

# **Execution Status of Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances (CSCL) (2006)**

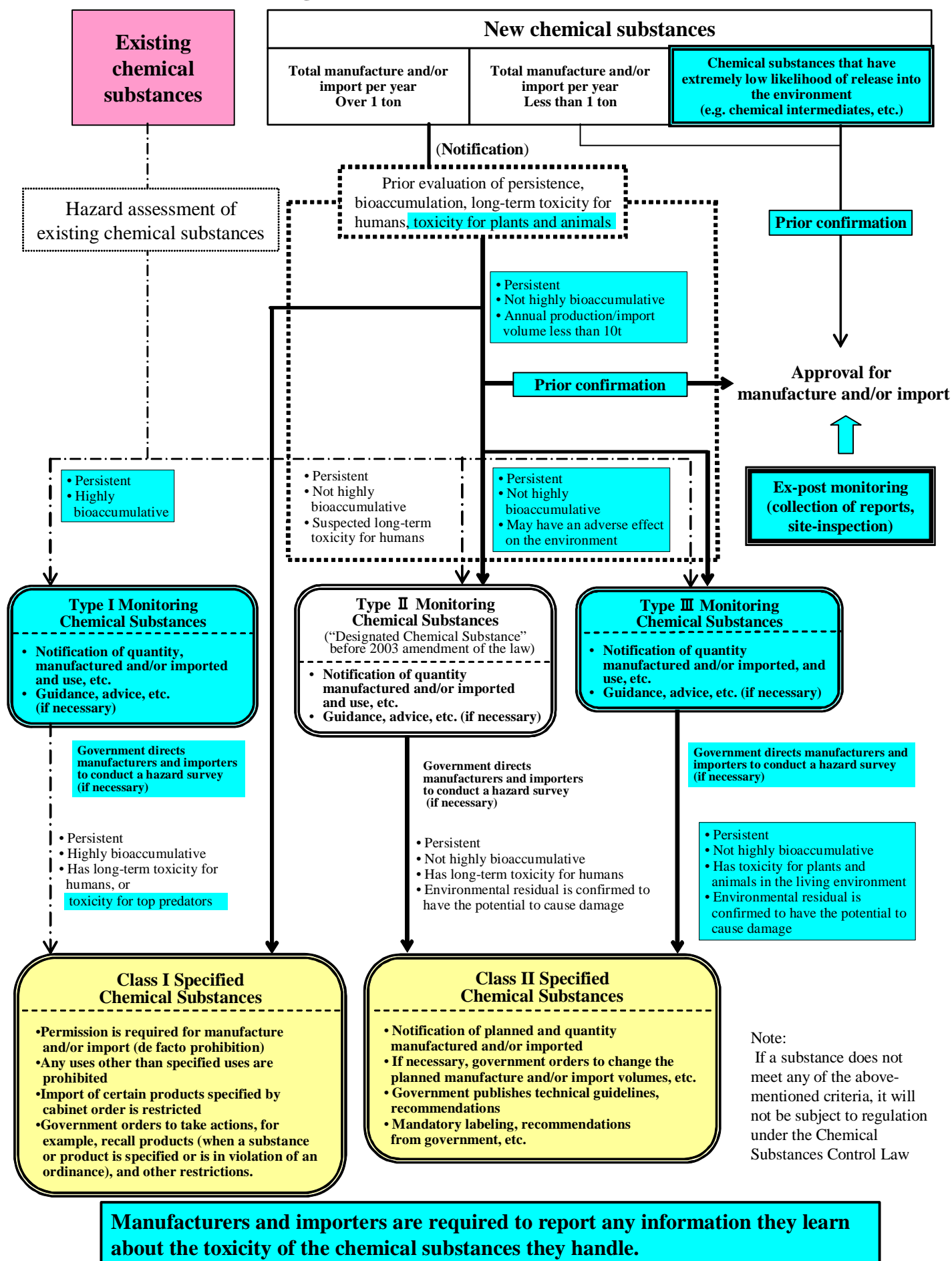
July 20, 2007

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

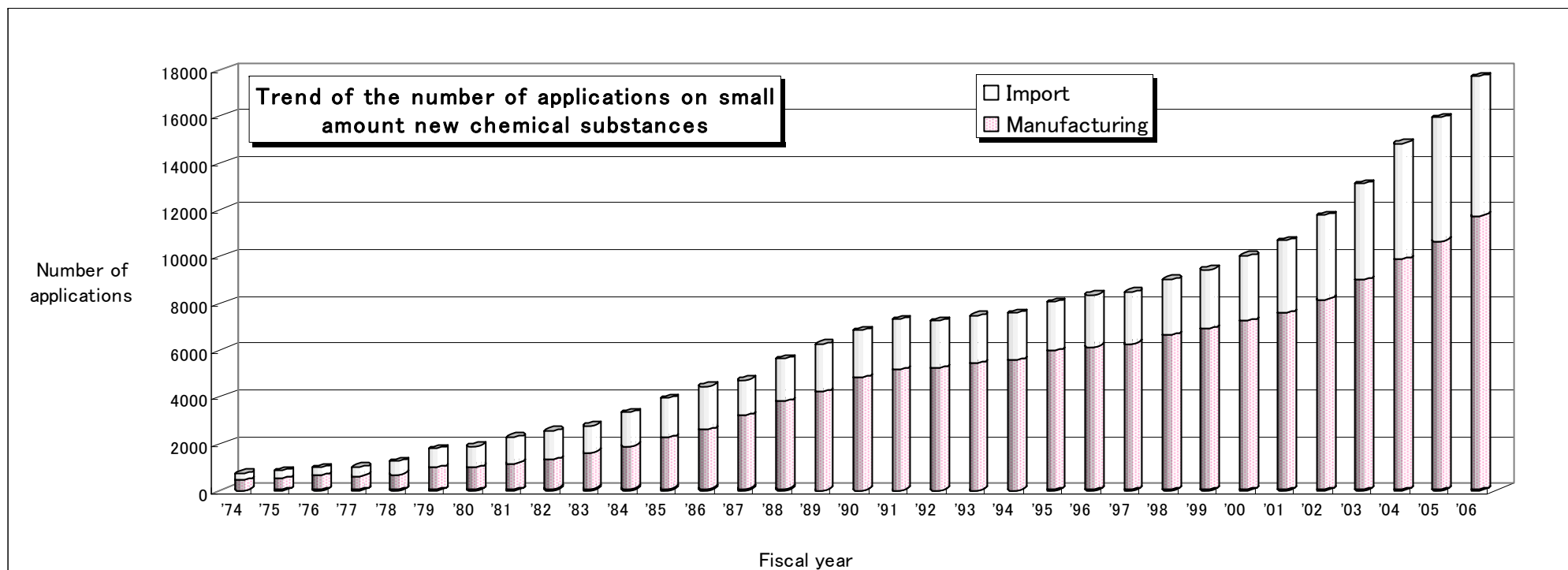
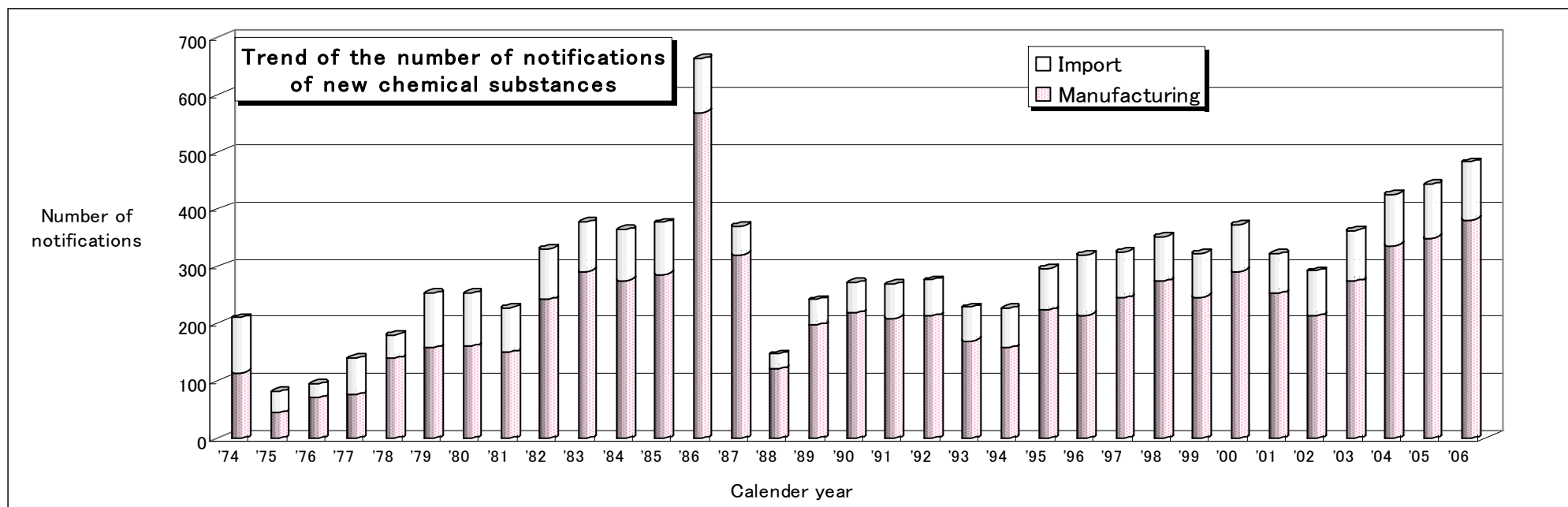
## Table of contents

Outline of review and regulations according to the amended Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances .....	1
Trend of the number of notifications of new chemical substances.....	2
Trend of the number of applications on small amount new chemical substances .....	2
Use classification of new chemical substances in 2006 .....	3
Use classification of small amount new chemical substances in 2006.....	3
Trend of the distribution ratio of the number of notifications of new chemical substances .....	4
Trend of the distribution ratio of the number of applications on small amount new chemical substances .....	5
Reason for judgment of non-specified chemical substances under Original CSCL.....	6
Reason for judgment of non-specified and designated chemical substances under CSCL (amended in 1986).....	6
Reason for judgment of non-specified / monitoring chemical substances under CSCL (amended in 2003) .....	6
Reason for judgment in 2006 (biodegradability, bioaccumulation, and toxicity) .....	7
Number of confirmation of intermediates and execution in 2006 .....	8
Number of reporting information on hazardousness in 2006 .....	8
Number of notification of new chemical substances .....	9
Trend of the number of applications and confirmation relating to small amount new chemical substances.....	12
Status of assessment .....	13

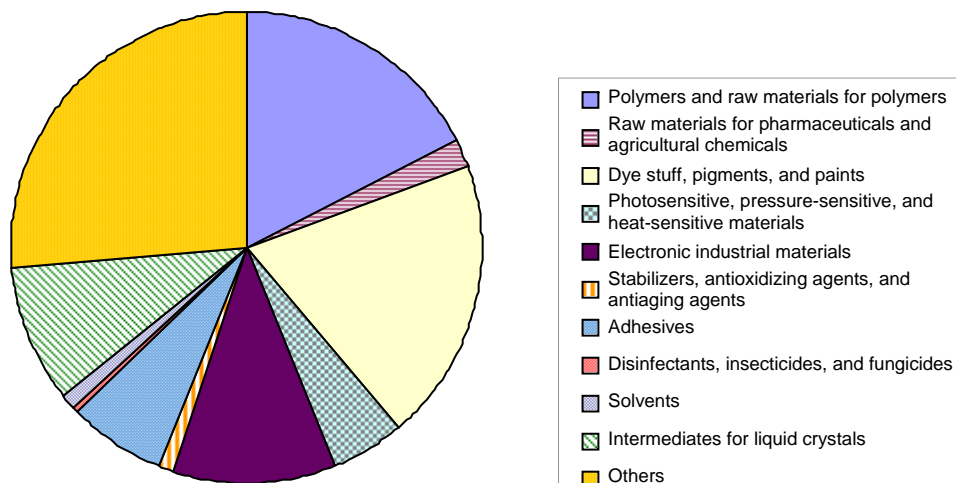
# Outline of review and regulations according to the amended Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances



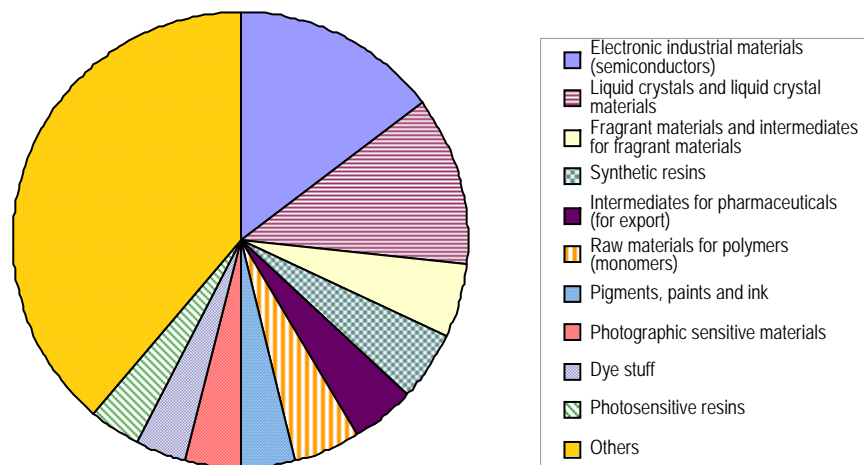
(Current revisions to the law are marked with      )



### Use classification of new chemical substances in 2006



### Use classification of small amount new chemical substances in 2006



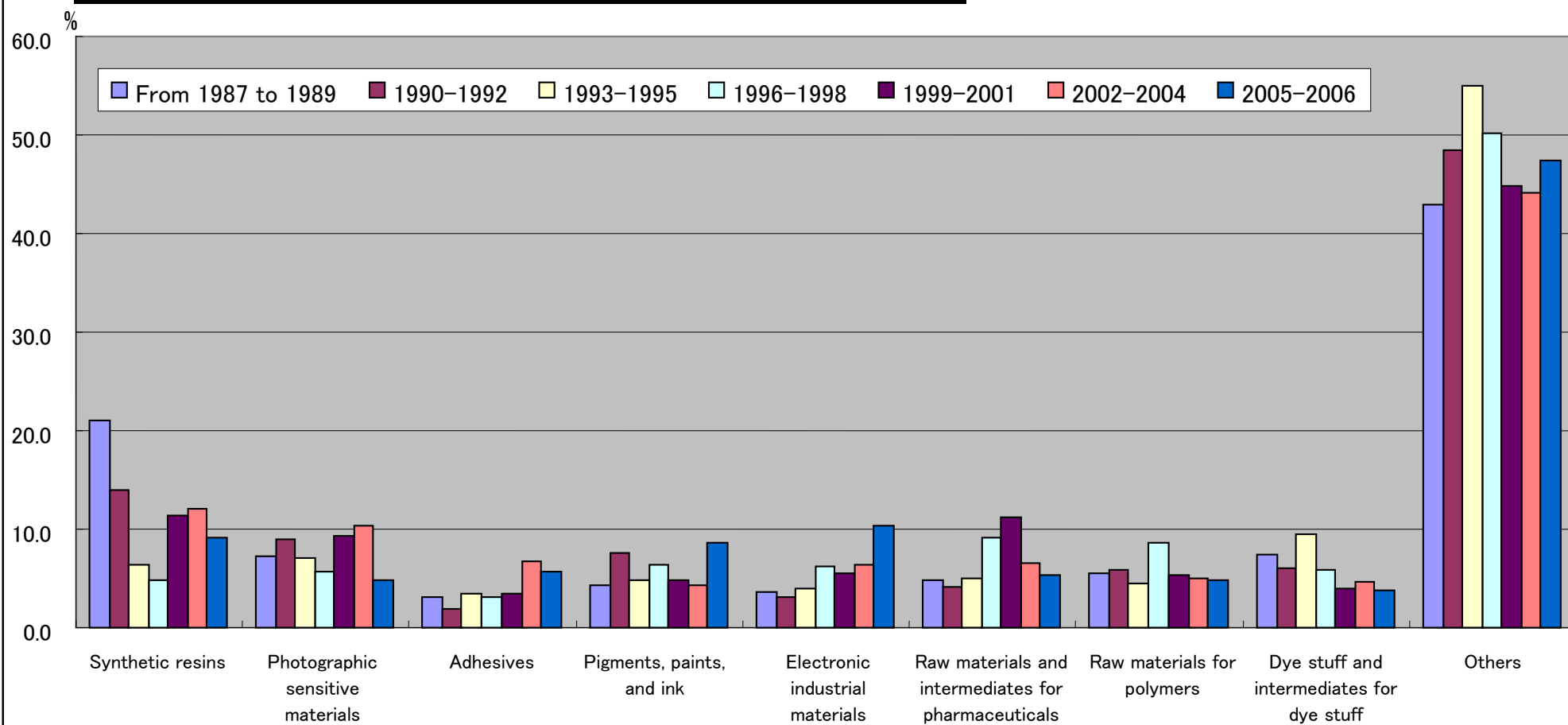
### Use classification of new chemical substances in 2006

	Number of cases	(%)
Polymers and raw materials for polymers	84	17.5
Raw materials for pharmaceuticals and agricultural chemicals	9	1.9
Dye stuff, pigments, and paints	94	19.5
Photosensitive, pressure-sensitive, and heat-sensitive materials	24	5.0
Electronic industrial materials	54	11.2
Stabilizers, antioxidizing agents, and antiaging agents	5	1.0
Adhesives	32	6.7
Disinfectants, insecticides, and fungicides	1	0.2
Solvents	5	1.0
Intermediates for liquid crystals	46	9.6
Others	127	26.4
<b>Total</b>	<b>481</b>	<b>100.0</b>

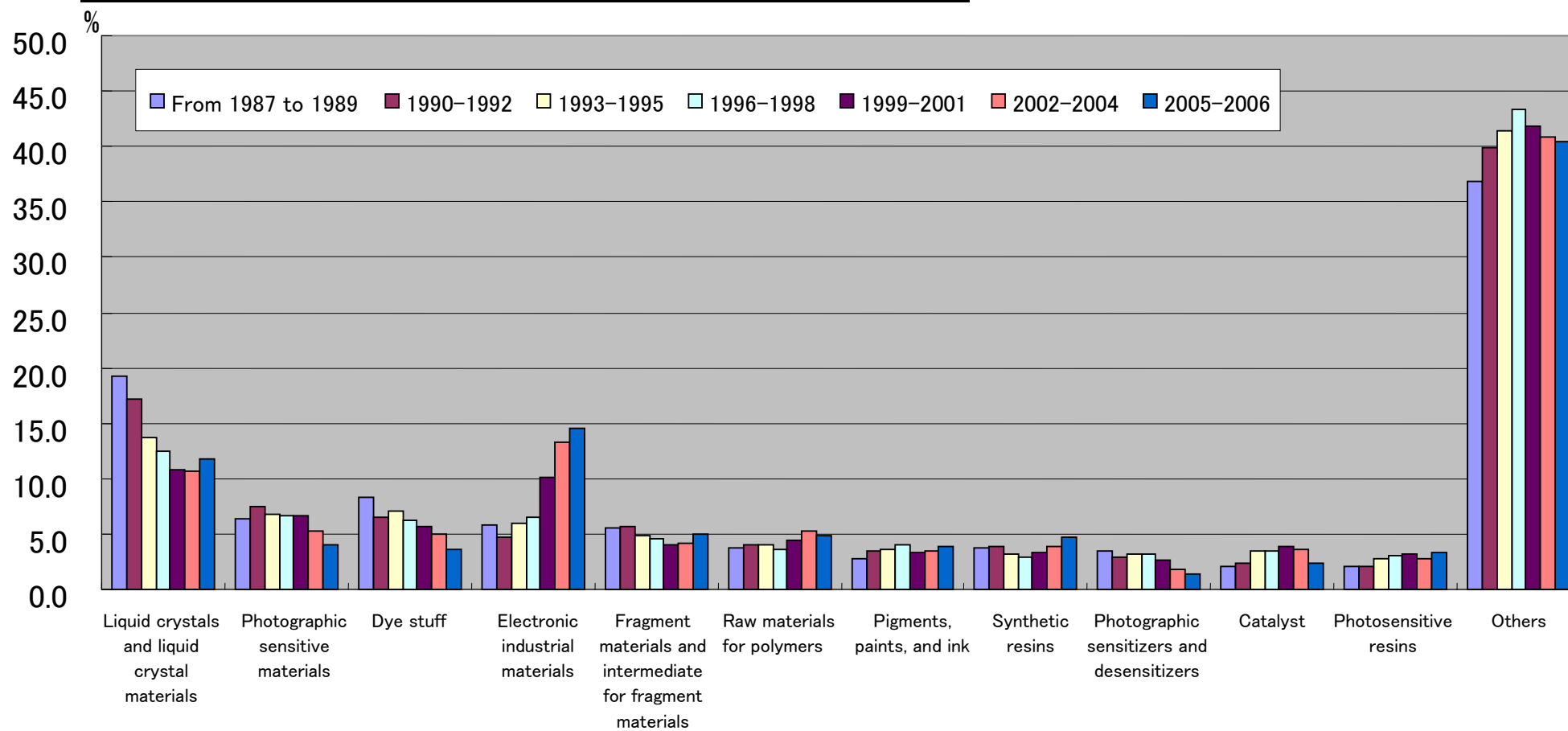
### Use classification of small amount new chemical substances in 2006

	Number of cases
Electronic industrial materials (semiconductors)	2619
Liquid crystals and liquid crystal materials	2117
Intermediates for pharmaceuticals (for export)	932
Raw materials for polymers (monomers)	856
Fragrant materials and intermediates for fragrant materials	817
Synthetic resins	813
Photographic sensitive materials	701
Pigments, paints and ink	688
Dye stuff	642
Photosensitive resins	608
Others	6894
<b>Total</b>	<b>17687</b>

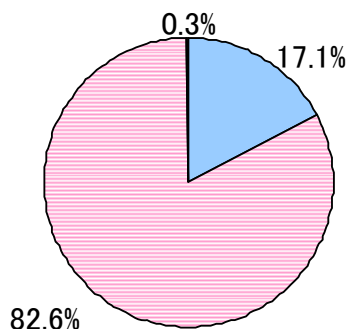
**Trend of the distribution ratio of the number of notifications of new chemical substances**



**Trend of the distribution ratio of the number of applications on small amount new chemical substances**

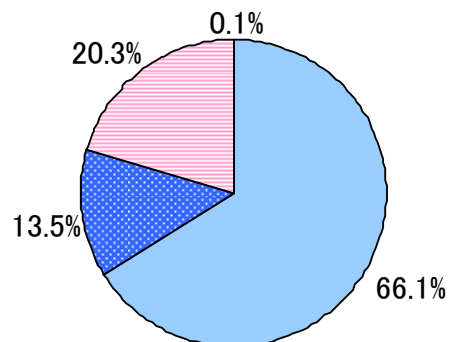


Reason for judgment of non-specified chemical substances under Original CSCL



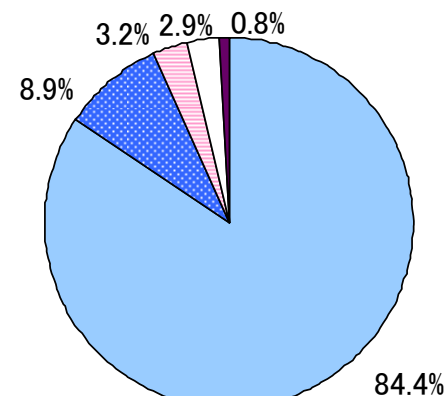
■ Ready biodegradable  
■ Non-biodegradable and not highly bioaccumulative  
■ No long-term toxicity

Reason for judgment of non-specified/designated chemical substances under CSCL (amended in 1986)



■ No suspicion for long-term toxicity  
■ Ready biodegradable  
■ Designated chemical substances  
■ No long-term toxicity

Reason for judgment of non-specified/monitoring chemical substances under CSCL (amended in 2003)



■ No suspicion for long-term toxicity  
■ Ready biodegradable  
■ Type II monitoring chemical substances (not Type III monitoring chemical substances)  
■ Type II monitoring chemical substances and Type III monitoring chemical substances  
■ Type III monitoring chemical substances (not Type II monitoring chemical substances)

Reason for judgment of non-specified chemical substances under Original CSCL

	Number of cases	(%)
Ready biodegradable	536	17.1
Non-biodegradable and not highly bioaccumulative	2588	82.6
No long-term toxicity	8	0.3
Total	3132	100.0

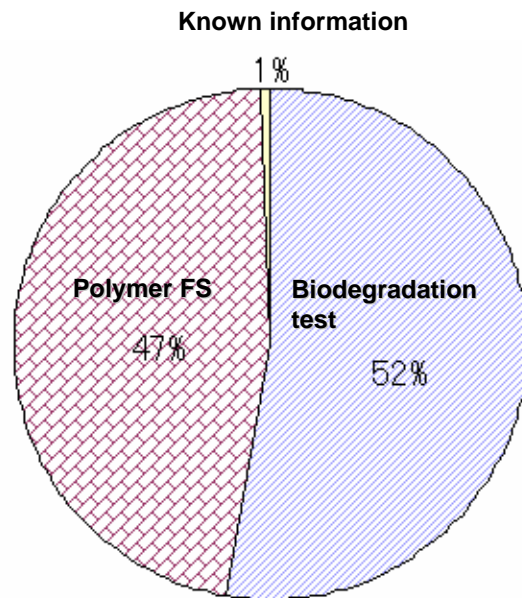
Reason for judgment of non-specified/designated chemical substances under CSCL (amended in 1986)

	Number of cases	(%)
No suspicion for long-term toxicity	2974	66.1
Ready biodegradable	605	13.5
Designated chemical substances	913	20.3
No long-term toxicity	6	0.1
Total	4498	100.0

Reason for judgment of non-specified/monitoring chemical substances under CSCL (amended in 2003)

	Number of cases	(%)
No suspicion for long-term toxicity	561	84.4
Ready biodegradable	59	8.9
Type II monitoring chemical substances (not Type III monitoring chemical substance)	21	3.2
Type II monitoring chemical substances and Type III monitoring chemical substances	19	2.9
Type III monitoring chemical substances (not Type II monitoring chemical substances)	5	0.8
Total	665	100.0

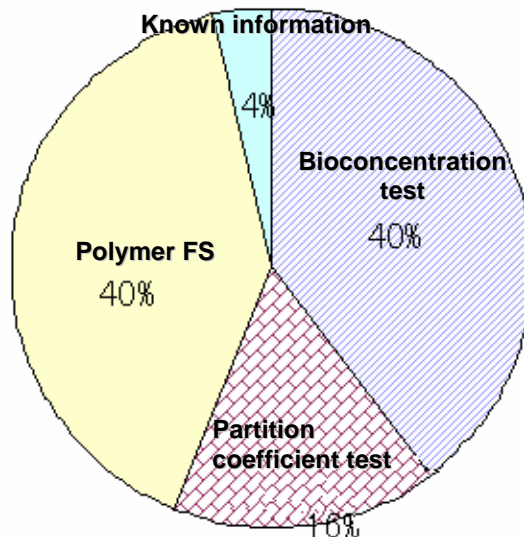
Reason for the judgment of biodegradability in 2006



Reason for the judgment of biodegradability in 2006

	Number of cases	(%)
Biodegradation test	192	53
Polymer flow scheme	169	47
Known information, etc.	2	1
Total	363	100

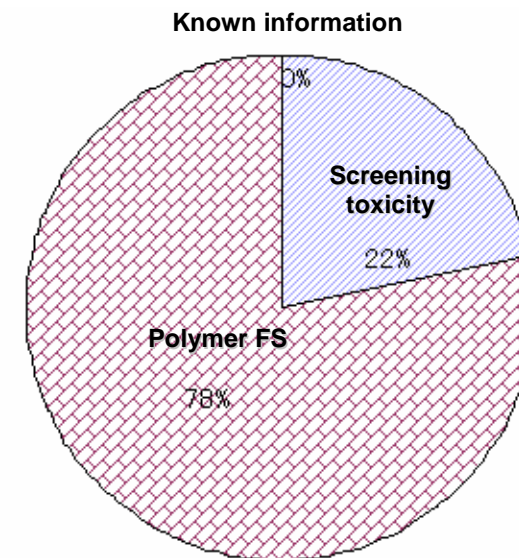
Reason for the judgment of bioaccumulation in 2006



Reason for the judgment of bioaccumulation in 2006

	Number of cases	(%)
Bioconcentration test	167	40
Partition coefficient test	69	16
Polymer flow scheme	169	40
Known information, etc.	15	4
Total	420	100

Reason for the judgment of toxicity in 2006

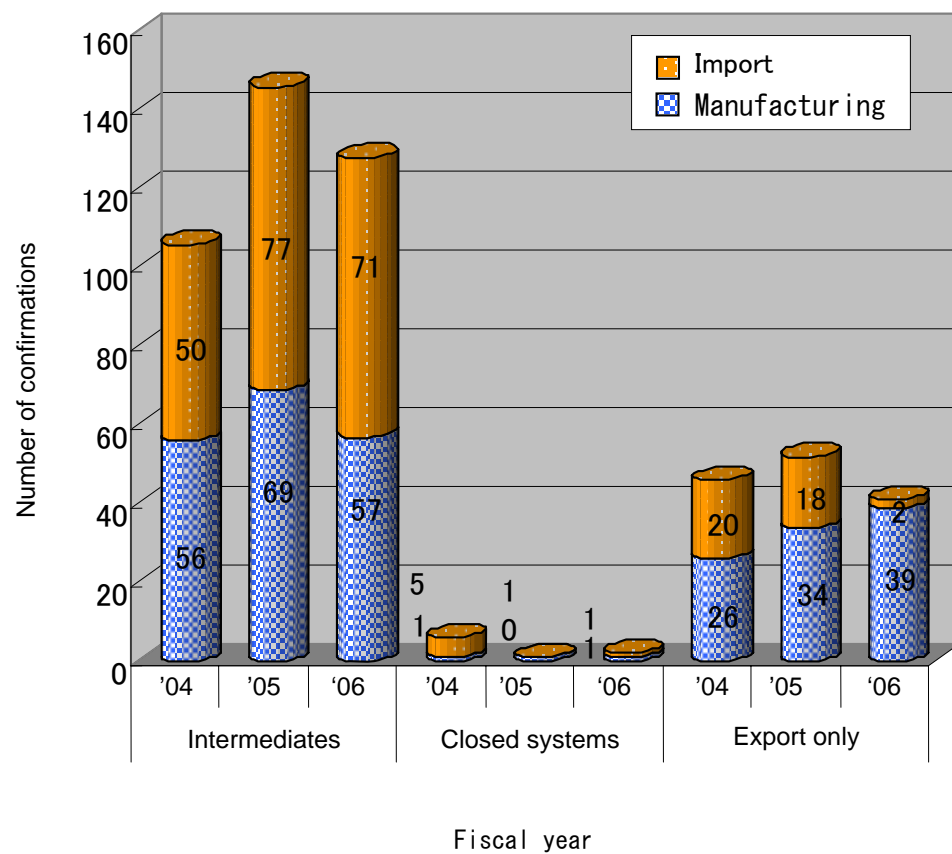


Reason for the judgment of toxicity in 2006

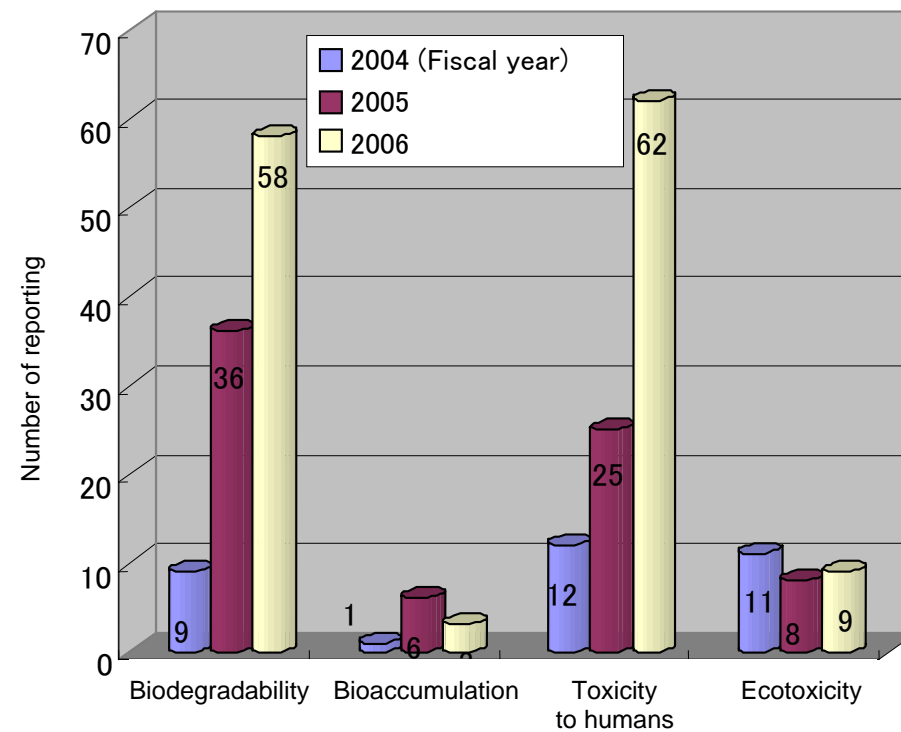
	Number of cases	(%)
Screening toxicity	46	22
Polymer flow scheme	167	78
Known information, etc.	0	0
Total	213	100

Since these figures include derivative materials and exclude notifications of the same materials, the numbers are different from those described in the data on the number of notification.

Number of confirmation of intermediates, closed system, and export only in 2006



Number of reporting information on hazardousness in 2006



## Execution status of CSCL

Number of notifications of new chemical substances (Original CSCL)

Calendar year	'74	'75	'76	'77	'78	'79	'80	'81	'82	'83	'84	'85	'86	'87 (January to March)	Subtotal
Number of notifications	210	82	95	140	180	53	253	228	331	377	364	376	662	313	3864
Manufacturing	114	45	70	76	140	158	160	150	242	291	275	286	568	269	2844
Import	96	37	25	64	40	95	93	78	89	86	89	90	94	44	1020
Those that correspond to the Paragraph 1, Article 4 of the Original CSCL	29	28	57	111	144	230	199	213	305	345	322	327	553	269	3132
Manufacturing	15	15	42	61	113	141	135	142	227	268	243	247	476	229	2354
Import	14	13	15	50	31	89	64	71	78	77	79	80	77	40	778
Judgment based on biodegradability	12	15	24	26	38	46	28	42	78	47	53	61	55	11	536
Manufacturing	6	10	20	17	35	41	26	38	62	36	44	56	44	9	444
Import	6	5	4	9	3	5	2	4	16	11	9	5	11	2	92
Judgment based on bioaccumulation	16	13	33	85	106	184	171	171	226	298	266	264	497	258	2588
Manufacturing	8	5	22	44	78	100	109	104	164	232	199	189	431	220	1905
Import	8	8	11	41	28	84	62	67	62	66	67	75	66	38	683
Judgment based on long-term toxicity	1	0	0	0	0	0	0	0	1	0	3	2	1	0	8
Manufacturing	1	0	0	0	0	0	0	0	1	0	0	2	1	0	5
Import	0	0	0	0	0	0	0	0	0	0	3	0	0	0	3

(January to March for 1987.)

## Number of notifications of new chemical substances (CSCL amended in 1986)

Calendar year	'87 (April to December)	'88	'89	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04 (January to March)	Subtotal
Number of notifications	57	147	242	272	269	276	229	227	296	320	325	352	323	373	322	292	362	121	4805
Manufacturing	51	121	198	218	209	213	170	157	223	215	245	274	246	291	253	214	274	91	3663
Import	6	26	44	54	60	63	59	70	73	105	80	78	77	82	69	78	88	30	1142
Those that correspond to Item 3, Paragraph 1, Article 4 of CSCL (1986)	48	125	197	215	196	210	173	165	220	249	224	226	230	267	253	200	293	94	3585
Manufacturing	42	105	168	171	162	171	131	121	168	160	166	188	177	210	205	153	228	69	2795
Import	6	20	29	44	34	39	42	44	52	89	58	38	53	57	48	47	65	25	790
Ready biodegradable	23	37	32	27	49	43	25	31	37	48	37	28	34	44	45	19	37	9	605
Manufacturing	19	31	28	18	39	37	20	25	31	46	31	23	25	35	38	16	31	7	500
Import	4	6	4	9	10	6	5	6	6	2	6	5	9	9	7	3	6	2	105
No suspicion for long-term toxicity	25	84	163	188	147	167	148	134	183	201	187	198	196	223	208	181	256	85	2974
Manufacturing	23	71	140	153	123	134	111	96	137	114	135	165	152	175	169	137	197	62	2294
Import	2	13	23	35	24	33	37	38	46	87	52	33	44	48	39	44	59	23	680
No long-term toxicity	0	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6
Manufacturing	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
Import	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
Number of designated chemical substances	3	14	30	26	41	38	41	39	63	52	62	99	81	93	62	77	65	27	913
Manufacturing	3	11	20	23	28	23	31	21	48	42	46	67	59	73	44	53	42	22	656
Import	0	3	10	3	13	15	10	18	15	10	16	32	22	20	18	24	23	5	257

\* The number of notifications includes the notifications of the same materials and the number of notifications of materials that have been withdrawn.

\* From April to December for 1987 and from January to March for 2004.

\* The number for import includes the notifications from overseas in accordance with the provisions stipulated in 2, Article 5 of the CSCL(1986) (export).

# Number of notifications of new chemical substances (CSCL amended in 2003)

Calendar year	'04 (April to December)	'05	'06	Subtotal
Number of notifications	305	443	482	1230
Manufacturing	245	349	381	975
Import	60	94	101	255
Those that correspond to Item 5, Paragraph 1, Article 4 of the CSCL (2003)	156	235	231	622
Manufacturing	134	206	196	536
Import	22	29	35	86
Biodegradable	20	24	15	59
Manufacturing	14	18	13	45
Import	6	6	2	14
No suspicion for long-term toxicity	136	211	216	563
Manufacturing	120	188	183	491
Import	16	23	33	72
No long-term toxicity	0	0	0	0
Manufacturing	0	0	0	0
Import	0	0	0	0
Type II monitoring chemical substances	8	17	15	40
Manufacturing	3	10	10	23
Import	5	7	5	17
Type III monitoring chemical substances	5	13	6	24
Manufacturing	1	8	4	13
Import	4	5	2	11
Type II and Type III monitoring chemical substances (included in the above figures)	5	8	6	19
Manufacturing	1	4	4	9
Import	4	4	2	10
Those that correspond to each Item of Paragraph 1, Article 4-2 of the CSCL(low production volume)	141	186	236	563

\* The number of notifications includes the notifications of the same substances and the reports according to Paragraph 7, Article 4-2 of the CSCL (continuation of the examination of new chemical substances whose production volume is small.)

\* The number for import includes the notifications from overseas in accordance with the provisions stipulated in Article 5-2 of the CSCL (export).

**Trend of the number of applications and confirmations of small amount new chemical substances**

Fiscal year	'74	'75	'76	'77	'78	'79	'80	'81	'82	'83	'84	'85	'86	'87	'88	'89	'90	'91
Applications	714	773	931	949	1170	1722	1833	2216	2484	2699	3278	3893	4399	4660	5562	6262	6848	7305
Manufacturing	415	469	576	545	617	915	937	1084	1273	1557	1834	2177	2548	3123	3749	4218	4799	5138
Import	299	304	355	404	553	807	896	1132	1211	1142	1444	1716	1851	1537	1813	2044	2049	2167
Confirmation (included in the above figures)	661	773	851	949	1170	1722	1833	2213	2479	2691	3271	3458	4399	4643	5517	6212	6800	7155
Manufacturing	392	469	523	545	617	915	937	1084	1272	1556	1833	1933	2548	3111	3722	4188	4772	5089
Import	269	304	328	404	553	807	896	1129	1207	1135	1438	1525	1851	1532	1795	2024	2028	2066

Fiscal year	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04	'05	'06
Applications	7236	7473	7567	8050	8333	8468	9007	9438	10032	10669	11763	13087	14823	15923	17687
Manufacturing	5220	5405	5555	5951	6113	6261	6659	6886	7222	7559	8153	8973	9889	10650	11718
Import	2016	2068	2012	2099	2220	2207	2348	2552	2810	3110	3610	4114	4934	5273	5969
Confirmation (included in the above figures)	7196	7432	7524	8008	8277	8423	8967	9381	9963	10577	10093	12980	14629	15749	17362
Manufacturing	5202	5393	5529	5923	6076	6245	6637	6853	7185	7515	7120	8932	9826	10583	11542
Import	1994	2039	1995	2085	2201	2178	2330	2528	2778	3059	2973	4048	4803	5166	5820

Status of the assessment of existing chemical substances (Original CSCL amended in 1986)

Calendar year	'73	'74	'75	'76	'77	'78	'79	'80	'81	'82	'83	'84	'85	'86	'87	'88
Results of assessment			<del>40</del> <sup>*1</sup> 39	<del>37</del> <sup>*1</sup> 35	<del>88</del> <sup>*1</sup> 85	<del>56</del> <sup>*2</sup> 54	<del>79</del> <sup>*2</sup> 78	59	40	<del>74</del> <sup>*3</sup> 69	<del>45</del> <sup>*3</sup> 42	<del>40</del> <sup>*3</sup> 39	56	47	<del>49</del> <sup>*4</sup> 48	41
Biodegradable			<del>29</del> 28	<del>26</del> 24	<del>37</del> 34	14	26	27	8	16	8	9	11	12	8	17
Not highly bioconcentrative			8	11	50	<del>44</del> 39	<del>53</del> 52	32	28	<del>57</del> 52	<del>37</del> 34	<del>34</del> 30	44	34	38	24
Highly bioconcentrative			3	0	1	1	0	0	4	1	0	0	1	1	<del>3</del> 2	0
Number of substances designated as Class I specified chemical substances	0	1	0	0	0	0	2	0	4	0	0	0	0	1	0	0
Number of substances designated as designated chemical substances <sup>5</sup>	—	—	—	—	—	—	—	—	—	—	—	—	—	—	8 (3)	15 (14)
Number of substances designated as Class II specified chemical substances	—	—	—	—	—	—	—	—	—	—	—	—	—	—	0	0

Calendar year	'89	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03
Results of assessment	61	42	49	21	52	48	39	30	36	36	30	44	47	78	<del>64</del> <sup>*4</sup> 60
Ready biodegradable	31	10	20	4	45	25	20	14	20	5	13	18	17	26	10
Not highly bioconcentrative	30	31	28	16	7	23	19	16	16	30	17	26	28	52	40
Highly bioconcentrative	0	1	1	1	0	0	0	0	0	1	0	0	2	0	<del>44</del> 10
Number of substances designated as Class I specified chemical substances	1	0	0	0	0	0	0	0	0	0	0	2	0	2	0
Number of substances designated as designated chemical substances <sup>5</sup>	9 (6)	2	1	1	0	0	0	0	0	0	0	77	0	21	12
Number of substances designated as Class II specified chemical substances	10	13	0	0	0	0	0	0	0	0	0	0	0	0	0

(\*1) The reason why a substance is reduced from the figure of 1975, two substances are reduced from the figure of 1976, and three substances are reduced from the figure of 1977 is as follows. Since reconfirmation tests of the six substances that had been judged as "degradable" revealed that they are not degradable, bioconcentration tests were conducted in 1999 and 2000. The results of tests were "not highly bioconcentrative."

(\*2) The reason why two substances are reduced from the figure of 1978 and a substance is reduced from the figure of 1979 is that the assessment of the three substances was changed from "not highly bioconcentrative" to "highly bioconcentrative" in 2003.

(\*3) The reason why five substances are reduced from the figure of 1982 and three substances are reduced from the figure of 1983 and a substance is reduced from the figure of 1975 is that the assessment of the nine substances was changed from "not highly bioconcentrative" to "highly bioconcentrative" in 2002 and 2004.

(\*4) The reason why a substance is reduced from the figure of 1987 and a substance is reduced from the figure of 2003 is that polybromobiphenyl (the numbers of bromine is limited to two to five) that contains the two substances was judged as "highly bioconcentrative" in 2004.

(\*5) Figures in parentheses indicate the cancellation of designation due to the change from designated chemical substances to Class II specified chemical substances.

Status of assessment of existing chemical substances (CSCL amended in 2003)

Calendar year	04	'05	'06	Total
Results of assessment	46	34	30	1515
Ready biodegradable	10	7	3	540
Not highly bioconcentrative	31	24	15	925
Highly bioconcentrative	5	3	12	50
Number of substances designated as Class I specified chemical substances	0	2	0	15
Number of substances designated as Class II specified chemical substances	0	0	0	23
Number of substances designated as Type I monitoring chemical substances	18	4	3	25 <sup>*6</sup>
Number of substances designated as Type II monitoring chemical substances	41	0	17	204 (23)
Number of substances designated as Type III monitoring chemical substances	0	0	51	51

(\*6) Adding the three substances notified on January 29, 2007 and eight substances notified on May 31, 2007 the current total number of Type I monitoring chemical substances is 36.