経済産業省
Ministry of Economy, Trade and Industry
METI

Recent Progress of Chemical Substances Control Law (CSCL)

(FY2014)

December 2015

Chemical Safety Office
Chemical Management Policy Division
Ministry of Economy, Trade and Industry (METI)

Contents

1. Outline of CSCL

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 substance created through chemical reactions.
- Industrial chemicals

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

Outline

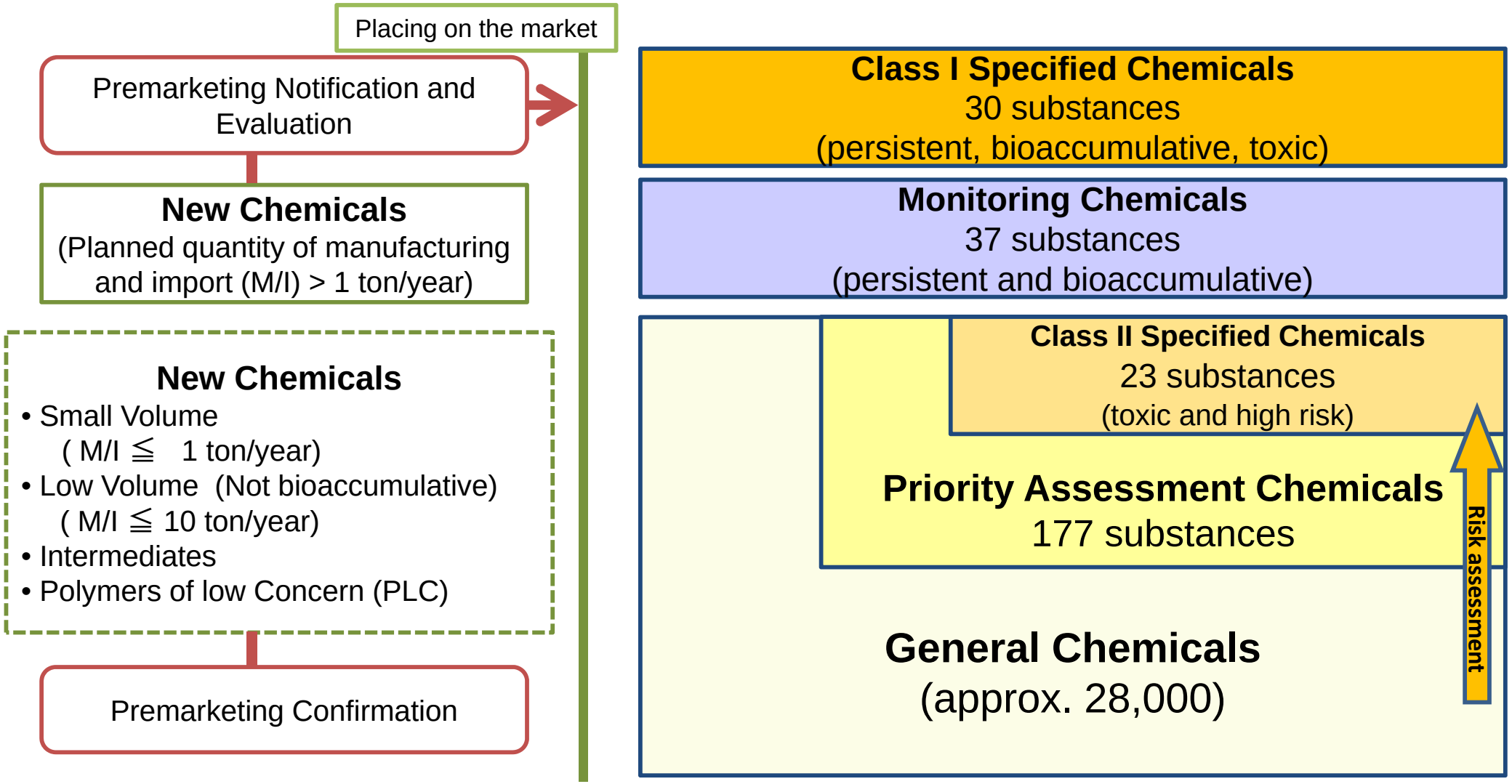
- New Chemicals

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

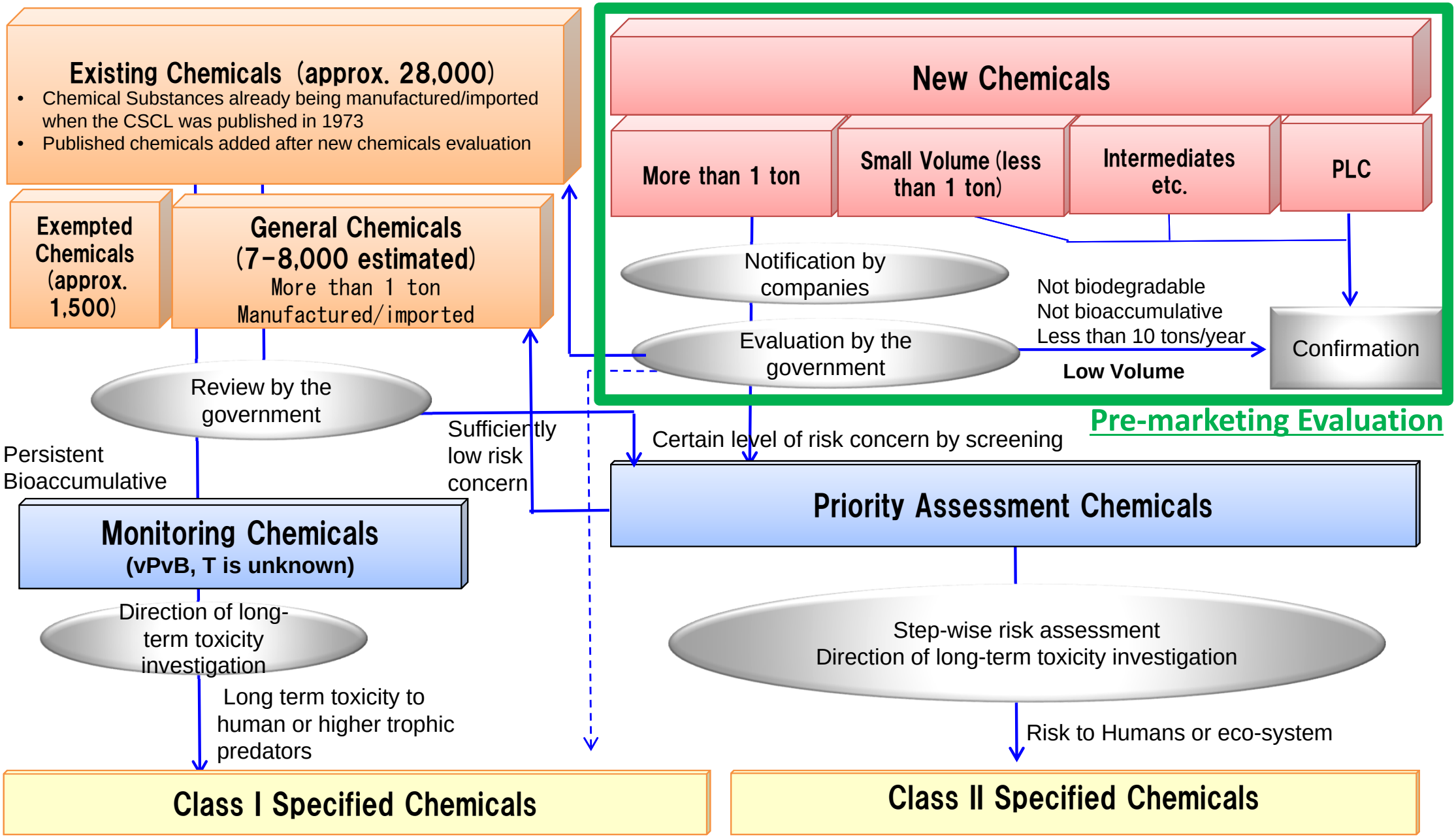
  Annual report of manufacture/import volume and usage is mandatory. The government conducts risk assessment based on this annual notification and may request additional toxicity information to the manufactures/importers if necessary.

Overview of CSCL

- The Japanese 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.



Evaluation/Assessment Flow of CSCL

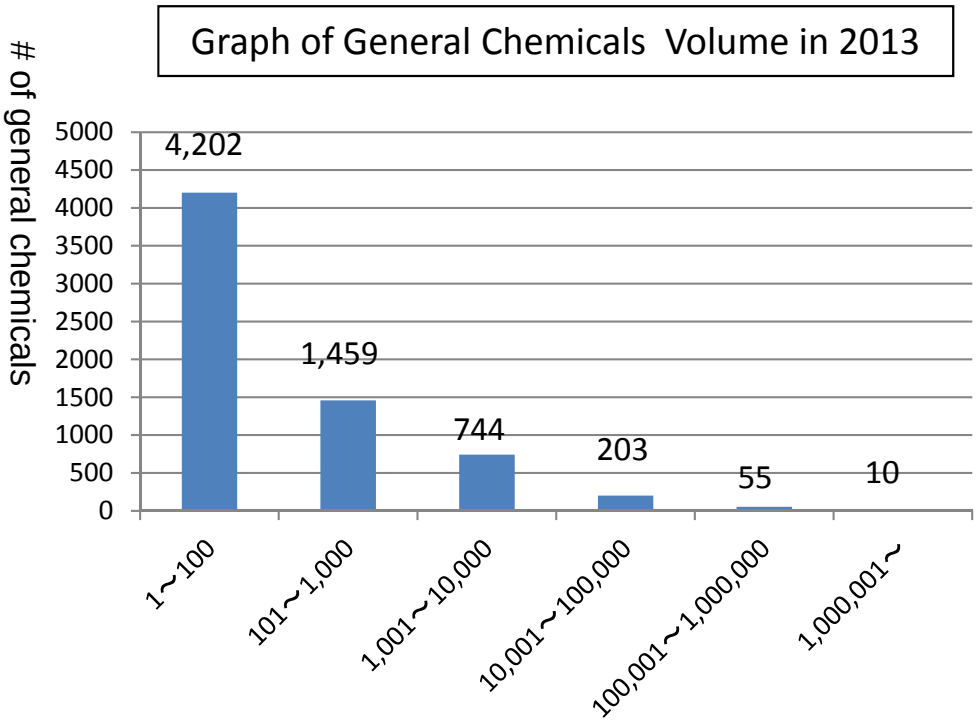


2. Recent Progress of CSCL (Existing Chemicals)

Notification information (General Chemical Substances in 2013)

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

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



- ✓ Volume of 2013 were notified in 2014.
- ✓ As companies manufacture the same chemical substance, the gross total submitted number is about 30,000
- ✓ # of chemicals is based on "CSCL registration number" referenced.

Notification information (Priority Assessment Chemical Substance in 2013)

- Notification information is used for exposure assessment in screenings and risk assessments for chemical substances.

Manufacture/ Import year	# of Companies	# of priority assessment Chemicals
2010	349	854
2011	402	1,049
2012	481	1,733
2013	554	1,990

The difference in the notification information , between the general chemical substance- and priority assessment chemical substances

	General Chemical Substance	Priority Assessment Chemical Substance
Manufacturing Location	—	Name and address of manufactory (that manufactured the substance)
Volume of manufacturing and imported	Manufactured and imported volume of the year	Manufacturing volume by prefecture and imported volume by exporting country / region for each chemical substance of the year
Shipping Volume	Shipping volume by use category	Shipping volume by prefecture and by use sub-category
Classification for use category	Approx. 50 use categories	Approx. 280 use sub-categories

The trend of reporting on hazard information

- When manufacturer or importer get publicly unknown hazard information of their chemicals, they have to report it to the Government (Article 41, CSCL).

(the number of report)

Fiscal year	2010	2011	2012	2013	2014
Biodegradability	74	101	88	112	103
Bioaccumulation	3	3	5	1	6
Physicochemical properties	6	4	10	3	2
Toxicity to humans	90	79	113	104	77
Ecotoxicity	48	37	51	49	31
Total	221	224	267	269	219

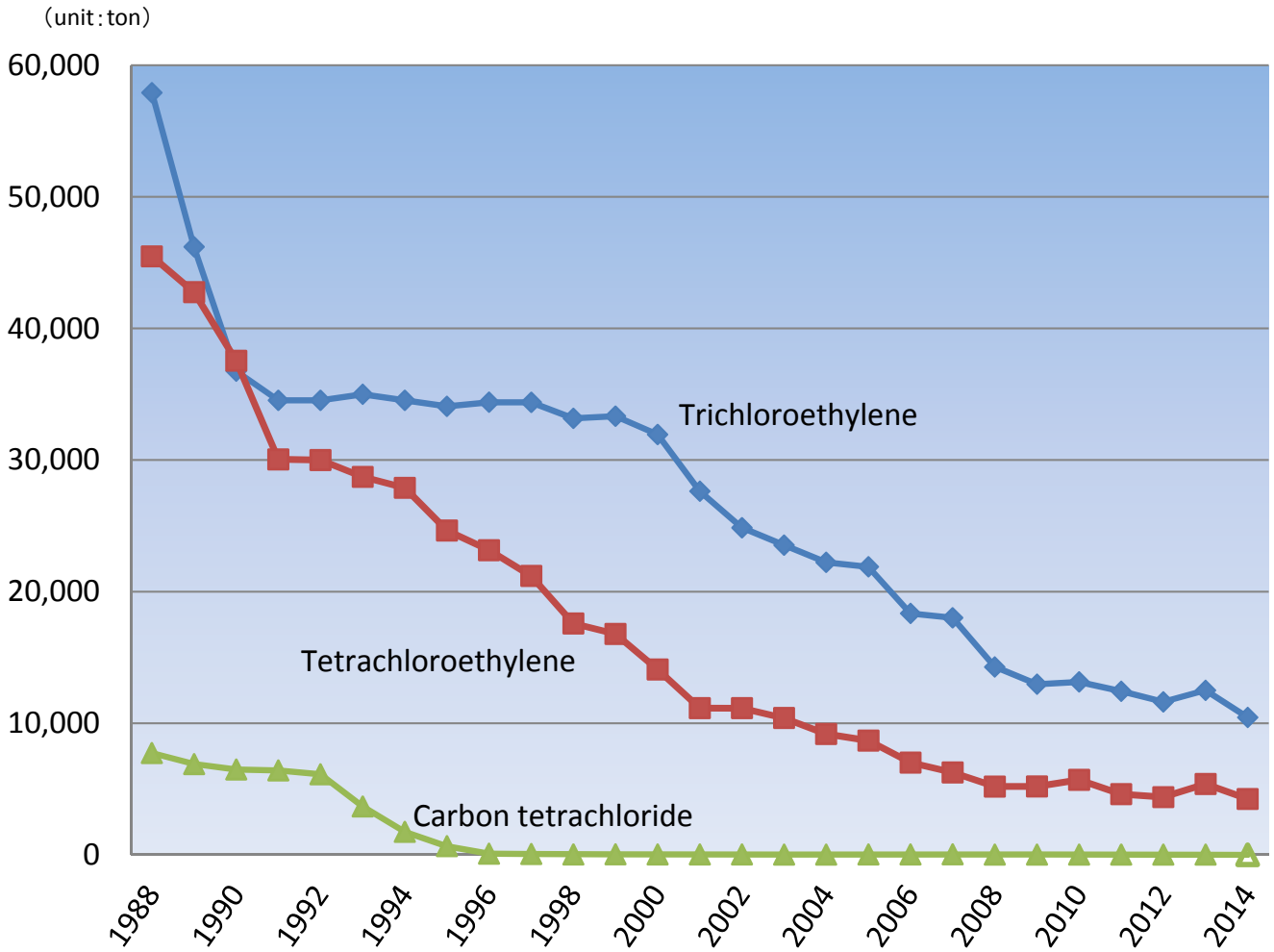
Trend in Shipping Class II Specified Chemical Substances

- Currently, trichloroethylene, tetrachloroethylene and carbon tetrachloride, which are defined as Class II Specified Chemical Substances, are also manufactured and imported for other purposes than testing or research use.
- The shipments are on the decline except for exports and intermediate use.

Shipped volume of Class Ⅱ chemical substances

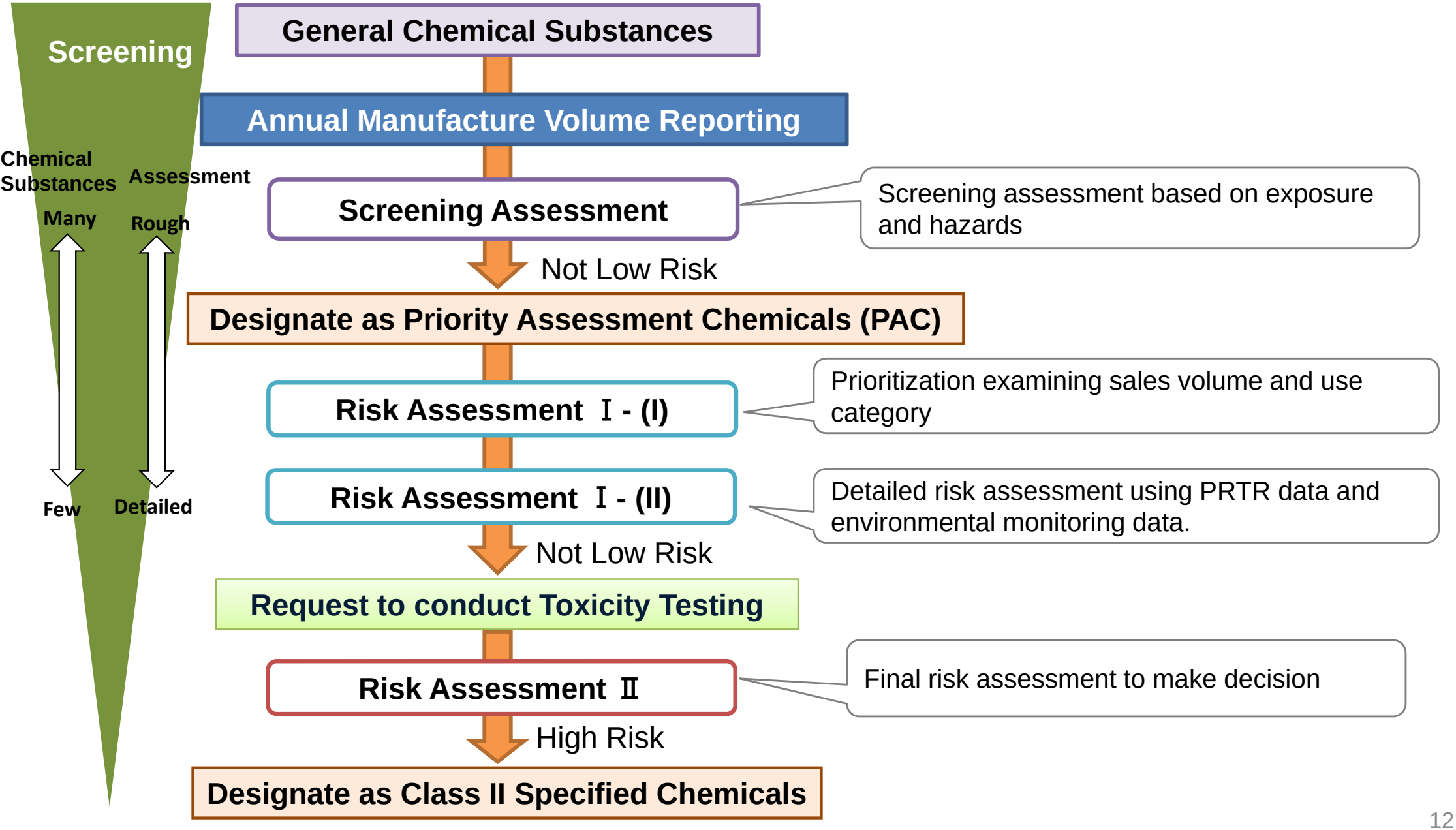
(unit : ton)

	Trichloro ethylene	Tetrachloro ethylene	Carbon tetrachloride
1988	57,922	45,483	7,736
1989	46,201	42,760	6,904
1990	36,762	37,554	6,492
1991	34,546	30,059	6,420
1992	34,546	30,009	6,127
1993	35,002	28,727	3,681
1994	34,541	27,892	1,747
1995	34,084	24,648	658
1996	34,396	23,159	89
1997	34,394	21,200	70
1998	33,179	17,585	37
1999	33,340	16,787	44
2000	31,952	14,089	27
2001	27,634	11,153	37
2002	24,863	11,148	29
2003	23,537	10,397	22
2004	22,233	9,191	22
2005	21,889	8,683	30
2006	18,351	7,013	27
2007	18,020	6,270	40
2008	14,284	5,198	20
2009	12,971	5,200	16
2010	13,142	5,703	17
2011	12,437	4,618	18
2012	11,628	4,391	15
2013	12,507	5,392	15
2014	10,452	4,253	0



Flow of Risk Assessment of Existing Chemicals

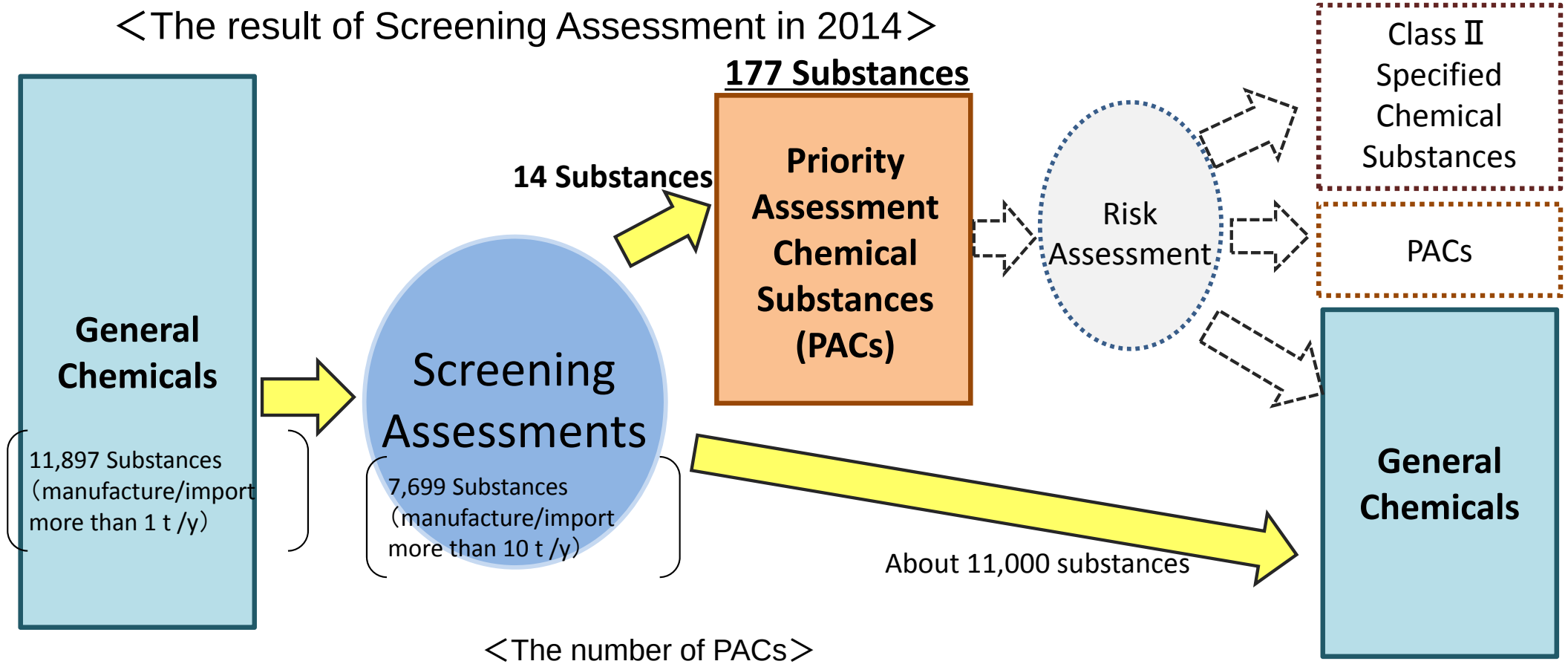
- The Japanese government conducts risk assessment on existing chemicals in a step by step manner as follows: (This flow was introduced in the latest revision of CSCL in 2011.)



Current Situation of Screening Assessment

- The government has conducted screening assessments for general chemicals every year since 2012.
- The number of PACs reached 177 in April, 2015.

＜The result of Screening Assessment in 2014＞



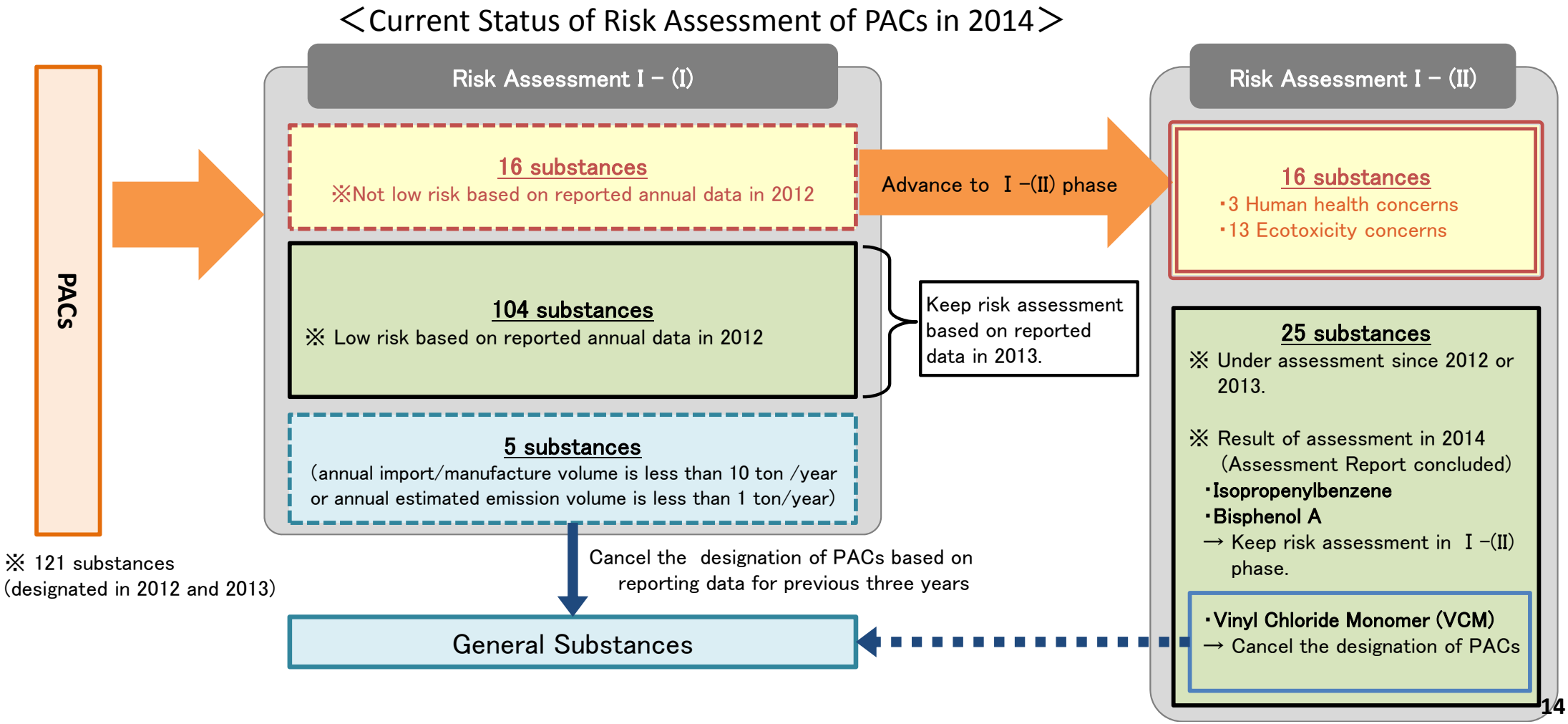
※ Most assessment units are CAS.

＜The number of PACs＞

	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

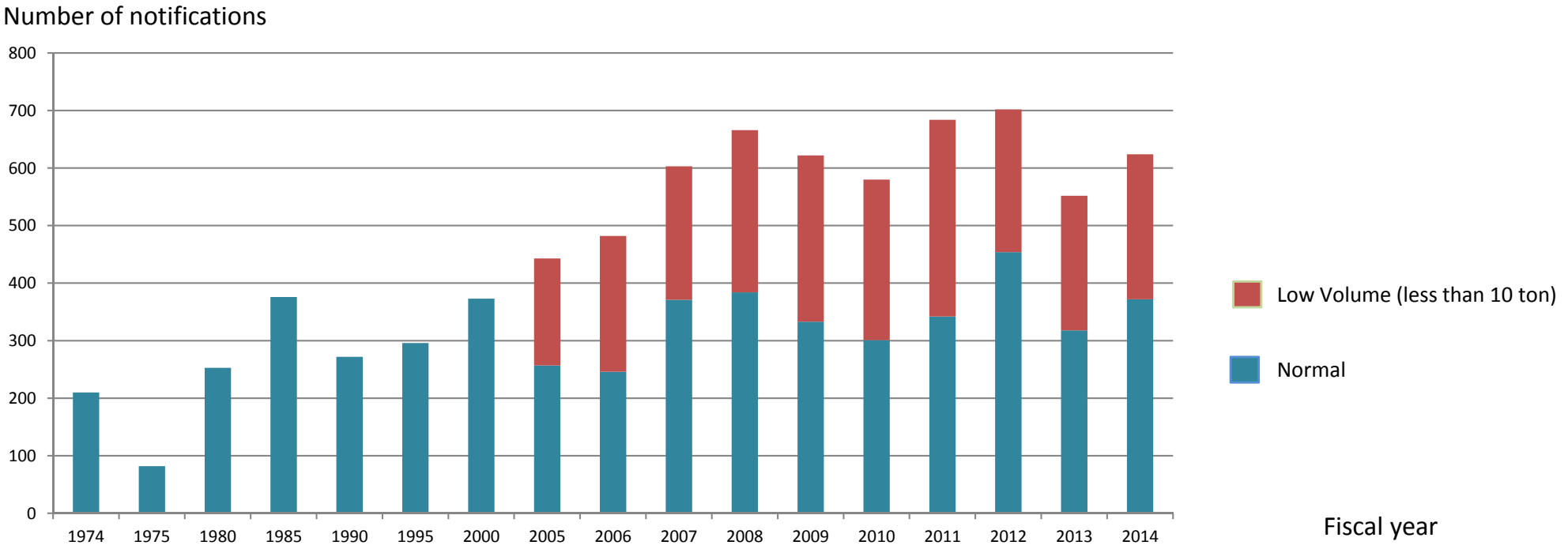
- The government made assessment reports on two PACs for the first time in June 2014.
- The government decided to rescind the designation on VCM after conducting risk assessment, for the first time in Dec. 2014.
- The government is now considering more efficient assessment for PACs.



3. Recent Progress of CSCL (New Chemicals)

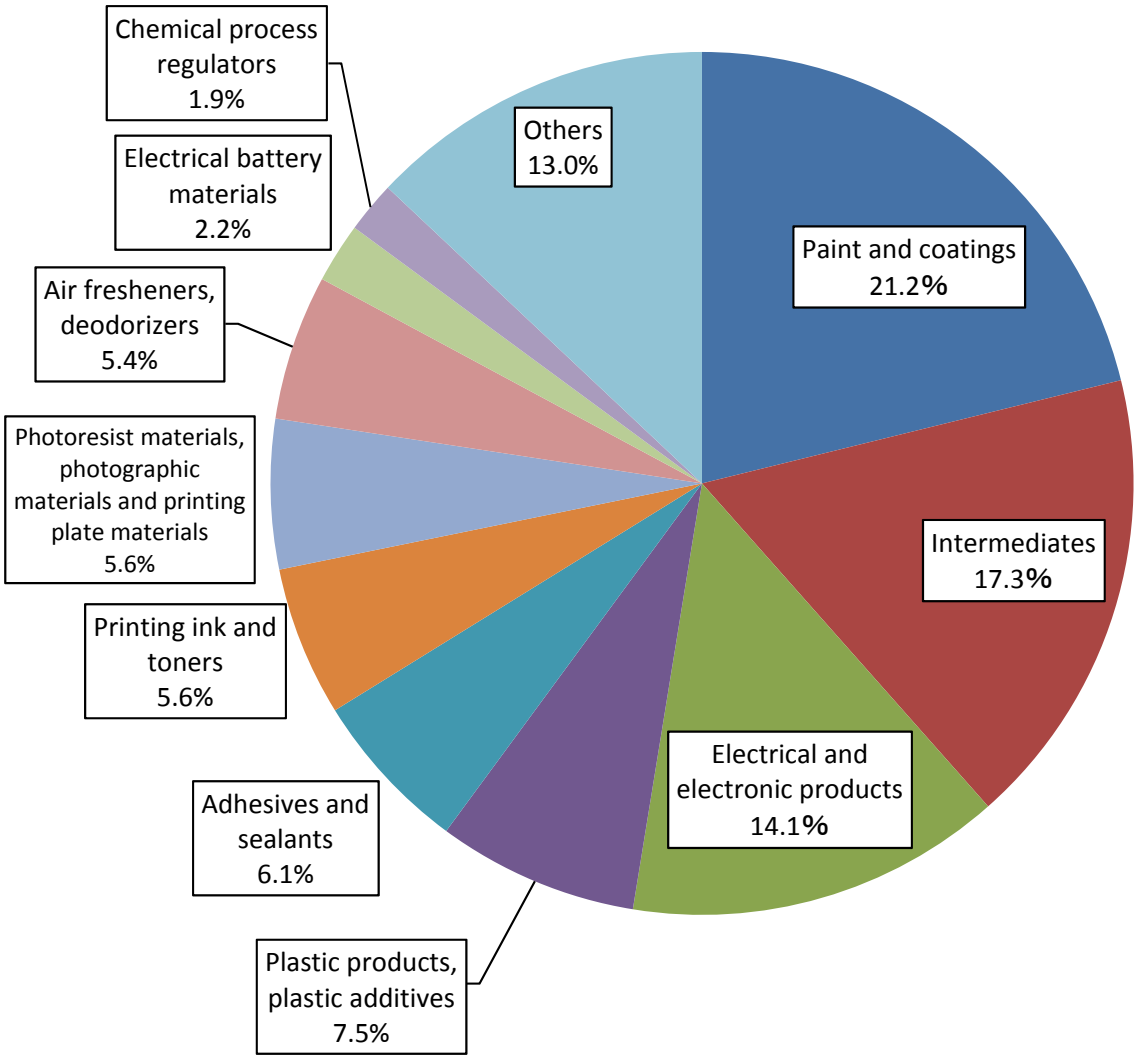
Trend of Notification of New Chemicals

- The number of notifications has been around 600/y, and low volume accounts for about 40%.
- About 60% of normal chemicals are polymers.



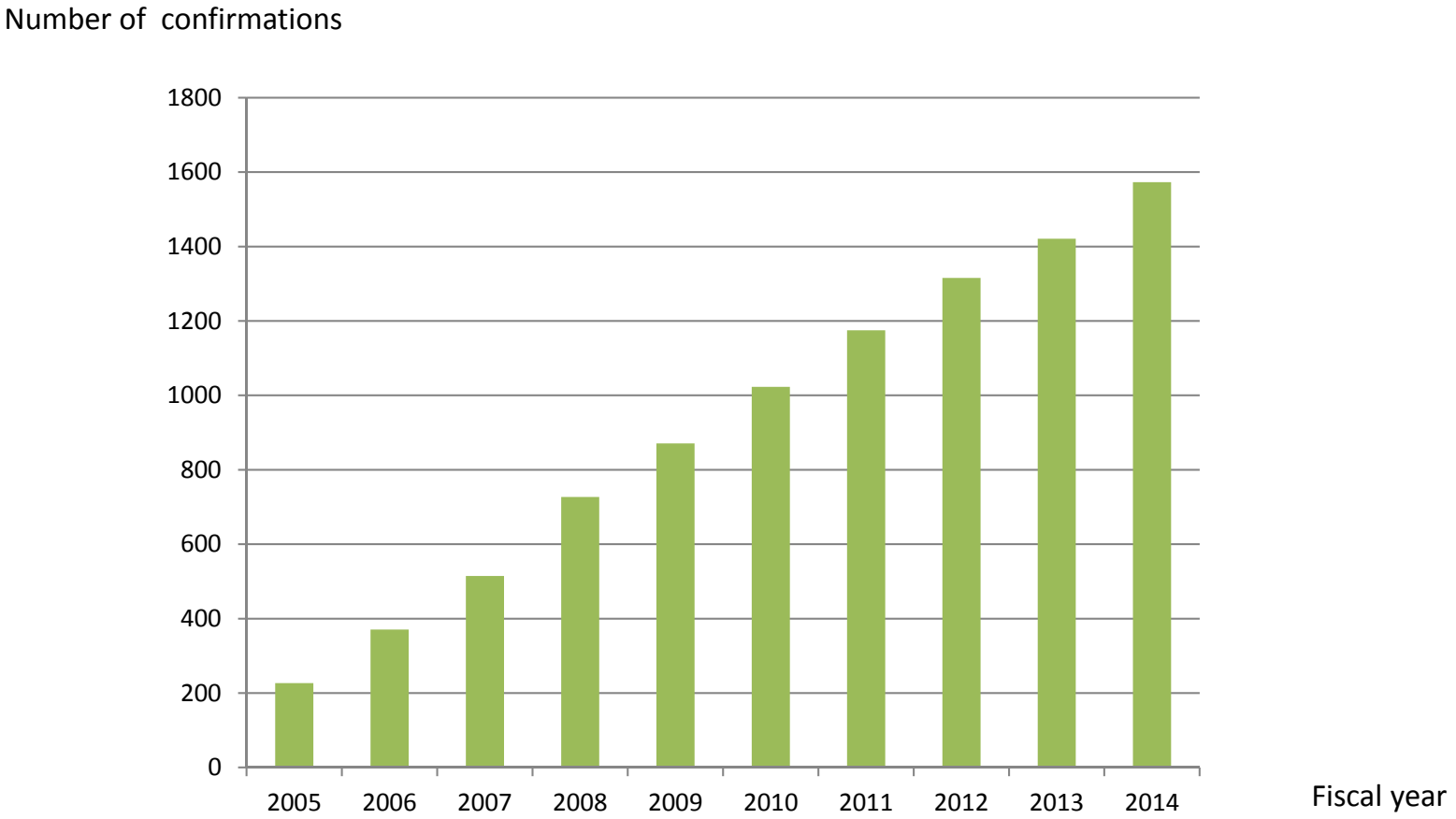
	1974	1975	1980	1985	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Manufacture	114	45	160	286	218	223	291	349	381	452	502	440	402				
Import	96	37	93	90	54	73	82	94	101	151	164	182	151				
Manufacture/ Import													27	684	702	552	624
Total	210	82	253	376	272	296	373	443	482	603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

Uses of New chemicals (in 2014)



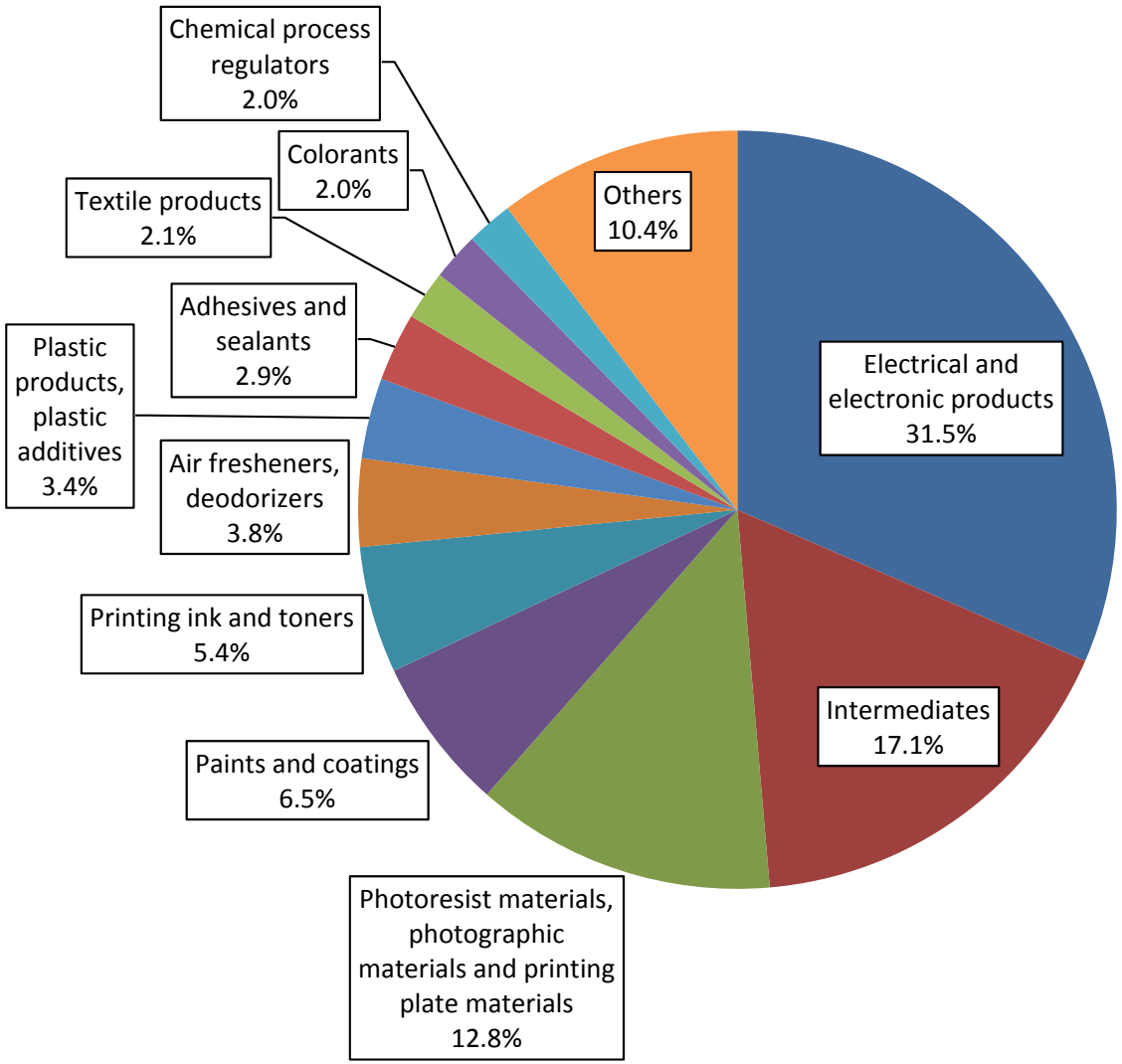
Use Category	#	%
Paints and coatings	132	21.2%
Intermediates	108	17.3%
Electrical and electronic products	88	14.1%
Plastic products, plastic additives	47	7.5%
Adhesives and sealants	38	6.1%
Printing ink and toners	35	5.6%
Photoresist materials, photographic materials and printing plate materials	35	5.6%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

Trend of confirmed low volume New Chemicals



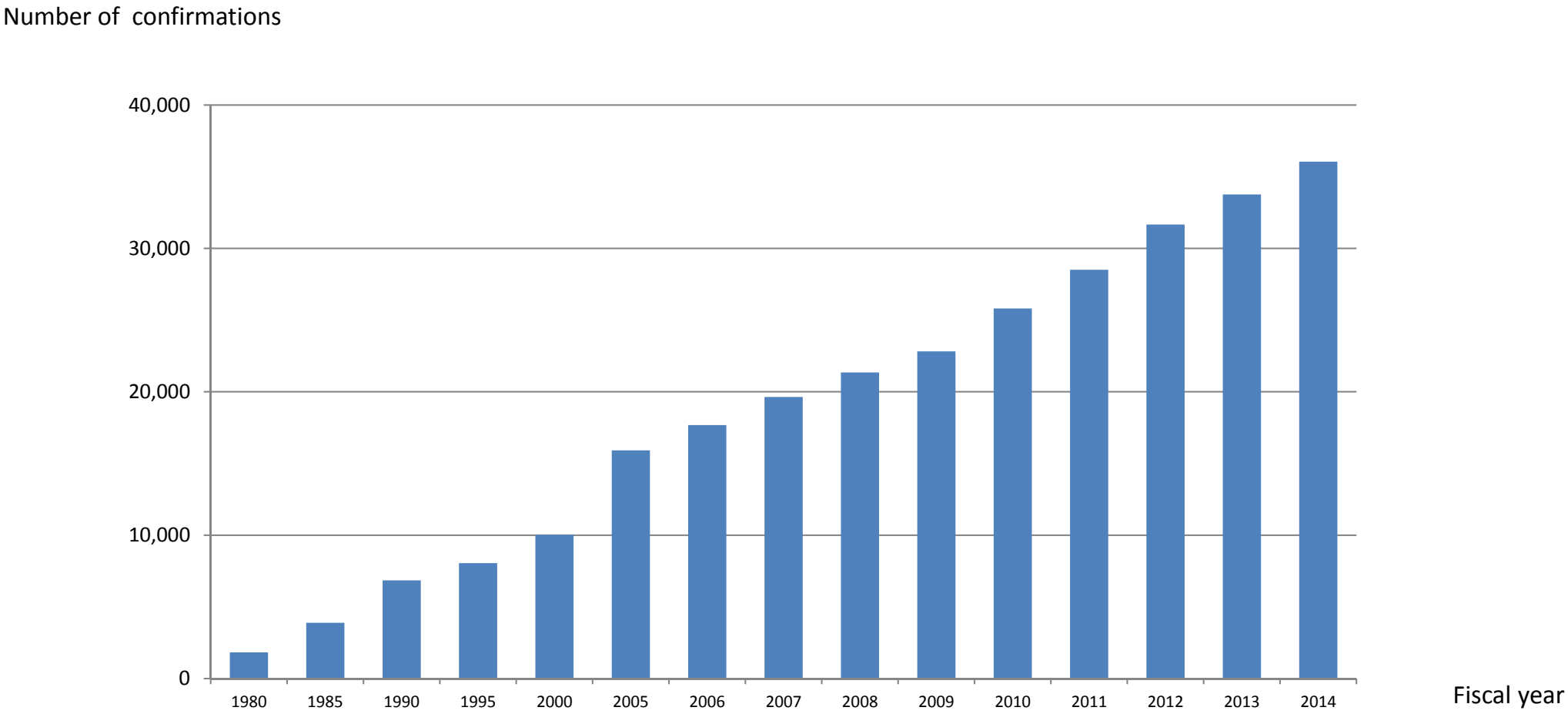
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Manufacture	156	261	341	477	569					
Import	71	110	174	250	302					
Manufacture/ Import						1,023	1,175	1,316	1,421	1,573
Total	227	371	515	727	871	1,023	1,175	1,316	1,421	1,573

Uses of Low Volume New Chemicals (in 2014)



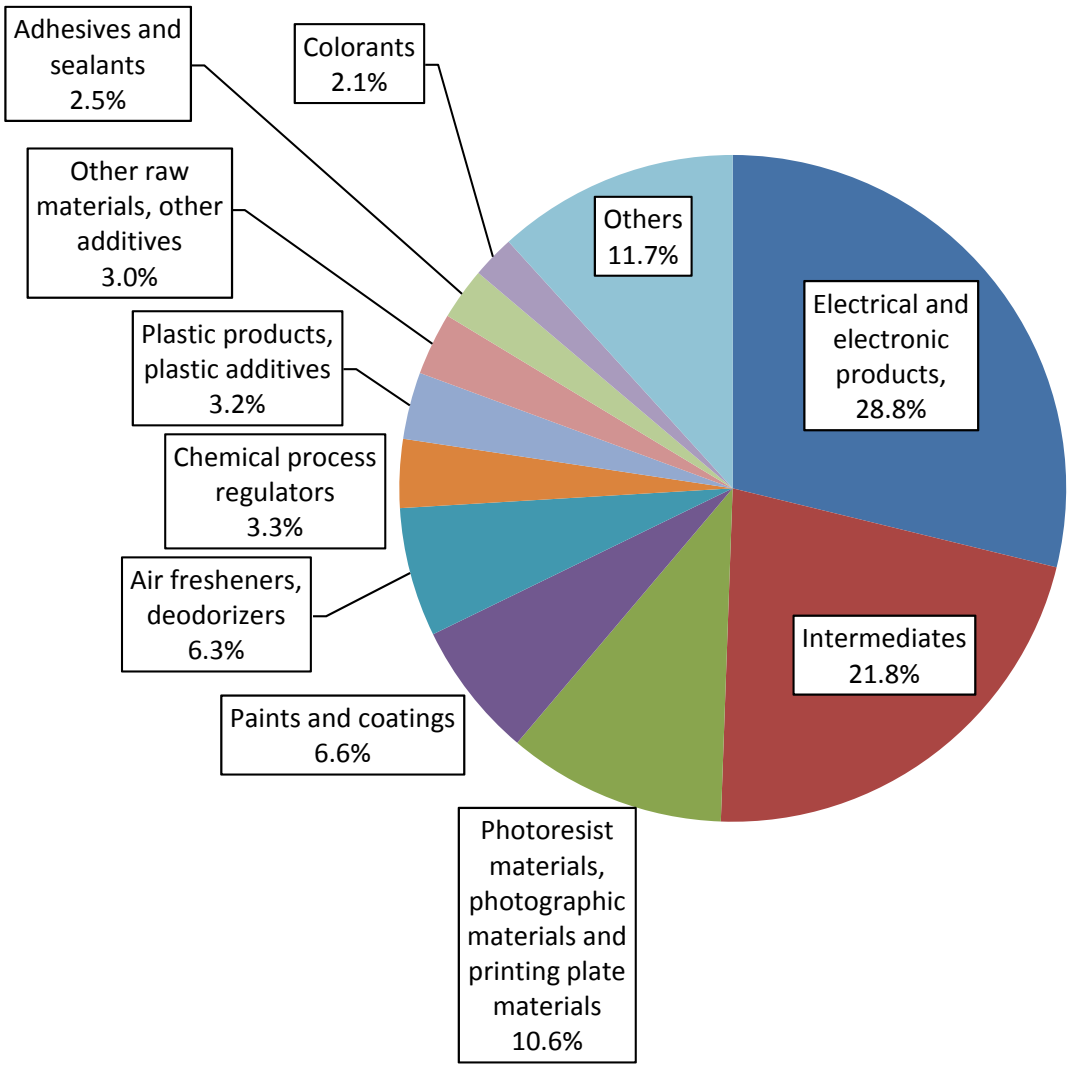
Use Category	#	%
Electrical and electronic products	496	31.5%
Intermediates	269	17.1%
Photoresist materials, photographic materials and printing plate materials	202	12.8%
Paints and coatings	103	6.5%
Printing ink and toners	85	5.4%
Air fresheners, deodorizers	59	3.8%
Plastic products, plastic additives	54	3.4%
Adhesives and sealants	46	2.9%
Textile products	33	2.1%
Colorants	32	2.0%
Chemical process regulators	31	2.0%
Others	163	10.4%
Total	1,573	

Trend of confirmed Small Volume New Chemicals



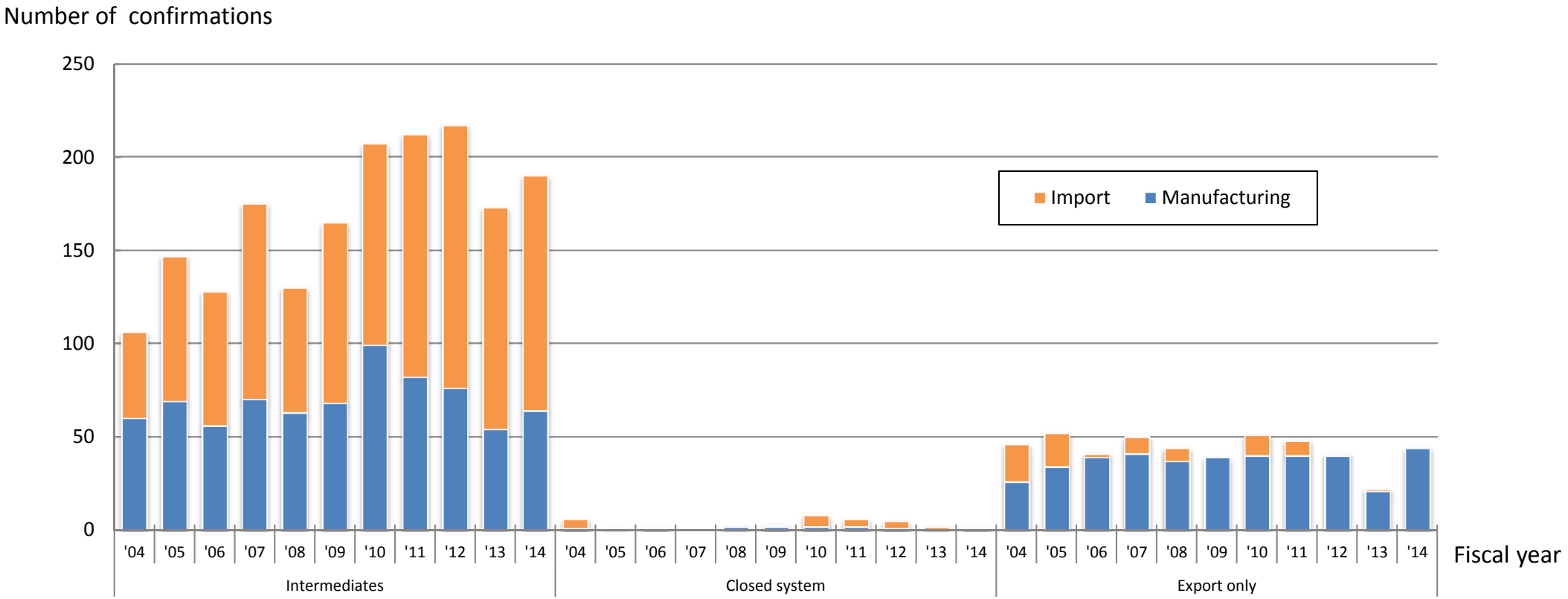
	1980	1985	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Manufacture	937	2,177	4,799	5,951	7,222	10,650	11,644	12,694	13,550	14,123					
Import	896	1,716	2,049	2,099	2,810	5,273	6,040	6,947	7,805	8,704					
Manufacture/ Import											25,815	28,519	31,672	33,766	36,052
Total	1,833	3,893	6,848	8,050	10,032	15,923	17,684	19,641	21,355	22,827	25,815	28,519	31,672	33,766	36,052

Uses of Small Volume New Chemicals (in 2014)



Use Category	#	%
Electrical and electronic products	10,386	28.8%
Intermediates	7,846	21.8%
Photoresist materials, photographic materials and printing plate materials	3,827	10.6%
Paints and coatings	2,380	6.6%
Air fresheners, deodorizers	2,258	3.3%
Chemical process regulators	1,200	3.3%
Plastic products, plastic additives	1,171	3.2%
Other raw materials, other additives	1,092	3.0%
Adhesives and sealants	910	2.5%
Colorants	750	2.1%
Others	4,232	11.7%
Total	36,052	

Trend of confirmed Chemicals of Intermediates , Closed system and Export only



		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Intermediates		**106**	**147**	**128**	**175**	**130**	**165**	**207**	**212**	**217**	**173**	**190**
	Manufacture	60	69	56	70	63	68	99	82	76	54	64
	Import	46	78	72	105	67	97	108	130	141	119	126
Closed system		**6**	**1**	**2**	**0**	**2**	**3**	**8**	**6**	**5**	**2**	**2**
	Manufacture	1	1	1	0	2	2	2	2	1	0	1
	Import	5	0	1	0	0	1	6	4	4	2	1
Export only		**46**	**52**	**41**	**50**	**44**	**39**	**51**	**48**	**41**	**22**	**44**
	Manufacture	26	34	39	41	37	39	40	40	40	21	44
	Import	20	18	2	9	7	0	11	8	1	1	0
Total		**158**	**200**	**171**	**225**	**176**	**207**	**266**	**266**	**263**	**197**	**236**
	Manufacture	87	104	96	111	102	109	141	124	117	75	109
	Import	71	96	75	114	74	98	125	142	146	122	127

A New Rule for Small Volume Intermediate/Export only

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

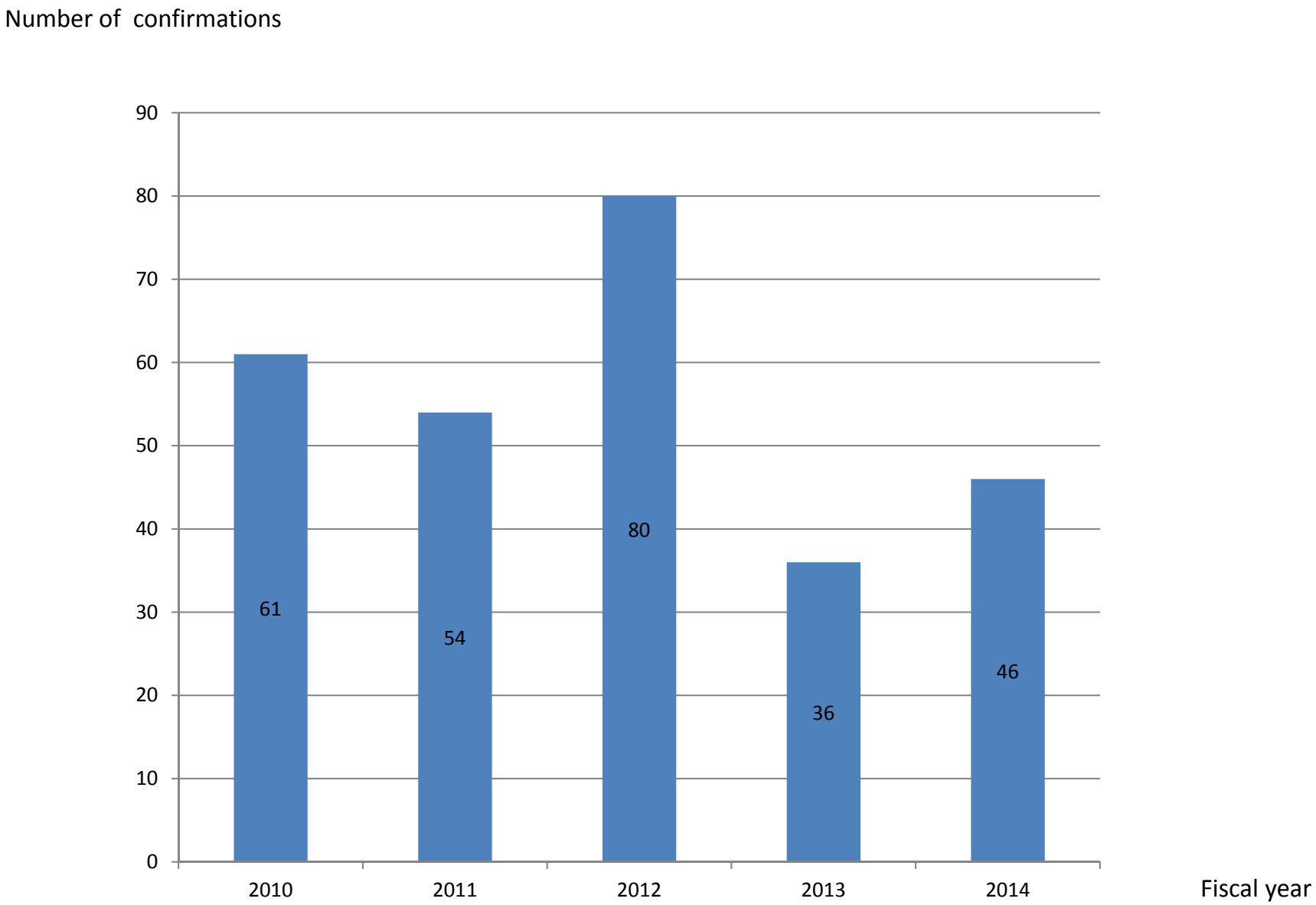
Small Volume Intermediate/Export only

- 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.
- A company with this approval can manufacture/import this new chemical substance for intermediates, of less than or equal to 1 ton/year without undergoing normal assessment (evaluation) procedures by the government.

Characteristic:

- There is already “Intermediate” rule for exemption. But it may take time to get confirmation (approval) as many application documents are required.
- Getting confirmation of “Small Volume Intermediates” is much easier and faster than getting confirmation of “Intermediates.”

Trend of PLC（Polymers of Low Concern）

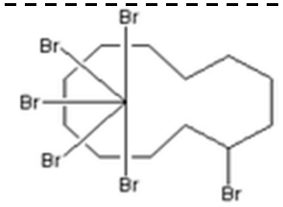


4. Recent Progress of CSCL (additional matter)

New Regulatory Measures on HBCD

- In Japan, HBCD (Hexabromocyclododecane) was classified as a Class I Specified Chemical Substance under CSCL on May 1, 2014.

(HBCD) has been used as a flame-retardant.



- Manufacture and import of HBCD are prohibited (as of May 1, 2014).
- The following four products in which HBCD is used are prohibited for import (as of October 1, 2014).
  - [i] Flame retardant textiles
  - [ii] Chemicals for flame-retardant treatment for textiles
  - [iii] Expandable polystyrene for flame-retardant EPS, expanded polystyrene
  - [iv] Flame-retardant curtains

Appendix

New Guidance for Bioaccumulation Assessment

1. Bioaccumulation Assessment by using QSAR and Analogous

- In response to the request to reduce testing cost and time and the international demand to reduce animal tests, Japan made a new guidance on bioaccumulation assessment by using analogous and QSAR in September, 2013.
- Please see the appendix for details.

2. Bioaccumulation Assessment of Ionic Substances

- If log Pow is <3.5, that substance is assessed to be not highly bioaccumulative.
- However, measuring log Pow of ionic substances in undissociated state is difficult.
- In order to simplify bioaccumulation assessment of ionic substances, Japan made a new guidance to use log Dow (the partition coefficient determined around a pH of 7) in June, 2014.
- Please see the appendix for details.

Guidance for Bioaccumulation Assessment by using QSAR

1. Bioaccumulation Assessment by using QSAR and Read-Across

If chemical A meets following criteria, chemical A can be assessed to be not highly bioaccumulative:

(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 (bioconcentration 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.

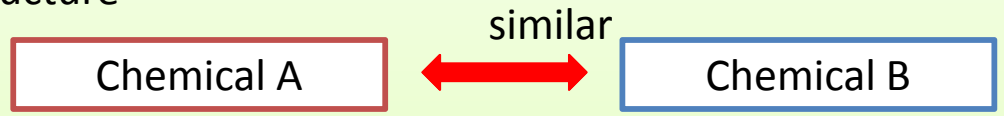
※ Recommended QSAR model is either BCFBAF (EPI SUITE) or BCF base-line model (OASIS Catalogic).

※ Japan added the published measured BCF data on the website in Sep. this year in order to facilitate the above approach.
Following NITE website is very useful to search measured BCF data because it includes how to use it by OECD QSAR toolbox. (both in Japanese…)
http://www.nite.go.jp/chem/qsar/bunchiku_qsar.html

Example (1)

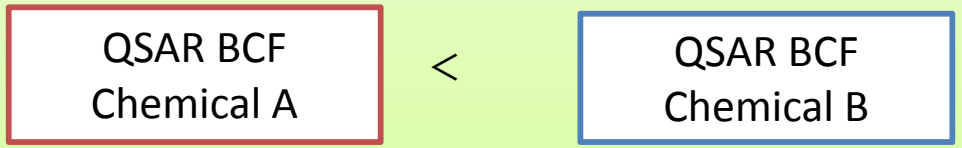
Case 1

(1) Chemical Structure



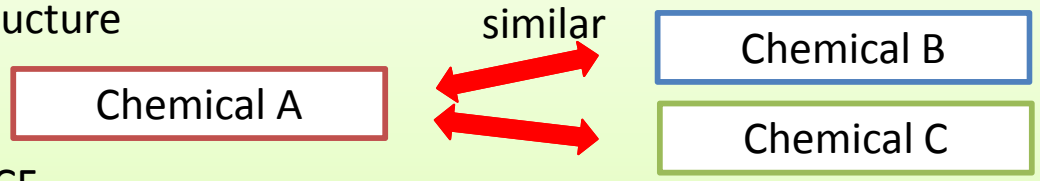
(2) Measured BCF

(3) Calculated BCF by using QSAR

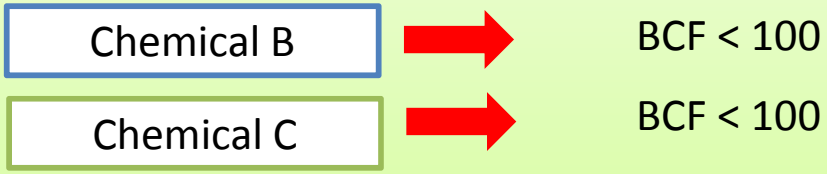


Case 2

(1) Chemical Structure



(2) Measured BCF



Chemical A is not highly bioaccumulative in both cases.

Guidance for Bioaccumulation Assessment using Analogous

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

If chemical A meets the following criteria, chemical A can be assessed to be not highly bioaccumulative:

(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.

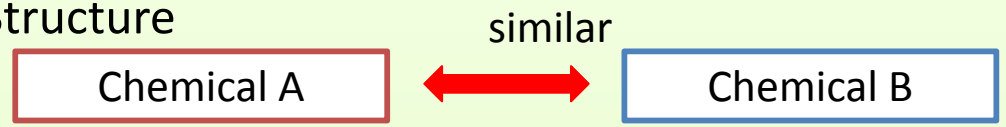
(3) It is observed that chemical A is more hydrophilic (polar) than chemical B by reversed-phase HPLC.

※ This analogous method does not apply to surfactants, organic metallic compounds, low purity compound and inorganic compound.

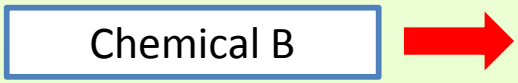
Example (2)

Case 3

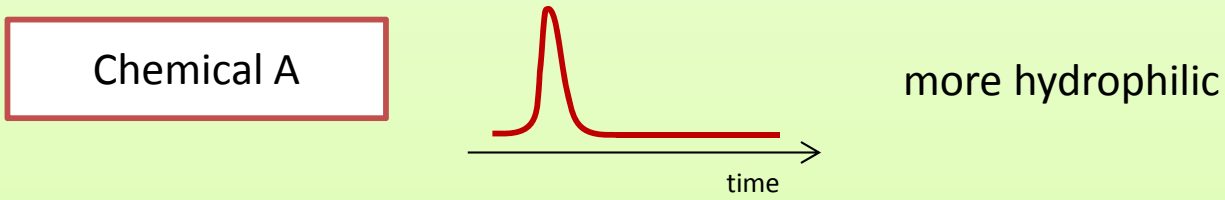
(1) Chemical Structure

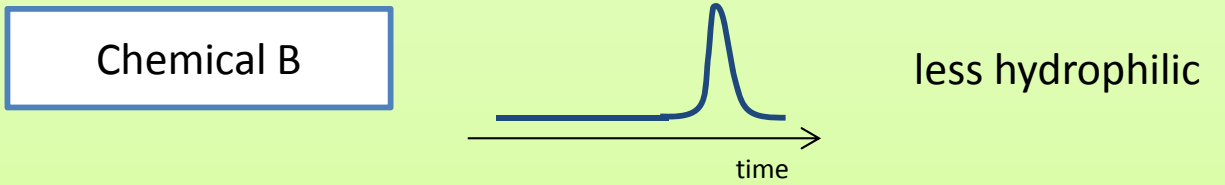


(2) Measured BCF



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





Chemical A is not highly bioaccumulative.

Guidance for Bioaccumulation Assessment of Ionic Substances

- 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-) in their structure.

※Under OECD TG107 (Shake-Flask method) and TG117 (HPLC method), log Pow should be measured in undissociated state.
※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 base.
※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.
※Please consult with METI for using this method.
※Both Shake-Flask method and HPLC method are applicable to measure log Dow.