Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology

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Decision by the Councillor for Environmental Health and Food Safety,
Minister's Secretariat

I. Definition

1. Genome editing technology

Genome editing technology is defined as a technology to modify a specific site of a specific base sequence on a chromosome using an enzyme recognizing the base sequence in order to provide specific functions. The technology that brings the final product that results in including foreign genes and their parts falls under recombinant DNA technology (the technology stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959; "Public Notice on the Specifications and Standards")).

2. Foods derived from genome editing technology

Foods derived from genome editing technology are foods that fall under any of the following items:

(1) An entire organism or its parts obtained by genome editing technology.

(2) A food including the entire organism or its parts obtained by genome editing technology.

(3) A food manufactured using microorganisms obtained by genome editing technology or a food containing such food.

3. Additives derived from genome editing technology

Additives derived from genome editing technology are defined as additives manufactured using organisms obtained by genome editing technology.

Moreover, additives derived from genome editing technology, when their final products are highly purified to be non-proteinous (such as amino acids) and meet both the following conditions (1) and (2), are handled as highly purified nonprotein additives (the additives decided by the Food Safety Commission of Japan (FSCJ) on April 28, 2005 as the additives stipulated in the standards for assessment*).

* Stance on Safety Assessments of Additives Produced Using Genetically Modified Microorganisms, Whose End Product Is Regarded as a Highly Purified Nonprotein Additive, Such as Amino Acids (supplementary provisions of Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms decided by the FSCJ on March 25, 2004)

(1) Purity of the product is high. For example, more than or equal to that of amino acids, nucleotides, vitamins, and monosaccharides, which are notified as designated additives.

(2) As compared with conventional additives, the contents of existing inactive ingredients in such additive do not significantly increase up to around the levels with safety concerns and such additive does not contain new inactive ingredients suggesting adverse effects.

II. Foods derived from genome editing technology for which notification is required

Notification described in section IV is required for any food derived from genome editing technology when the food satisfies either a or b, and also satisfies c below.

a. the food is an entire organism or its parts obtained by genome editing technology.

b. the food is an item manufactured using a microorganism obtained by genome editing technology.

c. the results brought from the technology show that the gene status of the organism or microorganism indicates no remaining foreign gene or its parts, and that deletion of bases, substitution and insertion of several bases, resulting insertion of one to several

mutations by cleavage etc. with an enzyme recognizing the specific base sequence occur.

When the gene status finally shows that foreign gene and its parts remain, the technology used for the item falls under recombinant DNA technology and such item is subject to safety assessment according to the Procedures for safety assessment of foods and additives derived from recombinant DNA technology (Public Notice of the Ministry of Health and Welfare No. 233 of 2000, "Public Notice on Procedures for Safety Assessment").

When the gene status of foods does not fall under the above conditions in section II, the necessity of notification or safety assessment is determined on a specific case-by-case basis by the Ministry of Health, Labour and Welfare (MHLW).

Foods manufactured and processed using notified foods derived from genome editing technology do not require notification.

III. Additives derived from genome editing technology for which notification is required

1. Additives derived from genome editing technology using microorganisms

Basically, it is assumed that additives comply with the compositional standards specified in the Public Notice on the Specifications and Standards.

Notification described in section IV is required for additives derived from genome editing technology when microorganisms used in manufacturing of such additives meet the following conditions:

- the gene status indicates no remaining foreign gene or its parts; and
- deletion of bases, substitution and insertion of several bases, resulting insertion of one to several mutations by cleavage etc. with an enzyme recognizing the specific base sequence occur.

However, notification is not required for items that fall under the following (1) or (2).

(1) Such additive is manufactured using a microorganism obtained by genome editing technology and it is clear that the gene constitution of the microorganism is equal to that of microorganisms belonging to the taxonomically identical species or naturally occurring microorganisms.

(2) Such additive is manufactured using a microorganism obtained by genome editing technology and is a highly purified nonprotein additive.

When the gene status finally shows that foreign gene and its parts remain, the technology used for the item falls under recombinant DNA technology and such item is subject to safety assessment according to the Public Notice on Procedures for Safety Assessment.

When the gene status of foods does not fall under the above conditions in section III, the necessity of notification or safety assessment is determined on a specific case-by-case basis by the MHLW.

2. Additives derived from genome editing technology using materials other than microorganisms

Follow the handling in section II.

IV. Procedure for notification, etc. (see Appendix)

1. As for foods derived from genome editing technology and additives derived from genome editing technology for which notification is required mentioned in the above sections II and III (hereinafter referred to as “foods etc. derived from genome editing technology”), the developer of such items, its representative, or a person/institute that can submit appropriate information (hereinafter referred to as “developer, etc.”) in order to confirm whether such foods, etc. fall under a target of notification or safety assessment, the developer, etc. request a prior consultation with the Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, the MHLW using Attachments 1-1 and 1-2 for foods and additives, respectively.

Foods, etc. derived from genome editing technology to be subject to a prior consultation are limited to those which have been developed for commercialization. For consultation, the information mentioned in section V, 1 or 2 is provided as much as possible.

2. The MHLW gives the developer, etc. the results about whether foods, etc. that have undergone a prior consultation fall under a target of notification or safety assessment using Attachment 2, as appropriate, confirming with Subcommittee on Genetically Modified Foods, Newly Developed Food Committee of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as "the Subcommittee").

   During the confirmation, when the Subcommittee determines to request for advice from the Food Safety Commission, Cabinet Office (hereinafter referred to as "the Food Safety Commission"), the Minister of Health, Labour and Welfare consults with the Food Safety Commission, and then based on the advice, determines how to proceed, and gives the results to the developer, etc.

3. For foods, etc. derived from genome editing technology, which have been confirmed to be subject to notification in a prior consultation, the developer, etc. notify the MHLW of the information mentioned in section V, 1 or 2 about the foods, etc. using Attachment 3 with necessary supporting data prior to marketing. The year and month of marketing are reported using Attachment 4 at a future date when such foods, etc. are marketed.

4. After receiving the notification of above 3, the MHLW posts and publishes the information mentioned in section V, 3 or 4 on the MHLW website promptly. The year and month of marketing are published after receiving a report of Attachment 4 by the developer, etc.

5. The same procedures are followed for imported products. Importers, etc. may perform the procedures instead of the developer, etc. when feasible.

6. Out of additives derived from genome editing technology subject to notification, those which are determined to fall under section III, 1, (1) or (2) by the developer, etc. are subject to a prior consultation with the reasons of determination and the materials as necessary. Items that fall under section III, 1, (1) or (2) based on the results of prior consultation are considered to have been notified by such prior consultation and do not require the procedures in the above sections 3 and 4.

V. Information to be notified and published

1. For foods derived from genome editing technology subject to notification, developer, etc. notify the MHLW of the following information.
   (1) Names of item and breed and summary (usage and intended use) of the developed food
   (2) Method of genome editing technology used and details of modification
   (3) Information on confirmation that there are no remaining foreign genes or their parts
   (4) Information on confirmation that confirmed changes in DNA do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained
   (5) For items in which modification affecting the metabolic system was performed in order to increase or decrease specific components, information on changes in major components (nutrient components only) related to the target metabolic system
   (6) Year and month of marketing (*Notify the MHLW of it after marketing)

2. For additives derived from genome editing technology, developer, etc. notify the MHLW of the following information.
   (1) Name of item and summary (usage and intended use) of the developed additive
   (2) Method of genome editing technology used and details of modification
   (3) Information on confirmation that there are no remaining foreign genes or their parts

(4) The fact that the additive complies with the compositional standards specified in the Public Notice on the Specifications and Standards
(5) Year and month of marketing (*Notify the MHLW of it after marketing)

3. For foods derived from genome editing technology, the MHLW publishes the following information.
(1) Names of notifier and developer, and date (year/month/day) of notification
(2) Names of item and breed and summary (usage and intended use)
(3) Summary of genome editing technology and gene modification used
(4) The fact that it is conformed that confirmed changes in DNA do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained
(5) Summary of changes in major components (nutrient components only) related to the target metabolic system
(6) Year and month of marketing (*Publish it after receipt of notification mentioned in 1, (6))

4. For additives derived from genome editing technology, the MHLW publishes the following information.
(1) Names of notifier and developer, and date (year/month/day) of notification
(2) Names of item
(3) Summary of genome editing technology and gene modification used
(4) The fact that the additive complies with the compositional standards specified in the Public Notice on the specifications and standards
(5) Year and month of marketing (*Publish it after receipt of notification mentioned in 2, (5))

VI. Handling of crossbred progeny

For crossbred progeny obtained through a traditional breeding technique between a conventional breed etc.* and a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, the developer etc. concerned is not required to consult with the MHLW in advance and to notify the MHLW of the obtained product.

* A conventional breed etc. means: (i) a conventional breed, (ii) a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, or (iii) a breed made known to the public as a product evaluated to be safe as a food derived from recombinant DNA technology.

VII. Others

The items specified in this procedures are reviewed, when necessary, based on usage record, future substantial scientific knowledge, or global trends, etc. for foods, etc. derived from genome editing technology.

It should be noted that when any fact not complying with this notice is found, the background, etc. are confirmed, conformity to the Food Sanitation Act and other acts are checked, and these results may be published with the information about such developer, etc.

This procedure comes into force on October 1, 2019.

Attachment 1-1: Prior Consultation Form: Food

Attachment 1-2: Prior Consultation Form: Additive

Attachment 2: Response Form

Attachment 3-1: Notification and Publication Form: Food

Attachment 3-2: Notification and Publication Form: Additive

Attachment 4: Notification Form for Marketing

Appendix: Flow diagram on the handling of foods derived from genome editing technology