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March 31, 2011

(No. 0331005, Pharmaceutical and Food Safety Bureau, MHLW;
No. 3, Manufacturing Industries Bureau, METI (March 29, 2011)
No.110331007, Environmental Policy Bureau, MOE)

Director General, Pharmaceutical and Food 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

Implementation of the Act on the Evaluation of Chemical Substances and Regulation of
Their Manufacture, etc.

With the coming into force of the Act to Amend the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No. 39, 2009), implementation of the Act concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117, 1973, hereinafter referred to as the Act) shall be conducted as follows, effective April 1, 2011.

In conjunction with the above, "Implementation of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc." dated March 30, 2010 (No. 0329004, Pharmaceutical and Food Safety Bureau, MHLW; No.2, Manufacturing Industries Bureau, METI; and No. 100329004, Environmental Policy Bureau, MOE) is rescinded as of March 31, 2011.

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, adhesives or coating mediums that cause chemical reactions when used) or the reaction products are handled as waste without being separated for use, the reaction is not regarded as “causing chemical reactions.”

(4) The products stipulated in Order for Enforcement of the Act on the Evaluation of Chemical Substances Regulation of Their Manufacture etc.(Cabinet Order No.202, 1974; hereinafter referred to as the Enforcement Order) are not regarded as “compounds” and are dealt with pursuant to Article 24 (Restrictions on Import of Products), Article 28 (Obligation of Conformity to Standards), Article 29 (Labeling, etc.), Article 30 (Order for Improvement), Article 34 (Order to Take Measures in Connection with Designation, etc. of Class I Specified Chemical Substances), Article 35 (Notification of the Planned Quantity of Manufacture, etc.), Article 36 (Publication of Technical Guidelines, etc.), Article 37 (Labeling, etc.), Article 39 (Guidance and Advice), Article 42 (Reporting on the Status of Handling), Article 43 (Collection of Reports), Article 44 (On-Site Inspections, etc.), and Article 48 (Requests) of the Law. Products that are not stipulated in the Enforcement Order and that fall under item (i) or (ii) below are not regarded as “compounds” but treated as “products” to be regulated

by other relevant statutes of the Law, etc.

(i) Products that possess specific shapes and do not change in their composition or shape when in use (e.g. synthetic resin storage containers, plates, tubes, rods, and films). However, any change in the shape of a product that does not lead to any loss of its original function in use (deformation in use or modification of a dimension that does not cause any modification of its functions), any change in the shape of a product due to exercise of its original function (e.g. wear on a rubber eraser), and any change that incidentally causes loss of its function as a commercial product (damage in use), are not treated as changes in the composition or shape.

(ii) Mixtures in sufficiently subdivided states and in forms that will permit them to be sold over the counter, etc., if minimal modification such as labeling, etc., is made (e.g. synthetic resin paints containing pigments and household detergents).

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 6 of the Act 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 6 of the Act.

b. Chemical substances confirmed in accordance with Article 3, Paragraph 1, Clause 5 or 6 or Article 5, Paragraph 4 of the Act (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 5, Paragraph 8 of the Act (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 7, 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, etc. (referring to monomers or to polymers having molecular-weight distribution) that comprise more than 99% by weight of a polymer made up of two or more monomers, etc., is an existing chemical substance, etc. (excluding those chemical substances that have received the confirmation provided for in Article 3, Paragraph 1, Clause 5 or 6 of the Law), or when another polymer obtained from monomers, etc., that comprise more than 98% by weight of the polymer made up of two or more monomers, etc., is an existing chemical substance, etc. (excluding those chemical substances that have received the confirmation provided for in Article 3, Paragraph 1, Clause 5 or 6 of the Law) and monomers, etc., that comprise the remaining less than 2% by weight of the polymer are existing chemical substances, etc. (excluding Class I Specified Chemical Substances and Class II

Specified Chemical Substances), 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, etc. (excluding those chemical substances that have received the confirmation provided for in Article 3, Paragraph 1, Clause 5 or 6 of the Law), such copolymer of A, B, and C is not treated as a new chemical substance. Also, in cases where the sum of the percent by weight of A and B in a copolymer obtained from A, B, and C exceeds 98%, and the copolymer of A and B is an existing chemical substance, etc. (excluding those chemical substances that have received the confirmation provided for in Article 3, Paragraph 1, Clause 5 or 6 of the Law), if C is an existing chemical substance, etc. (excluding Class I Specified Chemical Substances and Class II Specified Chemical Substances), such copolymer obtained from 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 3, Clause 2 of the Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc., if the facilities are used by unspecified users.

2-6 Relationship between Article 1, Paragraph 1, Clauses 2.c and d, and Article 1, Paragraphs 2 and 3 of the Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring 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 4, Paragraph 1, Clause 2.b) of the Act, even when the substance is not bioaccumulative. The possibility of correspondence to Article 2, Paragraph 3, Clause 1 of the Act shall be determined based on the test results carried out in accordance with Article 1, Paragraph 2 of the Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances (Ordinance No. General Administrative Agency of the Cabinet; Ministry of Health and Welfare; and Ministry of International Trade and Industry, , hereinafter referred to as “Ordinance on Test Items”), and the possibility of correspondence to the Clause of Article 4, Paragraph 1, Clause 2.b of the Law shall be determined based on the test results in accordance with Article 1, 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 1, Paragraph 1, Clauses 2.c and 4 of Ordinance on Test Items.

2-7 Relationship between Article 55 and Article 3, Paragraph 1 of the Act

“Chemical substances listed in the following items” as stipulated in Article 55 of the Act 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 Act 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, etc. of Class I Specified Chemical Substances, Class II Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, and General Chemical Substances

3-1 General chemical substances contained in mixtures

When the content of a general chemical substance contained in a mixture is less than 10% by weight (including those treated as mixtures pursuant to 3-2 below), the provisions related to general chemical substances are not applied.

3-2 Chemical substances having any Class I Specified Chemical Substances, Class II Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, or general chemical substances as part of their structure or as component parts thereof

Chemical substances that are not determined to be treated as new chemical substances pursuant to “2 Notification of manufacture/import of new chemical substances” are treated as follows:

- (1) Chemical substances (limited only to intermolecular compounds, inclusion compounds, hydrates, double salts, solid solutions, block polymers, and graft polymers) having any Class I Specified Chemical Substances, Class II Specified Chemical Substances (hereinafter referred to as Specified Chemical Substances), Monitoring Chemical Substances, Priority Assessment Chemical Substances, or general chemical substances as part of their structure are treated as mixtures containing Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, or general chemical substances, respectively. Regarding the manufacture, etc., of these mixtures, provisions related to Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, or general chemical substances are applied.

In this regard, however, the polymer specified in item 2-1(2)(iii)d of “2 Notification of manufacture/import of new chemical substances” is subject to the application of the provisions related to Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, or general chemical substances, since it can be regarded as the same chemical substance, etc., as “another polymer (that) is an existing chemical substance, etc. (excluding those

chemical substances that received the confirmation provided for in Article 3, Paragraph 1, Clause 5 or 6 of the Act)” stipulated in the same item.

(2) Chemical substances (limited only to adduct salts and onium salts) having as part of their structure any component part (limited only to anions or cations) of Specified Chemical Substances, Monitoring Chemical Substances, or Priority Assessment Chemical Substances are treated as mixtures containing Specified Chemical Substances, Monitoring Chemical Substance, or Priority Assessment Chemical Substance, respectively. The manufacture, etc., of such substances is subject to the application of the provisions for Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, or general chemical substances.

(Example: An onium salt in which any of the counterions are a component part of any Priority Assessment Chemical Substance is treated as a mixture containing such Priority Assessment Chemical Substance, in which case Article 9, Article 10, etc., are applied regarding the manufacture, etc., of the onium salt.)

However, those chemical substances are not treated as Specified Chemical Substances or Priority Assessment Chemical Substances in the following cases:

- a. Cases where such component part falls under any of those that are cited in 4 of the “Knowledge concerning the composition, properties, etc., thereof already obtained” (March 31, 2011, No. 0331004 Pharmaceutical and Food Safety Bureau, MHLW; No. 2, Manufacturing Industries Bureau, METI, March 31,2011; No. 110331006, Environmental Policy Bureau, MOE) as those not relevant to Article 2, Paragraph 2, Clause 1 and Paragraph , Clause 1 of the same Article as well as those not suspected to be relevant to Paragraph 3, Clause 1.a of the same Article of the Act; and
- b. Cases where any ion that is a constituent of a Specified Chemical Substance, etc., as counterion for tributyltin cation, triphenyltin cation, or perfluorinated (octane-1-sulphonic acid) anion is a constituent of an adduct salt or an onium salt.

(3) Those adduct salts or onium salts that are neither listed in the list of existing chemical substances nor treated as new chemical substances (excluding those that are treated as mixtures containing any Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, or general chemical substances) are treated as either those chemical substances listed in the list

of existing chemical substances that are component parts of such adduct salts or onium salts, or any mixtures of those chemical substances, in which case the manufacture, etc., of these chemical substances is subject to the application of the provisions related to general chemical substances.

3-3 Chemical substances falling under the category of Class I Specified Chemical Substances and contained as impurities

In cases where any chemical substance falling under the category of Class I Specified Chemical Substances is contained in any other chemical substances in a minute amount as a by-product, if such bi-product poses no risk of impairing human health or intervening with the inhabitation or growth of flora and fauna through environmental pollution, and if the percentage of its content is considered to have decreased to a technically and economically feasible level, the bi-product is not treated as a Class I Specified Chemical Substance.

3-4 Chemical substances other than new chemical substances and Class I Specified Chemical Substances, contained as impurities

Monitoring Chemical Substances and Priority Assessment Chemical Substances contained in any other chemical substances as impurities are not subject to the application of the provisions related to Monitoring Chemical Substances and Priority Assessment Chemical Substances, respectively, insofar as their content is less than 1% by weight (including those treated as mixtures pursuant to 3-2).

Furthermore, general chemical substances contained in any other chemical substances as impurities are not subject to the application of the provisions related to general chemical substances, insofar as their content is less than 10% by weight (including those treated as mixtures pursuant to 3-2).

3-5 Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances, and general chemical substances to be totally changed into other chemical substances

(1) Class I Specified Chemical Substances

In cases where any person who intends to manufacture a chemical substance (A) obtains in the manufacturing process thereof a Class I Specified Chemical Substance (B) (excluding any chemical substance regarding which Appendix A or Annotation iii of Appendix B of the Stockholm Convention concerning Residual Organic Pollutants is not applied) and totally turns it into the chemical substance (A) by causing it to react

chemically, such an act does not fall under any manufacture of a Class I Specified Chemical Substance as far as it is conducted in a closed process (referring to a process in which the chemical substance (B) does not come out of the set of chemical reactor) within an establishment (in principle, limited only to one that is geographically integrated, e.g. that is not separated by a third party's road, etc.) in which the chemical substance (B) is obtained.

Thus, the chemical substance (B) is considered to be manufactured in this process whenever any part of the Class I Specified Chemical Substance (B) is taken out of the closed process for which permission must be obtained pursuant to Article 17 of the Law. In addition, the provisions of Article 28, etc., of the Act 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 13, Paragraph 1, or Article 35, Paragraph 1 or 6 of the Law, since a Class II Specified Chemical Substance or Monitoring Chemical substance is manufactured at establishment X. Article 14 of the Act is also applied.

(3) Priority Assessment Chemical Substances and general chemical substances

In cases where any person who intends to manufacture a chemical substance (A) obtains in the manufacturing process thereof a general chemical substance (B) and turns it totally into the chemical substance (A) by causing it to react chemically, such an act does not fall under the act of manufacturing a Priority Assessment Chemical Substance or a general chemical substance, insofar as the chemical substance (A) is manufactured within the same establishment as the one in which the relevant chemical substance (B) is obtained, or insofar as the relevant chemical substance (B) is obtained by using the person's own facility.

Namely, even in cases where the relevant chemical substance (B) is totally turned into

another chemical substance (A), if the person who obtains the relevant chemical substance (B) is not identical with the person who turns it into the chemical substance (A) by causing it to react chemically, the act of obtaining the chemical substance (B) falls under the act of manufacturing a Priority Assessment Chemical Substance or a general chemical substance, in which case the notification under Article 8, Paragraph 1 (including cases of *mutatis mutandis* application thereof in Paragraph 2 of the same Article; hereinafter the same) or Article 9, Paragraph 1 of the Act is obligatory.

Also, in cases where the process of obtaining the relevant chemical substance (B) and the process of turning it into the chemical substance (A) by causing it to react chemically are carried out in more than one establishment, if the owner of the facility used for the process of obtaining the relevant chemical substance (B) is not identical with the owner of the facility used for the process of turning it into the chemical substance (A), the act similarly falls under the act of manufacturing a Priority Assessment Chemical Substance or a general chemical substance, in which case the notification under Article 8, Paragraph 1 or Article 9, Paragraph 1 of the Act is obligatory.

3-6 Scope of the use of Class I Specified Chemical Substances for testing and research purposes

The phrase “for testing and research purposes” stipulated in Article 18, Article 22, Paragraph 1, and Article 25 of the Act refers to the case in which any person intends to manufacture, import or use any Class I Specified Chemical Substance for the purpose of providing it in its total amount for use in tests, experiments, researches, inspections, etc., carried out in schools, laboratories, and inspection institutes, regardless of whether they are public or private (not limited only to those cases where the person intending to manufacture, import or use the Class I Specified Chemical Substance makes use of it for the person’s own testing and research purposes), provided that the amount of the Class I Specified Chemical Substance is of a scale for use in laboratories.

Accordingly, whenever the relevant Class I Specified Chemical Substance, or even part thereof, is commercially provided for use in the manufacture of any other chemical substance or product, the application for permission, etc., under Article 17 of the Act is required.