

**Gestión global de la seguridad de productos químicos. ¿Se aplica REACH globalment?
2 de Febrero 2018, ICEX España Exportación e Inversiones**

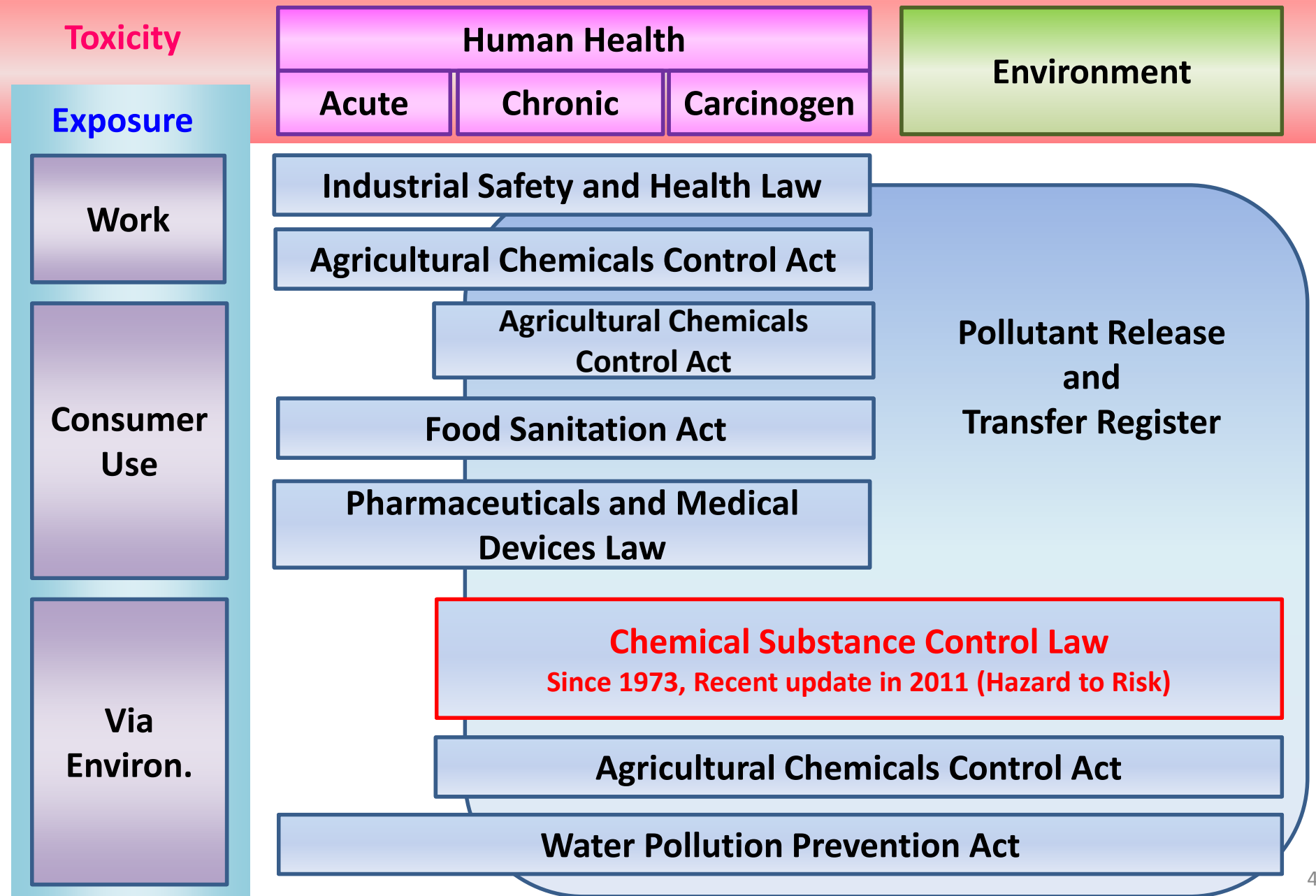
Chemical Substance Control Law; CSCL Japan

**Takahiro Suzuki
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- 1. What is Chemical Substance Control Law?**
- 2. CSCL in Detail**
 - Safety Studies**
 - Risk Assessment**
 - Polymer Flow Scheme**
- 3. Summary -in comparison with REACH-**

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Brief Overview of Chemical Laws in Japan



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 or growth of flora and fauna.

Scope

Chemical substances

Chemical substance created through chemical reactions.

Industrial chemicals

Chemicals that are subject to other laws such as medicines, cosmetics and pesticides etc. are outside the scope of CSCL.

Outline

New chemicals

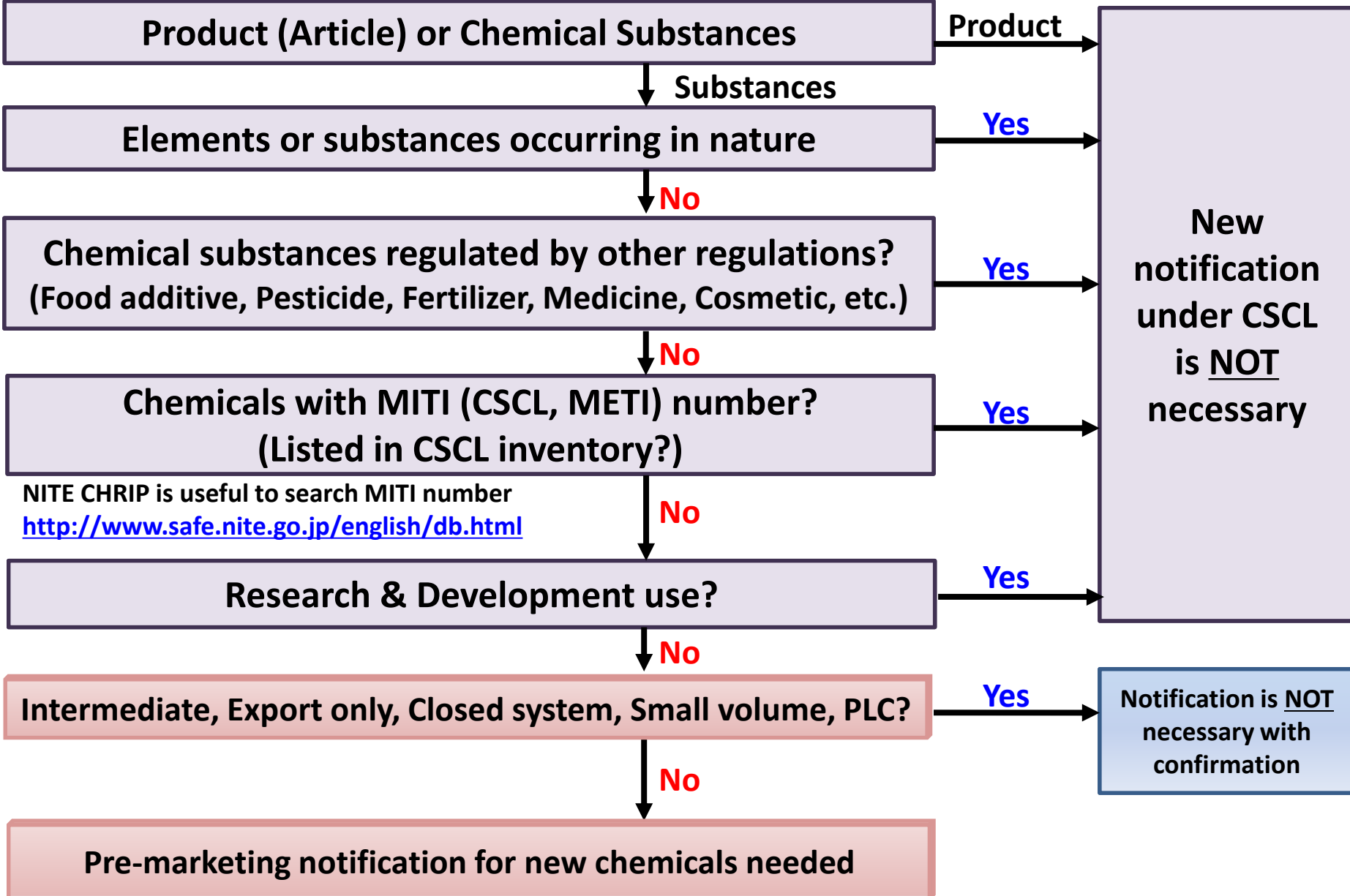
Notification to and evaluation by the government are required before manufacture/import.

Existing chemicals

Annual report of manufacture/import volume and usage is mandatory. The government conducts risk assessment based in this annual notification and may request additional toxicity information to the manufactures/importers if necessary.

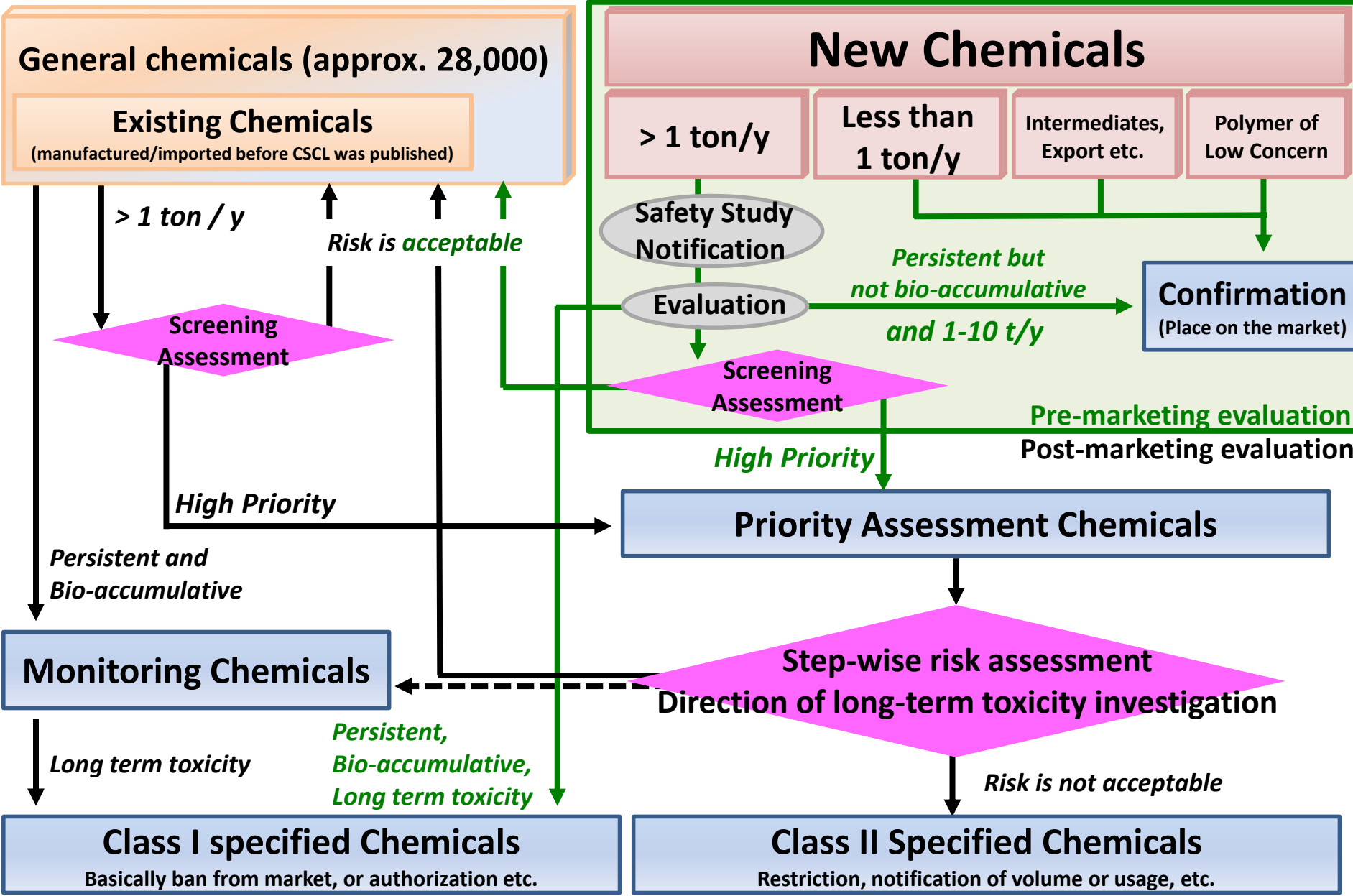
If the chemicals are already listed in CSCL inventory, no new notification is required.

New Notification is necessary?



Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>

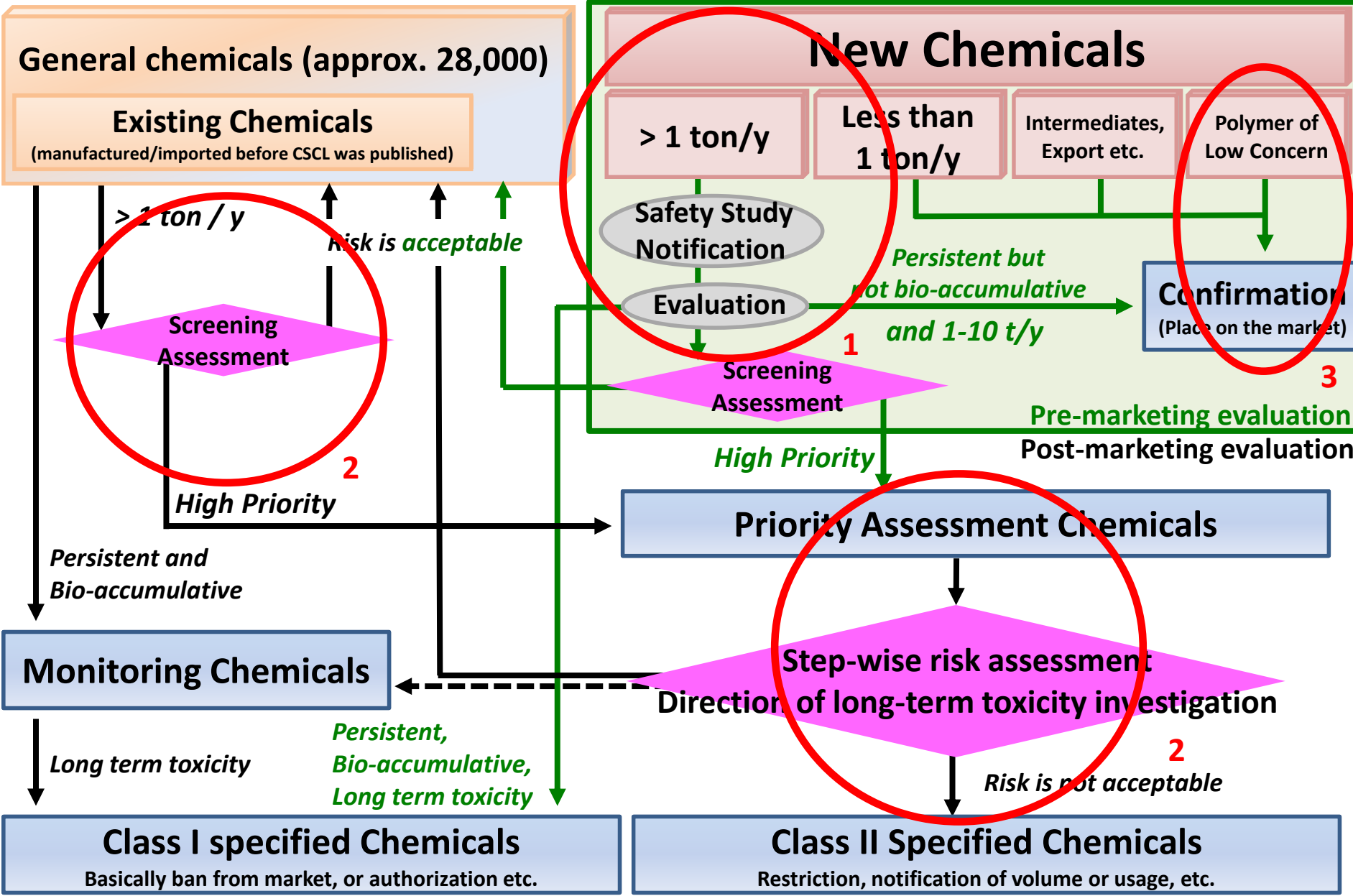
Evaluation / Assessment Flow



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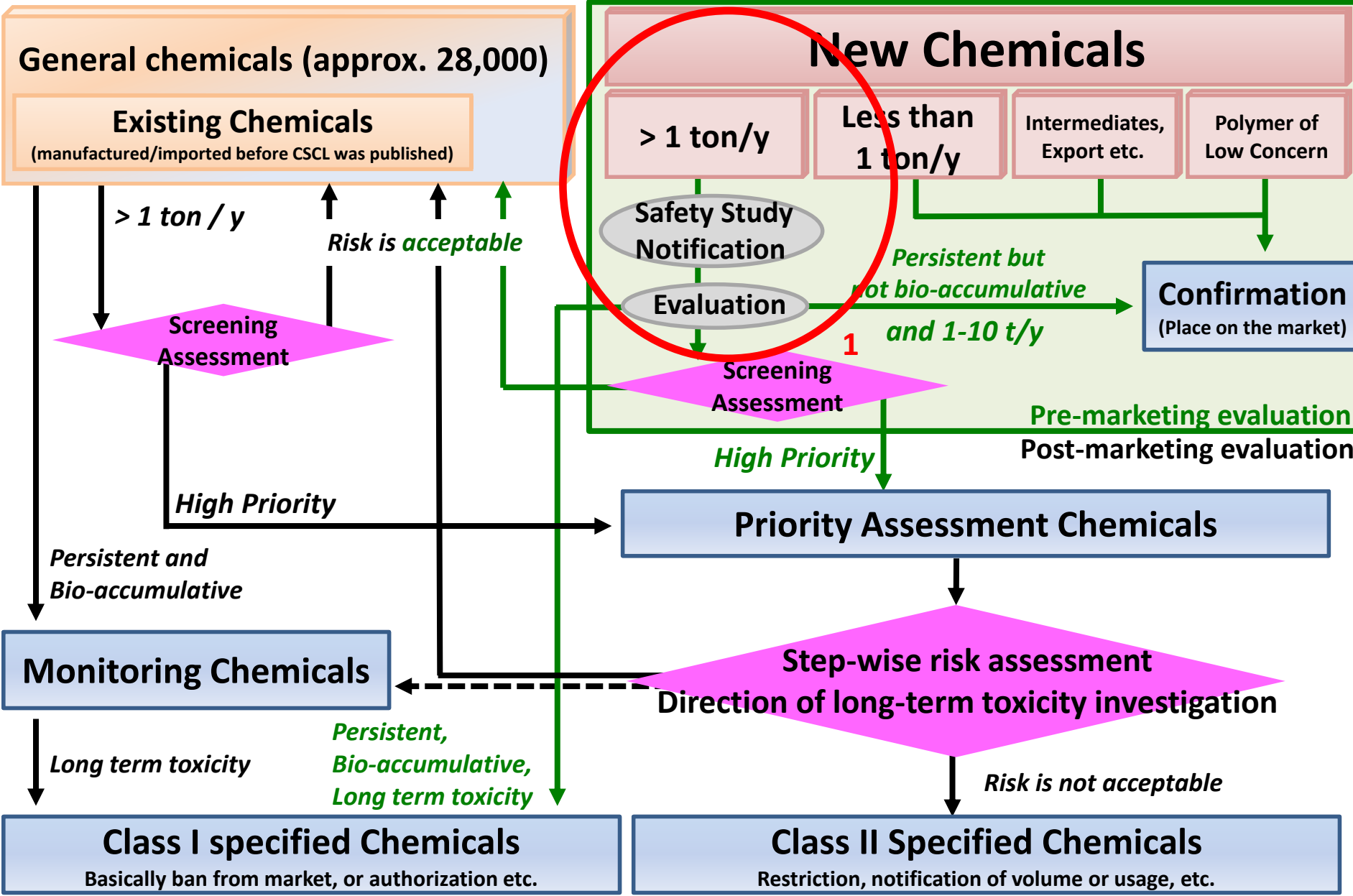
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Flow of Safety tests (>1 ton/y)

Biodegradation OECD TG 301C

Ready (Good) Biodegradable
(>60%, No metabolites remained)

YES

No further tests needed
Results are considered for screening assessment

NO

Remaining substance should be identified and subjected to following tests

Log Pow
OECD TG 107, 117

BCF test
OECD TG 305-I, II

Long term toxicity
Such as OECD TG 206, 414, 416, 417, 451, 452 are considered

<3.5

NO

YES

<5,000*

NO

YES

These results are considered for Class I evaluation

Tonnage band: 1-10 t / y?

YES

No further tests needed
(Premarketing Confirmation)

NO

Toxicity to Human

Eco-toxicity

- 28 days repeated dose test OECD TG 407
- Ames test OECD TG 471
- Chromosomal aberration test OECD TG 473 or 476

- Algal growth inhibition test OECD TG 201
- Acute daphnia immobilization test OECD TG 202
- Acute fish toxicity test OECD TG 203

*If BCF value exceeds 1,000, other information such as discharge rate is considered.

These results are considered for screening assessment

Biodegradation OECD TG 301C

The most stringent test condition in OECD 301 Series

Reason 1: Test concentration and sludge

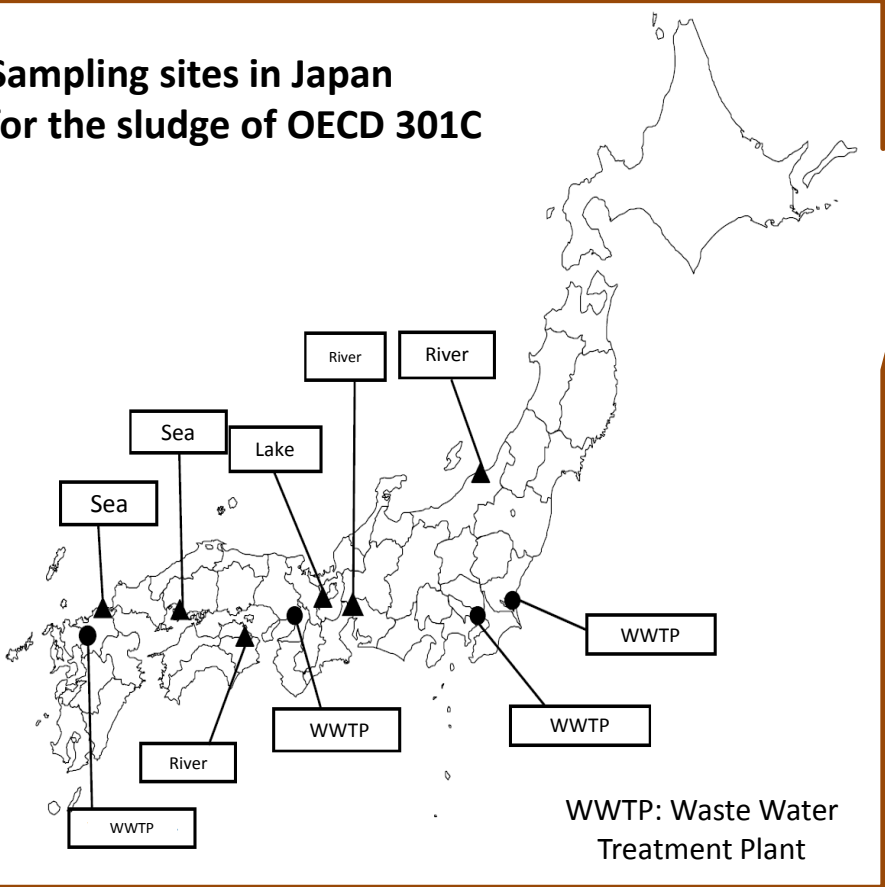
Test concentration: 100 mg/L

Inoculum concentration: 30 mg/L

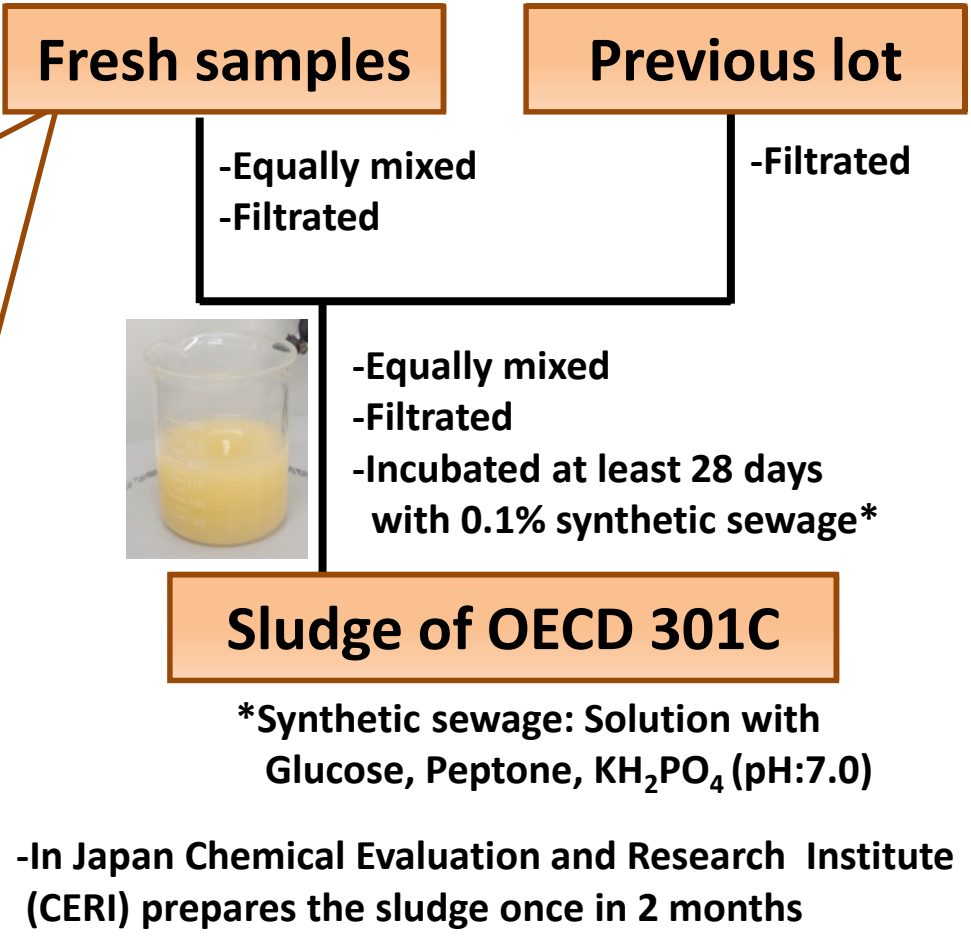
Inoculum: Collect fresh samples from no fewer than 10 sites, mainly in areas where a variety of chemicals are used and discharged. From site such as sewage treatment works, rivers, lakes, seas, sludges, etc. and mix through together

Biodegradation-Inoculum-

Sampling sites in Japan for the sludge of OECD 301C



http://www.meti.go.jp/meti_lib/report/2014fy/E004405.pdf



From our experience, the degradation activity of the sludge is lower than the sludges from WWTP

Biodegradation-Criteria-

Reason 2: Judgment criteria of ready (good) biodegradation

**In at least 2 out of 3 vessels, BOD degradation (%) must be >60%,
and the average BOD degradation (%) must be >60%**

+

No parent chemicals, or metabolites are remained (confirmed by HPLC or GC)

**Besides of BOD and DOC, chemical analysis must be conducted to
quantify the parent substance and identify and quantify metabolites**

Biodegradation-Other Methods-

OECD 302C

Even if criteria for OECD 301C are not met, but the data suggests the biodegradation continues after 28 days (e.g. degradation curve are increasing), the judgment can be made by OECD 302C

Test concentration: 30 mg/L

Inoculum concentration: 100 mg/L

OECD 301D

If the substance is highly volatile, 301D could be conducted

Test concentration: 2-5 mg/L

Inoculum concentration: less than 5 ml of effluent/L

Implementation of OECD 301F

The discussion is still on-going including following topics

- OECD 301F should be included in CSCL?
- Protocol of OECD 301F should be modified for CSCL?
- Protocol of OECD 301C should be modified?

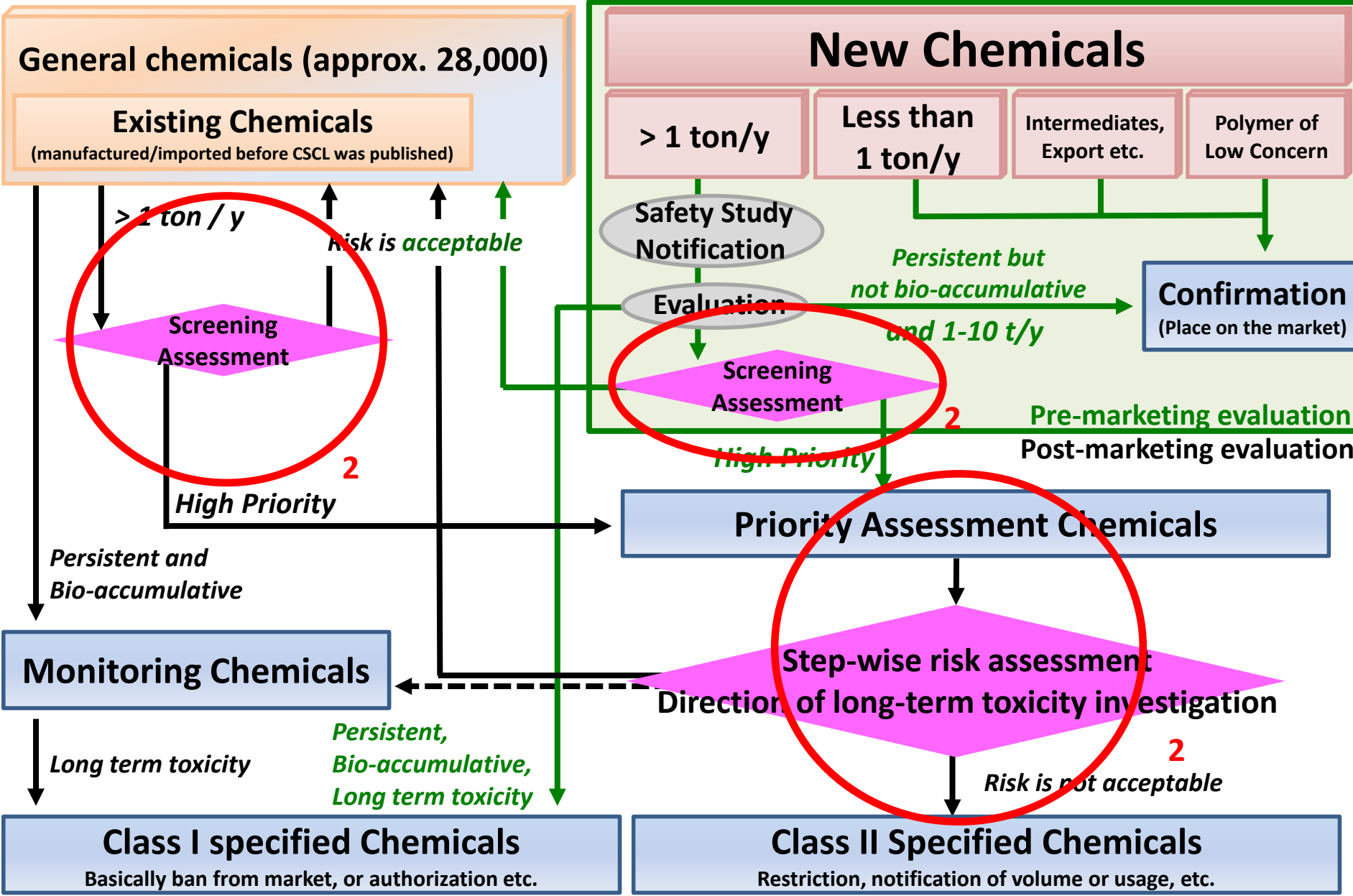
Log Pow OECD TG 107, 117

- Substance with Log Pow < 3.5 can be assessed as not highly bio-accumulative (except for ionic substances)
- For ionic substances, CSCL applies Log Dow (The partition coefficient determined at pH 7)
- Substance with Log Dow < 2.5 can be assessed as not highly bio-accumulative

BCF test OECD TG 305-I,II

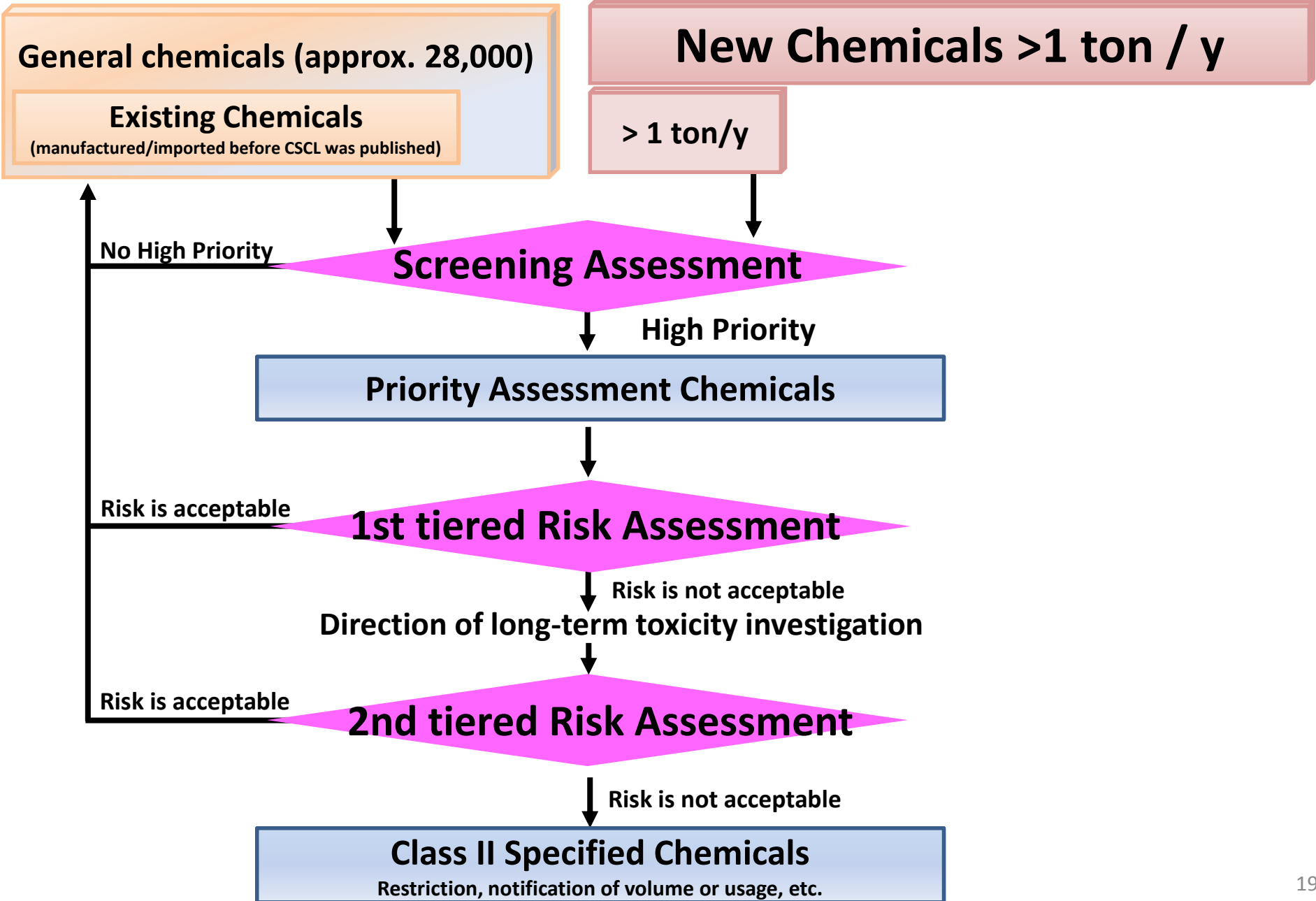
- Remaining degradation substances are considered for BCF study
- Implementation of OECD 305-III is under discussion
- BCF > 5000 : highly bio-accumulative, BCF < 1000 : not highly bio-accumulative
- BCF: 1000-5000: factors (distribution, discharge rate) are considered for judgment
- QSAR and Read-Across could be used but only in very limited conditions

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Risk Assessment of Chemicals



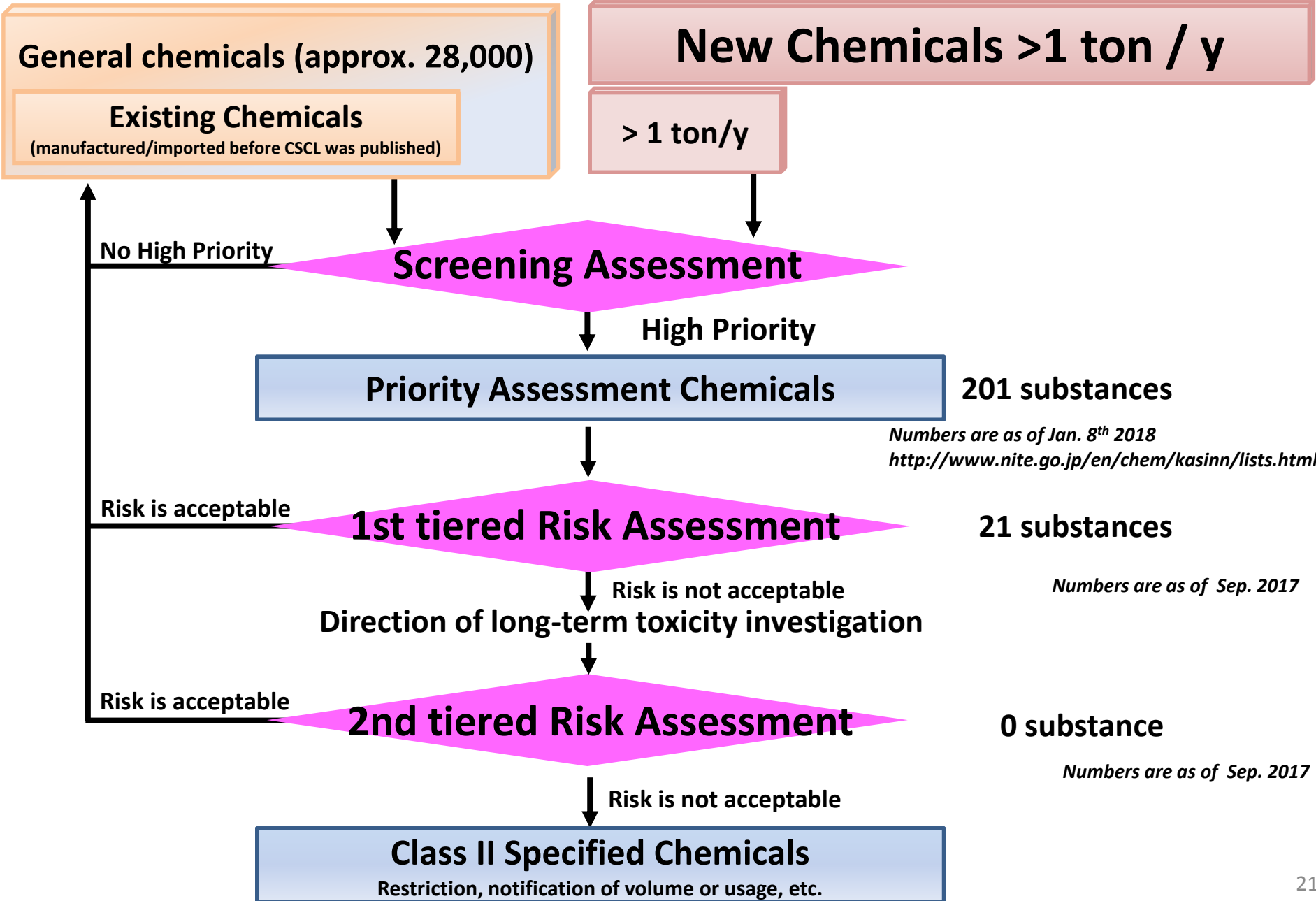
Risk Assessment of Chemicals

Screening Assessment

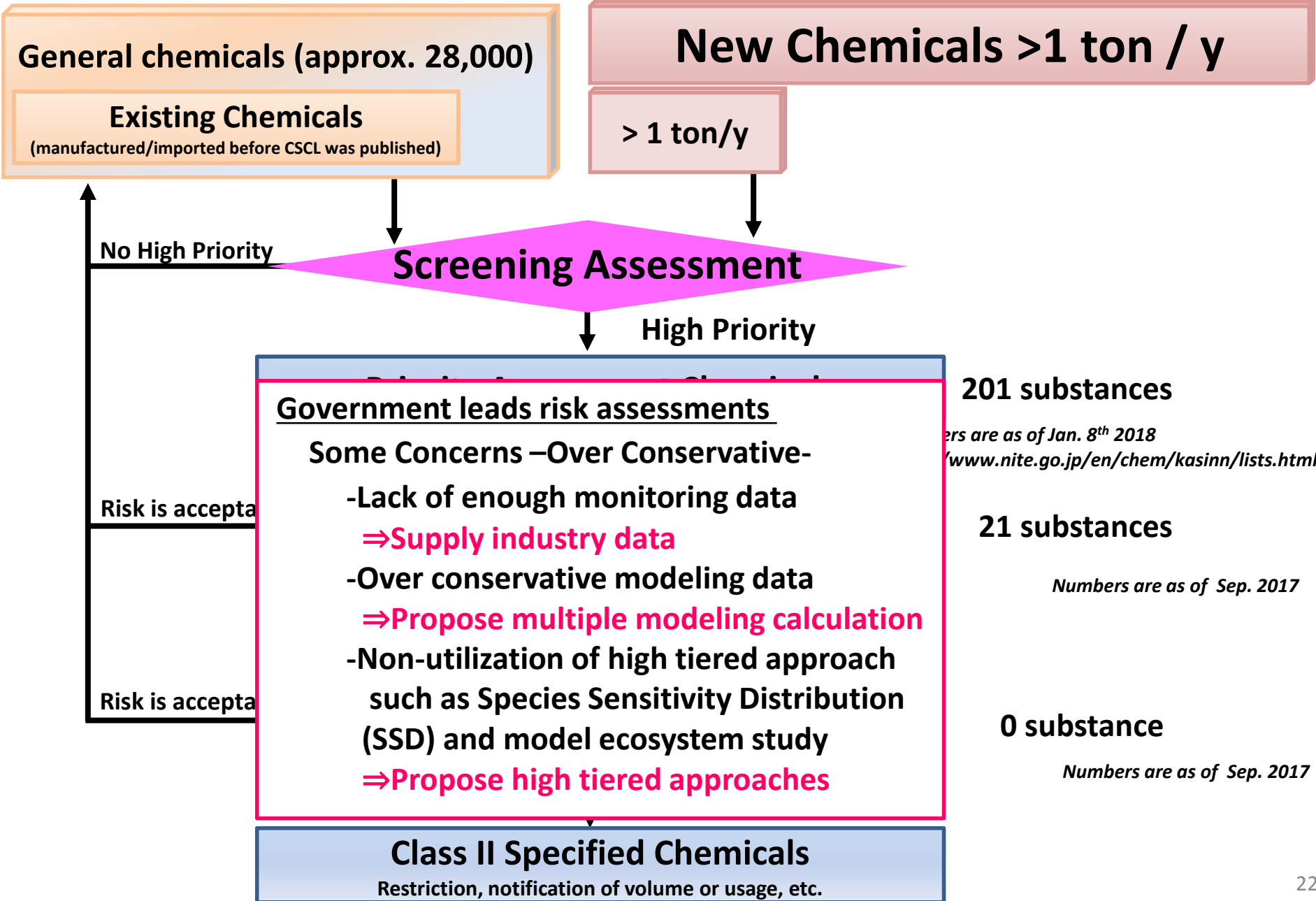
			<i>Strong</i> (Eco-) Toxicity (Such as PNEC mg/L)				<i>Weak</i>
			1	2	3	4	Out of Class
			Less than 0.001	0.001-0.01	0.01-0.1	0.1-1	>1
Exposure Class (exposure factors could be applied)	1	> 10000 t/y	High Priority	High Priority	High Priority	High Priority	Out of Class
	2	1000 – 10000 t/y	High Priority	High Priority	High Priority	Middle Priority	
	3	100 - 1000 t/y	High Priority	High Priority	Middle Priority	Middle Priority	
	4	10 - 100 t/y	High Priority	Middle Priority	Middle Priority	Low Priority	
	5	1 - 10 t/y	Middle Priority	Middle Priority	Low Priority	Low Priority	
	Out of Class	Less than 1 t/y	Out of Class				

High Priority Chemicals are categorized as
“Priority Assessment Chemicals”

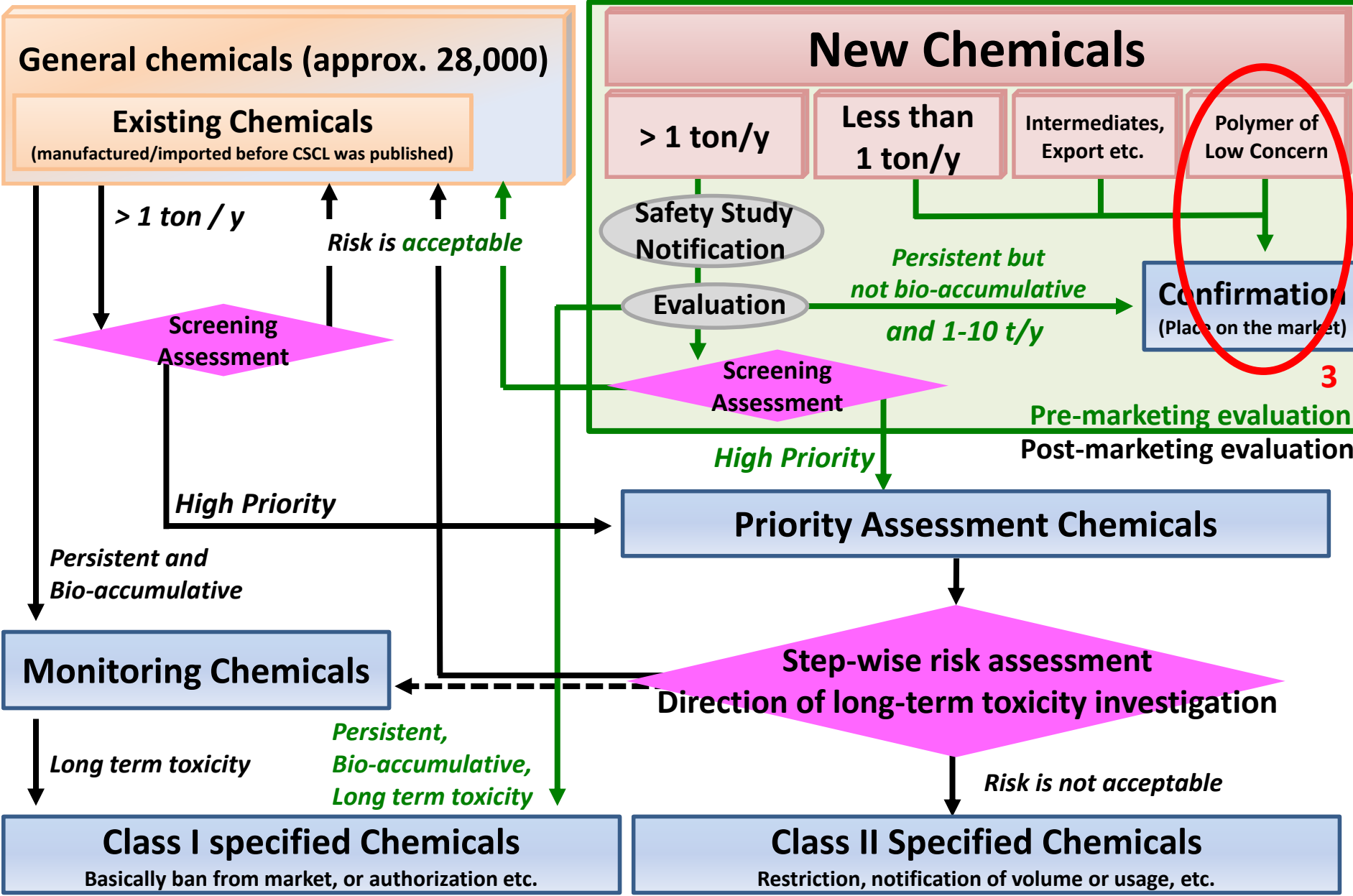
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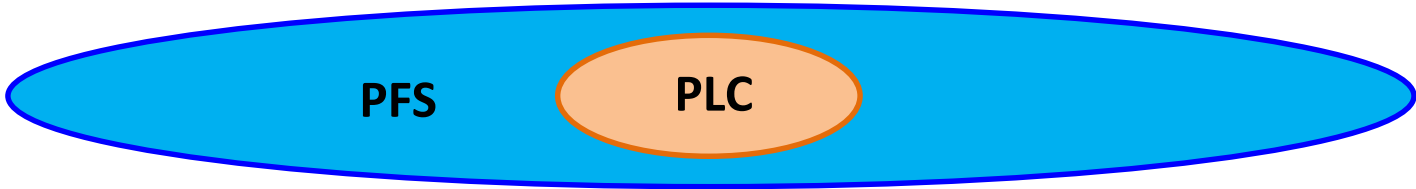
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Registration of Polymers

- Registration through Polymer Flow Scheme (PFS) may be possible
- If the criteria of Polymers of Low Concern (PLC) is met, the process can be shortened



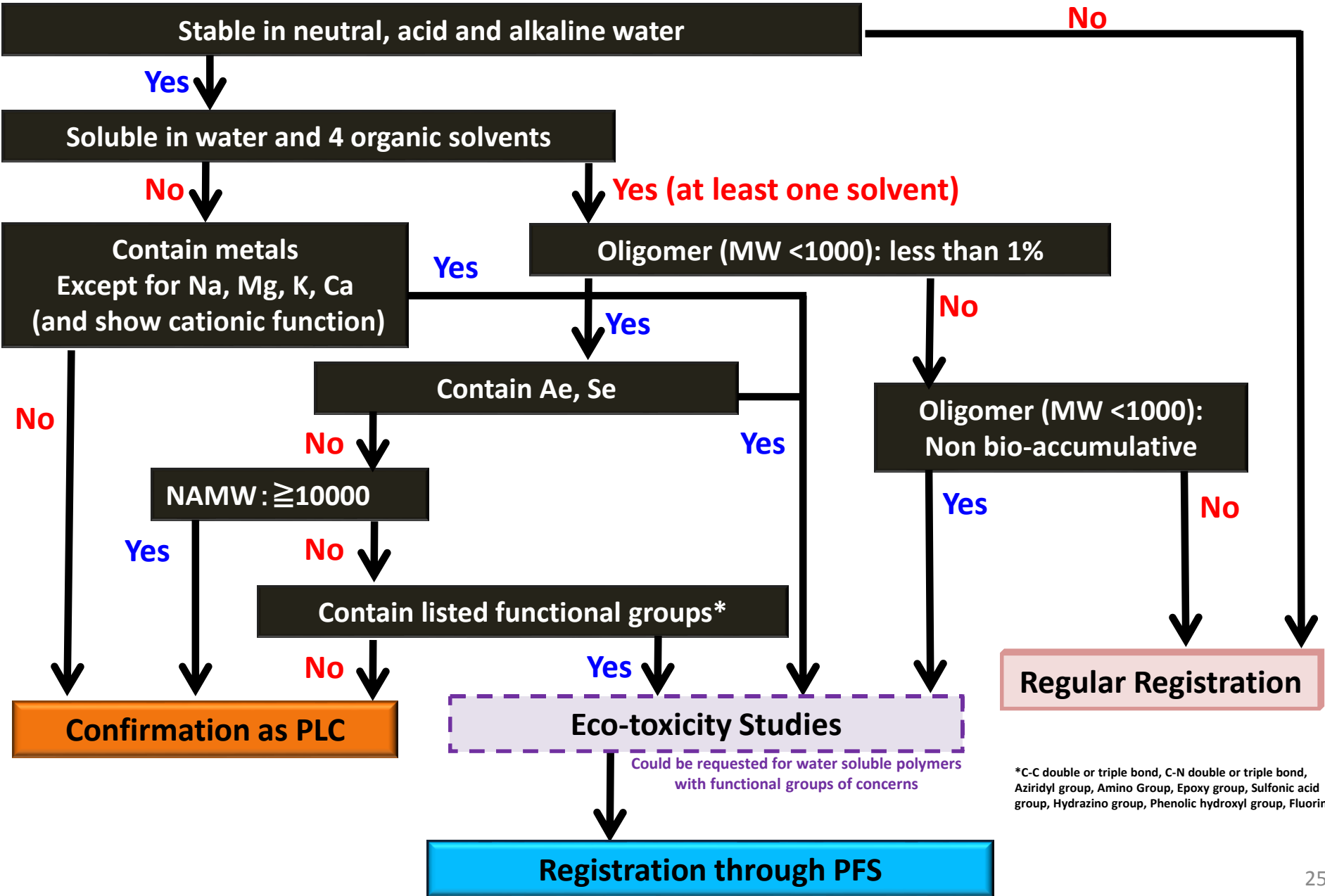
	Polymers that pass PFS	Polymers meeting PLC
Assessment by experts (in the Chemical Councils)	Yes	No
Time of government procedure	Long (approx. 2-4 months)	Short (about 1month)
Listed in the Inventory	Listed	Not listed

-Polymer definition in CSCL

- Molecules are characterized by the sequence of one or more types of monomer units
- The weight % of molecules containing three monomer units or above is 50% of the total weight or more
- The weight % of any molecule of the same molecular weight is less than 50% of the total weight
- NAMW (Number Average of Molecular Weight) is 1000 or more

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Polymer Flow Scheme (PFS)



*C-C double or triple bond, C-N double or triple bond, Aziridyl group, Amino Group, Epoxy group, Sulfonic acid group, Hydrazino group, Phenolic hydroxyl group, Fluorine

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Summary –in comparison with REACH-

	CSCL, Japan	REACH, EU
Start	1973, recent update in 2011	2007 (came into force)
Objectives	Environment and Human Health (long-term) via environmental exposure	Workers, Consumers and Environment
Registration	New chemicals (mainly >1 t/y)	New and existing chemicals (>1 t/y)
	No new notification required if the chemicals are already in the inventory	Registration required even if the same substances are already registered
Number of Studies	1-10 t/y: 1-2 , >10 t/y: 1-8	1-10 t/y: approx. 20, >10 t/y: >20
	Depending on the biodegradation result and tonnage	Depending on the tonnage and substance properties etc.
Evaluation	Pre-market (Risk assessment in post-market)	Post-market (random) (IT automatic check in pre-market)
Risk Assessment	All chemicals* (new and existing), tiered approach, leaded by authority	>10 t/y and classified substances, conducted by registrants
Polymers**	Could be registered thought PFS	Exempted (Monomers have to be registered)

*Except for the candidates for Monitoring, or Class I specified Chemicals

** The definition varies in each regulation

Thank you for your kind attention!!