

Implementation of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.

(March 25, 2004: No. 0325001, Pharmaceutical and Food Safety Bureau, MHLW;
No. 3, Manufacturing Industries Bureau, METI;
No. 040325001, Environmental Policy Bureau, MOE)

Director General, Pharmaceutical and Medical Safety Bureau,
Ministry of Health, Labour and Welfare

Director General, Manufacturing Industries Bureau,
Ministry of Economy, Trade and Industry

Director General, Environmental Policy Bureau,
Ministry of the Environment

Final Amendment: October 15, 2007

With the coming into force of the Law to Amend the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No. 49, 2003), implementation of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No. 117, 1973, hereinafter referred to as the Law) shall be conducted as follows, effective April 1, 2004.

In conjunction with the above, "Operation of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc." dated March 24, 1987 (No. 291, Pharmaceutical Affairs Bureau, MHW; and No.171, Basic Industries Bureau, MITI) and "Operation of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc." dated April 19, 1989 (No. 27, EISEI , MHW; and No. 278, Basic Industries Bureau, MITI) are rescinded as of March 31, 2004.

1 Range of chemical substances

The Law stipulates in Article 2, Paragraph 1 that the term "chemical substance" refers to any chemical compound obtained by causing chemical reactions to elements or compounds, and excludes any radioactive substance and the following substances that are omitted here. This definition shall be interpreted as follows:

(1) An "element" refers to all the states of a substance (e.g., excited state and radicals) comprised of one kind of atom without distinction as to isotopes; the same applies hereinafter. An alloy is regarded as a mixture of elements that does not fall within the category of "chemical substances."

(2) A "compound" refers to a substance consisting of two or more different kinds of atoms (at least one of them being H, He, B, C, N, O, F, Ne, P, S, Cl, Ar, As, Se, Br, Kr, Te, I, Xe, At, or Rn) formed by covalent bonding, ionic bonding, coordinate bonding, or any arbitrary combination of these types of bonding.

(3) Since “causing chemical reactions” refers to artificial reactions, natural reactions are not included. When organisms (whether alive or dead) or components of organisms are obtained by breeding, cultivation, or incubation, such breeding, cultivation, or incubation are not regarded as artificial chemical reactions even if chemical reactions take place in the organisms.

When an artificial chemical reaction is limited to specific parts (e.g., surface treatment of metals) or the reaction products are handled as waste without being separated for use, the reaction is not regarded as “causing chemical reactions.”

(4) Products corresponding to (i) and (ii) described below are not regarded as “compounds” but treated as “products” to be regulated by Article 13 (Restrictions on the Import of Products), Article 14 (Restriction on Use), Article 22 (Orders Requiring Measures to be Taken in Connection with the Designation of Class I Specified Chemical Substances), Article 26 (Notification of Planned Quantity of Manufacture, etc.), Article 28 (Labeling, etc.), Article 29 (Cautionary Notices), Article 30 (Guidance and Advice), or other relevant statutes of the Law.

(i) Products that possess specific shapes that are mainly for an end use (e.g. synthetic resin storage containers, plates, tubes, rods, and films).

(ii) Mixtures that are manufactured only by mixing and mainly for an end use (e.g. synthetic resin paints containing pigments and photosensitive emulsions).

However, substances obtained by mixing for particular purposes that are not accompanied by essential changes in function are excluded even when they are for an end use. The purposes of such mixing operations include the maintenance or improvement of the functions of chemical substances by changing the shape for the sake of convenience of use in operation (such as the maintenance of functions and properties of chemical substances (e.g., the addition of a stabilizer and an anti-oxidizing agent); fine conditioning (e.g., color matching of dye stuffs, standardization of concentration of bulk powders and stock solutions); changes in shape and properties for convenience in packing, transportation, and use process (e.g., dissolution, pulverization, granulation, agglomeration, slurring, moistening, and addition of anti-dusting agents where applicable according to the purpose); or mixing for the purpose of identification and prevention of diversion (e.g., addition of coloring agents or odorants)).

2 Notification of manufacture/import of new chemical substances

2-1 Classification of chemical substances

General rules for the classification and naming used for specifying new chemical substances in accordance with Article 2, Paragraph 7 of the Law are as follows:

(1) Common rules

(i) Each compound comprises a segment in principle and a name is given to each segment. However, when the ingredients are unknown or the substance is a mixture that cannot be separated into components, etc., the substance is segmented and named based on the method of manufacture, properties, and mixing conditions, etc. Therefore, when all the components comprising a mixture are applied to any of the following chemical substances (hereinafter referred to as “existing chemical substances, etc.,” the mixture is not regarded as a new chemical substance.

- a. Chemical substances specified in each Clause of Article 2, Paragraph 7 of the Law.
- b. Chemical substances confirmed in accordance with Article 3, Paragraph 1, Clause 5 or Article 4.2, Paragraph 4 of the Law (applied only when a person who has received the confirmation carries out the manufacture/import as confirmed).
- c. Chemical substances that have received a notice of determination pursuant to Article 4, Paragraphs 1 or 2, or Article 4.2, Paragraph 8 of the Law (applied only when the establishment that has received the notice carries out the manufacture/import).

d. Chemical substances that have received a notice of determination to be subject to Article 4, Paragraph 1, Clause 5, pursuant to Article 4, Paragraph 1 or 2, which applies mutatis mutandis to Article 5.2, Paragraph 2 (applied only when a person who has received the notice carries out the import).

(ii) When the content of an impure compound is less than one percent by weight, the compound is not regarded as a new chemical substance. An "impurity" refers to unintended substances such as unreacted raw materials, reaction catalysts, chemical indicators, by-products generated by reactions that are not intended, etc. (the same is applied hereinafter).

(iii) When all the individual chemical substances composing an intermolecular compound, inclusion compound, or hydrate (including crystallization water) are existing chemical substances, these compounds are not regarded as new chemical substances.

(iv) When all the acids and bases composing an organic adduct salt (excluding metallic salts) are existing chemical substances, etc., the organic adduct salt is not regarded as a new chemical substance.

(v) When the counter ion of an onium salt is a component of existing chemical substances, etc. the onium salt is not regarded as a new chemical substance.

(2) Treatment by individual categories

(i) Inorganic compounds

a. Compounds forming an ionic lattice are treated in accordance with their constitutional unit (e.g., NaCl).

b. When the individual salts (including the acid in the case of an acidic salt and the base in the case of a basic salt) composing a double salt (including acidic salts and basic salts) are existing chemical substances, etc., the double salt is not regarded as a new chemical substance.

c. Solid solutions are treated as mixtures.

d. When all monomers composing an inorganic polymer are existing chemical substances, etc., the inorganic polymer is not regarded as a new chemical substance. (Example: phosphoric acid and polyphosphoric acid.)

(ii) Organic low molecular weight compounds

a. When a compound includes different carbon chains such as alkyl groups and alkenyl groups due to the use of natural raw materials, etc., the compound may be treated as a lump. (Example: beef tallow fatty acid soda→fatty acid (C₁₄~18) soda).

b. When a compound includes multiple substitutions and the positions or the number of substitutions, or both of them are different, the compound may be treated as a lump. (Example 1: orth-, meta-, para-xylene→xylene.

Example 2: 30%-chlorinated paraffin and 25%-chlorinated paraffin→chlorinated paraffin).

c. When the individual metallic salts composing a mixture of metallic salts are existing chemical substances, etc., the mixture of metallic salts is not regarded as a new chemical substance. (Examples: aluminum salt of sodium ethylenediaminetetraacetate, aluminum ethylenediaminetetraacetate, and monosodium ethylenediaminetetraacetate).

(iii) Polymers

a. In case the repeating unit (including monomers and condensation polymers) and type of polymerization are same, in principle, discrimination in manner of polymerization, degree of crystallinity, steric regularity or degree of polymerization (including degree of condensation) is not made.

b. In case the unit polymers constituting a block polymer are all existing chemical substances, the block polymer is not treated as a new chemical substance.

c. When the stem and branch polymers constituting a graft polymer are all existing chemical substances, the graft polymer is not treated as a new chemical substance.

d. When another polymer obtained from monomers (refers to monomers or polymers having a molecular-weight distribution) that compose more than 99% by weight of a polymer made up of two or more monomers is an existing chemical substance, this polymer is not treated as a new chemical substance. (Example: When the sum of the percent by weight of A and B in a copolymer obtained from A, B, and C exceeds 99%, and the copolymer of A and B is an existing chemical substance, the copolymer of A, B, and C is not treated as a new chemical substance.)

(3) Concerning the list of Existing Chemical Substances

In the column for name in the list of existing chemical substances, “ · ” and other marks mean as follows:

(i) “ · ” generally stands for “and.”

(ii) “,” generally stands for “or” except when it indicates the end of a paragraph.

(iii) When the number of substituents is not shown, the number is one in principle.

2-2 New chemical substances all of which are converted into other substances

When a new chemical substance B is manufactured in the course of producing a chemical substance A and all of substance B is converted into substance A through chemical reactions performed by the same manufacturer, the manufacture of new chemical substance B does not correspond to “manufacture of a new chemical substance” as specified in Article 3, Paragraph 1 of the Law if substance A is manufactured in the same establishment where substance B is manufactured, or if new chemical substance B and chemical substance A are manufactured using facilities owned by the manufacturer.

Therefore, even when all the new chemical substance B is converted into another chemical substance A, the manufacture of new chemical substance B is regarded as the “manufacture of a new chemical substance” as specified in the above-mentioned Paragraph if the manufacturer of new chemical substance B is different from the manufacturer of chemical substance A through chemical reactions even when these chemical reactions are continuously carried out within an establishment ostensibly.

Furthermore, the manufacture of chemical substance B corresponds to the aforesaid “manufacture of a new chemical substance,” if the process for obtaining new chemical substance B and the process for obtaining chemical substance A by converting chemical substance B are carried out at multiple establishments and the owner of the facilities used for obtaining the new chemical substance B is different from the owner of the facilities used for the conversion of chemical substance B into chemical substance A.

2-3 Range of testing and research

The provision of “where the new substance is to be manufactured or imported for testing and research purposes” in Article 3, Paragraph 1, Clause 2 refers to those occasions when the new chemical substances are manufactured/imported so that all of them are used for testing, experiments, research, development, or inspection at schools, research institutes, laboratories or testing institutes regardless of whether these institutes are public or private (it is not a requirement that the manufacturer or importer carry out the testing and research itself).

Therefore, the notification stipulated in Article 3, Paragraph 1 of the Law is required when even a minimal amount of the new chemical substance is used for a commercial purpose.

When the new chemical substance is manufactured in a so-called “test plant” in order to verify the possibility of the practical application of the results of testing and research, for example, the notification as stipulated in Article 3, Paragraph 1 of the Law is not required, provided that the new chemical substance is manufactured for the purpose of testing, experiments, research, development, or inspection carried out by the manufacturer or the recipient of the new chemical substance.

2-4 Range of reagents

The term “reagents,” described as “any chemical substance used for the detection or quantification of a substance by a chemical process, or for experimental synthesis of a substance, or for measurements of the physical characteristics of a substance” in Article 3, Paragraph 1, Clause 3 of the Law, refers to those used for chemical analysis, experiments, testing and research, and inspection, etc. It should be determined by the type of manufacture and form of packing whether or not the substance is a reagent. Even when the substance is marked as a reagent, it is not regarded as a “reagent” under the Law if it is used as an industrial chemical or industrial raw material.

2-5 Range of applications such as closed systems

Even when a new chemical substance is used in a specific closed system, the new chemical substance is not considered to correspond to Article 2, Clause 2 of the Enforcement Order of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Cabinet Order No. 202, 1974) if the facilities are used by unspecified users.

2-6 Relationship between Article 2, Paragraph 1, Clauses 3 and 4, and Paragraphs 2 and 3 of the same Article of the Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Type I Monitored Chemical Substances and Type II Monitored Chemical Substances

Regarding any new chemical substance that is persistent (including persistent chemical substances generated by chemical transformations through natural processes), it must be determined whether the substance corresponds to Article 2, Paragraph 3, Clause 1 of the Law and whether the substance corresponds to the Items of Article 2, Paragraph 6 of the Law, even when the substance is not bioaccumulative. The possibility of correspondence to Article 2, Paragraph 3, Clause 1 of the Law shall be determined based on the test results carried out in accordance with Article 2, Paragraph 2 of the Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Type I Monitored Chemical Substances and Type II Monitored Chemical Substances (Ministerial Ordinance No. 1: General Administrative Agency of the Cabinet; Ministry of Health and Welfare; and Ministry of International Trade and Industry, July 13, 1974, hereinafter referred to as "Ministerial Ordinance on Test Items"), and the possibility of correspondence to the Clause of Article 2, Paragraph 6 of the Law shall be determined based on the test results in accordance with Article 2, Paragraph 3 of the Ministerial Ordinance on Test Items.

When a new chemical substance is persistent and bioaccumulative, it may correspond to a Class I Specified Chemical Substance depending on the properties specified in Article 2, Paragraph 2, Clause 1.b, and the classification shall be determined based on the test results in accordance with Article 2, Paragraph 1, Clauses 3 and 4 of the Ministerial Ordinance on Test Items.

2-7 Relationship between Article 40 and Article 3, Paragraph 1 of the Law

"Chemical substances listed in the following items" as stipulated in Article 40 of the Law include not only substances consisting of a single new chemical substance but also those consisting of multiple new chemical substances and those consisting of existing chemical substance(s) and new chemical substance(s). In such cases, the new chemical substances are considered to be "raw materials" and notification pursuant to Article 3, Paragraph 1 of the Law is not required, provided that they are manufactured/imported as raw materials used for the products listed in the Items of the above-mentioned Article.

3 Manufacture of Class I Specified Chemical Substances, Class II Specified Chemical Substances, and Monitoring Chemical Substances

3-1 Among the chemical substances that are not regarded as new chemical substances in accordance with "2 Notification of manufacture/import of new chemical substances," those containing, as part of their structure, Class I Specified Chemical Substances or Class II Specified Chemical Substances (hereinafter referred to as "Specified Chemical Substances"), or Monitoring Chemical Substances (e.g., intermolecular compounds, block polymers, and graft polymers) and those composed of Specified Chemical Substance(s) or Monitoring Substance(s) as components (e.g., adduct salts and onium salts) are treated as a mixture containing Specified Chemical Substances or Monitoring Chemical Substances. Manufacture/import of such chemical substances are subject to the requirements for Specified Chemical Substances and Monitoring Chemical Substances. (e.g. when any of the counter ions of an onium salt is composed of a Class II Monitoring Chemical Substance, the substance is treated as a mixture containing the Class II Monitoring Chemical Substance, and Articles 23 and 24 and other requirements of the Law are applied.)

3-2 When Class I Specified Chemical Substances are contained in other chemical substances as by-products in trace amounts, the by-products are not treated as Class I Specified Chemical Substances, if the by-products have no potential to be hazardous to human health and do not impair the life or growth of flora or fauna through environmental pollution, and the content of the by-products is reduced to the lowest possible technically and economically feasible level.

3-3 When the volume of Monitoring Chemical substances contained in other chemical substances as impurities is less than one percent by weight (including the mixtures specified in 3-1), the requirements for Monitoring Chemical Substances are not applied.

3-4 Class I Specified Chemical Substances, Class II Specified Chemical Substances and Monitoring Chemical Substances all of which are converted into other chemical substances are treated as follows:

(1) Class I Specified Chemical Substances

When a chemical substance B, which is a Class I Specified Chemical Substance, is manufactured in a process to manufacture chemical substance A and all of the substance B is converted into substance A through a chemical reaction, the manufacture of B is not regarded as the manufacture of a Class I Specified Chemical Substance provided the process is carried out within a closed system (chemical substance B is not removed from an integrated chemical reaction system) in the establishment where B is manufactured (the establishment must be geographically integrated and not separated by outside roads in principle). Therefore, when any of the Class I Specified Chemical Substance B is removed from the closed system, B is considered to be manufactured in an outside process, and permission must be obtained in accordance with Article 6 of the Law and other requirements of the Law such as Article 17 are applied.

(2) Class II Specified Chemical Substances and Monitoring Chemical Substances

When a chemical substance B, which is a Class II Specified Chemical Substance or Monitoring Chemical substance, is manufactured by the manufacturer of chemical substance A in the process to manufacture chemical substance A and all of B is converted into A by a chemical reaction, the manufacture of A is not regarded as that of a Class II Specified Chemical Substance or Monitoring Chemical substance if A is manufactured in the establishment where B is manufactured. Therefore, when a Class II Specified Chemical Substance or Monitoring Chemical substance B is manufactured at a certain establishment X and transferred to another establishment Y of the same company, where all of B is converted into chemical substance A, the manufacture of substance B must be notified in accordance with Article 5.3, Paragraph 1; Article 23, Paragraph 1; Article 25.2, Paragraph 1; or Article 26, Paragraph 1 or Paragraph 6 of the Law, since a Class II Specified Chemical Substance or Monitoring Chemical substance is manufactured at X. Article 5.4 and other requirements are also applied.

Concerning “Available Information on Compositions and Properties of Chemical Substances”

(March 25, 2004: No. 0325002, Pharmaceutical and Food Safety Bureau, MHLW;
No. 4, Manufacturing Industries Bureau, METI;
No. 040325002, Environmental Policy Bureau, MOE)

Final amendment: September 16, 2004

The following is applied to the treatment of “available Information on compositions and properties” stipulated in Article 4, Paragraph 1 (including the application *mutatis mutandis* in Article 5.2, Paragraph 2) and Article 4.2, Paragraph 1 of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No. 117, 1973, hereinafter referred to as the Law)

1 Polymers that meet all the conditions from (1) to (3) described below are considered to be chemically stable against natural processes and not accumulative in living organisms; and polymers that meet all the conditions from (1) to (4) described below are regarded as those that do not correspond to Class II Monitoring Chemical substances, and polymers that meet all the conditions from (1) to (3) and (5) described below are regarded as those that do not correspond to Class III Monitoring Chemical Substances. Tests to determine whether the following conditions from (1) to (3) are satisfied shall be conducted on the attached safety evaluation test methods for polymers.

(1) Chemical substances with a number-average molecular weight of 1,000 or higher and a distribution of molecular weights that are characterized by poorly defined physicochemical properties such as solubility and melting point.

(2) No weight change exceeding the error range of the measurement shall be caused by light, heat, and change in pH. When a weight change exceeding the error range is observed, it must be proved by using other analytical methods that the polymer is physically and chemically stable e.g. no structural changes.

(3) Either condition of (i) or (ii) must be satisfied.

(i) No weight change exceeding the error range of the measurement shall occur when treated with water, lipophilicity solvents, or general-purpose solvents, therefore, the polymer is confirmed to insoluble in these solvents, and it must be confirmed that the polymer has a specific structural characteristic (such as a cross-linked structure and crystallinity) or is insoluble to acids and alkalis.

(ii) When solubility in water, lipophilicity solvents, and general-purpose solvents is confirmed and (i) are not satisfied, the content of polymers with a molecular weight of less than 1,000 is 1% or less and no information to indicate high accumulation in living organisms.

(4) No heavy metal content and, judging from information on the relationship between the chemical structure and long-term toxicity, etc. there is no indication that long-term ingestion causes adverse effects on human health.

(5) No heavy metal content, and cationic behavior is not shown when soluble in water, acids or alkalis; and judging from information on the relationship between chemical structure and toxicity to animals and plants, etc., there is no indication that there is no potential for adverse effects on the habitats or development of animals and plants.

2 Inorganic compounds that are chemically stable under light in air and water are regarded as persistent

against chemical changes due to natural processes.

3 Chemical substances with a molecular weight of 800 or higher (1,000 or higher for compounds containing two or more halogen elements) are regarded as non-accumulative in living organisms. However, this principle does not apply when the application is inappropriate judging from the structure of the chemical substance, etc.

4 Chemical substances (including elements) generated by degradability tests of chemical substances using microorganisms, etc. that do not correspond to Article 2, Paragraph 2, Clause 1 of the Law or Paragraph 6, Clause 1 of the same Article, and those that are regarded, without doubt, as chemical substances that do not correspond to Paragraph 3, Clause 1.a of the same Article are published separately.

Handling of chemical substances generated by degradability tests, etc.

September 16, 2004

Office of Chemical Safety,
Evaluation and Licensing Division,
Pharmaceutical and Medical Safety Bureau,
Ministry of Health, Labour and Welfare

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

Chemical Evaluation Office,
Policy Planning Division,
Environmental Health Department,
Environmental Policy Bureau,
Ministry of the Environment

Chemical substances (including elements) to be separately published described in Item 4 of Concerning "Information on known compositions and properties" (March 25, 2004: No. 0325002, Pharmaceutical and Food Safety Bureau, MHLW; No. 4, Manufacturing Industries Bureau, METI; No. 040325002, Environmental Policy Bureau, MOE) are as follows:

1 Chemical substances that do not correspond to Article 2, Paragraph 2, Item 1 and Paragraph 6, Item 1 of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as the Law) and chemical substances that are regarded, without doubt, as not corresponding to Paragraph 3, Clause 1.a of the same Article are as follows:

Na^+ , K^+ , NH_4^+ , Mg^{2+} , Ca^{2+} , BO_3^{3-} , SiO_4^{4-} , PO_4^{3-} , SO_4^{2-} , F^- , Cl^- , Br^- , I^-

2 Chemical substances that do not correspond to Article 2, Paragraph 2, Clause 1 of the Law and chemical substances that are regarded, without doubt, as not corresponding to Paragraph 3, Clause 1.a of the same Article are as follows:

Fe^{2+} , Fe^{3+} , Zn^{2+} , Al^{3+}