

**Execution Status of  
Act on the Evaluation of Chemical  
Substances and Regulation of their  
Manufacture, etc. (CSCL) (2007)**

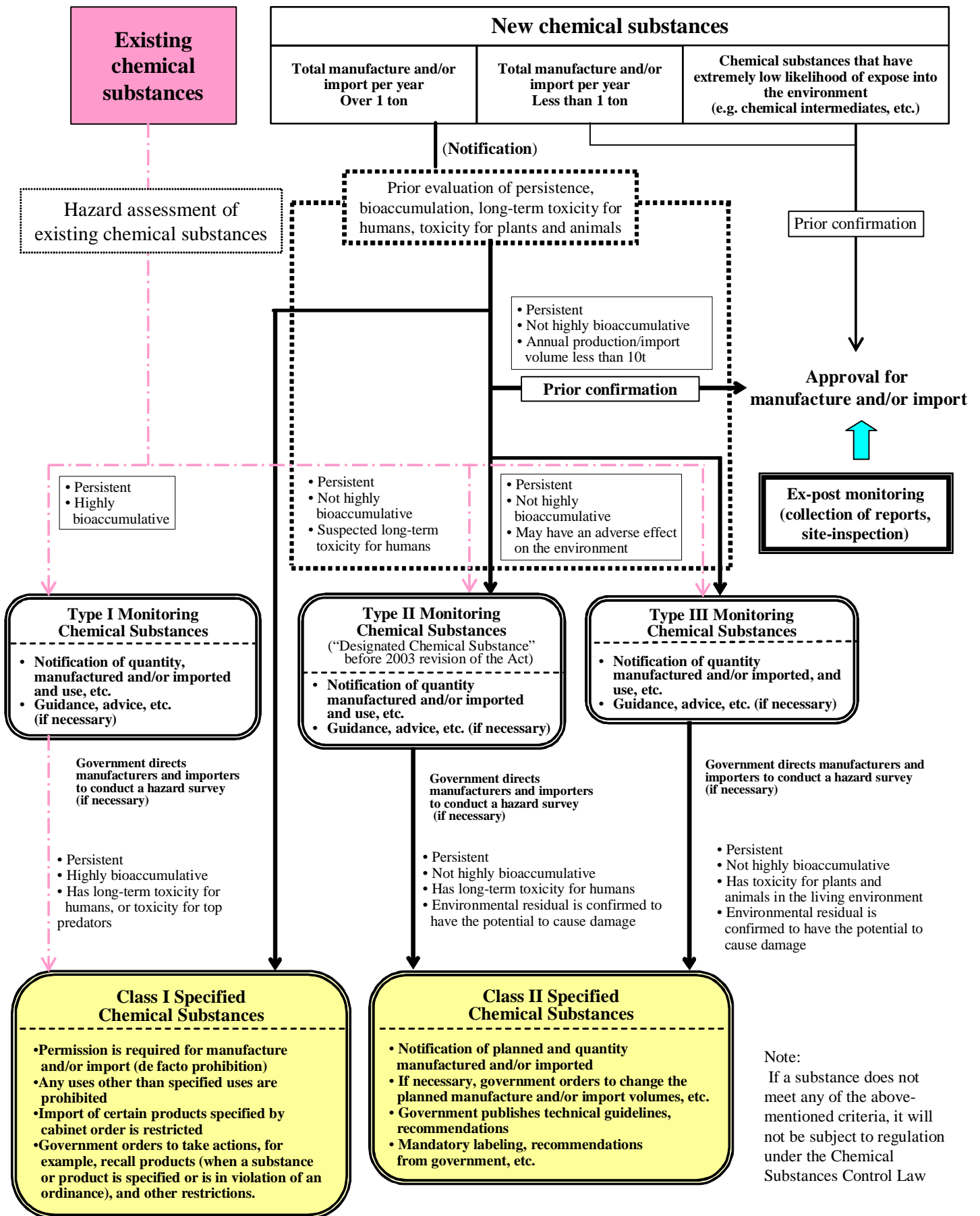
July 14, 2008

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

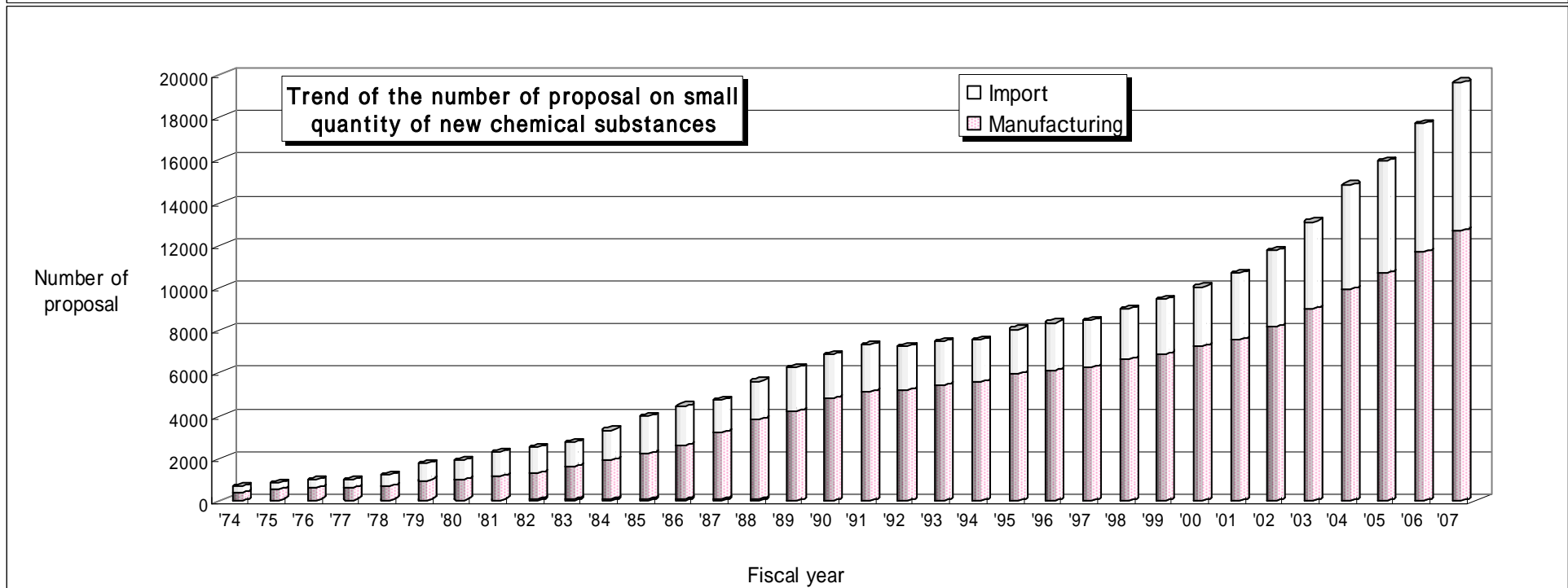
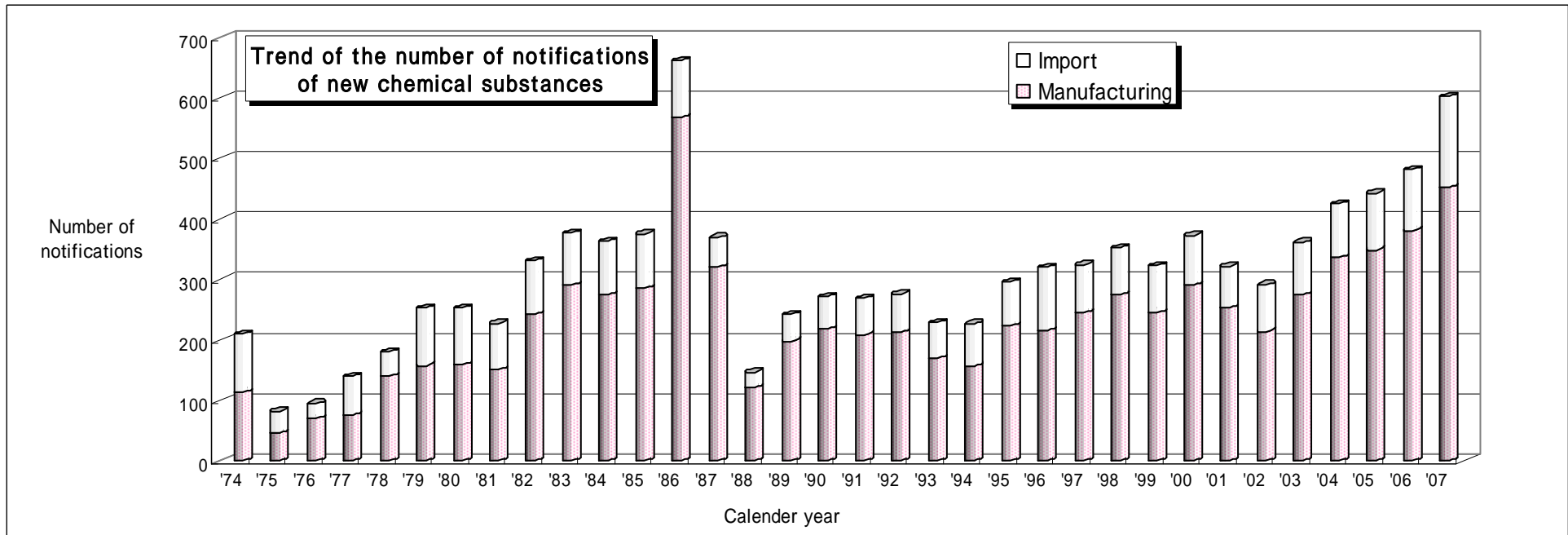
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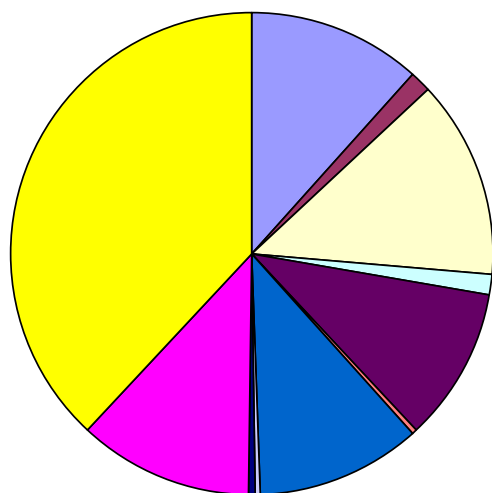
# Outline of review and regulations according to the Act on the Evaluation of the chemical substances and Regulation of their Manufacture, etc.



**Manufacturers and importers are required to report any information they learn about the toxicity of the chemical substances they handle.**



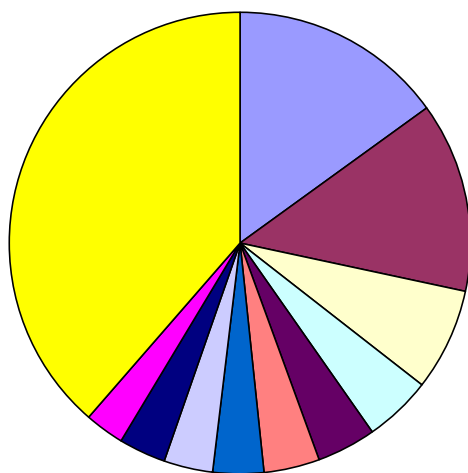
### Use classification of new chemical substances in 2007



- Polymers and raw materials for polymers
- Raw materials for pharmaceuticals and agricultural chemicals
- Dye stuff, pigments, and paints
- Photosensitive, pressure-sensitive, and heat-sensitive materials
- Electronic industrial materials
- Stabilizers, antioxidizing agents, and antiaging agents
- Adhesives
- Disinfectants, insecticides, and fungicides
- Solvents
- Intermediates for liquid crystals
- Others

	Number	(%)
Polymers and raw materials for polymers	71	11.8
Raw materials for pharmaceuticals and agricultural chemicals	8	1.3
Dye stuff, pigments, and paints	80	13.3
Photosensitive, pressure-sensitive, and heat-sensitive materials	8	1.3
Electronic industrial materials	62	10.3
Stabilizers, antioxidizing agents, and antiaging agents	2	0.3
Adhesives	67	11.1
Disinfectants, insecticides, and fungicides	1	0.2
Solvents	3	0.5
Intermediates for liquid crystals	71	11.8
Others	229	38.0
<b>Total</b>	<b>602</b>	<b>100.0</b>

### Use classification of small quantity of new chemical substances in 2007

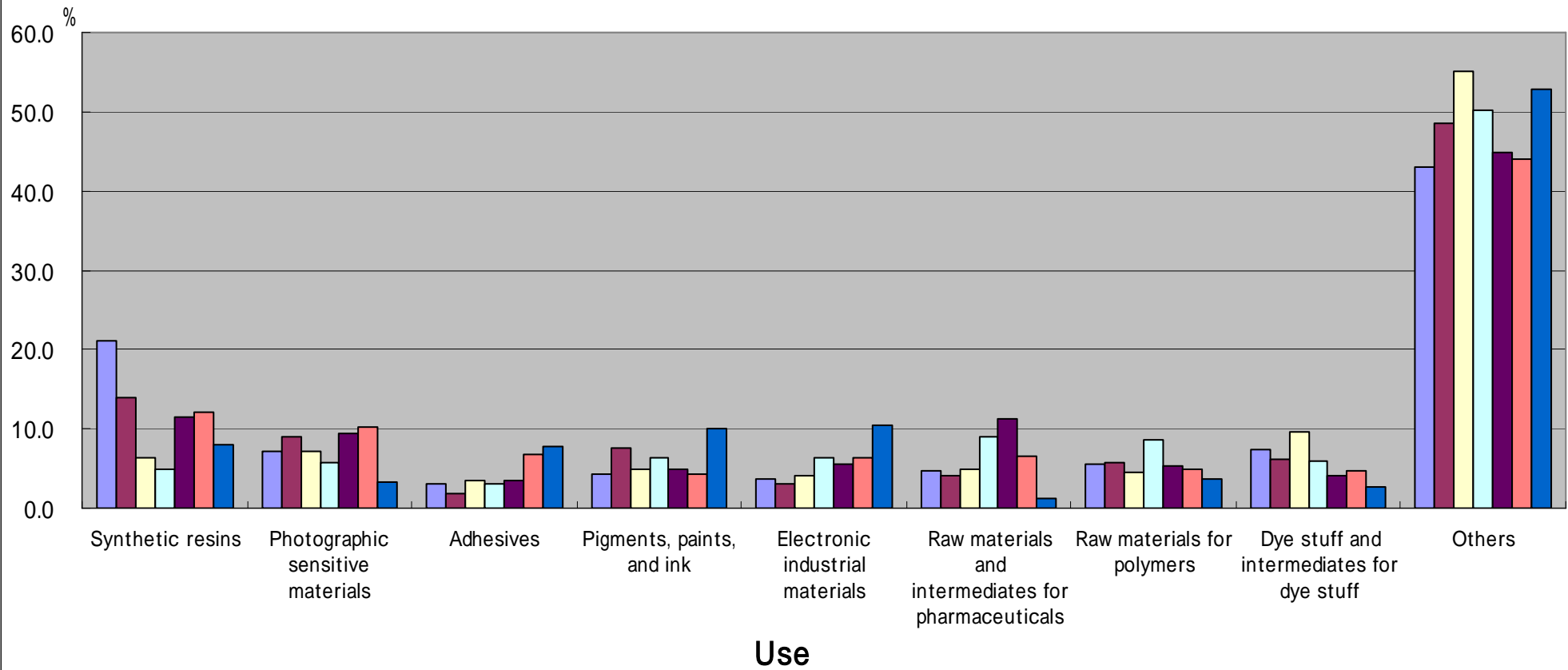


- Electronic industrial materials (semiconductors)
- Liquid crystals and liquid crystal materials
- Fragrant materials and intermediates for fragrant materials
- Synthetic resins
- Raw materials for polymers (monomers)
- Pigments, paints, and ink
- Photosensitive resins
- Photographic sensitive materials
- Dye stuff
- Optic materials
- Others

	Number	(%)
Electronic industrial materials (semiconductors)	2952	15.0
Liquid crystals and liquid crystal materials	2635	13.4
Fragrant materials and intermediates for fragrant materials	1371	7.0
Synthetic resins	981	5.0
Raw materials for polymers (monomers)	808	4.1
Pigments, paints, and ink	759	3.9
Photosensitive resins	704	3.6
Photographic sensitive materials	658	3.3
Dye stuff	652	3.3
Optic materials	565	2.9
Others	7560	38.5
<b>Total</b>	<b>19645</b>	<b>100.0</b>

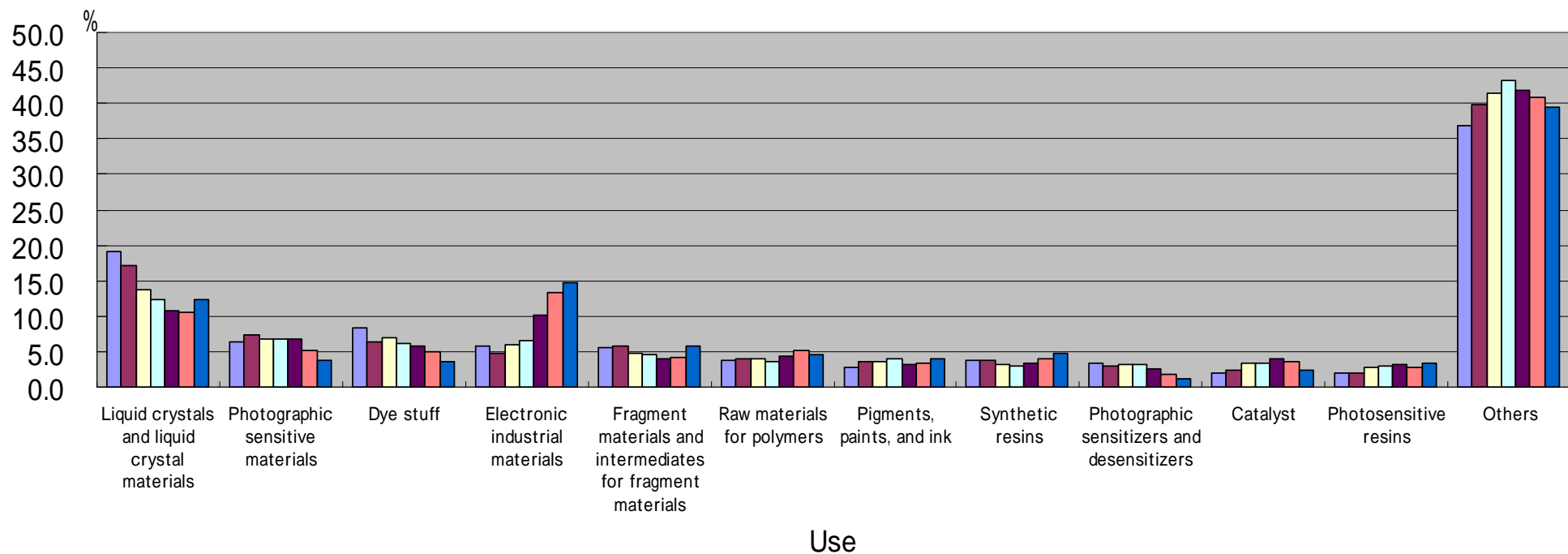
## Trend of the distribution ratio of the number of notification of new chemical substances

■ From 1987 to 1989  
 ■ 1990-1992  
 ■ 1993-1995  
 ■ 1996-1998  
 ■ 1999-2001  
 ■ 2002-2004  
 ■ 2005-2007

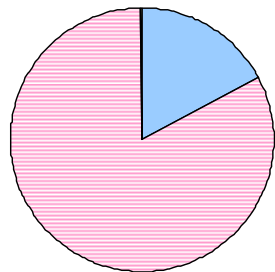


## Trend of the distribution ratio of the number of proposal on small quantity of new chemical substances

■ From 1987 to 1989  
 ■ 1990-1992  
 ■ 1993-1995  
 ■ 1996-1998  
 ■ 1999-2001  
 ■ 2002-2004  
 ■ 2005-2007



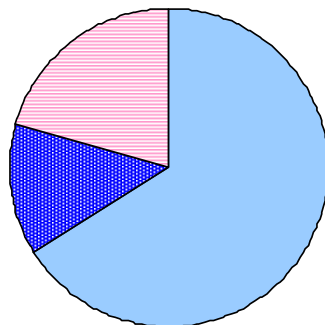
Reason for judgment of non-specified chemical substances under Original CSCL



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

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

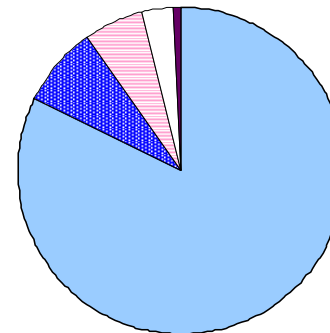
Reason for judgment of non-specified/designated chemical substances under CSCL (revised in 1986)



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

	Number	(%)
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
<b>Total</b>	<b>4498</b>	<b>100.0</b>

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

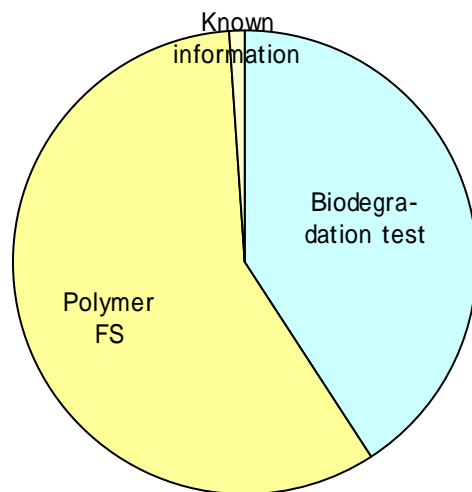


- No suspicion for long-term toxicity
- Ready biodegradable
- Type II monitoring chemical substances (not Type III monitoring chemical substances)
- Type II monitoring chemical substances and Type III monitoring chemical substances
- Type III monitoring chemical substances (not Type II monitoring chemical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

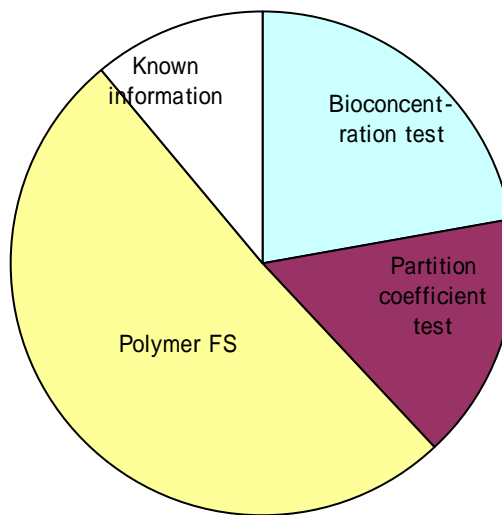
	Number	(%)
No suspicion for long-term toxicity	798	82.4
Ready biodegradable	76	7.8
Type II monitoring chemical substances (not Type III monitoring chemical substances)	58	6.0
Type II monitoring chemical substances and Type III monitoring chemical substances	29	3.0
Type III monitoring chemical substances (not Type II monitoring chemical substances)	8	0.8
<b>Total</b>	<b>969</b>	<b>100.0</b>



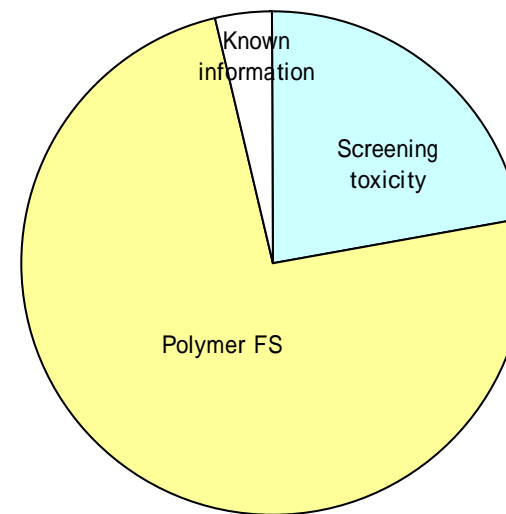
Reason for the judgment of biodegradability in 2007



Reason for the judgment of bioaccumulation in 2007



Reason for the judgment of toxicity in 2007



Reason for the judgment of biodegradability in 2007

	Number	(%)
Biodegradation test	165	41
Polymer flow scheme	236	58
Known information, etc.	4	1
Total	405	100

Reason for the judgment of bioaccumulation in 2007

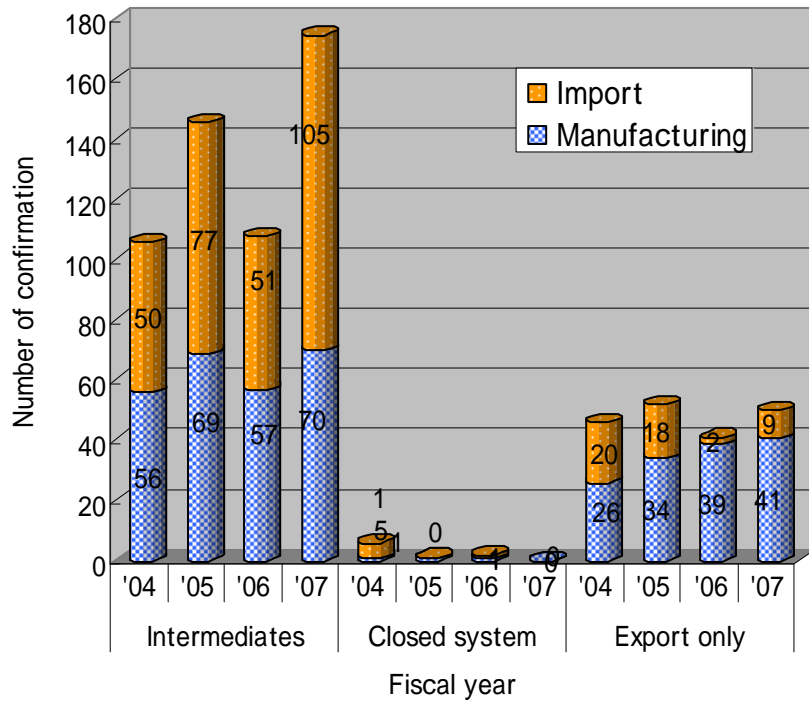
	Number	(%)
Bioconcentration test	103	22
Partition coefficient test	73	16
Polymer flow scheme	236	51
Known information, etc.	51	11
Total	463	100

Reason for the judgment of toxicity in 2007

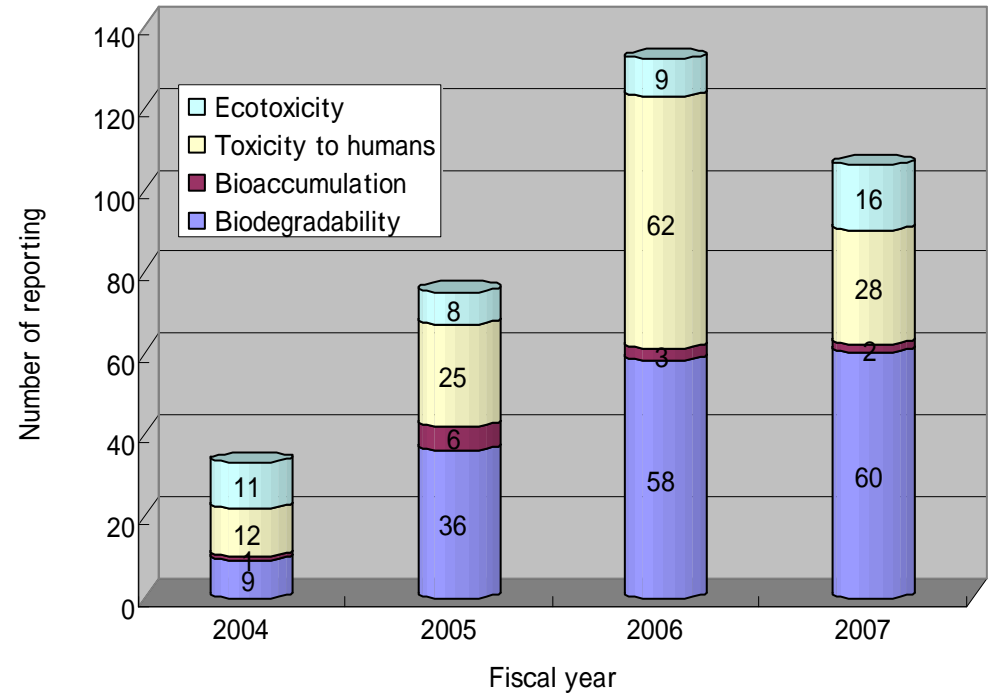
	Number	(%)
Screening toxicity	70	22
Polymer flow scheme	235	74
Known information, etc.	11	3
Total	213	100

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 2007



Number of reporting information on hazardouness in 2007



## 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#1	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) of 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

#1 January to March

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

Calendar year	'87 <sup>#2</sup>	'88	'89	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04 <sup>#1</sup>	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 (iii) of paragraph (1) of 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

#2 April to December

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

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

**Number of notifications of new chemical substances (CSCL revised in 2003)**

Calendar year	'04 <sup>#2</sup>	'05	'06	'07	Subtotal
Number of notifications	305	443	482	603	1833
Manufacturing	245	975	349	452	1427
Import	60	255	94	151	406
Those that correspond to item (v) of paragraph (1) of Article 4 of the CSCL (2003)	156	235	231	321	943
Manufacturing	134	536	206	270	805
Import	22	86	29	51	138
Biodegradable	20	59	24	20	79
Manufacturing	45	14	18	16	61
Import	14	6	6	4	18
No suspicion for long-term toxicity	136	563	211	301	864
Manufacturing	491	120	188	253	744
Import	72	16	23	47	119
No long-term toxicity	0	0	0	0	0
Manufacturing	0	0	0	0	0
Import	0	0	0	0	0
Type II monitoring chemical substances	8	17	15	47	87
Manufacturing	3	23	10	33	56
Import	5	17	7	14	31
Type III monitoring chemical substances	5	13	6	13	37
Manufacturing	1	13	8	8	21
Import	4	11	5	5	16
Type II and Type III monitoring chemical substances (included in the above figures)	5	8	6	10	29
Manufacturing	1	9	4	7	16
Import	4	10	4	3	13
Those that correspond to each item of paragraph 1 of Article 4-2 of the CSCL (low production volume)	141	186	236	232	795

\*The number of notifications includes the notifications of the same substances and the reports according to paragraph (7) of article 4-2 of the CSCL (continuation of the evaluation of low production volume of new chemical substances.)

\* 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 proposal and confirmations relating to small quantity of new chemical substances**

Fiscal year	'74	'75	'76	'77	'78	'79	'80	'81	'82	'83	'84	'85	'86	'87	'88	'89	'90	'91
Proposal	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	'07
Proposal	7236	7473	7567	8050	8333	8468	9007	9438	10032	10669	11763	13087	14823	15923	17687	19641
Manufacturing	5220	5405	5555	5951	6113	6261	6659	6886	7222	7559	8153	8973	9889	11718	11718	12694
Import	2016	2068	2012	2099	2220	2207	2348	2552	2810	3110	3610	4114	4934	5969	5969	6947
Confirmation (included in the above figures)	7196	7432	7524	8008	8277	8423	8967	9381	9963	10577	10093	12980	14629	15749	17362	19320
Manufacturing	5202	5393	5529	5923	6076	6245	6637	6853	7185	7515	7120	8932	9826	11542	11542	12588
Import	1994	2039	1995	2085	2201	2178	2330	2528	2778	3059	2973	4048	4803	5820	5820	6732

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

Calendar year	'73	'74	'75	'76	'77	'78	'79	'80	'81	'82	'83	'84	'85	'86	'87	'88
Results of assessment			40 <sup>*1</sup> 39	37 <sup>*1</sup> 35	88 <sup>*1</sup> 85	56 <sup>*2</sup> 54	70 <sup>*2</sup> 78	59	40	74 <sup>*3</sup> 69	46 <sup>*3</sup> 42	40 <sup>*3</sup> 39	56	47	40 <sup>*4</sup> 48	41
Biodegradable			29 28	26 24	37 34	14	26	27	8	16	8	9	11	12	8	17
Not highly bioconcentrative			8	11	50	44 39	53 52	32	28	57 52	37 34	34 30	44	34	38	24
Highly bioconcentrative			3	0	1	1	0	0	4	1	0	0	1	1	3 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	64 <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	44 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 revised in 2003)

Calendar year	'04	'05	'06	'07	Total
Results of assessment	46	34	30	28	1543
Ready biodegradable	10	7	3	10	550
Not highly bioconcentrative	31	24	15	18	943
Highly bioconcentrative	5	3	12	0	50
Number of substances designated as Class I specified chemical substances	0	2	0	1	16
Number of substances designated as Class II specified chemical substances	0	0	0	0	23
Number of substances designated as Type I monitoring chemical substances	18	4	3	8	35 <sup>*6</sup>
Number of substances designated as Type II monitoring chemical substances	41	0	17	33	237 (23)
Number of substances designated as Type III monitoring chemical substances	0	0	51	54	105

(\*6) It is the number of Type I monitoring chemical substance as of July 2008, and less than total number of Type I monitoring chemical substance from '04 to '07, because some of them were designated to Class I specified chemical substance.