

Implementation guidelines

Implementation guidelines for the survey of distribution status of existing food additives to prepare the List of Food Additives to Be Eliminated

1. Target substances

- (1) Out of 357 existing food additives listed in the List of Existing Food Additives (“the List”), 78 substances that are unlikely to be served for sale, manufacturing, import, processing, use, storage, and display (“sale, etc.”) as food additives (see Appendix 1)

The substances used as ingredients for apparatus, containers, and packaging are not targeted for this survey.

- (2) Substance that may be considered as the additive to be eliminated from the List, judging from the results of this survey

Please note that substances for which quality as existing food additives is not assured and that are not considered to be being sold will be considered as the additive to be eliminated from the List. Specifically, it means that these substances fall under any of the substances given from (i) to (iv).

- (i) The substance for which no voluntary specifications to ensure its quality are established by its business person
- (ii) The substance for which the business person is unable to provide a certificate to certify that the substance meets the voluntary specifications
- (iii) The substance for which the business person is unable to prove that the substance, as an additive whose quality is assured with the certificate above (ii), has sales records or is distributed
- (iv) The substance for which samples of its commercial products cannot be submitted for testing

2. Notifier

In principle, notifiers should be companies who manufacture target food additives. However, if a company who does not manufacture target additives* collects

information on the corresponding additive voluntarily and submits the necessary documents, the notification will be accepted. Please note that if the information of the substance is insufficient, the substance will be considered as the one falls under items in above 1.(2) and as a result, considered as the additive to be eliminated from the List.

* Companies who do not manufacture target food additives, for example, include one who manufactures foods with target food additives or one who sells such foods.

3. How to notify

If a substance listed in Appendix 1 has records of the sale, etc. as food additive, notify the MHLW of the fact by e-mail by September 19, 2023. Specifically, download Appendixes 2-1 and 2-2 from the following website, enter the required information, and e-mail to the following address, attaching other required documents to Appendixes.

Note: Business persons are not required to notify the MHLW that they do not distribute the substances targeted for the survey.

Website for downloading

Appendixes: <https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000188410.html>

Contact address: Food additives section, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

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

- (1) For Appendix 2-1, enter required information and attach as Excel file.
Description columns must not be added or deleted.
- (2) For Appendix 2-2, enter required information and attach as Word file with Appendix 2-1.
- (3) For documents relating to Appendixes 2-1 and 2-2, attach as PDF file with them.

4. Notes to fill out Appendixes

- (1) Appendix 2-1: 1. Information about the existing food additive

Number and the name of the substance on the List

Choose from the drop-down list.

(2) Appendix 2-1: 2. Information about the notifier

- (i) Date of notification
- (ii) Company's name
- (iii) Company's address
- (iv) Information about the person in charge

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

(3) Appendix 2-1: 3. Information about specifications and sample submission

- (i) Presence of voluntary specifications of the food additive

Choose "Yes" or "No" from the drop-down list. When you choose "yes," please fill out the specifications and other matters in Appendix 2-2 with reference to from (5) to (7) below.

- (ii) Presence of a certificate of the food additive

Choose "Yes" or "No" from the drop-down list. When you choose "yes," please attach the certificate.

- (iii) Presence of documents proving that the food additive is being sold or distributed

Choose "Yes" or "No" from the drop-down list. When you choose "yes," please enter the information in "4. Information about sales records and distribution status of the food additive" in Appendix 2-1 with reference (4) below, and attach the relevant documents.

- (iv) Sample submission of a commercial product of the food additive

Choose the relevant item from the drop-down list. When you choose (2), describe the timing of sample submission. When you choose (3), describe the reason.

The sample means a sample of the food additive itself; therefore, foods and preparations in which the food additive is used are not considered as the sample to be submitted.

(4) Appendix 2-1: 4. Information about sales records and distribution status of the food additive

Enter the following information from (i) to (vi).

In addition to the information, as proof of sales or distribution of the food additive, attach documents, such as the following items, to the e-mail:

- copies of documents concerning the sales results and the distribution status corresponding to the period from the start of the selling to the present
- copies of delivery slips that show the sales quantity
- picture of packaging label that shows ingredients of the commercial products in which the substance is used

If the food additive is sold to multiple companies, enter information on dealings with a major client.

(i) Commercial name

The commercial name of the substance

(ii) Period of sales etc.

The period of sales etc. of the substance with month and year. (e.g., April 1995–June 2023)

(iii) Sales quantity

The annual average sales quantity of the food additive during the period above (ii)

(iv) Purpose of use in food

The purpose of use of the food additive for foods, referring to the Attached Tables 6 and 7 of the Food Labeling Standards (Cabinet Office Ordinance No. 10 of 2015; Japanese text only) (e.g., preservative)

(v) Commercial name of the food

The commercial name of a main food in which the food additive is used

(vi) Name of the business person handling the food

The name of the business person who manufacture or import the food above (v)

(5) Appendix 2-2: I. Specifications

Enter the following information about the specifications for the existing food additive.

(i) 1. “Number and the name of the substance on the List”

Enter the same information as ones in Appendix 2-1, 1. “Information about the existing food additive.”

(ii) Information from 2. “English name” to 20. “Storage standards”

Enter information of the specifications that are voluntarily established by manufacturers, distributors, or others.

As a reference, besides the Public Notice No. 370, see (1) Draft specifications of 5.3.3. Examples of description 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 (voluntarily set specifications), attach (A) documents showing measured values that served as the basis of the specifications and (B) a certificate to certify that the substance meets the voluntary specification.

The certificate is required to contain the following information including measurement results on test items of the voluntary specifications.

- Measurement date
- Measurer’s name
- Name of the substance
- Commercial name of the substance used for the testing (including the product number and the lot number)
- Measurement results such as:
 - 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

Please describe the justifiable reason if the certificate is not able to be submitted. A substance on which information is considered as insufficient may be treated as an additive to be eliminated.

(6) Appendix 2-2: II. Manufacturing methods (process)

Describe an overall manufacturing process of the substance including the following information:

- raw material (place of the origin and the portion to use)
- solvents to be used
- the purification method
- the extraction method
- the synthetic method
- the cultivation method
- sterilization treatment

As necessary, attach materials such as diagrams and a flowchart of the manufacturing process.

(7) Appendix 2-2: III. Other necessary matters

As necessary, describe information to be mentioned specially for the notification.

5. Others

- (1) After compiling the survey results, the MHLW is going to publish the “List of Food Additives to Be Eliminated” by the end of 2024 at the earliest. Through a 6-month period for correction request, the MHLW will amend the List of Existing Food Additives within one year from the publication of the “List of Food Additives to Be Eliminated.”
- (2) For existing food additives, the safety confirmation is carried out and specifications are established in a systematic manner. Component analyses of the substances are also conducted one by one. For the substances for which distribution status is confirmed, the MHLW may ask business persons for the provision of the specimen (the sample of the commercial products) necessary for the analyses. Your cooperation would be appreciated.