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

(Pharmaceutical Safety and Environmental Health Notification 0903 No. 1 dated September 3, 2018, 20180829 Manufacturing Bureau No. 2, Environmental Health Planning No. 1808319 by the joints names of Director General, Pharmaceutical Safety and Environmental Health Bureau, Minister of Health, Labour and Welfare; Director General, Manufacturing Industries Bureau, Minister of Economy, Trade and Industry; Director General, Environmental Health Dept., Minister’s Secretariat, Ministry of the Environment)

Last revision Dec. 3, 2018

Pharmaceutical Safety and Environmental Health Notification 1203 No. 1, 20181101 Manufacturing Bureau No. 1, Environmental Health Planning No. 1811273

Implementation of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (Act No. 117 of 1973; hereafter referred to as the “Act.”) shall be enacted from April 1, 2019 as described below.

“Implementation of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances” (Pharmaceutical Safety and Environmental Health Notification 0303 No. 5 dated March 30, 2018, 20180329 Manufacturing Bureau No. 1, Environmental Health Planning No. 18033011 by the joint names of Director General, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare; Director General, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry; Director General, Environmental Health Dept., Minister’s Secretariat, Ministry of the Environment) shall be repealed as of March 31, 2019.

1 Scope of chemical substances

In Article 2, paragraph (1) of the Act, the following definition is prescribed: “ ‘Chemical substances’ refer to compounds obtained by causing elements or compounds to react chemically (excluding ...(omitted)...radioactive substances...)”. This definition is interpreted as follows.

- (1) An “element” refers to a substance in all states (e.g. excited state, radical) composed of one kind type of atom (without distinction as to the type of isotope; the same applies hereinafter). Alloys are construed as a mixture of “elements” and are therefore regarded as outside the scope of “chemical substances”
- (2) A “compound” refers to a substance composed of two or more different kinds of atoms (at least one of them must be H, He, B, C, N, O, F, Ne, P, S, Cl, Ar, As, Se, Br, Kr, Te, I, Xe, At or Rn) and those are bound by covalent bonding, ionic bonding, coordination bonding or an arbitrary combination of these types of bonding.
- (3) “By causing it to react chemically.” refers to causing something artificially. Therefore, something occurring through natural process is non-applicable. When producing an organism itself through breeding, cultivation or culture, etc. of living organisms or when obtaining biological components of an organism, even if chemical reactions occur within the organism, the Act of breeding, cultivation or culture, etc. itself is not treated as the Act which artificially causes a chemical reaction.

In addition, “by causing it to react chemically.” does not apply in the event that a chemical reaction is caused artificially but is limited in specific local (e.g. surface treatment of metals, adhesive and paint wherein chemical reactions occur during use) or when products become waste without being separated for use.

- (4) Products prescribed in Order for Enforcement of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (Cabinet Order No.202 of 1974; Hereafter referred to as “Order for Enforcement.”) are not regarded as “compounds” but are handled in accordance with Article 24 of the Act (Restrictions on Import of Products), Article 28 (Obligation of Conformity to Standards), Article 29 (Labeling), Article 30 (Order for Improvement), Article 34 (Order to Take Measures in Connection with Designation of Class I Specified Chemical Substances), Article 35 (Notification of the Planned Quantity to Be Manufactured), Article 36 (Publication of Technical Guidelines), Article 37 (Labeling), Article 39 (Guidance and Advice), Article 42 (Reporting on the Status of Handling), Article 43 (Collection of Reports), Article 44 (On-Site Inspection), Article 48 (Requests). In addition, there are items not set forth under Order for Enforcement, and when such are applicable to the following item (i) or (ii), they are regarded as “Products” and handled in accordance with relevant laws and regulations not stated herein.

(i) Products which possess unique product shape and which do not change in composition or shape during use (e.g. synthetic resin storage container, plates, tubes, sticks, film). However, in the event that during its use those products undergo changes within the scope of not losing their original function (deformation during use, change in size not affecting its function), undergo change in shape to serve their function (e.g. wear of an eraser), undergo change which cause

them to accidentally lose their function as products (damage during use), these will not be handled as change in composition or shape.

(ii) Mixtures that are subdivided as needed and are in a state of being sold at stores, etc. by minimum changes to their labeling, etc. (e.g. synthetic resin paint with pigment, household detergent, etc.)

2 Notifications of the Manufacture or Import of new chemical substances

2-1 Method of Identification of Chemical Substances

General rules for identification 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) In principle, each compound is assigned one identification, and its name is given to each identification.

However, if the compositions thereof are unknown or it is a mixture which cannot be separated, the compound is identified and named based on the manufacturing method, properties, and multi constituent state, etc.

(e.g. 1: When a name is given for each identification:

benzene, ethanol, hexane, etc.

e.g. 2: When the compositions are unknown and a name is given based on the

manufacturing method: A, B, C copolymers, or A, B, C reaction products, etc.

e.g. 3: When a name is provided based on the multi constituent state for a mixture which cannot be separated, etc.: mixture of A (main ingredient) , B and C, or mixture of A, B, C (in case main ingredient is unknown).

Therefore, with respect to mixtures, when chemical substances contained in that mixture correspond to one of the following chemical substances below (hereafter referred to as “existing chemical substances, etc.”), they shall not be handled as new chemical substances.

(a) Chemical substances specified in Article 2, paragraph (6) the respective items.

(b) Chemical substances which have been confirmed in accordance with Article 3, paragraph(1), item(v), item(vi) or Article 5, paragraph(4) of the Act (limited to manufacturing or importing in accordance with the scope of confirmation by the person who received the confirmation)

(c) Chemical substances which have received notification of determination as prescribed in Article 4, paragraph(1) and Article 4, paragraph(2) or Article 5, paragraph(8) (limited to manufacture or import by the person receiving that notification of determination and in accordance with that determination)

(d) Chemical substances which have received notification of determination that they correspond to Article 4, paragraph (1), items(ii) through (v) based on the provisions under Article 4, paragraph (1) or paragraph (2) which apply mutatis mutandis pursuant to Article 7, paragraph(2) of the Act (limited to import by the person receiving that notification of determination).

(ii) With regard to chemical compounds contained as impurities, if the content thereof is less than 1 wt.%, those chemical compounds shall not be handled as a new chemical substance.

“Impurities” refer to unintended substances such as unreacted raw materials, reaction catalysts, indicators or by-products (substances generated through unintended reaction), etc. (The same is applied hereafter.)

(iii) With regard to intermolecular compounds, inclusion compounds, hydrates (including water of crystallization), etc. when individual chemical substances constituting the compound are all existing chemical substances, such compound shall not be considered as a new chemical substance.

(iv) Regarding “addition salts of organic compounds” (excluding metallic salt), when the acid and base constituting the salts are all existing chemical substances, those addition salts shall not be regarded as a new chemical substance.

(e.g. : In the case of aniline hydrochloride, aniline and hydrogen chloride which constitute the salts are respectively existing chemical substances; thus, it shall not be handled as a new chemical substance.)

(v) In the case of onium salt, if the counter ion is a constituent of an existing chemical substance, that onium salt shall not be handled as a new chemical substance.

(e.g. In the case of ammonium acetate wherein acetate ion and ammonium ion constitute the salt which are constituent ions of ammonium nitrate and sodium acetate, since they are respectively existing chemical substances, ammonium acetate shall not be handled as a new chemical substance.)

(vi) In the case of “acid or base”, when “the anion in the acid” or “cation in the base” are constituents of addition salts (excluding metallic salt) or onium salt which are existing chemical substances, that “acid or base” shall not be handled as a new chemical substance.

(e.g. fluorophosphoric acid is a constituent of the anion in the diammonium fluorophosphate which is an existing chemical substance, thus it shall not be handled as new chemical substance.)

(2) Handling according to individual category

(i) Inorganic compounds

(a) Even when they form an ionic lattice, they shall be handled according to the constituting unit (e.g. NaCl).

(b) Solid solution or complex oxide shall be handled as a mixture of oxides they constitute.

(e.g. Complex oxides in which zinc, iron and chromium coexist shall be handled as a mixture of zinc oxide (1-561), iron oxide (1-357) or chromium oxide (1-284).)

(c) In the case of double salt (including acid salt and basic salt) where the respective constituent salt (acid in the case of acid salt and base in the case of basic salt) is an existing chemical substance, that double salt shall not be handled as a new chemical substance.

(e.g. For alum (aluminum potassium sulfate), because aluminum sulfate (1-25) and potassium sulfate (1-454) are existing chemical substances, thus it shall not be handled as new chemical substance.

(d) In the case of inorganic polymers, when the monomers constituting them are existing chemical substances, those polymers shall not be handled as new chemical substances.

(e.g. phosphoric acid and polyphosphoric acid)

(ii) Organic low molecular weight compounds

(a) Due to use of natural raw materials etc., when materials contain different number of carbon chains such as an alkyl group or an alkenyl group, the compound can be handled collectively.

(e.g. beef tallow fatty acid soda → fatty acid (C14-18) soda)

(b) When a compound has a plurality of substituents and seems to contain mixtures with different positions and/or numbers, it can be handled collectively.

(e.g. 1: ortho, meta, paraxylene → xylene

e.g. 2: 30% chlorinated paraffin, 25% chlorinated paraffin → chlorinated paraffin)

(c) When individual metallic salts which constitute mixed metallic salts are existing chemical substances, that mixed metallic salts shall not be handled as new chemical substance.

(e.g. sodium salt of ethylenediaminetetraacetic acid, aluminum salt of ethylenediaminetetraacetic acid and aluminum salt of monosodium salt of ethylenediaminetetraacetic acid)

(iii) Organic polymers

(a) Polymers are not distinguished by manner of polymerization, degree of crystallinity, tacticity or degree of polymerization (incl. degree of condensation) when the polymers do not have differences from the repeating unites (monomers and other reactants for polycondensation) and manner of polymerization.

(b) With regard to a compound that is an organic polymer which includes an initiator or chain transfer agent in the structure and the weight percentage of the initiator or chain transfer agent is less than 1% (if there are multiple initiators or chain transfer agents, weight percentage of each should be less than 1%), if the name of the aforementioned is not included in an organic polymer that is an existing chemical substance, it is handled as the same existing chemical substance.

(e.g. In a copolymer with B and C with A as the initiator, if the weight percentage of A is less than 1% and the copolymer consisting of B and C is an existing chemical substance, the copolymer is handled as the same copolymer consisting of B and C, which is the existing chemical substance.)

(c) When a polymer segment (limited to one with molecular weight distribution) constituting a block polymer is made up of all existing chemical substances, the block polymer shall not be handled as a new chemical substance.

(d) When the stem and branch polymers constituting the graft polymer are all existing chemical substances, that graft polymer shall not be handled as a new chemical substance.

(e) In the case of an organic polymer obtained from 2 or more types of monomers (refers to polymers with a monomer, initiator, chain transfer agent or that have molecular weight distribution. The same applies hereafter), if another organic polymer obtained from monomers in which the total of the aforementioned weight percentage exceeds 99% and is an existing chemical substance (excluding chemical substances confirmed in accordance

with of Article 3, paragraph (1), item (v) and item (vi) of the Act), or if another organic polymer obtained from monomers in which the total weight percentage exceeds 98% (excluding chemical substances confirmed in accordance with Article 3, paragraph(1), item(v) and item (vi) of the Act) and the monomers constituting less than 2% of the remaining weight percentage are existing chemical substances (excluding chemical substances which are Class I Specific Chemical Substances or Class II Chemical Substances or have a part of the structure constituted of Class I Specific Chemical Substances or Class II Chemical Substances), it shall not be handled as a new chemical substance.

(e.g. In a copolymer constituted of A,B and C, if the total of weight percentage of A and B exceeds 99% and the copolymer of A and B are existing chemical substances (excluding chemical substances confirmed in accordance with Article 3, paragraph(1), item(v) and item(vi) of the Act), that copolymer constituted of A,B and C shall not be handled as a new chemical substance. Moreover, in the case of a copolymer constituted of A,B and C, if the total weight percentage of A and B exceeds 98% and the copolymer constituted of A and B is an existing chemical substance (excluding chemical substances confirmed in accordance with Article 3, paragraph (1), item (v) and item (vi) of the Act) and C is an existing chemical substance (excluding Class I Specified Chemical Substances and Class II Specified Chemical Substances), that copolymer constituted of A, B and C shall not be handled as a new chemical substance.)

(f) In the case of an organic polymer compound obtained from 2 or more kinds types of monomers, if the total weight percentage exceeding 90% is obtained from another organic polymer compound which is an existing chemical substance (excluding chemical substances confirmed in accordance with Article 3, paragraph(1), item(v) of the Act) and the monomers constituting the remaining weight percentage of less than 10% correspond to all of the following items (i) through (vi), it will not be treated as a new chemical substance.

(i) If each monomer is an existing chemical substance, the content shall be below 2 wt.% (below 1 wt.% if it is not an existing chemical substance). (However, even if it is another monomer, if the substance has the same chemical structure as the organic polymer by reaction, it shall be handled as the same monomer.)

(ii) It shall not be a chemical substance belonging to Class I Specified Chemical Substances or Class II Chemical Substances or a part of the structure containing Class I Specified Chemical Substances or Class II Chemical Substances.

(iii) It shall not include metals other than sodium, magnesium, potassium or calcium.

(iv) It shall not generate cationic property in the main structure of the organic polymer.

(v) It shall not contain arsenic or selenium.

(vi) It shall not generate within the chemical structure of the organic polymer carbon a carbon-carbon double bond, carbon-carbon triple bond, carbon-nitrogen double

bond, carbon-nitrogen triple bond, aziridinyl group, amino group, epoxy group, sulfonic acid group, hydrazino group, phenolic hydroxyl group or fluoro group.

(e.g. In a copolymer constituted of A, B, C, D, E, F and G, if the total of weight percentage of A and B exceeds 90% and the copolymer of A and B is an existing chemical substance (excluding chemical substances confirmed in accordance with Article 3, paragraph(1), item(v) of the Act), and D, E, F and G correspond to all of the items (i) through (vi), the copolymer constituted of A, B, C, D, E, F and G shall not be handled as a new chemical substance.)

(g) In the case of an organic polymer obtained from 2 or more kinds of monomers with number average molecular weight of 10,000 or more, if another organic polymer obtained from monomers exceeding the total weight percentage of the aforementioned exceeding 90% is an existing chemical substance (excluding chemical substances confirmed in accordance with Article 3, paragraph (1), item (v)) of the Act and the remaining monomers constituting less than 10% of the weight percentage corresponds to all the items (i) through (v), it shall not be handled as a new chemical substance.)

(e.g. In a copolymer constituted of A, B, C, D, E, F and G with number average molecular weight of 10,000, if the total weight percentage of A and B exceeds 90% and the copolymer constituted of A and B is an existing chemical substance (excluding chemical substances confirmed in accordance with Article 3, paragraph(1), item (v) of the Act) and C, D, E, F and G corresponds to all of (i) through (v), that copolymer constituted of A, B, C, D, E, F and G shall not be handled as a new chemical substance.)

(3) List of Existing Chemical Substances

The symbol “ · ” included in the name of a chemical substance in the List of Existing Chemical Substance means the following.

(i) As a rule, “ · ” means “and.”

(e.g. ethylene · vinyl chloride · vinyl acetate copolymer (6-25))

This is a copolymer constituted of ethylene, vinyl chloride and vinyl acetate copolymer, so the copolymer constituted of ethylene and vinyl chloride is not included in that name.)

(ii) As a rule, the symbol “,” excluding the instance when it refers to a paragraph, means “or.”

(iii) When the number of substituents is not specified, the number of that is one (mono).

(e.g. Methylcyclohexane (3-2230))

This is a compound in which a cyclohexane has one (mono) methyl group substitute and compounds in which a cyclohexane has multiple methyl groups substitutes are not included in this name.)

(iv) Regarding salt, unless there are no specific remarks, there is no distinction among normal salt, acid salt or basic salt.

(e.g. Sodium carbonate includes sodium hydrogen carbonate.)

In the manufacturing method of a person who is manufacturing a chemical substance (A), in the event the person obtains a new chemical substance (B) and by causing a chemical reaction thereto is able to convert the total quantity to chemical substance (A), if the person manufactures chemical substance (A) within an establishment which manufactures a new chemical substance (B) or the person manufactures a new chemical substance (B) then manufactures chemical substance (A) in the person's own facility, the act of obtaining new chemical substance (B) does not correspond to "manufacturing a new chemical substance." in accordance with Article 3, paragraph(1) of the Act.

In other words, when converting the total quantity of new chemical substance (B) to another chemical substance (A), if the person obtaining a new chemical substance (B) and the person causing a chemical reaction thereto in order to obtain chemical substance (A) differ, even if the entire process in obtaining chemical substance (A) ostensibly within the same establishment is carried out successively, the Act of obtaining a new chemical substance (B) corresponds to "manufacturing a new chemical substance" prescribed in the same clause.

In addition, in the event that the process of obtaining a new chemical substance (B) and the process of converting it to chemical substance (A) is carried out in multiple establishments, if the owner of the facility wherein the process of obtaining that new chemical substance (B) takes place and the owner of the facility wherein the process of converting chemical substance (B) to chemical substance (A) takes place differ, the Act corresponds to "manufacturing a new chemical substance" prescribed in the same clause.

2-3 Scope of testing and research

"When manufacturing or importing new chemical substances for testing and research purposes." as prescribed in Article 3, paragraph (1), item (ii) of the Act, refers to when a new chemical substance is manufactured or imported for use in its entirety for tests, experiments, research, development and inspections at schools, research institutes, laboratories, inspection agencies, regardless of whether they are private or public (not limited to whether the person manufacturing or importing is using that new chemical substance for the person's own testing and research). Therefore, even if only a portion of that new chemical substance is used, if it is used for the commercial manufacture of other chemical substances or products, a notification based on Article 3, paragraph (1) of the Act is required. For example, in the case of manufacturing a new chemical substance in a so-called "test plant" in order to consider the possibility of practical application of testing and research results, within the scope of manufacture of that new chemical product for tests, experiments, research, development and inspections, the person manufacturing that new chemical substance or the person assigned that new chemical substance is not required to submit a notification in accordance with Article 3, paragraph (1) of the Act.

2-4 Scope of reagents

"Reagent" is defined according to Article 3, paragraph (1), item (iii) of the Act as "a chemical substance used to detect or quantify a substance using a chemical method or a chemical substance used for experiments in synthesis of substances or measurements of a substance's physical properties," and as the aforementioned indicates, it refers to that which is used for chemical analysis,

experiments, testing and research, and inspections, and the determination of whether or not a substance is a reagent, as a rule, is dependent on the type of manufacture and packaging. In such an instance, even if a substance is labeled as a reagent, if it is used for industrial chemicals or industrial raw materials, it does not correspond to a “reagent.”

2-5 Scope of closed system application, etc

Even if a new chemical product is used only in a specific closed system device, if it is used by unspecified and great number of users, it does not fall under Article 3, paragraph (2) of Order for Enforcement.

2-6 Relationship between Article 1, paragraph (1), item (ii), (c) and (d) of the Ministerial Order Specifying Items Concerning the Testing of New Chemical Substances and Study of the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances and Article 1, paragraph (2) and paragraph (3), of the relevant Ministerial Order.

If the new chemical substance is not readily degradable properties (including cases where a chemical substance is generated by a chemical transformation through a natural process), even if the properties are not easily bioaccumulated within a living organism, determination is required as to whether it is suspected to apply to Article 2, paragraph (3), item (i) of the Act or it corresponds to Article 4, paragraph (1), item (ii), (b) of the Act. In such an instance, in order to evaluate whether it falls under Article 2, paragraph (3), item (i) of the Act, determination will be based on the achievements of the test prescribed in Article 1, paragraph (2) of the Ministerial Order Specifying Items Concerning the Testing of New Chemical Substances and Study of the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances (Ministerial Order No. 3 dated March 31, 2010 by the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry and Ministry of the Environment. Hereafter referred to as “Ministerial Order of Testing Items”), and as to whether it falls under Article 4, paragraph (1), item (ii), (b) of the Act, determination will be based on the achievements of the test prescribed in Article 1, paragraph (3) of the Ministerial Order of Testing Items.

Furthermore, if the substance is not readily degradable properties and is easily bioaccumulated within a living organism, there is a possibility that it may correspond to Class 1 Specified Chemical Substance depending on the properties prescribed in under Article 2, paragraph (2), item (i), (b) of the Act, and determination will be made thereof based on achievements of the test prescribed in Article 1, paragraph (1), item (ii), (c) and (d) of the Ministerial Order of Test Items.

2-7 Relationship between Article 55 and Article 3, paragraph (1) of the Act

“Chemical substances which fall under the following items” as prescribed in Article 55 of the Act refer not only each of the items in that article being a new chemical substance constituted from a single new chemical substance but also applies to a mixture of multiple new chemical substances or a mixture of existing chemical substances and new chemical substances applicable as “chemical substances which fall under the following items.” In such a case, the new chemical substance is regarded as “materials”, and within the scope of manufacturing or importing such materials under

the corresponding items of that article, despite being a new chemical substance, notification in accordance with Article 3, paragraph (1) of the Act is not required.

3 Handling of Manufacturing, etc of Class I Specified Chemical Substance, Class II Specified Chemical Substance, Monitoring Chemical Substance, Priority Assessment Chemical Substance and General Chemical Substance

3-1 Handling of Class I Specified Chemical Substance, Class II Specified Chemical Substance, Monitoring Chemical Substance, Priority Assessment Chemical Substance and General Chemical Substance or a substance with a part of its structure or component containing the aforementioned

The handling of substances determined not categorized as a new chemical substance based on notifications regarding the manufacturing and importing of new chemical substances in accordance with this notification shall be as follows. In addition, provisions related to specified general chemical substances in addition to provisions related to general chemical substances shall apply to chemical substances which correspond to specified general chemical substances under the general chemical substance category.

- (1) Regarding substances with a part of its structure containing Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances (limited to intermolecular compounds, inclusion compounds, hydrates, double salt, inorganic polymer, mixtures of metallic salts, block polymers, graft polymers), they shall be handled as Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances. Provisions for Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances shall apply to the manufacture of these substances.

However, organic polymer which are not handled as new chemical substances in this notification (excluding block polymers and graft polymers), provisions for Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances shall apply as chemical substances equivalent to other organic polymer which

- (2) Regarding substances having as part of its structure (limited to addition salt and onium salt) constituents of Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances (limited to anion and cation), they shall respectively be handled regarded as Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances. Provisions for Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances shall apply to the manufacture of these substances.

(e.g. Regarding onium salt which is constituted of ions which are constituents of Priority Assessment Chemical Substances and General Chemical Substances, that onium salt will comprise one category and regarding the manufacture thereof, Provisions for Priority Assessment Chemical Substance (Article 9, Article 10, etc. of the Act) shall apply.)

However, the following shall not be handled regarded as Class I Specified Chemical Substances, Class II Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances.

- (a) In the case where that constituent does not correspond to Article 2, paragraph (2), item (i) and of Article 4, paragraph (1), item (ii), (b), (1) of the Act regarding item (iv) of “Knowledge About the Composition and Properties Already Obtained) (Pharmaceutical Safety and Environmental Health Notification 0313 No. 8 dated March 14, 2018, 20180308 Manufacturing Bureau No. 2, Environmental Health Planning No 1803124 by the joint names of the Director General, Pharmaceutical and Health Dept., Minister of Health, Labour and Welfare, Director General, Manufacturing Industries Bureau, Minister of Economy, Trade and Industry, Director General, Environmental Health Dept., Ministry’s Secretariat, Ministry of the Environment) or is not suspected of corresponding to that Article, paragraph (3) item (i), (a).
 - (b) When ions which are components of Class I Specified Chemical Substances or Class II Chemical Substances as counter ions of tributyltin cation, triphenyltin cation, belfluoroanion (oxthane-1 sulfuric acid), anion, pentachlorophenol anion are components of addition salt or onium salt
- (3) Regarding the handling of notifications of quantity of manufacturing volume of intermolecular compounds, inclusion compounds, hydrates, double salt, inorganic polymer compounds, mixtures of metallic mixed metal salts, block polymers, graft polymers, addition salt or onium salt which are regarded as Class II Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances or General Chemical Substances in (1) or (2), as a rule, one category is allotted per each compound. Article 35 of the Act shall apply to compounds containing Class II Specified Chemical Substances, Article 13 of the Act shall apply to compounds containing Monitoring Assessment Chemical Substances (excluding those containing Class II Specific Chemical Substances), Article 9 of the Act shall apply to compounds containing Priority Assessment Chemical Substances (excluding those containing Class II Chemical Substances) and Article 8 of the Act shall apply to compounds containing General Chemical Substances (excluding those containing Class II Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances).

3-2 Handling of Notifications of quantity of manufacture of Priority Assessment Chemical Substances or General Chemical Substances

Regarding the handling of notifications of quantity of manufacture of Priority Assessment Chemical Substances or General Chemical Substances as prescribed in Article 9 or Article 8 of the Act, as a rule, one category is allotted per each compound, and substances which are unknown or

which cannot be separated shall be classified based on the manufacturing method, properties or state of mixture.

3-3 Handling of General Chemical Substances in a mixture

Regarding General Chemical Substances contained in a mixture, if the content is below 10 wt.%, the provisions for General Chemical Substances shall not apply.

3-4 Handling of Chemical substances that contain Class I Specified Chemical Substances as impurities

If Class I Specified Chemical Substances are contained in other chemical substances in minute amounts as byproducts, and if environmental pollution caused by that byproducts poses no harm to human health or hindrance to the inhabitation and/or growth of flora or fauna therefrom, and the content is reduced to a technically and economically best available level, that byproducts shall not be handled as Class I Specified Chemical Substances.

3-5 Handling of Chemical substances that contain other than new chemical substances and Class I Specified Chemical Substances as impurities

Regarding Class II Specified Chemical Substances, Monitoring Chemical Substances and Priority Assessment Chemical Substances contained as impurities in other chemical substances, if the content thereof is below 1 wt.%, the respective provisions for Class II Chemical Substances, Monitoring Chemical Substances and Priority Assessment Chemical Substances shall not apply.

In addition, regarding General Chemical Substances contained in other chemical substances as impurities, if the content thereof is below 10 wt.%, the provisions for General Chemical Substances shall not apply.

3-6 Handling of Class I Specified Chemical Substances, Class II Specified Chemical Substances, Monitoring Chemical Substances, Priority Assessment Chemical Substances and General Chemical Substances chemically transformed in total quantity to other chemical substances

(1) Class I Specified Chemical Substances

If a person who intend to manufacture chemical substance (A), in the course of manufacturing method, obtains Class I Specified Chemical Substances (B) (excluding chemical substances not applicable to Remarks iii of “Annex A” or “Annex B” of the Stockholm Convention on persistent organic pollutants), and by causing chemical reactions thereto changes the total quantity to chemical substance (A), limited to the process being carried out in as a closed process (when chemical substance (B) is contained within the series of chemical reaction device in that process) within the establishment where chemical substance (B) is obtained (as a rule, it shall be limited to a geographically integrated location where it is not divided by a third party road), that the Act shall not apply to the manufacture of Class I Specified Chemical Substances.

Therefore, if a part of Class I Specified Chemical Substances is taken out of the closed process and chemical substance (B) is manufactured in this process, a permission in accordance with Article 17 of the Act must be obtained. In addition, the provisions under Article 28, etc. of the Act shall be applied.

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

If a person who intend to manufacture chemical substance (A), in the course of manufacturing method, obtains Class II Specified Chemical Substances or Monitoring Chemical Substances (B), and by causing a chemical reaction thereto changes the total quantity to chemical substance (A), if the chemical substance (A) is manufactured within the same place of business where the person obtains Class II Specified Chemical Substances or Monitoring Chemical Substances (B), the act of manufacturing Class II Specified Chemical Substances or Monitoring Chemical Substances is not applicable in this case.

Therefore, if Class II Specified Chemical Substances or Monitoring Chemical Substances (B) is manufactured in a given place of business (a) and transported to another place of business of the same company (b), even if the total quantity is changed to another chemical substance at place of business (bc), this act amounts to manufacturing Class II Specified Chemical Substances or Monitoring Chemical Substances in place of business (a), thereby requiring notification to be submitted in accordance with Article 13, paragraph (1), Article 35, paragraph (1) or Article 35, paragraph (1), paragraph (6) of the Act. In addition, the provisions under Article 14 of the Act shall be applied.

(3) Priority Assessment Chemical Substances and General Chemical Substances

If a person who intends manufacture chemical substance (A), in the course of manufacturing method, obtains Priority Assessment Chemical Substances or General Chemical Substances (B), and by causing chemical reaction thereto changes the total quantity to chemical substance (A), as long as chemical substance (A) is manufactured within the same place of business where the person obtains Priority Assessment Chemical Substances or General Chemical Substances (B), of if the person's own facility is used to obtain Priority Assessment Chemical Substances or General Chemical Substances (B) to manufacture chemical substance (A), the Act of manufacturing Priority Assessment Chemical Substances or General Chemical Substances is not applicable in this case.

In other words, even if the total quantity of Priority Assessment Chemical Substances or General Chemical Substances (B) is chemically transformed to chemical substance (A), if a person obtaining Priority Assessment Chemical Substances or General Substances (B) and a person causing a chemical reaction thereto to chemical transform the aforementioned to chemical substance (A) differ, notwithstanding the entire series of reactions to obtain chemical substance (A) occurring sequentially ostensibly within the same place of business, the Act of obtaining chemical substance (B) corresponds to manufacturing Priority Assessment Chemical Substances or General Chemical Substances, thereby requiring notification shall be submitted in accordance with Article 8, paragraph (1) of the Act (including cases where the article 8, paragraph (2) apply *mutatis mutandis*. The same applies hereafter.) or Article 9, paragraph (1) of the Act.

Moreover, if the process of obtaining Priority Assessment Chemical Substances or General Chemical Substances (B) takes place in multiple place of business and the owner of the facility wherein the process in obtaining Priority Assessment Chemical Substances or General Chemical Substances takes place and the owner the facility where these are chemically transformed to chemical substance (A) differ, since these likewise amount to the Act of manufacturing Priority Assessment Chemical Substances or General Chemical Substances, notification shall be submitted in accordance with Article 8, paragraph(1) or Article 9,paragraph(1) of the Act.

3-7 Scope of Class I Specified Chemical Substances for testing and research purposes

“For testing and research purposes” as prescribed in Article 18, Article 22, paragraph (1) and Article 25 of the Act refers to cases wherein Class I Specified Chemical Substances are manufactured, imported or used in total quantity (not limited to the person manufacturing or importing to use those Class I Specified Chemical Substances for their own testing and research) for testing, experiments, research and inspections, etc. at schools, research institutes, laboratories and inspection agencies, regardless of whether they are public or private, and shall be an amount used at a laboratory-scale.

Therefore, even if that Class I Specified Chemical Substances constitute only a part thereof, if they are used for commercial manufacture of other chemical substances or products, permit application in accordance with Article 17 of the Act is require.

