

Notification of the Manufacturing
Amount, etc. of General Chemical
Substances and Priority
Assessment Chemical Substances
Preliminary Preparation Materials

December 2010

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

* These materials are current as of December, 2010. As we plan on updating the materials sequentially, please check whether the version is the latest one on the Ministry of Economy, Trade and Industry website, etc.

1. Chemical Substance Control Law (Overview of Amendment, etc.)

About these materials

These preliminary preparation materials explain the procedures for notifications of the manufacturing amount, etc. and methods for filling out documents to be submitted in accordance with the establishment of a new system for notifications of the manufacturing and import amounts, etc. for “general chemical substances” and “priority assessment chemical substances” starting on April 1, 2011 due to an amendment to the “Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” (Law No. 117, 1973, hereinafter referred to as the Chemical Substance Control Law).

Starting with notifications submitted in FY2011 (notifications regarding actual results from FY2010; hereinafter the same shall apply), in addition to the existing Class II and Class III Monitoring Chemical Substances, notifications of the manufacturing amount, etc. for “general chemical substances” and from among these, “priority assessment chemical substances” that are not recognized as having low risks, for which the obligation of notification of manufacturing amount, etc. had not been previously required, will become necessary.

In association with this change in the notification system, we have gathered information on an overview of the system and compiled responses to inquiries that we have received beforehand. Please look at these materials and make preparations for notifications.

Overview of Chemical Substance Control Law and Background of Amendment

As part of measures to ensure safety of chemical substances, the METI is promoting assessment of new chemical substances and hazard assessment of existing chemical substances as based on the Chemical Substance Control Law, and is also striving to promote voluntary management of chemical substances by businesses.

In recent years, there has been increasing interest by the public in safety and security, including chemical substances, and based on an agreement made at the Environmental Summit in 2002, further strengthening of management of chemical substances has been sought after globally, as exemplified by the implementation of new regulations (REACH) in Europe; Japan has also been reviewing approaches.

Based on such a problem-consciousness, the Chemical Substance Control Law was amended in FY2009, in order to review measures related to hazard assessment of chemical substances, and to establish measures, etc. to rationalize regulations to reflect international trends. This amendment was enforced in 2 phases; the first phase has already been enforced since April 1, 2010, while the second phase, which includes the change in notification system, is planned on being enforced starting on April 1, 2011.

Under the legal system after the amendment, chemical substance management will shift from “hazard-based management” that only takes the intrinsic hazardous properties of chemical substances into account to “risk-based management” that also takes emissions (exposure) to the environment into consideration, and in order to comprehend the exposure amount, notifications of the manufacturing amount, etc. for all chemical substances will be needed.

Changes in Regulatory Classifications Associated with the Amendment

Due to the amendment of the Chemical Substance Control Law, regulatory classifications will change as shown in the chart below, starting in FY2011. In particular, please note that even for existing substances for which it was not obligatory to submit notifications of manufacturing and import amounts up until now, it will become obligatory for businesses that manufactured or imported 1 ton or more of such chemical substances to submit notifications of manufacturing/import volumes for every fiscal year.

Regulatory classification before amendment	Regulatory classification in amended law (Notifications starting in FY2011)	Necessity of notifications of manufacturing/import amount
Type I Monitoring Chemical Substances	Monitoring Chemical Substances (Name change)	Necessary (Same as before amendment)
Class II Specified Chemical Substances	Class II Specified Chemical Substances (Same as before amendment)	Necessary (Same as before amendment)
Type II Monitoring Chemical Substances	General chemical substances or priority assessment chemical substances (newly established) *For notifications submitted in FY2011, submit notifications for only substances designated in the official gazette as "priority assessment chemical substances," and all other substances as "general chemical substances."	Necessary
Type III Monitoring Chemical Substances		
Existing chemical substances	General chemical substances or priority assessment chemical substances (newly established) * For notifications submitted in FY2011, submit all as "general chemical substances."	Necessary * Newly made obligatory to submit notifications due to amendment of law.
Newly announced chemical substances		
New chemical substances before announcement that have received a notice of decision		

* Type II Monitoring Chemical Substances and Type III Monitoring Chemical Substances will be discontinued starting on April 1, 2011 after the second phase of the amendment.

(Reference) Specification of priority assessment chemical substances

Priority assessment chemical substances are planned on being designated by the Minister as needed after undergoing a chemical substance screening assessment by the national government. (The concept behind screening assessment methods is reviewed in joint councils among the Ministry of Health, Labour and Welfare, the Ministry of the Environment, and the METI, and has been open to public comments starting on October 16.)

However, in FY2010, priority assessment chemical substances are planned on being designated from among substances that are designated as Type II and Type III Monitoring Chemical Substances as of April 1, 2010, and concrete selection of substances is planned on being announced in the official gazette on April 1, 2011 based on discussions in councils that are planned on being held around January 2011.

2. Notification Targets and Contents

Parties Applicable to Notification

Notifications are obligatory for parties who have manufactured or imported general chemical substances or priority assessment chemical substances based on the regulations of the Chemical Substance Control Law. (If a notification is not submitted, or is falsified, a penalty is imposed.)

(1) Parties applicable to notification

Parties that are applicable to notification are companies that manufactured in Japan or imported into Japan 1.0 tons or more of a single chemical substance per company of general chemical substances (or priority assessment chemical substances) in FY2010.

(2) Parties not applicable to notification

In the following kinds of cases, notification of manufacture/import volume is not necessary

<1> Cases where notification is not necessary due to lack of applicability to “manufacturing” of chemical substances as in the Chemical Substance Control Law

- (1) Cases where chemical substances purchased from a company in Japan are sold as is
- (2) Cases where chemical substances purchased from a company in Japan are made into a product based on a mixing, forming, or purification process, etc. that does not cause chemical reactions

<2> Cases where notification is not necessary due to lack of applicability to “importing” of chemical substances as in the Chemical Substance Control Law

- (3) Cases where products that possess specific shapes or mixtures that are sold to general consumers (“product” as in the Chemical Substance Control Law) are imported^{*1}

*1 Please note that handling of products that make use of specified chemical substances differ.

<3> Other cases where notifications are specified as being unnecessary due to laws, etc.

- (4) Cases where the total of the amount of chemical substances manufactured in Japan and the amount of chemical substances imported into Japan during FY2010 is less than 1 ton per company for each chemical substance
- (5) Cases where chemical substances are manufactured or imported for testing and research purposes
- (6) Cases where the substances have been confirmed as being an intermediate, etc., polymers of low concern, or low production
- (7) Cases where a substance excepted from notification^{*2} (substances designated by the 3 Ministers as there being no necessity to conduct risk assessment) was manufactured or imported

*2 Substances excepted from notification are planned on being added every year.

Format for Notifications

For general chemical substances and priority assessment chemical substances, notification items are specified in Article 9-2 and Article 9-3 of the “Ministry of Economy, Trade and Industry-related Ordinance for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” For FY2011 notifications, the format for notifications of the amount etc. of manufacture (import) of general chemical substances follows “Form 11” (P. 6 to 7) of the abovementioned Regulation, and the format for notifications of the amount etc. of manufacture (import) of priority assessment chemical substances follows “Form 12” (P. 10 to 12) of the Regulation.

Contents of Notifications

Information that is to be notified consists of the name and address of the notifying party (name of the representative in the case of juridical person), name of the chemical substance, the Class Reference Number in the gazette list (MITI Number), the manufacturing, import and shipment amounts (actual results from the previous fiscal year) of the general chemical substance or priority assessment chemical substance, etc. In FY2011, please submit notifications based on actual results from FY2010.

- General chemical substances
 - Manufacturing amount
 - Import amount
 - Shipment amount: It is necessary to submit notifications by intended use.

- Priority assessment chemical substances
 - Manufacturing amount: It is necessary to submit notifications by prefecture.
 - Import amount: It is necessary to submit notifications by the import country/region.
 - Shipment amount: It is necessary to submit notifications by prefecture and by use category (sub use category).

The Use No. and the Prefecture or Country/Region No. are common for all substances, including Class II Specified Chemical Substances and Monitoring Chemical Substances.

When searching for regulatory classifications and Class Reference Number in the gazette list, etc., it is recommended to use the Chemical Risk Information Platform (CHRIP) by the National Institute of Technology and Evaluation (NITE).

http://www.safe.nite.go.jp/japan/sougou/view/SystemTop_jp.faces

Reception of Notifications

In FY2011, please submit notifications between April 1 and the end of June of 2011 to the Chemical Safety Office, Chemical Management Policy Division, Manufacturing Industries Bureau of the Ministry of Economy, Trade and Industry (to the person in charge of Safety Management).

Please submit notifications by paper, FD, CD, or electronically.

With regard to electronic submission, the METI is in the process of creating support software that would enable all companies to create notification documents, etc. efficiently. After this software is completed, it will be distributed free of charge.

Use of Notification Information

Notifications are handled as administrative documents of the METI, and notification information will be used for exposure assessment in risk assessment and screening assessment of chemical substances.

Notification of Manufacturing Amount etc. for General Chemical Substances
 Ministry of Economy, Trade and Industry-related Enforcement Regulations for the Law concerning the Evaluation of
 Chemical Substances and Regulation of Their Manufacture, etc.
 (Ordinance of the Ministry of International Trade and Industry No. 40 of June 7, 1974) Form 11

Form 11 (Related to Article 9-2, Paragraph 2)

[Document Name] Notification of Manufacturing Amount, etc. of General Chemical Substance 1/2

[Date of submission]

[Submitted to] Minister of Economy, Trade and Industry

1. Name and address of notifier

[Name or designation of notifier and in the case of a juridical person, the name of its representative]

_____ Sea

1

[Address of notifier]

*Fill in the name and contact information of the person in charge

[Notifier, etc. Code or Notifier, etc. Reference Code]

2. Manufacturing amount, import amount, and shipping amount

(1) Name, etc. of chemical substance

Refer to the CHRIP database, etc.

Fill in the CAS No.

2

[Substance Name] _____

3

[Class Reference No. in Gazette List]

4

[Other numbers]

5

[Applicability to polymers (Circle if applicable)]

Polymers shall be those that fall under items (1) and (2) below:
 (1) Any chemical substance composed of an aggregation of those molecules that are produced by linkages of one or more types of monomeric units, in which the total weight of those molecules that are composed of 3 or more linkages makes up 50% or more of the weight of the whole substance and the total weight of those molecules with identical molecular weight is less than 50% of the weight of the whole substance; and
 (2) Any chemical substance whose number average molecular weight is 1,000 or more.

Remarks

1. Use A-4 size paper, as defined in the Japanese Industrial Standards.
2. Notifier, etc. Code is the code that was provided beforehand based on the provision in Article 21, Paragraph 2 of the "Ministry of Economy, Trade and Industry-related Ordinance for Enforcement of Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc."
3. A signature may be used in lieu of a name (name of representative in the case of a juridical person) and seal.
4. The juridical person shall state the department and person responsible for the said notification as well as contact information at the end of the notification document.
5. Do not include the captive consumption quantity within the same company in the shipping amount.
6. Use t as the units, and fill out the form using numbers with a single significant digit. Cases where the amount is 1.0 t or higher before rounding are subject to notification.
7. For the Notifier, etc. Reference Code, Reference No. in Gazette List, other numbers, applicability to polymers, and Use No., refer to the steps for filling out the form
8. In the field for Concrete use, write down a specific intended use if, from among the uses listed in the steps for filling out the form, "98 (Other)" is entered in the field for Use No.
9. It is possible to attach documents that include items that serve as a reference to new findings obtained with respect to substances subject to notification, and the state of their manufacture, use, import, etc.

Actual value for fiscal year

Fill in using a number with a single significant digit

6

Manufacturing Amount (t)

Import Amount (t)

Total for fiscal year

8

7

Concrete use

()

Shipping Amount (Total: t)

Fill in using a number with a single significant digit. As a result, it is acceptable if the total value does not match the total of individual "Shipping Amounts."

When there is no corresponding Use No., fill in "98 (Other)" and write down the use inside the parentheses as specifically as possible.

1

Notifier, etc. Code or Notifier Reference Code

Starting in FY2011, a new “Notifier, etc. (Reference) Code” will be required of all companies submitting notifications of general chemical substances and priority assessment chemical substances. Please note that the Notifier, etc. Codes for Monitoring Chemical Substances, etc. that had been used up until now can no longer be used, and that it is necessary to switch to the new codes. In addition, please also note that these codes are not used in common with the Notifier, etc. Codes used in the notification system for limited volume new chemical substances.

- Parties that have submitted notifications of Monitoring Chemical Substances for the past 5 years
 - New codes will be provided by the METI around the beginning of 2011.
- All other parties
 - It is necessary to obtain codes before submitting notifications. Information on how to obtain codes is planned on being listed on the website, etc. of the METI around the beginning of 2011.

2

Substance Name

Write down the name listed in the gazette list.

3

Class Reference No. in Gazette List

Refers to the Class Reference Numbers by category in the gazette list (MITI No.) when the substance has been specified in a regulatory classification (for example, chloroform is “2-37”).

When searching for regulatory classifications and Class Reference Numbers in the gazette list, etc., it is recommended to use the Chemical Risk Information Platform (CHRIP) by the National Institute of Technology and Evaluation (NITE).

http://www.safe.nite.go.jp/japan/sougou/view/SystemTop_jp.faces

4

Other numbers

Write down the CAS No.

5

Applicability to polymers

“Polymers” refer to “polymers that fulfill Standard No. 1 (number average molecular weight of 1,000 or more) in Joint Ministerial Announcement No. 1 of 2009, MLHW, METI, MOE, as having no risk of causing damage to human health or the habitat and/or growth of flora and fauna in the human living environment by causing environmental pollution.” (In other words, polymers that fall under (1) and (2) as follows. (1) Any chemical substance composed of an aggregation of those molecules that are produced by linkages of one or more types of monomeric units, in which the total weight of those molecules that are composed of 3 or more linkages makes up 50% or more of the weight of the whole substance and the total weight of those

molecules with identical molecular weight is less than 50% of the weight of the whole substance. (2) Any chemical substance whose number average molecular weight is 1,000 or more.)

When this is applicable, make a circle in the field provided.

6

Manufacture/Import Amount

The unit used for notification amounts is tons (t). For general chemical substances, round the amount and report it as a number with a single significant digit. (For example, for 17.27 tons, write down 20 tons.)

7

Shipment Amount

The unit used for notification amounts is tons (t). For general chemical substances, round the amount and report it as a number with a single significant digit. (For example, for 17.27 tons, write down 20 tons.)

For "Shipment Amount (Total)," write down the proper total value upon rounding it so that the number contains a single significant digit, rather than the value obtained after totaling the numbers after they are adjusted for fractions. Accordingly, there are cases where "Shipment Amount (Total)" does not match the total of individual "Shipment Amounts."

Regardless of the year of manufacture or import, submit notifications of the amount of chemical substances that were shipped in the applicable fiscal year.

8

Use No. Related to Shipment

For use related to shipment, write down the Use No. (2-digit number) for the use that is normally anticipated for the substance (if there is information from the shipping destination, etc., the use that reflects such information). In cases where it is thought that there is no corresponding Use No., write down "98 (Other Material, Other Additive)" as the Use No. and write down the intended use as specifically as possible within the parentheses on the right side of "Concrete Use." In addition, when "09 (Other Additive)" is entered, write down the intended use as specifically as possible within the parentheses on the right side of "Concrete Use."

When a Use No. other than "98 (Other Material, Other Additive)" and "09 (Other Additive)" are entered, it is not necessary to write down a description within the parentheses on the right side of "Concrete Use."

Use Nos. are used in common for all substances including Class II Specified Chemical Substances and Monitoring Chemical Substances.

Notification of Manufacturing Amount, etc. for Priority Assessment Chemical Substances
 Ministry of Economy, Trade and Industry-related Enforcement Regulations for the Law concerning the Evaluation of
 Chemical Substances and Regulation of Their Manufacture, etc.
 (Ordinance of the Ministry of International Trade and Industry No. 40 of June 7, 1974) Form 12

Form 12 (Related to Article 9-3, Paragraph 2)

[Document Name] Notification of Manufacturing Amount, etc. of 1/3
 Priority Assessment Chemical Substance

[Date of submission]

[Submitted to] Minister of Economy, Trade and Industry

1. Name and address of notifier

[Name or designation of notifier and in the case of a juridical person, the name of its representative]

Seal

[Address of notifier]

*Fill in the name and contact information of the person in charge



[Notifier, etc. Code or Notifier, etc. Reference Code]

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Remarks

1. Use A-4 size paper, as defined in the Japanese Industrial Standards.
2. Notifier, etc. Code is the code that was provided beforehand based on the provision in Article 21, Paragraph 2 of the "Ministry of Economy, Trade and Industry-related Ordinance for Enforcement of Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc."
3. A signature may be used in lieu of a name (name of representative in the case of a juridical person) and seal.
4. The juridical person shall state the department and person responsible for the said notification as well as contact information at the end of the notification document.
5. Do not include the captive consumption quantity within the same company in the shipping amount.
6. Use t as the units, and fill out the form using numbers with a single significant digit. Cases where the amount is 1.0 t or higher before rounding are subject to notification.
7. For the Notifier, etc. Reference Code, Reference No. in Gazette List, other numbers, applicability to polymers, and Use No., refer to the steps for filling out the form
8. In the field for Concrete use, write down a specific intended use if, from among the uses listed in the steps for filling out the form, "98 (Other)" is entered in the field for Use No.
9. It is possible to attach documents that include items that serve as a reference to new findings obtained with respect to substances subject to notification, and the state of their manufacture, use, import, etc.

2. Manufacturing amount, import amount, and shipping amount

2/3

(1) Name, etc. of chemical substance

Refer to the CHRIP database, etc.

[Substance Name] _____

[Substance Control No.]

_____ - _____

Fill in the CAS No.

[Class Reference No. in Gazette List]

_____ - _____

[Other numbers]

_____ - _____ - _____

[Applicability to polymers (Circle if applicable)]

(2) Manufacturing amount, import amount, and shipping (Units: t)

Round off to the nearest whole number and write down a real number

Total value for fiscal year

Total for

Manufacturing amount (t)

Import amount (t)

Shipping amount (t)

3. Manufacture, etc. of chemical substance

(1) Name and address of establishment that manufactured the substance

Write down the Prefecture (or Country/Region) No.

(2) Manufacturing amount by prefecture in which the applicable chemical substance was manufactured, or the import amount by country/region

Prefecture No.

Manufacturing amount (t)

Country/Region No.

Import amount (t)

0 _____

_____ (t)

_____ (t)

0 _____

_____ (t)

_____ (t)

Round off to the nearest whole number and write down a real number

0 _____

_____ (t)

_____ (t)

0 _____

_____ (t)

_____ (t)

Polymers shall be those that fall under items (1) and (2) below:
 (1) Any chemical substance composed of an aggregation of those molecules that are produced by linkages of one or more types of monomeric units, in which the total weight of those molecules that are composed of 3 or more linkages makes up 50% or more of the weight of the whole substance and the total weight of those molecules with identical molecular weight is less than 50% of the weight of the whole substance; and
 (2) Any chemical substance whose number average molecular weight is 1,000 or more.

1

Noifier, etc. Code or Noifier Reference Code

Starting in FY2011, a new “Noifier, etc. (Reference) Code” will be required of all companies submitting notifications of general chemical substances and priority assessment chemical substances. Please note that the Noifier, etc. Codes for Monitoring Chemical Substances, etc. that had been used up until now can no longer be used, and that it is necessary to switch to the new codes. In addition, please also note that this code is not used in common with the Noifier, etc. Codes used in the notification system for limited volume new chemical substances.

- Parties that have submitted notifications of Monitoring Chemical Substances for the past 5 years
 - New codes will be provided by the METI around the beginning of 2011.
- All other parties
 - It is necessary to obtain codes before submitting notifications. Information on how to obtain codes is planned on being listed on the website, etc. of the METI around the beginning of 2011.

2

Substance Name

Write down the name listed in the gazette list.

3

Substance Control No.

Write down the Class Reference Number in the gazette list from when the substance was designated as a priority assessment chemical substance.

For notifications submitted during FY2011, submit only substances specified in the official gazette on April 1, 2011 (planned) as “priority assessment chemical substances.”

When searching for regulatory classifications and Class Reference Numbers in the gazette list, etc., it is recommended to use the Chemical Risk Information Platform (CHRIP) by the National Institute of Technology and Evaluation (NITE).

http://www.safe.nite.go.jp/japan/sougou/view/SystemTop_jp.faces

4

Class Reference No. in Gazette List

Refers to the Class Reference Numbers by category in the gazette list (MITI No.) when the substance has been specified in a regulatory classification (for example, chloroform is “2-37”).

When searching for regulatory classifications and Class Reference Numbers in the gazette list, etc., it is recommended to use the Chemical Risk Information Platform (CHRIP) by the National Institute of Technology and Evaluation (NITE).

http://www.safe.nite.go.jp/japan/sougou/view/SystemTop_jp.faces

5

Other numbers

Write down the CAS No.

6

Applicability to polymers

“Polymers” refer to “polymers that fulfill Standard No. 1 (number average molecular weight of 1,000 or more) in Joint Ministerial Announcement No. 1 of 2009, MLHW, METI MOE, as having no risk of causing damage to human health or the habitat and/or growth of flora and fauna in the human living environment by causing environmental pollution.” (In other words, polymers that fall under (1) and (2) as follows. (1) Any chemical substance composed of an aggregation of those molecules that are produced by linkages of one or more types of monomeric units, in which the total weight of those molecules that are composed of 3 or more linkages makes up 50% or more of the weight of the whole substance and the total weight of those molecules with identical molecular weight is less than 50% of the weight of the whole substance. (2) Any chemical substance whose number average molecular weight is 1,000 or more.)

When this is applicable, make a circle in the field provided.

7

Manufacturing/Import Amounts

The unit used for notification amounts is tons (t). For priority assessment chemical substances, round off to the nearest whole number and report the amount as a real number. (For example, if the amount is 17.27 tons, write down 17 tons.)

8

Manufacturing amount by prefecture in which applicable chemical substance was manufactured, or Import amount by country/region

Write down the Prefecture No. (2 digits) or the Country/Region No. (3 digits).

The Prefecture or Country/Region No. are common for all substances, including Class II Specified Chemical Substances and Monitoring Chemical Substances.

9

Shipment amount by prefecture (or country/region) and by intended use

The unit used for notification amounts is tons (t). For priority assessment chemical substances, round off to the nearest whole number and report the amount as a real number. (For example, if the amount is 17.27 tons, write down 17 tons.)

For “Shipment Amount (Total),” write down the proper total value using upon rounding off to the nearest whole number rather than the value obtained after totaling the numbers after they are adjusted for fractions. Accordingly, there are cases where “Shipment Amount (Total)” does not match the total of individual “Shipment Amounts.”

Regardless of the year of manufacture or import, submit notifications of the amount of chemical substances that were shipped in the applicable fiscal year by prefecture (by country/region for imports) and

by intended use.

10

Prefecture (or Country/Region) No. Related to Shipment

For cases where the substance was shipped within Japan, write down the Prefecture No. (2 digits) aligned to the right, and for cases where the substance was shipped abroad (exported), write down the Country/Region No. (3 digits).

Prefecture and Country/Region Nos. are common for all substances, including Class II Specified Chemical Substances and Monitoring Chemical Substances.

11

Use No. Related to Shipment

For use related to shipment, write down the Use No. (2-digit number) and Sub Use No. (single alphabet character) for the use that is normally anticipated for the substance (if there is information from the shipping destination, etc., the use that reflects such information).

In cases where it is thought that there is no corresponding Use No., write down “98-z (Other Material, Other Additive)” as the Use No. and Sub Use No., and write down the intended use as specifically as possible within the parentheses on the right side of “Concrete Use.”

In addition, when there is a corresponding 2-digit Use No. but no corresponding Sub Use No., write down “△△(←2-digit category) -y or z (Other),” and write down the intended use as specifically as possible within the parentheses on the right side of “Concrete Use.”

When a Sub Use No. other than y or z (Other) is written down, it is not necessary to write down a description within the parentheses on the right side of “Concrete Use.”

The Use No. and the Prefecture or Country/Region No. are used in common for all substances including Class II Specified Chemical Substances and Monitoring Chemical Substances.

3. Frequently Asked Questions

Necessity/Unnecessity of Notifications of Manufacturing Amount, etc. for General Chemical Substances and Priority Assessment Chemical Substances

(1) Applicability/Non-applicability towards “Manufacture of Chemical Substances”

(Ex. 1) Even in cases where the cleaning solution of alkali soap used for washing is disposed of as waste, is it necessary to submit a notification of the manufacturing amount, etc. if a chemical reaction occurs with the alkali soap and a different chemical substance is generated? (Does this correspond to “manufacture of chemical substances” as in the Chemical Substance Control Law)?

→ Even in cases where a chemical reaction occurs, if the cleaning solution becomes waste in its entirety and is disposed of based on the “Waste Disposal and Public Cleansing Act (Waste Disposal Act),” it is not subject to notification of the manufacturing amount, etc.

(Ex. 2) Is it necessary to submit a notification of the manufacturing amount, etc. if a chemical reaction occurs when using an adhesive agent?

→ This is not subject to notifications of the manufacturing amount, etc.

(Ex. 3-1) Is it necessary to submit a notification of the manufacturing amount, etc. if a chemical reaction occurs when coating the surface of paint, metal plates, plastics, or glass?

(Ex. 3-2) Is it necessary to submit a notification of the manufacturing amount, etc. when shipping a product upon bonding it by coating it with an adhesive agent and causing a chemical reaction?

→ Cases when an artificial chemical reaction is limited to specific parts are not subject to notifications of the manufacturing amount, etc.

(Ex. 4) Is it necessary to submit a notification of the manufacturing amount, etc. in cases where salt was obtained by drying rock salt out in the sun or where pyrethrin in insect flowers is purified/separated?

→ Cases where chemical substances are obtained from natural products without causing a chemical reaction are not subject to notifications of the manufacturing amount, etc.

(Ex. 5) Is it necessary to submit a notification of the manufacturing amount, etc. in cases where alcohol is obtained for use in chemical engineering through alcohol fermentation?

→ Such cases correspond to “manufacture of chemical substances” as in the Chemical Substance Control Law, and in principle, notifications of the manufacturing amount, etc. are necessary.

(Ex. 6) Is it necessary to submit a notification of the manufacturing amount, etc. for compounds obtained during inventory holding in cases where after a compound is obtained through chemical reactions and is subsequently turned into a product that can be shipped/used, a different compound is obtained through oxidation reaction during inventory holding?

→ Such cases are not subject to notifications of the manufacturing amount, etc.

(Ex. 7-1) In a case such as where thermoset A is poured into a formwork, and by applying heat and pressure, a product such as screws made from resin B are created and shipped, is it necessary to submit a notification of the manufacturing amount, etc. of resin B?

(Ex. 7-2) Is it necessary to submit a notification of the manufacturing amount, etc. when a concrete product is formed by making cement, etc. undergo chemical reactions, and the concrete product is shipped?

→ Such cases are not subject to notifications of the manufacturing amount, etc.

(2) Applicability/Non-applicability towards “Products”

(Ex. 1) Is it necessary to submit a notification of the manufacturing amount, etc. when large-sized boards, film, adhesive sheets, etc. are imported, and are distributed as a product or part of a product after they undergo only a cutting process in Japan?

→ Such cases are not subject to notifications of the manufacturing amount, etc.

(Ex. 2) Is it necessary to submit a notification of the manufacturing amount, etc. when textiles and yarns are imported, processed in Japan without undergoing chemical reactions, and distributed as a product such as clothing?

→ Such cases are not subject to notifications of the manufacturing amount, etc.

(Ex. 3) Is it necessary to submit a notification of the import amount when ink for ballpoint pens is imported?

→ Ballpoint pens that are filled with ink are not subject to notifications of the import amount, since ballpoint pens as a whole, including the ink that they contain, are handled as “products” in the Chemical Substance Control Law. Even cases where such ballpoint pens are sold in small portions in stores, etc. are not applicable to notifications of the manufacturing amount, etc. However, when imported from abroad in ink form without being repacked into smaller sizes, in principle, notifications of the import amount are necessary.

Units for Notifications of Manufacturing Amount, etc.

1. Notifications in cases where there are several CAS numbers that correspond to a single Class Reference Number in the gazette list (Arbitrary)

As a legal obligation, although it is acceptable to submit a notification for each Class Reference Number in the gazette list, in cases where there are multiple CAS numbers that correspond to the Class Reference Number in the gazette list, and it is possible to comprehend the manufacturing amount, etc. in units of CAS numbers, please categorize substances according to each CAS number as much as possible, and submit a notification for each substance.

In principle, although cases where 1 or more tons is manufactured/imported per company based on

Class Reference Numbers in the gazette list are applicable to notifications of the manufacturing amount, etc. in the Chemical Substance Control Law, if making notifications for each CAS number, notifications are not necessary unless the amount of substance based on CAS numbers exceeds 1 ton.

2. Notifications in cases where there are multiple Class Reference Numbers in the gazette list that correspond to a chemical substance being manufactured/imported

Please submit notifications by making deductions for each Class Reference Number in the gazette list, in accordance with appropriate reasoning such as the percentage of components, etc., and submitting a notification for each. If the reasoning for deduction is unclear, it is acceptable to submit notifications by assuming that the total amount for each Class Reference Number in the gazette list was manufactured/imported.

Handling of Individual Chemical Substances in Mixtures

- General chemical substances

: For general chemical substances that are included in mixtures or that are included in other chemical substances as impurities, notifications are not necessary if the content ratio is less than 10% by weight. (Operation Notification 3-1)

- Priority assessment chemical substances

: For priority assessment chemical substances that are contained in other chemical substances as impurities, it is not necessary to submit notifications when their content ratio is less than 1% by weight. (Operation Notification 3-4)

*Judgment for when dilution and inspissation of a mixture is carried out

- When dilution of a mixture is carried out, please submit notifications based on the state before carrying out dilution. (For example, in cases where dye is diluted using water and India ink or pigment is obtained, please make judgments based on the state of the dye before it is diluted.)
- When separating a mixture based on distillation and shipping each component, submit notifications by making judgments based on the state after separation. (For example, in cases where a mixture of Compound A and Compound B is obtained, and B is disposed of after eliminating B until the point where it is less than 1% by weight, please submit a notification upon deeming that A was manufactured.)

Substances that Are Completely Consumed within One's Own Company

- Manufacture

: Regardless of whether within the same establishment, chemical substances of which the entire weight is consumed as an intermediate of other chemical substances within one's own company do not correspond to manufacturing as in the Chemical Substance Control Law and thus, they are not

applicable to notifications of the manufacturing amount.

- Import

: Even in cases where the entire weight is consumed within one's own company, importing of chemical substances is subject to notifications.

Cases Where There Is a Gap Between the Fiscal Year of Manufacture/Import and the Fiscal Year of Shipment

In cases where, after manufacturing/importing, shipment is carried out the following fiscal year, there is no statutory obligation to submit a notification, etc. for fiscal years where the manufacturing/import amount does not exceed 1 ton. However, in order to further accurately comprehend the emissions amount, your cooperation in submitting notifications based on "Form 11" or "Form 12" as mentioned previously regarding the shipping amount and intended use is requested. In such a case, as with other notification forms, the notification form is handled as an administrative document of the METI, and notification information is used for assessment of exposures in risk assessment and screening assessment of chemical substances.

Approaches When the Shipping Designation and Intended Use of Chemical Substances Are Unknown (Could Not Be Known)

For shipping destination and intended use, fill out the shipping destination and intended use that are normally anticipated (if there is information regarding the shipping destination, etc., fill in the shipping destination, etc. that reflects such information).

When a party other than parties subject to notification possesses information relating to the shipment destination and intended use of a particular chemical substance, although it is preferable for the party subject to notification to obtain this information if possible, when it is difficult to obtain information, it is acceptable, for example, to list the address of the sale destination as the shipping destination, and to fill out "Other" as intended use.

When "98-z Other" is selected as the use category and the sub use category, risk assessment of the applicable chemical substance is carried out based on the assumption that its entire weight was emitted in the environment through its overall life stage. (In a notification for a priority assessment chemical substance, when the 2-digit number for the use category is known but further details are unknown and the sub use category is "z Other," the highest emission coefficient is applied in the applicable 2-digit category in risk assessment.)

Approaches When Information on the Component Structure of a Mixture Cannot Be Learned Due to It Being a Corporate Secret

Firstly, taking into consideration the rule that notifications on the manufacturing weight, etc. are not necessary when the content ratio of a general chemical substance contained in a mixture is less than 10%

by weight (in other words, notifications are requested only for main components of mixtures), conduct a detailed check as to whether conveying the component structure of the mixture to other companies is a problem with respect to corporate secrets. If there is a problem in doing so, please consult individually.

Addition of Substances That Do Not Require Notifications

As hazard assessment of polymers of existing chemical substances and new chemical substances (limited to only those that were determined to be non-hazardous between FY1974 and FY1986), in cases where test results equivalent to non-hazardous based on the Polymer Flow Scheme or test results that fulfill confirmation standards for polymers of low concern are obtained, notifications that are provided to the METI will be used as basic data when selecting general chemical substances for which it is acknowledged that there is no necessity in conducting risk assessment (substances that do not require notifications). Substances that do not require notifications are planned on being added every fiscal year.

Inquiries

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

TEL: 03-3501-0605 FAX: 03-3501-2084

- National Institute of Technology and Evaluation (NITE)

(Chemical Management Center, **Chemical Substance Control Law Risk Assessment Preparation Office**)

TEL: 03-3468-4256 FAX: 03-3481-2900

- For information on the law and to download, etc. notification forms, visit the URL below.

http://www.meti.go.jp/policy/chemical_management/kasinhou/index.html

* English versions of various pamphlets, etc. are also available.

- To check the regulatory classifications in the Chemical Substance Control Law, Class Reference Numbers in the gazette list, etc. and to refer to the chemical substances database ↓

CHRIP: <http://www.safe.nite.go.jp/japan/db.html>

J-CHECK: <http://www.safe.nite.go.jp/jcheck/Top.do>