

Attachment 1-1: Prior Consultation Form: Food

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and
Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)

Name (For a corporation, its name and the representative's)

I/We hereby apply for prior consultation on the following food derived from
genome editing technology according to the Food Hygiene Handling Procedures
for Food and Additives Derived from Genome Editing Technology (Decision by
the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the food)

Attachment 1-1: Prior Consultation Form: Food

(1) Names of item and breed, and the summary (usage and intended use) of the food

(2) Method of genome editing technology used and details of the modification

(3) Information on confirmation that there are no remaining foreign genes or their parts

(4) 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

Confirmed Unconfirmed

(5) Whether modification performed in order to increase or decrease specific components affects the metabolic system.

The modification affects the metabolic system.
 The modification does not affect the metabolic system.

(6) Year and month of marketing (If decided)

Notes:

- ✓ Information on above items (1) to (3) are mandatory.
- ✓ For above items (3) to (5), provide documents used for the confirmation.

Attachment 1-2: Prior Consultation Form: Additive

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)

Name (For a corporation, its name and the representative's)

I/We hereby apply for prior consultation on the following additive derived from genome editing technology according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the additive)

Attachment 1-2: Prior Consultation Form: Additive

- (1) Name of item and summary (usage and intended use) of the 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) Confirmation that the additive complies with the compositional standards specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959)
 - Confirmed Unconfirmed
- (5) Year and month of marketing (If decided)
- (6) Notification is not required for items that fall under either of the following conditions. Developer, etc. should provide information that explains the reason in prior consultation.
 - The 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.
 - The additive is manufactured using a microorganism obtained by genome editing technology and is a highly purified nonprotein additive.

Notes:

- ✓ Information on above items (1) to (4) are mandatory.
- ✓ For above item (3), provide documents used for the confirmation.

Attachment 2: Response Form

Date/Year/Month

To:

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

The MHLW responds as below on AA consulted by BB.

The food or additive derived from genome editing technology is subject to:

(1) the notification.

Please notify the food or additive according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

(2) the safety assessment.

The food or additive is categorized as a food or an additive derived from recombinant DNA technology, which requires safety assessment. Please consult with the MHLW about procedures to be carried out.

Attachment 3-1: Notification Form: Food

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)

Name (For a corporation, its name and the representative's)

I/We hereby notify the following food derived from genome editing technology before marketing according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the food)

Name of developer etc. (For a corporation, its name and the representative's)

Remarks

Attachment 3-1: Notification Form: Food

(1) Names of item and breed, and the summary (usage and intended use) of the food

(2) Method of genome editing technology used and details of the modification

(3) Confirmation that there are no remaining foreign genes or their parts

Confirmed Unconfirmed

(4) Confirmation that changes in DNA by genome editing technology do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained

Confirmed Unconfirmed

(5) Whether modification performed in order to increase or decrease specific components affects the metabolic system.

The modification affects the metabolic system.
 The modification does not affect the metabolic system.

* If modification affecting the metabolic system was performed, information on changes in major components (nutrient components only) related to the target metabolic system

Attachment 3-1: Publication Form: Food

(1) Names of item and breed, and the summary (usage and intended use) of the food

(2) Method of genome editing technology used and summary of the modification

(3) Confirmation that changes in DNA by genome editing technology do not cause production of new allergens having adverse effects on human health or increase of known toxic substances contained

- Confirmed Unconfirmed

(4) Whether modification performed in order to increase or decrease specific components affects the metabolic system.

- The modification affects the metabolic system.
 The modification does not affect the metabolic system.

* If modification affecting the metabolic system was performed, a summary on changes in major components (nutrient components only) related to the target metabolic system

Please note that this information will be published by the MHLW.

Attachment 3-2: Notification Form: Additive

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)

Name (For a corporation, its name and the representative's)

I/We hereby notify the following additive derived from genome editing technology before marketing according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the additive)

Name of developer etc. (For a corporation, its name and the representative's)

Remarks

Attachment 3-2: Notification Form: Additive

(1) Names of item and breed, and the summary (usage and intended use) of the additive

(2) Method of genome editing technology used and details of the modification

(3) Confirmation that there are no remaining foreign genes or their parts

Confirmed Unconfirmed

(4) The fact that the additive complies with the compositional standards specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959)

Confirmed Unconfirmed

Attachment 3-2: Publication Form: Additive

(1) Name of item (the additive)

(2) Method of genome editing technology used and summary of the modification

(3) The fact that the additive complies with the compositional standards specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959)

Confirmed Unconfirmed

Please note that this information will be published by the MHLW.

Attachment 4: Notification Form for Marketing

Date/Year/Month

Office of Health Policy on Newly Developed Food, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)

Name (For a corporation, its name and the representative's)

I/We hereby notify the start of selling of the following food or additive derived from genome editing technology according to the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (Decision by the Councillor for Environmental Health and Food Safety, September 19, 2019).

Name of item (the food or the additive)

Name of developer etc. (For a corporation, its name and the representative's)

Year and month of marketing