

YakuShoku-Ki No. 0620-1 of June 20, 2023

To: Heads of bureaus and departments in charge of hygiene and sanitation of all prefectures, cities with health centers, and special wards

Director of Food Safety Standards and Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Seal omitted)

The survey of distribution status of existing food additives to prepare the “List of Food Additives to Be Eliminated”

Pursuant to the provision in Article 2-3 of the Supplementary Provisions of the Act to Partially Revise the Food Sanitation Act and the Nutrition Improvement Act (Act No.101 of 1995; “delisting provisions”), when the Minister of Health, Labour and Welfare (“the Minister”) judges that an additive listed in the List of Existing Food Additives (Public Notice of the Ministry of Health and Welfare No.120 of 1996, “the List”) is no longer served for the purpose of sale judging from the situation on sale, manufacturing, import, processing, use, storage, and display (“sale, etc.”), the Minister may eliminate the name of the additive from the List. The elimination is implemented through the preparation and public issuance of the “List of Food Additives to Be Eliminated,” and necessary procedures. To date, 132 substances have been eliminated from the List.

The Ministry of Health, Labour and Welfare (MHLW) had conducted a preliminary survey of 357 substances on the List to investigate actual conditions of sale, etc., as part of the Health and Labour Sciences Research, etc. The result found that the 78 substances, listed in the Appendix 1, are unlikely to be served for sale, etc. Therefore, the MHLW has decided to conduct a full-scale survey on the 78 substances.

From this background, the MHLW asks you to inform the business persons who sell existing food additives, or preparations or foods including them (“existing food additives etc.”) in your jurisdiction, by providing the implementation guidelines (Attachment) or by other means, that they should notify the MHLW of that fact using Appendixes 2-1 and 2-2 if they have records of sales, etc. for the substances listed in Appendix 1. Please note that if any notification of an existing food additive etc. is not made using the Appendixes, the

substance is not considered to be being distributed and will be listed in the “the List of Food Additives to Be Eliminated.”

The MHLW is informing relevant business persons of the survey mainly by posting specific information on the websites of the MHLW* and by putting it up on bulletin boards of quarantine stations. The MHLW has already requested the following associations to thoroughly disseminate this matter to their association members.

Japan Food Hygiene Association; Japan Food Industry Association; Association for the Safety of Imported Food, Japan; Japan Health and Nutrition Food Association; and Japan Food Additives Association

Furthermore, the MHLW asks you to take thorough measures to reach this information to non-association members because there are many cases that they handle the existing food additives etc.

The survey is aimed to obtain information on whether the substances listed in Appendix 1 are distributed as food additives. Please note that no notification is required, if these substances are exclusively used as ingredient for apparatus, containers, and packaging. Also, a notification to the effect that the substances listed in Appendix 1 are not being distributed is not necessary. Even the substances listed in Appendix 1 are not targeted for notification, if they are not used as food additives. However, for substances listed in Appendix 1 that fall under vitamins and minerals used for food fortification, in cases where they are used not as additives but as foods, they are targeted for notification.

Please also note that if the name of a substance is once eliminated from the List pursuant to the delisting provisions, the substance will be prohibited from domestic distribution as a food additive unless the substance is designated again as a food additive pursuant to the provision in Article 12 of the Food Sanitation Act (Act No. 233 of 1947).

* The page of food additives under Pharmaceutical Safety and Environmental Health Bureau, MHLW

<http://www.mhlw.go.jp/topics/bukyoku/iyaku/syokuten/index.html>