

(Attachment)

Implementation guidelines of the fact-finding survey on the sale, etc. of
existing food additives

Food Safety Standards and Evaluation Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

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This document is the English translation of “*既存添加物の販売等の実態調査実施要領*.” The Ministry of Health, Labour and Welfare offers this translation as a service to a broad international audience and readers. While the ministry has attempted to obtain translation that is as faithful as possible to the Japanese version, we recognize that the translated version may not be as precise, clear, or complete as the original version. The official version of this document is the Japanese version.

Implementation guidelines of the fact-finding survey on sale, etc. of existing food additives

1. Subjects for the survey

68 out of 365 existing food additives listed on the List of Existing Food Additives, whose documents enough to show distribution or use on the sale, etc. as additives were not submitted (see Appendix 1)

The substances used only for foods, utensils, or containers and packaging are excluded from this survey.

2. Procedure of notification

(1) It is not required to report that the existing food additives targeted for this survey are not sold, manufactured, imported, processed, used, stored or displayed.

(2) If a substance listed in Appendix 1 has actual conditions of the sale, etc. as food additive, a notification is need to be submitted by e-mail to the following address by 26 September, 2018. To make a notification, download Appendix 2-1 and 2-2 from the following URL, enter required information, and e-mail to the following address attaching the forms with other required documents.

URL for downloading Appendixes:

<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000188409.html>

Contact address: Person in charge of food additives, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

E-mail address: kizonshoujo@mhlw.go.jp

- i) For Appendix 2-1, enter required information and attach in Microsoft Excel file format. Description columns must not be added or deleted.
- ii) For Appendix 2-2, enter required information and attach in Microsoft Word file format with Appendix 2-1.
- iii) For attaching documents concerning Appendix 2-1 and 2-2, scan or take pictures of the documents, and attach in PDF or image file format (JPEG, PNG etc.) with Appendix 2-1 and 2-2.

3. Notes for description in Appendixes

(1) In 1 of Appendix 2-1, enter the following information.

i) Number and the name of the substance in the List of the Existing Food Additives

Choose from the drop-down list.

ii) Date of notification

iii) Company's address

iv) Company's name

v) Information about the contact person

Enter affiliation, name, telephone and fax number, and e-mail address in the corresponding column.

vi) Whether sample of the technical product of the food additive is able to be submitted.

Choose the relevant item from the drop-down list. If choose (2), describe when the sample is able to be submitted. If choose (3), describe the reason why the sample is not able to be submitted.

The sample of technical product means sample of the food additive itself; therefore, foods and preparations containing the food additive are not suitable for the sample.

(2) In 2 of Appendix 2-1, enter the following information.

In addition to the information, prepare the following documents etc. as proof of sale, etc. of the food additive and attach the copies to the e-mail:

-documents concerning the sales results and the distribution corresponding to the period from the start of the selling to the present

-delivery slips that show the sales quantity

-packaging that shows ingredients of the food including the food additive

For cases such as the food additive is sold to multiple companies, select main dealings and enter information about the dealings.

i) Product name of the food additive

Enter product name of the food additive.

ii) Period of sales etc. of the food additive

Enter the period of sales etc. of the food additive using month and year.

iii) Sales quantity of the food additive

Enter the average of annual sales quantity of the food additive during the period entered in above ii).

iv) Name of a food

Enter the name of a principal food in which uses the food additive is used, using the name of the food in the Standard Tables of Food Composition in Japan.

v) Purpose of use for food

Describe the purpose of use of the food additive for food, using the Attached Table 6 and 7 of the Food Labeling Standards (Cabinet Office Ordinance No. 10 of March 10, 2015) (e.g., preservative).

vi) Name of a food product

Enter the name of a principal food product that uses the food additive

vii) Name of the business person and others handling the foods

Enter the name of the business person and others who manufacture or import the food entered in above vi.)

(3) In 3 of Appendix 2-1, choose "Yes" or "No" from the drop-down list for the following information.

i) Whether specifications of the food additive are stipulated in the Standards and Regulations of Foods, Food Additives, etc. (Ministry of Health and Welfare Notification No. 370 of December 1959).

ii) Whether the food additive has specifications established voluntarily by manufacturers, distributors and others.

iii) Whether test reports of the food additive are attached to the notification.

(4) In I of Appendix 2-2, enter the following information concerning the specifications of the food additive.

i) 1 “Number and the name of the substance in the List of the Existing Food Additives”

Enter same content as 1 of Appendix 2-1.

ii) From 2 “English name” to 20 “Storage standards”

For the existing food additives that are not stipulated in the Standards and Regulations of Foods, Food Additives, etc. (Ministry of Health and Welfare Notification No. 370 of December 1959), enter information about specifications that are established voluntarily by manufacturers, distributors and others.

For reference, use 5.3.3. Examples of description, (1) Draft specifications of the Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives.

(<http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/dl/tenkabutu-hyouka-shishin-english.pdf>)

Besides above information, attach test reports etc. that includes the following items:

- measured values or the like that become base of the specifications
- measurement date
- measurer's name
- name of the existing food additive
- product name used for the test (including the product number and the lot number)
- assay (content)
- description
- identification tests
- values expressing substance's properties (e.g., boiling point and pH)
- purity tests
- loss on drying
- residue on ignition
- microbial limit tests

For the existing food additives stipulated in the Standards and Regulations of Foods, Food Additives, etc., entries from 2 "English name" to 20 "Storage standards" and the attachment of test reports are not required.

(5) In II of Appendix 2-2, describe overall manufacturing process of the product including the following information as the one concerning manufacturing methods of the existing food additive:

- ingredients (place of the origin and information of the portion)
- solvent to use
- the refining method
- the extraction method
- the synthetic method
- the cultivation method
- sterilization treatment

Attach documents such as chart and flowchart of the manufacturing process as necessary.

(6) In III of Appendix 2-2, describe information that should be mentioned specially for the notification as necessary.

4. Others

For existing food additives, confirmation of the safety and establishment of the specifications are sequentially in progress. Component analysis or the like of the existing food additives are also conducted one by one. From this background, for the existing food additives confirmed their actual conditions of the sale, etc.,

submission of the specimen (an additive in markets itself) for the component analysis may be requested.