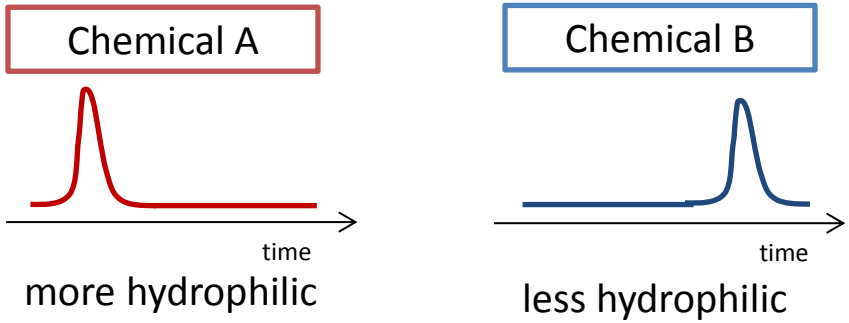
Case 3

(1) Chemical Structure



(2) Measured BCF

(3) Comparison of Hydrophilicity (Polarity) by reversed-phase HPLC



※ This approach is not applicable to surfactants, organic metallic compounds, low purity compound and inorganic compound.

3. Bioaccummulation Assessment of Ionic substances using Log D

<Background>

- If log Pow is <3.5, that substance is assessed to be not highly bioaccumlative.
- However, OECD TG107 (Shake-Flask method) and TG117 (HPLC method), log Pow should be measured in undissociated state.
- It means measuring log Pow of ionic substances in undissociated state is difficult although ionic substances are less bioaccumulative in general.
- In order to simplify bioaccumulation assessment of ionic substances, a new assessment guidance use log Dow (the partition coefficient determined around a pH of 7) was made available.

If log Dow of an ionic compound (e.g. sulfonic acids, carbonic acids, zwitterionic substances, quaternary amines, etc.) which is difficult to measure log Pow in undissociated state is < 2.5, that chemical substance can be assessed to be not highly bioaccumulative.

This method can not apply to any compounds which partially includes trifluoromethyl (CF3-) or tetrafluoroethylene (-CF2-CF2-) structure in their structure.

※Under this method, “an ionic compound which is difficult to measure log Pow in undissociated state” means, in principle, a compound whose pKa is less than 3 for acids and more than 11 for bases.

※This method does not apply to surfactants, mixture which has distribution of molecular weight, organic metallic compound, low purity compound (except for HPLC method) and inorganic compound.

※Prier consultation with METI/NITE is highly recommended.

※Both Shake-Flask method and HPLC method are applicable to measure log Dow.

A New Rule for Small Volume Intermediate/Export only

- A new confirmation rule for new chemicals, “Small Volume Intermediates/Export Only” started in October 2014.
- This is the new rule for small volume and intermediate chemicals to be exempted from normal new chemical assessment procedure under CSCL.

Small Volume Intermediate/Export only

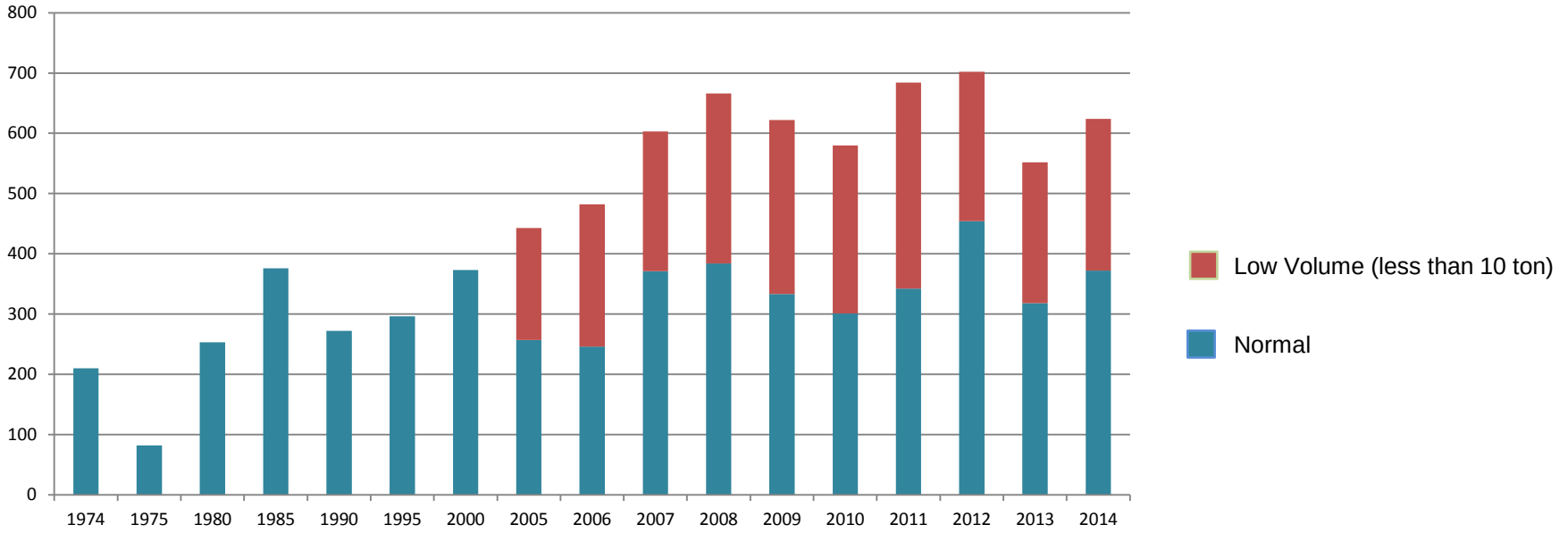
- A company that intends to manufacture/import a new chemical substance for intermediates, of less than or equal to 1 ton/year can get confirmation from the government.
- This company with this confirmation can manufacture/import this new chemical substance for intermediates, of less than or equal to 1 ton/year without normal assessment procedure by the government.

Characteristic:

- There is already “Intermediate” rule for exemption, but it needs time to get confirmation and many application documents are required.
- Getting confirmation of “Small Volume Intermediates” is much easier and faster than getting confirmation of “Intermediate.”

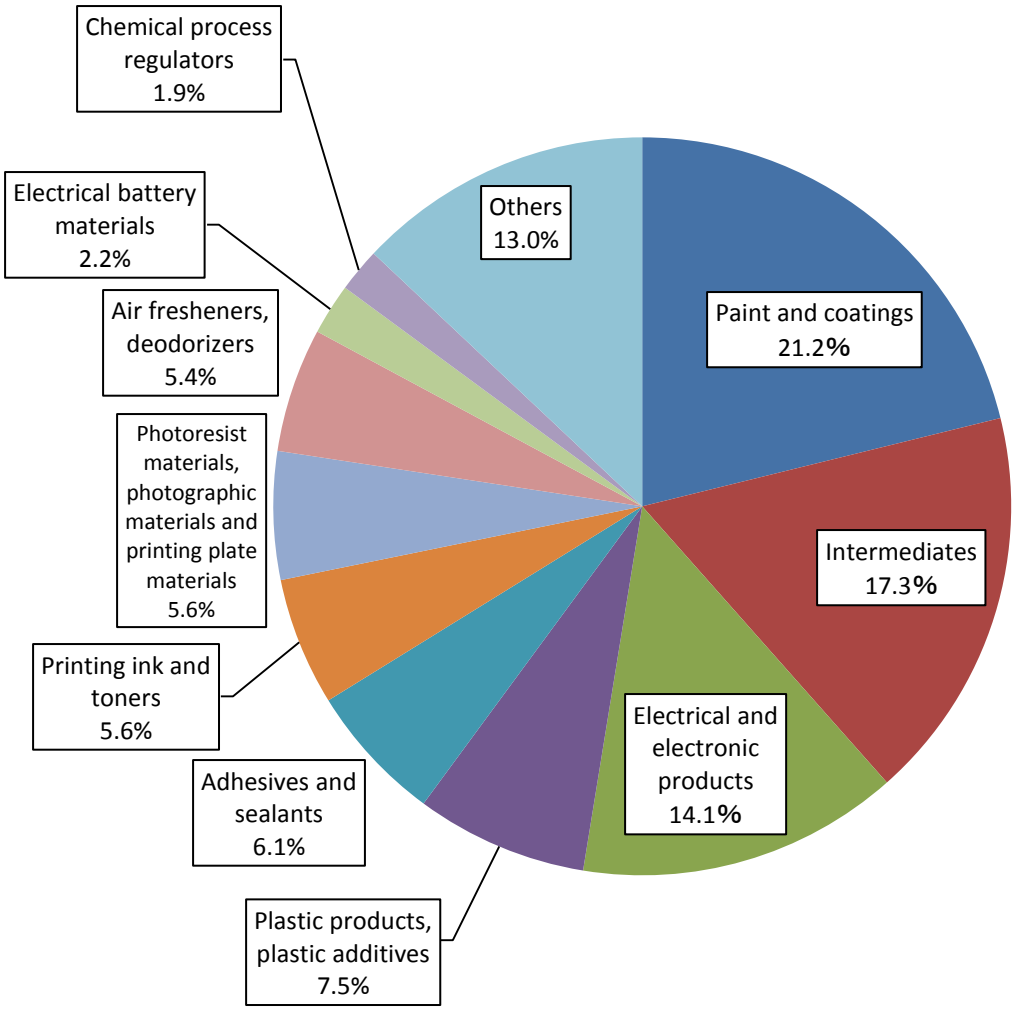
Trend of Evaluation of New Chemicals

- The number of evaluation of new chemicals has been around 600, and low volume accounts for about 40%.
- About 60% of normal evaluation chemicals is for polymers.



	1974	1975	1980	1985	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Manufacture	114	45	160	286	218	223	291	349	381	452	502	440	402				
Import	96	37	93	90	54	73	82	94	101	151	164	182	151				
Manufacture/ Import													27	684	702	552	624
Total	210	82	253	376	272	296	373	443	482	603	666	622	580	684	702	552	624

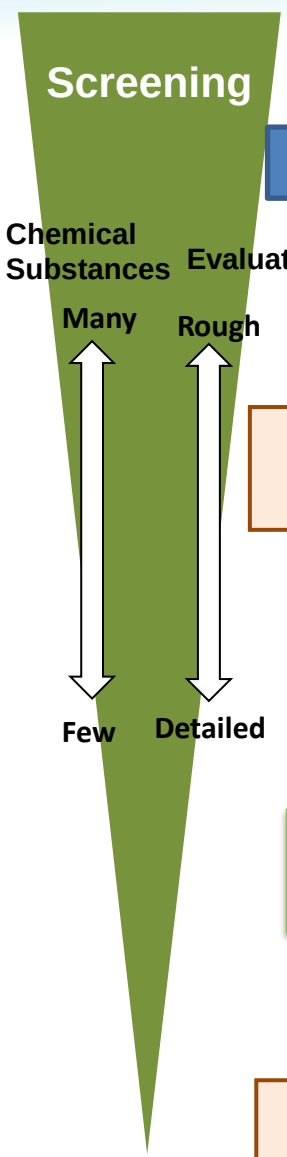
Uses of New chemicals (notified in 2014)



Use Category	#	%
Paints and coatings	132	21.2%
Intermediates	108	17.3%
Electrical and electronic products	88	14.1%
Plastic products, plastic additives	47	7.5%
Adhesives and sealants	38	6.1%
Printing ink and toners	35	5.6%
Photoresist materials, photographic materials and printing plate materials	35	5.6%
Air fresheners, deodorizers	34	5.4%
Electrical battery materials	14	2.2%
Chemical process regulators	12	1.9%
Others	81	13.0%
Total	624	

3. Existing Chemical Assessment

Flow of Risk Assessment of Existing Chemicals



General Chemical Substances

Annual Manufacture Volume Reporting

Screening Assessment

Screening assessment based on exposure and hazard using prioritization matrix

Not Low Risk

Designate as Priority Assessment Chemicals (PAC)

Risk Assessment Ⅰ - (I)

Prioritization by using detailed sales volume and use category

Risk Assessment Ⅰ - (II)

Detailed risk assessment by using PRTR data and environmental monitoring data.

Not Low Risk

Request to conduct Toxicity Testing

Risk Assessment Ⅱ

Final risk assessment to make decision

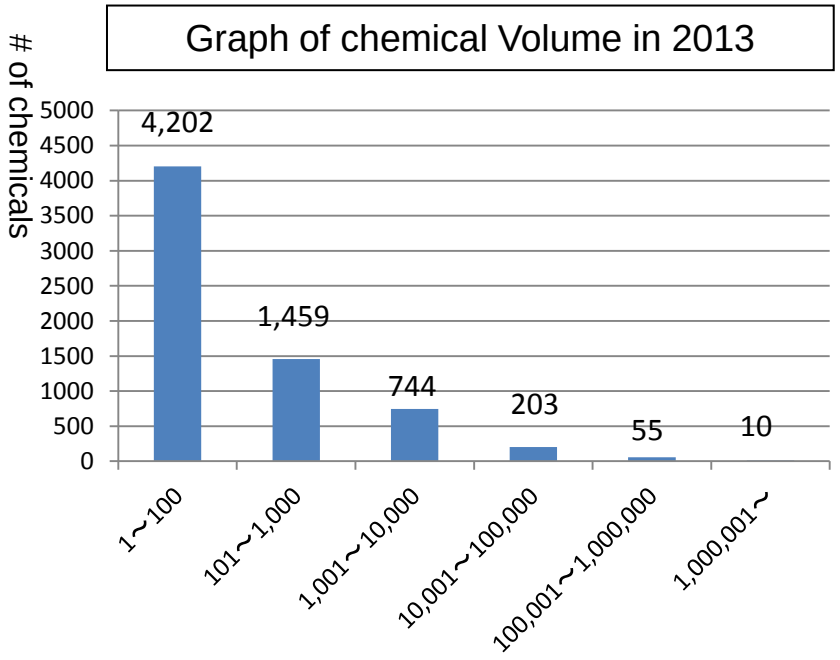
High Risk

Designate as Class II Specified Chemicals

The Result of Annual Volume Reporting (in 2013)

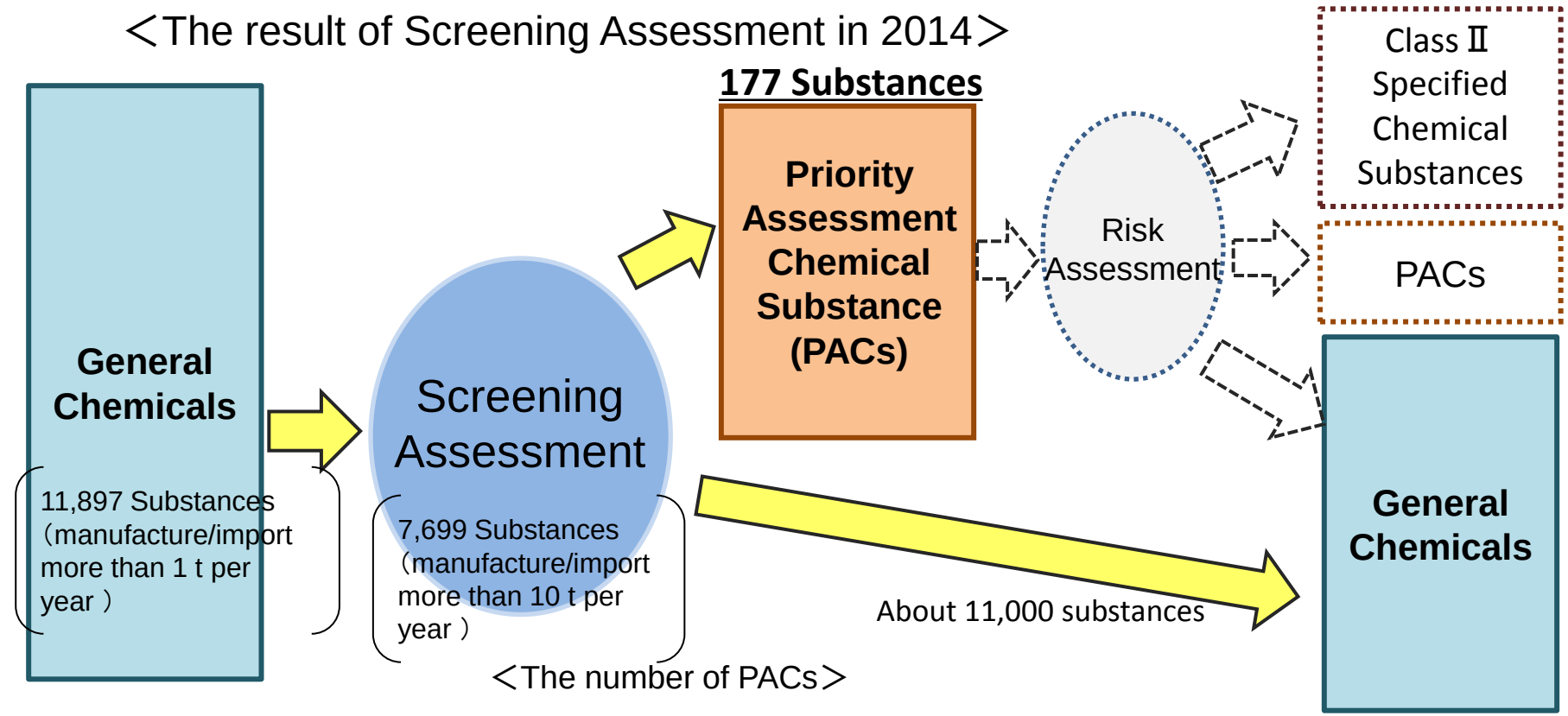
- Annual Volume Reporting introduced in the latest revision of CSCL started in 2011.
- The companies have to submit date such as manufactured volume and use to METI.
- Total number of annually reported chemicals has been around 7,000.
- Most of chemicals are manufactured less than 100 ton/year.

Manufacture/ Import year	# of Companies	# of Chemicals
2010	1,422	6,813
2011	1,406	7,067
2012	1,361	6,728
2013	1,348	6,673



✓ Volume in 2013 is reported in 2014.
✓ Since some companies manufacture the same chemical, the total reported number is about 30,000
✓ # of chemicals is “CSCL number” base.

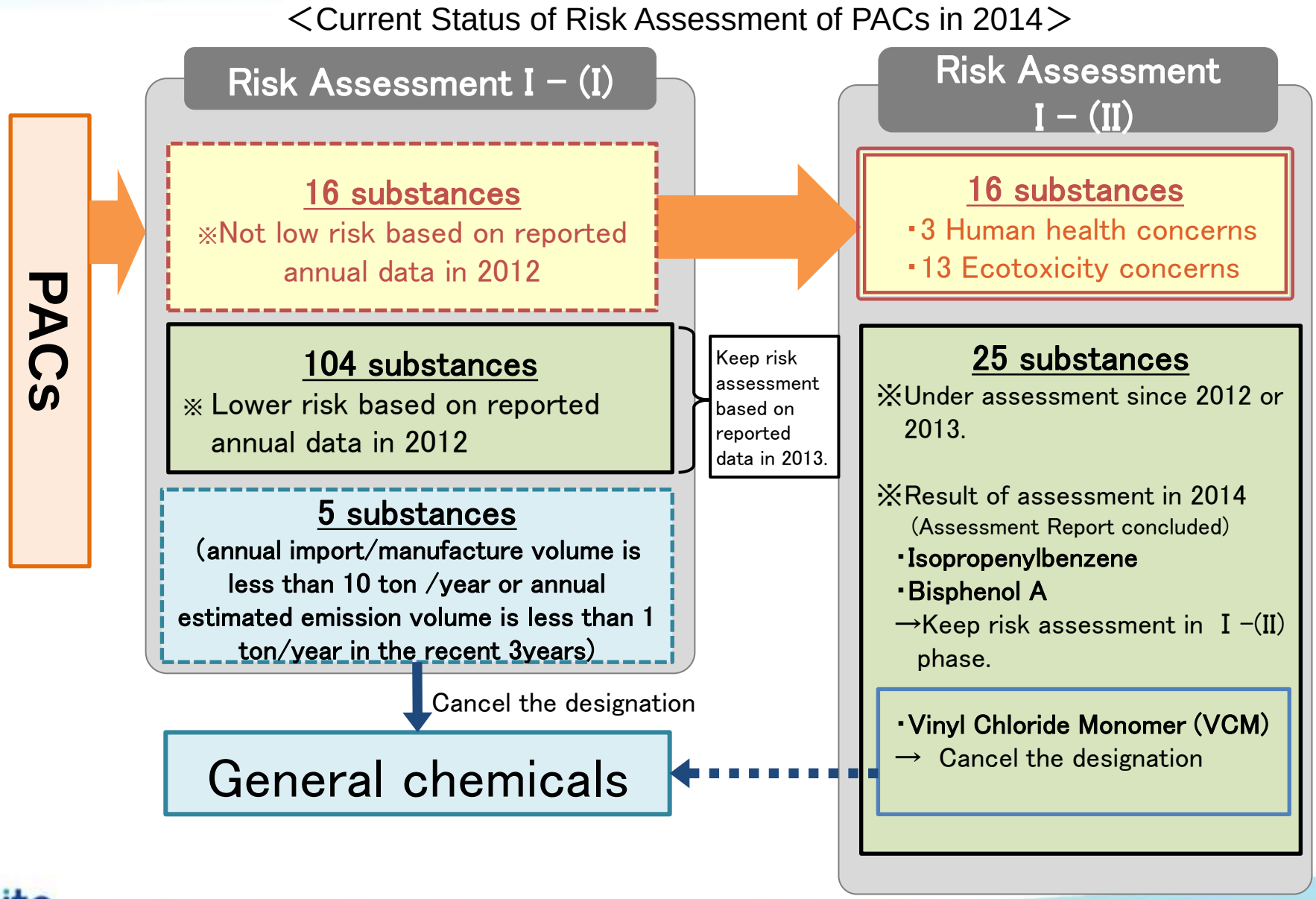
Current Situation of Screening Assessment



※ Most of assessment units are CAS.

	Total	(Human health)	(Ecotoxicity)
Oct. 2013	140	111	45
Oct. 2014	164	122	57
April 2015	177	122	77

Current Status of Risk Assessment of PACs



PAC undertaken for the Screening Assessment Ⅰ–(II) from FY2014

PAC undertaken for the Screening Assessment Ⅰ–(II) from FY2014;
(3 Chemical substances from a perspective on the effects to human health/ 13 substances from a perspective on the effects to eco-system）

Name of PACs	Perspective s
Carbon disulfide	Human health
Tetraethylthiuram disulfide (Synonym; Disulfiram)	Eco-system
N,N'-Ethylenebis(thiocarbamoylthiozinc) bis(N,N-dimethyldithiocarbamate) (Synonym; polycarbamate)	Eco-system
Aniline	Human health
4,4'-Diamino-3,3'-dichlorodiphenylmethane (Synonym; 4,4'-Methylenebis(2-chloroaniline)	Human health
N,N-Dimethylpropane-1,3-diyldiamine	Eco-system
N,N-dimethyldodecylamine N-oxide ***	Eco-system
Dodecan-1-ol ***	Eco-system
Trisodium 2,2',2''-nitrilotriacetate	Eco-system
2-[3-(Dodecanoylamino)prop-1-yl(dimethyl)aminio]acetate ***	Eco-system
Xylene	Eco-system
Benzyl benzoate	Eco-system
(R)-4-Isopropenyl-1-methylcyclohex-1-ene (Synonym; d-limonene)	Eco-system
1,3,5-Trichloro-1,3,5-triazinane-2,4,6-trione	Eco-system
(T-4)-Bis[2-(thioxo-kappaS)-pyridin-1(2H)-olato-kappaO]zinc(II)	Eco-system
Sodium alkylbenzenesulfonate(The alkyl is limited to the substituent groups derived from linear alkane of C=10-14.)	Eco-system

*** a withdrawal of PAC because of its inclusion in other PACs

Future schedule on Risk Assessment Ⅰ–(II) ①

【PAC to be discussed in the Council in FY2015：7 substances】

Name of PACs	Perspective s
1,3-Butadiene	Human health
1,2-Epoxypropane (Synonum ; propylene oxide)	Human health
n-Butyl acrylate	Eco-system
Acrylonitrile	Human health
1,2,4-Trimethylbenzene （Discussed on July 24, 2015）	Eco-system
p-Dichlorobenzene	Eco-system
2,6-Di-tert-butyl-4-methylphenol（Discussed on July 24, 2015）	Eco-system

【 PACs to be discussed in the Council in FY2016：15 substances】

Hydrazine	Human health , Eco-system
Dichloromethane (Synonym ; Methylene chloride）	Human health
Bromomethane (Synonym; Methyl bromide)	Eco-system
1,2-Dichloropropane	Human health
1,3-Dichloropropene (Synonym; D-D)	Eco-system
Ethylene oxide	Human health
Formaldehyde	Human health
Benzene	Human health
Naphthalene	Eco-system
Hydrogen peroxide	Eco-system
Benzyl benzoate	Eco-system
(R)-4-Isopropenyl-1-methylcyclohex-1-ene (Synonym; d-limonene)	Eco-system
1,3,5-Trichloro-1,3,5-triazinane-2,4,6-trione	Eco-system
(T-4)-Bis[2-(thioxo-kappaS)-pyridin-1(2H)-olato-kappaO]zinc(II)	Eco-system
Sodium alkylbenzenesulfonate(The alkyl is limited to the substituent groups derived from linear alkane of C=10-14.)	Eco-system

Future schedule on Risk Assessment Ⅰ–(II) ②

【 PACs to be discussed in the Council in FY2017： 16 substances】

Name of PACs	Perspective s of the assessment
Carbon disulfide	Human health
N,N-Dimethylformamide	Human health
Tetraethylthiuram disulfide (Synonym; disulfiram)	Eco-system
N,N'-Ethylenebis(thiocarbamoylthiozinc) bis(N,N-dimethyldithiocarbamate) (Synonym; polycarbamate)	Eco-system
Aniline	Human health
o-Toluidine	Human health
[3-(2-Ethylhexyloxy)propylamine]triphenylboron	Eco-system
4,4'-Diamino-3,3'-dichlorodiphenylmethane (Synonym; 4,4'-Methylenebis(2-chloroaniline)	Human health
alpha-(Nonylphenyl)-omega-hydroxypoly(oxyethylene) (Synonym; Polyoxyethylene nonylphenyl ether)	Eco-system
Acrylic acid	Eco-system
N,N-Dimethylpropane-1,3-diyldiamine	Eco-system
Xylene	Eco-system
Sodium salts of 2,2',2''-nitrilotriacetic acid	Eco-system
N,N-Dimethylalkan-1-amine oxide (C=10,12,14,16,18, normal chain), (Z)-N,N-dimethyloctadec-9-en-1-amine oxide or (9Z,12Z)-N,N-dimethyloctadeca-9,12-dien-1-amine oxide	Eco-system
Alkanol(C=10-16) (only the substances that contain any of C=11-14 components)	Eco-system
[(3-Alkanamide(C=8,10,12,14,16,18, normal chain)propyl)(dimethyl)ammonio]acetate or (Z)-{[3-(octadec-9-enamido)propyl](dimethyl)ammonio}acetate	Eco-system

※The future schedule is subject to change due to the latest information available, etc.

4. Other topics

New designation on Class I Specified Chemicals

○ PCNs(Polychlorinated Naphthalenes) and PCPs(pentachlorophenol and its salts and esters) were decided to prohibit* internationally on their manufacture and use in principle based on the Stockholm Convention on POPs (POPs convention). Taking into account, Japanese Government will amend the Cabinet Order of CSCL and plan to designate them as Class I specified chemicals under CSCL.

*elimination

Note: PCNs only containing 2 Chlorine atoms will be designated as Class I Chemicals because "PCNs (only those containing more than 2 chlorine atoms in the molecule)" has already designated as CLASS I Chemicals under CSCL .

○Future Schedule

・Around Spring in 2016

Prohibition on manufacture, import and use of PCNs only containing 2 Chlorine atoms and PCPs.

・ Around Autumn in 2016

Prohibition on import of the following products containing PCNs only containing 2 Chlorine atoms and PCPs.

＜PCNs＞

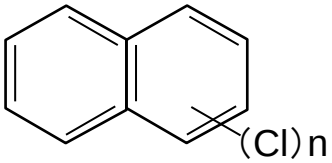
①Lubricant, Cutting fluid ②Wood Preservatives, repellents and fungicides, ③Paints(using for preserving, repelling and antimolding）

＜PCPs＞

① Wood Preservatives, repellents and fungicides ②Treated woods by preservatives, repellents and fungicides

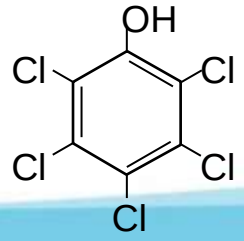
③ Plywood treated with preservatives, insecticides and fungicides ④Glue

（PCNs）



※n is 2 or more.

（PCPs）



Future approach to the implementation issues under CSCL

1. Steady implementation of the risk assessment on General Chemicals and PACs

In order to implement on the risk assessment(screening assessment) of general substances step by step, Japanese government(JG) is to organize and utilize its collected information corresponding to a request on provision of hazard information, etc., as well as consider to apply default value of hazard class, etc. concretely. In addition, in order to steadily advance risk assessment on PACs, JG is to consider developing a suitable schedule as well as, if a lack of available hazard information is expected, to request a submission of test results based on the Paragraph 1 of the Article 10 under CSCL.

2. Further rationalization of a review scheme on new chemicals

JG is to continuously consider how to rationalize a review scheme on new chemicals.

3. Appropriate measures taken into consideration of discussion based on POPs convention

JP is to contribute on a discussion of adding a new substances to POPs substance list in POPs review committee by actively providing information as well as, if substances are added in the POPs substance list, to promptly consider their designation as Class I Specified Chemical Substances under the CSCL.

4. Establishment of review committee on execution status of CSCL

Review Committee on execution status of CSCL were established in August 2015 in light of 5 years passing in April 2016 from the enforcement of amended CSCL in 2010(Entry into force on April 1, 2013). The Committee will preliminary review and discuss the execution status, in advance of the discussion in the related councils, in order to review it based on the Article 6 in supplementary provision, and will summarize the discussion issues etc. The committee will hold meetings around 5 times within FY2015.

Thank you !

謝謝