

Order for Enforcement of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (Tentative translation)

(Cabinet Order No. 202 of June 7, 1974)

(Class I Specified Chemical Substances)

Article 1 The Class I Specified Chemical Substances referred to in Article 2, paragraph (2) of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (hereinafter referred to as "Act") are the following chemical substances:

- (i) polychlorinated biphenyls;
- (ii) polychlorinated naphthalenes (limited to those containing two 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-dimethanonaphthalene (also known as aldrin; referred to as "aldrin" in row (iii) of the table in Article 7);
- (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-dimethanonaphthalene (also known as dieldrin; referred to as "dieldrin" in row (iv) of the table in Article 7);
- (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-dimethanonaphthalene (also known as endrin);
- (vii) 1, 1, 1-trichloro-2, 2-bis (4-chlorophenyl) ethane (also known as DDT; referred to as "DDT" in row (iii) of the table in Article 7);
- (viii) 1, 2, 4, 5, 6, 7, 8, 8-octachloro-2, 3, 3a, 4, 7, 7a-hexahydro-4, 7-methano1H-indene, 1, 4, 5, 6, 7, 8, 8-heptachloro-3a, 4, 7, 7a-tetrahydro-4, 7-methano1H-indene and their analogous compounds (also known as chlordane or heptachlor; referred to as "chlordanes" in row (v) of the table in Article 7);
- (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. 0. 0] decane (also known as mirex; referred to as "mirex" in row (ix) of the table in Article 7);
- (xiv) 2, 2, 2-trichloro-1-(2-chlorophenyl)-1-(4-chlorophenyl) ethanol or 2, 2, 2-trichloro-1, 1-bis (4-chlorophenyl) ethanol (also known as kelthane or dicofol);
- (xv) hexachlorobuta-1, 3-diene;

- (xvi) 2-(2H-1, 2, 3-benzotriazol-2-yl)-4, 6-di-tert-butylphenol;
- (xvii) perfluoro (octane-1-sulfonic acid) (also known as PFOS; hereinafter referred to as "PFOS") or its salts;
- (xviii) perfluoro (octane-1-sulfonyl) =fluoride (also known as PFOSF);
- (xix) pentachlorobenzene;
- (xx) r-1, c-2, t-3, c-4, t-5, t-6-hexachlorocyclohexane (also known as alpha-hexachlorocyclohexane);
- (xxi) r-1, t-2, c-3, t-4, c-5, t-6-hexachlorocyclohexane (also known as beta-hexachlorocyclohexane);
- (xxii) r-1, c-2, t-3, c-4, c-5, t-6-hexachlorocyclohexane (also known as gamma-hexachlorocyclohexane);
- (xxiii) decachloropentacyclo [5. 3. 0. 0(2, 6). 0(3, 9). 0(4, 8)] decan-5-one (also known as chlordecone);
- (xxiv) hexabromobiphenyl;
- (xxv) tetrabromo (phenoxybenzene) (also known as tetrabromodiphenyl ether; referred to as "tetrabromodiphenyl ether" in row (xii) of the table in Article 7);
- (xxvi) pentabromo (phenoxybenzene) (also known as pentabromodiphenyl ether; referred to as "pentabromodiphenyl ether" in row (xiii) of the table in Article 7);
- (xxvii) hexabromo (phenoxybenzene) (also known as hexabromodiphenyl ether);
- (xxviii) heptabromo (phenoxybenzene) (also known as heptabromodiphenyl ether);
- (xxix) 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3benzodioxathiepin-3-oxide (also known as endosulfan or benzoepin)
- (xxx) hexabromocyclododecane;
- (xxxi) pentachlorophenol or its salts or esters;
- (xxxii) polychlorinated normal paraffin (limited those in which the carbon number is 10 through 13 and the content of chlorine is more than 48% of the total weight);
- (xxxiii) 1,1'-oxybis (2,3,4,5,6-pentabromobenzene) (also known as decabromodiphenyl ether; referred to as "decabromodiphenyl ether" in row (xvii) of the table in Article 7); and
- (xxxiv) perfluorooctanoic acid (also known as PFOA; hereinafter referred to as "PFOA") or its salts.

(Class II Specified Chemical Substances)

Article 2 The Class II Specified Chemical Substances referred to in Article 2, paragraph (3) of the Act are 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 fatty acid salts (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) copolymer of alkyl acrylate, methyl=methacrylate and tributyltin=methacrylate (limited to those containing 8 carbon atoms in the alkyl group of the 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-7isopropyl-1, 4a-dimethyl-1-phenanthrenecarboxylate and its analogous compounds (also known as tributyltin rosin salt).

(Cases Not Requiring Notification of the Manufacture or Import of a New Chemical Substance)

Article 3 (1) The cases specified by Cabinet Order referred to in Article 3, paragraph (1), item (iv) of the Act are the following cases:

- (i) when a person intends to manufacture or import a new chemical substance as the intermediate to another chemical substance, and has taken the necessary measures to prevent environmental pollution from the new chemical substance during the period until the new chemical substance is transformed into the other chemical substance;
- (ii) when a person intends to manufacture or import a new chemical substance for use in a way that does not discharge the emissions outside the facility or equipment, and has taken the necessary measures to prevent environmental pollution from the new chemical substance during the period until the new

chemical substance is disposed of;

- (iii) when a person intends to manufacture or import a new chemical substance for the purpose of export (limited to when the export is to a region that has been designated by Order of the Ministry of Health, Labour and Welfare, Order of the Ministry of Economy, Trade and Industry, and Order of the Ministry of the Environment as a region where the necessary measures have been taken to prevent environmental pollution from the new chemical substance), and the person has taken the necessary measures to prevent environmental pollution from the new chemical substance during the period until the new chemical substance is exported.
- (2) The quantity specified by Cabinet Order referred to in Article 3, paragraph (1), item (v) of the Act is 1 ton.
- (3) The quantity specified by Cabinet Order referred to in Article 3, paragraph (2) of the Act is 1 ton.

(Cases Subject to Exception on an Evaluation)

- Article 4 (1) The quantity specified by Cabinet Order referred to in Article 5, paragraph (4), item (i) of the Act is 10 metric tons.
- (2) The quantity specified by Cabinet Order referred to in Article 5, paragraph (5) of the Act is 10 metric tons.

(Cases Not Requiring Notification of the Manufacture or Import of a General Chemical Substance)

- Article 5 The quantity specified by Cabinet Order referred to in Article 8, paragraph (1), item (ii) of the Act (including when applied mutatis mutandis pursuant to paragraph (2) of the relevant Article) is 1 metric ton.

(Cases Not Requiring Notification of the Manufacture or Import of a Priority Assessment Chemical Substance)

- Article 6 The quantity specified by Cabinet Order referred to in Article 9, paragraph (1), item (ii) of the Act is 1 metric ton.

(Products Prohibited from Import if a Class I Specified Chemical Substance Is Used)

- Article 7 The products specified by Cabinet Order referred to in Article 24, paragraph (1) of the Act are those listed in the right-hand column of the following table for the relevant Class I Specified Chemical Substance listed in the left-hand column of the table (excluding products designated by the Minister of Economy, Trade and Industry as being difficult to substitute with 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 up or sealing (iii) Paints (excluding water-based paints), printing inks, and carbonless copying paper (iv) Heating or cooling devices with a 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 two 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 those for 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 the water from adhering to surfaces) and printing inks (iii) Fishnets
(vii) N, N'-Ditolyl-pphenylenediamine, Ntolyl-N'-xylyl-p-phenylenediamine, or N, N'-dixylyl-pphenylenediamine	(i) Rubber antioxidants (ii) Styrene-butadiene rubber

(viii) 2, 4, 6-Tri-tertbutylphenol	(i) Antioxidants and other prepared additives (limited to those for lubricating and fuel oils) (ii) Lubricating oils
(ix) Mirex	Wood insecticides
(x) 2-(2H-1, 2, 3benzotriazol-2-yl)-4, 6-Ditert-butylphenol	(i) Decorative laminate (ii) Adhesives (excluding those of animal and botanical origin), putty, and filling materials for closing up 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)
(xi) PFOS or its salts	(i) Aircraft hydraulic oils (ii) Oils used to spin thread (iii) Etching agents used in metal machining (iv) Etching agents used in the manufacture of piezoelectric filters or semiconductors (v) Surface treatment agents and other prepared additives for plating use (vi) Anti-reflection agent used in the manufacture of semiconductors (vii) Resists for semiconductors (viii) Abrasives (ix) Fire extinguishers, fire-extinguishing agents for use in fire extinguishers use and fire extinguishing foam (x) Insecticides (limited to those used in the extermination of termites or ants.) (xi) Professional-use photographic films (xii) Photographic paper
(xii) Tetrabromodiphenyl ether	(i) Paints (ii) Adhesives
(xiii) Pentabromodiphenyl ether	(i) Paints

	(ii) Adhesives
(xiv) Hexabromocyclododecane	(i) Flame-retardant fabric, textiles (ii) Prepared additives for flame-retardant treatment for fabric, textiles (iii) Expandable polystyrene beads for flameretardant EPS* *Note: EPS refers to expanded polystyrene. (iv) Flame-retardant curtains
(xv) Pentachlorophenol or its salts or esters	(i) Wood antiseptics, insecticides, and fungicides (ii) Wood treated with antiseptics, insecticides, and fungicides (iii) Plywood treated with antiseptics, insecticides, and fungicides (iv) Glue
(xvi) Polychlorinated normal paraffin (limited those in which the carbon number is 10 through 13 and the content of chlorine is more than 48% of the total weight)	(i) Lubricating, cutting, and hydraulic oils (ii) Prepared additives for flame-retardant treatment for textiles (iii) Plasticizers for resin and rubber (iv) Paints (limited to waterproof and antifiammable) (v) Adhesives and sealing filler (vi) Fatliquoring agents for leather
(xvii) Decabromodiphenyl ether	(i) Flame-retardant textiles (ii) Prepared additives for flame-retardant treatment for textiles, resin and rubber (v) Adhesives and sealing fillers (iv) Flame-retardant floor covering (v) Flame-retardant curtains (vi) Flame-retardant banner-flags
(xviii) PFOA or its salts	(i) Water-resistant or oil-resistant paper (ii) Water-repellent or oil-repellent textiles (iii) Cleaning agents (iv) Anti-reflection agents used in the manufacture of semiconductors (v) Paints and varnish (vi) Water repellent and oil repellent (vii) Adhesives and sealing fillers

	(viii) Fire extinguishers, fire-extinguishing agents, and fire-extinguishing foam (ix) Toners (x) Water-repellant or oil-repellant clothes (xi) Water-repellant or oil-repellant floor coverings (xii) Floor waxes (xiii) Professional-use photographic films
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(Products for Which Notice Must Be Given with Regard to the Planned

Quantity to be Imported if a Class II Specified Chemical Substance Is Used)

Article 8 For the Class II Specified Chemical Substances listed in Article 2, items (xi) through (xxiii) (referred to as "tributyltin compounds" in row (iii) of the table set forth in following Article), the products specified by Cabinet Order referred to in Article 35, paragraph (1) of the Act are paints (limited to those used to prevent shellfish, algae, and other living organisms in the water from adhering to surfaces).

(Products in Which a Class II Specified Chemical Substance for

Which Technical Guidelines Are Published Are Used)

Article 9 The products specified by Cabinet Order referred to in Article 38, paragraph (1) of the Act are the products listed in the right-hand column of the following table for the relevant Class II Specified Chemical Substance listed in the left-hand column of the same 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 textiles
(iii) Tributyltin compounds	(i) Antiseptics and fungicides (ii) Paints (limited to those used to prevent shellfish, algae, and other living organisms in the water from adhering to surfaces)

(Fees)

Article 10 The fees that a person listed in the left-hand column of the following table must pay pursuant to the provisions of Article 49 of the Act are as shown in the middle column of the same table (or as shown in the right-hand column of the table in the case of an electronic application (meaning 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 in Administrative Procedures (Act No. 151 of 2002) pursuant to the provisions of the same paragraph; the same applies hereinafter)).

Persons who must pay fees	Amount	Amount in the case of an electronic application
(i) Persons seeking to obtain permission under Article 17, paragraph (1) of the Act	220,600 yen	213,700 yen
(ii) Persons seeking to obtain permission under Article 21, paragraph (1) of the Act	121,700 yen	117,200 yen
(iii) Persons seeking to obtain permission under of Article 22, paragraph (1) of the Act	46,700 yen	39,900 yen

(Advisory Councils Specified by Cabinet Order)

Article 11 The advisory councils, etc. pursuant to Article 56, paragraph (1) of the Act which are specified by Cabinet Order are those listed in the right-hand column of the following table for the relevant Minister listed in the left-hand column of the same 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

Supplementary Provisions

(Effective Date)

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

(Repeal of the Cabinet Order to Specify Cases Not Requiring Notification of the Manufacture or Import of a New Chemical Substance set forth in Article 3, paragraph (1) of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances)

(2) The Cabinet Order to Specify Cases Not Requiring Notification of the Manufacture or Import of a New Chemical Substance set forth in Article 3, paragraph (1) of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (Cabinet Order No. 102 of 1974) is hereby repealed.

(Transitional Measures)

(3) For the Class I Specified Chemical Substances listed in the left-hand column of the following table, the products specified by Cabinet Order referred to in Article 28, paragraph (2) of the Act are the products listed in the right-hand column of the same table, until otherwise provided for by law.

Class I Specified Chemical Substance	Product
PFOS or its salts	Fire extinguishers, fire extinguishing agents, and fire-extinguishing foam
PFOA or its salts	Fire extinguishers, fire extinguishing agents, and fire-extinguishing foam

Supplementary Provisions [Cabinet Order No. 419 of September 19, 2003]

(Effective Date)

(1) This Cabinet Order comes into effect as of the date of enforcement of the Act Partially Amending the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (hereinafter referred to as the "Amendment Act") (April 1, 2004).

(Persons Subject to Transitional Measures Involving Confirmation)

(2) The persons specified by Cabinet Order referred to in Article 2 of the Supplementary Provisions of the Amendment Act are those who manufacture or import a new chemical substance as the intermediate of medicines that are connected with 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. 322 of October 31, 2007]

This Cabinet Order comes into effect as of November 10, 2007; provided, however, that the provisions for amending Article 3 come into effect as of May 1,

2008.

Supplementary Provisions [Cabinet Order No. 256 of October 30, 2009]

This Cabinet Order comes into effect as of April 1, 2010; provided, however, that the provisions listed in each of the following items come into effect as of the day specified in the relevant item:

- (i) the provisions for amendment adding as follows to the table in Article 3: May 1, 2010; and
- (ii) the provisions for amendment adding two Articles after Article 3 (limited to the part involving Article 3-3), the provisions for amending paragraph (3) of the Supplementary Provisions and the provisions for amendment deleting paragraph (4) of the Supplementary Provisions: October 1, 2010.

Supplementary Provisions [Cabinet Order No. 257 of October 30, 2009]

This Cabinet Order comes into effect as of April 1, 2011.

Supplementary Provisions [Cabinet Order No. 35 of February 21, 2018]

This Cabinet Order comes into effect as of April 1, 2018; provided, however, that the provisions listed in each of the following items come into effect as of the day specified in the relevant item:

- (i) the provisions for amending the table under Article 7: October 1, 2018; and
- (ii) the provisions for amending Article 3 and the provisions for amending Article 4: the date of enforcement of the provisions listed in Article 1, item (ii) of the Supplementary Provisions of the Act Partially Amending the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (January 1, 2018).

Supplementary Provisions [Cabinet Order No. 144 of April 21, 2021]

This Cabinet Order comes into effect as of October 22, 2021.