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This English translation of the Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. has been prepared (up to the revisions of Cabinet Order No. 322 of 2007 (Yet to enter into force)) in compliance with the Standard Bilingual Dictionary March 2007 edition. This is an unofficial translation. Only the original Japanese texts of laws and regulations have legal effect, and the translations are to be used solely as reference material to aid in the understanding of Japanese laws and regulations. The Government of Japan shall not be responsible for the accuracy, reliability or currency of the legislative material provided in this Website, or for any consequence resulting from use of the information in this Website. For all purposes of interpreting and applying law to any legal issue or dispute, users should consult the original Japanese texts published in the Official Gazette.

Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Cabinet Order No. 202 of June 7, 1974)

The Cabinet shall enact this Cabinet Order pursuant to paragraph (2) of Article 2, the proviso of paragraph (1) of Article 3, paragraph (1) of Article 13, Article 14, and Article 28 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973).

Article 1 (Class I Specified Chemical Substances)

The Class I Specified Chemical Substances set forth in paragraph (2) of Article 2 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as the “Act”) shall be the following chemical substances:

- (i) Polychlorinated biphenyls
- (ii) Polychlorinated naphthalenes (limited to those containing three or more chlorine atoms)
- (iii) Hexachlorobenzene
- (iv)
 - 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-exo-1,4-endo-5,8-dimethano-naphthalene (also known as Aldrin; referred to as “Aldrin” in item (iii) of the table in Article 3)
- (v)

- 1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-exo-1,4-endo-5,8-dimethano naphthalene (also known as Dieldrin; referred to as “Dieldrin” in item (iv) of the table in Article 3)
- (vi) 1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-endo-1,4-endo-5,8-dimethano naphthalene (also known as Endrin)
- (vii) 1,1,1-Trichloro-2,2-bis(4-chlorophenyl) ethane (also known as DDT; referred to as “DDT” in item (iii) of the table in Article 3)
- (viii) Mixture of 1,2,4,5,6,7,8,8-Octachloro-2,3,3a,4,7,7a-hexahydro-4,7-methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methano-1H-indene and their analogous compounds (also known as Chlordane or Heptachlor; referred to as “Chlordanes” in item (v) of the table in Article 3)
- (ix) Bis(tributyltin) oxide
- (x) N,N'-Ditolyl-p-phenylenediamine, N-tolyl-N'-xylyl-p-phenylenediamine, or N,N'-dixylyl-p-phenylenediamine
- (xi) 2,4,6-Tri-tert-butylphenol
- (xii) Polychloro-2,2-dimethyl-3-methylidenebicyclo[2.2.1]heptane (also known as Toxaphene)
- (xiii) Dodecachloropentacyclo [5.3.0.0^{2.6}.0^{3.9}.0^{4.8}] decane (also known as Mirex; referred to as “Mirex” in item (ix) of the table in Article 3)
- (xiv) 2,2,2-Trichloro-1,1-bis(4-chlorophenyl) ethanol (also known as Kelthane or Dicofol)
- (xv) Hexachlorobuta-1,3-diene
- (xvi) Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(1,1-dimethylethyl)-

Article 1-2 (Class II Specified Chemical Substances)

The Class II Specified Chemical Substances set forth in paragraph (3) of Article 2 of the Act shall be the following chemical substances:

- (i) Trichloroethylene
- (ii) Tetrachloroethylene
- (iii) Carbon tetrachloride
- (iv) Triphenyltin=N,N-dimethyldithiocarbamate
- (v) Triphenyltin=fluoride
- (vi) Triphenyltin=acetate
- (vii) Triphenyltin=chloride
- (viii) Triphenyltin=hydroxide
- (ix) Triphenyltin=salts of fatty acid (limited to those containing 9, 10 or 11 carbon atoms in the fatty acid)
- (x) Triphenyltin=chloroacetate

- (xi) Tributyltin=methacrylate
- (xii) Bis(tributyltin)=fumarate
- (xiii) Tributyltin=fluoride
- (xiv) Bis(tributyltin)=2,3-dibromosuccinate
- (xv) Tributyltin=acetate
- (xvi) Tributyltin=laurate
- (xvii) Bis(tributyltin)=phthalate
- (xviii) Poly(Alkyl=acrylate-co-methyl=methacrylate-co-tributyltin=methacrylate)
(limited to those containing 8 carbon atoms in alkyl group of alkyl=acrylate)
- (xix) Tributyltin=sulfamate
- (xx) Bis(tributyltin)=maleate
- (xxi) Tributyltin=chloride
- (xxii) Mixture of tributyltin=cyclopentanecarboxylate and its analogous compounds
(also known as Tributyltin=naphthenate)
- (xxiii) Mixture of tributyltin=1,2,3,4,4a,4b,5,6,10,10a-decahydro-7-isopropyl-
1,4a-dimethyl-1-phenanthrenecarboxylate and its analogous compounds (also
known as Tributyltin salt of rosin)

Article 2 (Cases Not Requiring Notification of the Manufacture or Import of New Chemical Substances)

- (1) The cases specified by the Cabinet Order set forth in item (iv) of paragraph (1) of Article 3 of the Act shall be the following cases:
- (i) Where a person intends to manufacture or import a new chemical substance as an intermediate of another chemical substance, and has taken the necessary measures to prevent environmental pollution from said new chemical substance during the period until said new chemical substance is transformed into another chemical substance
 - (ii) Where a person intends to manufacture or import a new chemical substance to be used in such a way as to prevent any emission outside the facility or equipment, and has taken the necessary measures to prevent environmental pollution from said new chemical substance during the period until said new chemical substance is disposed of
 - (iii) Where a person intends to manufacture or import a new chemical substance for the purpose of export (limited to cases where the said export is to a region that has been designated as a region where the necessary measures have been taken to prevent environmental pollution from the new chemical substance by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment), and the person has taken the necessary measures to prevent environmental pollution from said new chemical substance during the period

until said new chemical substance is exported

(2) The quantity specified by the Cabinet Order set forth in item (v) of paragraph (1) of Article 3 of the Act shall be 1 ton.

Article 2-2 (Cases Subject to Exception to Evaluation)

The quantity specified by the Cabinet Order set forth in item (i) of paragraph (4) of Article 4-2 of the Act shall be 10 tons.

Article 3 (Products Whose Import is Prohibited When Class I Specified Chemical Substances are Used)

The products specified by the Cabinet Order set forth in paragraph (1) of Article 13 of the Act shall be those listed in the right-hand column of the following table for each Class I Specified Chemical Substance listed in the left-hand column of said table (excluding products designated by the Minister of Economy, Trade and Industry as being difficult to be substituted for by equivalent products produced in Japan and whose import is especially necessary in view of their usage).

| Class I Specified Chemical Substances | Products |
|--|---|
| (i) Polychlorinated biphenyls | (i) Lubricating, cutting, and hydraulic oils |
| | (ii) Adhesives (excluding those of animal and botanical origin), putty and filling materials for closing or sealing |
| | (iii) Paints (excluding water-based paints), printing inks, and carbonless copying paper |
| | (iv) Heating or cooling devices with liquid heating medium |
| | (v) Oil-filled transformers and paper condensers, and oil-filled condensers and organic-coated condensers |
| | (vi) Air conditioners, television receivers, and microwave ovens |
| (ii) Polychlorinated naphthalenes (limited to those containing three or more chlorine atoms) | (i) Lubricating and cutting oils |
| | (ii) Wood antiseptics, insecticides, and fungicides |
| | (iii) Paints (limited to those for antiseptic, insecticidal, and fungicidal use) |
| (iii) Aldrin and DDT | (i) Wood antiseptics, insecticides, and |

| | |
|--|---|
| | fungicides (ii) Paints (limited to those for antiseptic, insecticidal, and fungicidal use) |
| (iv) Dieldrin | (i) Wood antiseptics, insecticides, and fungicides (ii) Paints (limited to those for antiseptic, insecticidal, and fungicidal use) (iii) Wool (excluding greased wool) |
| (v) Chlordanes | (i) Wood antiseptics and insecticides (ii) Wood adhesives (iii) Paints (limited to antiseptic and insecticidal use) (iv) Wood treated with antiseptics and insecticides (v) Plywood treated with antiseptics and insecticides |
| (vi) Bis(tributyltin)=oxide | (i) Antiseptics and fungicides (ii) Paints (limited to those used to prevent shellfishes, algae, and other living organisms in water from adhering to surfaces) and printing inks (iii) Fishnet |
| (vii) N,N'-Ditolyl-p-phenylenediamine, N-tolyl-N'-xylyl-p-phenylenediamine, or N,N'-dixylyl-p-phenylenediamine | (i) Rubber antioxidants (ii) Styrene-butadiene rubber |
| (viii) 2,4,6-Tri-tert-butylphenol | (i) Antioxidant and other prepared additives (limited to those for lubricating and fuel oils) (ii) Lubricating oils |
| (ix) Mirex | Wood insecticides |
| (x) Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(1,1-dimethylethyl)- | (i) Decorative laminate (ii) Adhesives (excluding those of animal and botanical origin), putty, and filling materials for closing or sealing (iii) Paints and printing ink (iv) Helmets (v) Radiator grills and other auto parts (excluding those made of metals) |

| | |
|--|--|
| | (vi) Lighting covers (vii) Lenses for protective spectacles and frames for spectacles (viii) Deodorants (ix) Waxes (x) Surf-boards (xi) Inked ribbons (xii) Photographic paper (xiii) Buttons (xiv) Tubes, bathtubs, and other plastic products (limited to molded products) |
|--|--|

Article 4 (Products Whose Planned Quantity of Import, etc., Needs to be Notified When Class II Specified Chemical Substances are Used)

The products specified by the Cabinet Order set forth in paragraph (1) of Article 26 of the Act shall be paints (limited to those used to prevent shellfishes, algae, and other living organisms in water from adhering to surfaces) for Class II Specified Chemical Substances listed in items (xi) to (xxiii) of Article 1-2 (referred to as “Tributyltin compounds” in item (iii) of the table in the following Article).

Article 5 (Products for Which Labeling on Containers, etc. is Required When Class II Specified Chemical Substances are Used)

The products specified by the Cabinet Order set forth in paragraph (1) of Article 28 of the Act shall be those listed in the right-hand column of the following table for each Class II Specified Chemical Substance listed in the left-hand column of said table.

| Class II Specified Chemical Substances | Products |
|--|---|
| (i) Trichloroethylene | (i) Adhesives (excluding those of animal and botanical origin) (ii) Paints (excluding water-based paints) (iii) Metalworking fluids (iv) Cleaning agents |
| (ii) Tetrachloroethylene | (i) Vulcanized agents (ii) Adhesives (excluding those of animal and botanical origin) (iii) Paints (excluding water-based paints) (iv) Cleaning agents (v) Finishing agents for textile goods |

| | |
|-----------------------------|--|
| (iii) Tributyltin compounds | (i) Antiseptics and fungicides (ii) Paints (limited to those used to prevent shellfishes, algae, and other living organisms in water from adhering to surfaces) |
|-----------------------------|--|

Article 6 (Fees)

Fees which a person listed in the left-hand column of the following table shall pay under the provisions of Article 35 of the Act shall be as shown in the middle column of said table (or as shown in the right-hand column of said table in the case of an electronic application (which means an application filed using an electronic data processing system prescribed in paragraph (1) of Article 3 of the Act on the Use of Information and Communications Technologies for Administrative Procedures (Act No. 151 of 2002) pursuant to the provisions of said paragraph; the same shall apply hereinafter).

| Persons who shall pay fees | Amount | Amount in the case of an electronic application |
|---|-------------|---|
| (i) Persons seeking to obtain permission under paragraph (1) of Article 6 of the Act | 220,600 yen | 213,700 yen |
| (ii) Persons seeking to obtain permission under paragraph (1) of Article 10 of the Act | 121,700 yen | 117,200 yen |
| (iii) Persons seeking to obtain permission under paragraph (1) of Article 11 of the Act | 46,700 yen | 39,900 yen |

Article 7 (Advisory Councils, etc., Specified by the Cabinet Order)

(1) The advisory councils set forth in paragraph (1) of Article 41 of the Act which are specified by the Cabinet Order shall be those listed in the right-hand column of the following table for the respective Minister listed in the left-hand column of said table.

| | |
|---|--|
| Minister of Health, Labour and Welfare | Pharmaceutical Affairs and Food Sanitation Council |
| Minister of Economy, Trade and Industry | Chemical Substances Council |
| Minister of the Environment | Central Environment Council |

(2) The advisory councils set forth in paragraph (2) of Article 41 of the Act which are specified by the Cabinet Order shall be what are listed in the right-hand column of the following table for the respective Minister listed in the left-hand column of said

table.

| | |
|---|-----------------------------|
| Minister of Economy, Trade and Industry | Chemical Substances Council |
| Minister of the Environment | Central Environment Council |

Supplementary Provisions (Extract)

(Effective Date)

(1) This Cabinet Order shall come into effect as from June 10, 1974; provided, however, that the provisions of Article 3 shall come into effect as from August 1, 1974.

(Repeal of the Cabinet Order to Specify Cases Not Requiring Notification of the Manufacture or Import of New Chemical Substances under Paragraph (1) of Article 3 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.)

(2) The Cabinet Order to Specify Cases Not Requiring Notification of the Manufacture or Import of New Chemical Substances under Paragraph (1) of Article 3 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Cabinet Order No. 102 of 1974) shall be repealed.

Supplementary Provisions (Cabinet Order No. 225 of August 14, 1979)

This Cabinet Order shall come into effect as from August 20, 1979; provided, however, that the provisions for revising Article 3 shall come into effect as from October 11, 1979.

Supplementary Provisions (Cabinet Order No. 302 of October 2, 1981)

This Cabinet Order shall come into effect as from October 12, 1981; provided, however, that the provisions for revising Article 3 shall come into effect as from December 1, 1981.

Supplementary Provisions (Cabinet Order No. 97 of April 13, 1984)

This Cabinet Order shall come into effect as from April 20, 1984.

Supplementary Provisions (Cabinet Order No. 297 of September 17, 1986)

This Cabinet Order shall come into effect as from the day of promulgation;

provided, however, that the provisions for revising Article 3 shall come into effect as from November 21, 1986.

Supplementary Provisions (Cabinet Order No. 335 of October 31, 1986)
(Extract)

(Effective Date)

(1) This Cabinet Order shall come into effect as from the day of enforcement of the Act on the Partial Revision of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (April 1, 1987); provided, however, that the provisions for revising item (ii) of paragraph (1) of Article 2 shall come into effect as from March 1, 1987.

Supplementary Provisions (Cabinet Order No. 49 of March 20, 1987) (Extract)

(1) This Cabinet Order shall come into effect as from April 1, 1987.

Supplementary Provisions (Cabinet Order No. 59 of March 22, 1989) (Extract)

(1) This Cabinet Order shall come into effect as from April 1, 1989.

Supplementary Provisions (Cabinet Order No. 75 of March 29, 1989)

This Cabinet Order shall come into effect as from April 1, 1989.

Supplementary Provisions (Cabinet Order No. 351 of December 27, 1989)

(Effective Date)

(1) This Cabinet Order shall come into effect as from January 6, 1990; provided, however, that the provisions for revising Article 3 shall come into effect as from March 1, 1990.

(Transitional Measures)

(2) With regard to the application of penal provisions to acts committed prior to the enforcement of the provisions for revising Article 1-2, the provisions then in force shall remain applicable.

Supplementary Provisions (Cabinet Order No. 259 of September 12, 1990)

(Effective Date)

(1) This Cabinet Order shall come into effect as from the day of promulgation.

(Transitional Measures)

(2) With regard to the application of penal provisions to acts committed prior to the enforcement of the provisions for revising Article 1-2, the provisions then in force shall remain applicable.

Supplementary Provisions (Cabinet Order No. 49 of March 25, 1991)

This Cabinet Order shall come into effect as from April 1, 1991.

Supplementary Provisions (Cabinet Order No. 77 of March 24, 1994) (Extract)

(1) This Cabinet Order shall come into effect as from April 1, 1994.

Supplementary Provisions (Cabinet Order No. 67 of March 24, 1997)

(Effective Date)

(1) This Cabinet Order shall come into effect as from April 1, 1997.

(Transitional Measures)

(2) The provisions then in force shall remain applicable to fees to be paid by a person who intends to take the Information Technology Engineers Examination which has been publicly notified prior to the enforcement of this Cabinet Order.

Supplementary Provisions (Cabinet Order No. 98 of March 24, 2000)

(Effective Date)

(1) This Cabinet Order shall come into effect as from April 1, 2000; provided, however, that the provisions of Article 19 shall come into effect as from June 1, 2000.

(Transitional Measures)

(2) The provisions then in force shall remain applicable to fees to be paid by a person who intends to take a Second-Class electrician's examination which has been publicly notified prior to the enforcement of this Cabinet Order.

Supplementary Provisions (Cabinet Order No. 311 of June 7, 2000) (Extract)

Article 1 (Effective Date)

This Cabinet Order shall come into effect as from the date of enforcement of the Act on the Partial Revision of the Cabinet Act (Act No. 88 of 1999) (January 6, 2001).

Supplementary Provisions (Cabinet Order No. 542 of December 27, 2000)

This Cabinet Order shall come into effect as from January 6, 2001; provided, however, that the provisions for revising Article 3 shall come into effect as from July 1, 2001.

Supplementary Provisions (Cabinet Order No. 287 of September 4, 2002)

This Cabinet Order shall come into effect as from the day of promulgation; provided, however, that the provisions for revising Article 3 shall come into effect as from November 1, 2002.

Supplementary Provisions (Cabinet Order No. 5 of January 15, 2003)

This Cabinet Order shall come into effect as from March 15, 2003.

Supplementary Provisions (Cabinet Order No. 419 of September 19, 2003)

(Effective Date)

(1) This Cabinet Order shall come into effect as from the date of enforcement of the Act on the Partial Revision of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as the "Revising Act") (April 1, 2004).

(Persons Subject to Transitional Measures pertaining to Confirmation)

(2) The persons specified by the Cabinet Order set forth in Article 2 of the Supplementary Provisions of the Revising Act shall be those who manufacture or import a new chemical substance as an intermediate of medicines pertaining to the permission prescribed in paragraph (1) of Article 12 or paragraph (1) of Article 18 of the Pharmaceutical Affairs Act (Act No. 145 of 1960)

Supplementary Provisions (Cabinet Order No. 57 of March 24, 2004) (Extract)

This Cabinet Order shall come into effect as from March 31, 2004.

Supplementary Provisions (Cabinet Order No. 134 of April 1, 2005)

This Cabinet Order shall come into effect as from the day of promulgation.

Supplementary Provisions (Cabinet Order No. 322 of October 31, 2007)

This Cabinet Order shall come into effect as from November 10, 2007; provided, however, that the provisions for revising Article 3 shall come into effect as from May 1, 2008.