# Implementation Guidelines for the Survey on Distribution Status Necessary to Prepare the List of Food Additives to Be Eliminated and on Origin of 5'-Deaminase

### 1. Target food additives

Out of 357 substances listed in the List of Existing Food Additives ("the List"), 8 substances that are unlikely to be served for sale, manufacturing, import, processing, use, storage, and display ("sale, etc.") as food additives as well as 5' -deaminase (see Appendix 1).

The substances exclusively used as raw materials for apparatus, containers, or packaging are not targeted for this survey.

(2) Substances 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 may 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) may be considered as such additive.

(i) The substance for which the business person is unable to provide a certificate to certify that the substance meets the specifications in D. *Monographs* of Chapter II. *Food additives* of the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959).

(ii) 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 (i), has sales records or is distributed

(iii) The substance for which samples of its commercial products cannot be submitted for testing

#### 2. Notifier

In principle, notifiers should be business persons who manufacture and sale target food additives. However, if a business person who does not manufacture and sale target additives<sup>\*</sup> collects information on the corresponding additive voluntarily and submits the necessary documents, the notification will be accepted. <u>Please note that if</u> <u>the information of the substance is insufficient, the substance will be considered as</u> the one falls under items given in above 1.(2) and as a result, considered as the additive to be eliminated from the List.

\* A business person who does not manufacture and sale target food additives includes 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 Consumer Affairs Agency (CAA) of the fact by e-mail by March 31, 2025. Specifically, download Appendix 2, enter the required information, and e-mail to the following address, attaching other required documents to the appendix.

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

Contact address: Food Additives Section, Food Safety Standards and Evaluation Division, Consumer Affairs Agency

E-mail address: g.kijunfap@caa.go.jp

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

#### 4. Notes to fill out Appendix 2

#### 1. Information about the target food additive

Number and the name of the substance in the List Choose from the drop-down list.

#### 2. Information about the notifier

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

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

#### 3. Information about the specifications and sample submission

(i) 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.

(ii) 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 target food additive" in Appendix 2 referring to 4 below, and attach the relevant documents.

(iii) Sample submission of a commercial product of the food additiveChoose 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.

- (iv) When the additive on which information is submitted is 5'-deaminase
- a. Species and strains of the 5'-deaminase producing bacteria

Describe the names of bacterial species (genera and species) and strains.

Please note that in the future information on all enzymes may be disclosed on the name of the species and strains of the additive-producing bacteria after research and information collection is conducted.

b. Basis for the identification of the bacterial species

Attach documents showing the basis for identification of the bacterial species or describe the basis in Appendix 2.

The identification can be based on morphological observation, chemical properties, genome analysis, etc.

## 4. Information about sales records and distribution status of the target food additive Enter the following information from (i) to (vi).

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
- $\succ$  copies of delivery slips that show the sales quantity
- > picture of packaging label that shows ingredients of the commercial products in which the food additive 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 food additive

(ii) Period of sales etc.

The period of sales etc. of the food additive with month and year. (e.g., April 1995–June 2025)

(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 described in above (v)

### 5. Others

- (1) After compiling the survey results, the CAA is going to publish the "List of Food Additives to Be Eliminated" by the end of 2025 at the earliest. Through a 6-month period for correction request, the CAA 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 CAA 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.