

Voluntary Report – Voluntary - Public Distribution

Date: July 09, 2021

Report Number: JA2021-0106

Report Name: MHLW and MAFF Update Policies and Procedures for
Genome Edited Food and Agricultural Products

Country: Japan

Post: Tokyo

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Suguru Sato

Approved By: Zeke Spears

Report Highlights:

This report reflects updates made by the Government of Japan to its guidelines for handling food and agricultural products derived from genome editing technology. The Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) revised their handling procedures for products derived from the crossbreeding of genome edited varieties which have already been notified to the two ministries. Developers of these products are no longer expected to undergo the MHLW and MAFF consultation processes. This report is an update to GAIN JA2020-0184.

Disclaimer

This report provides a summary of the guidelines for handling genome edited food and agricultural products in Japan. Please consult the formal guidance issued by the relevant authorities before commercializing genome edited products in Japan.

Background

In February 2018, after Japan's Ministry of Environment (MOE) finalized policies for regulating genome editing technologies based on Japan's Cartagena Act ([JA9024](#)), the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labour and Welfare (MHLW) developed the regulatory policy and handling procedures for food and agricultural products derived from genome editing technology, providing developers of these products a pathway to commercial distribution in Japan ([JA2020-0184](#)). MAFF oversees two distinct sets of handling procedures for genome edited products, one for feed and feed additives and the other for biological diversity of products under its jurisdiction. MHLW oversees one set of handling procedures, for food and food additives.

When MAFF and MHLW first published the handling procedures for food and feed products, both required developers of products derived from the crossbreeding of genome edited varieties which have already been notified to the two ministries to undergo each ministry's respective preliminary consultation processes. Since then, both ministries have made updates to the requirements for food and feed products derived from crossbred progeny.

In December 2020, MHLW amended the handling procedures for products derived from the crossbreeding of genome edited varieties which have already been notified to MHLW. MHLW no longer requests developers of these products to undergo MHLW's consultation process for genome edited products ([JA2020-0214](#)).

In April 2021, MAFF amended the handling procedures for feed and feed additive products derived from the crossbreeding of genome edited varieties which have already been notified to MAFF. MAFF no longer requests developers of these products to undergo MAFF's consultation process for genome edited products ([JA2021-0073](#)).

Consultation and Notification Process for Genome Edited Products

The three handling producers outline similar processes for developers to notify their intent to commercialize a new genome edited food or agricultural product in Japan. Both MHLW and MAFF request that a product developer consult with them first so that the regulators can determine if they require the product in question to undergo the appropriate safety review as a genetically engineered (GE) product. While similar, there are differences in the methodologies and definitions used to determine which products MHLW and MAFF require to undergo the appropriate GE safety reviews.

If through this consultation, MHLW or MAFF determine the product does not need to undergo the GE safety review, then MHLW and MAFF expect the developer to complete a notification process defined within each of the guidelines. When the notification process is complete, MHLW and MAFF will publish a portion of the information, non-business sensitive, provided by the developer.

| Summary of Guidelines for Genome Edited Food and Food Additives | |
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| Competent Authority | Ministry of Health, Labour and Welfare |
| Legal Basis | Food Sanitation Act (English and Japanese) |
| Official Guidelines | Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology (English and Japanese) |
| Non-GE Product Definition (Section 3 of the Guidelines) | No foreign genes or fragments of such genes remain, and the genome editing results in deletion of base(s) or the substitution and/or insertion of a limited number of bases by cleavage with an enzyme recognizing specific base sequences. |
| If Determined by MHLW to be GE | Product must undergo MHLW safety review for food products (JA2020-0219). |
| If Determined by MHLW to not be GE | Developer requested to complete MHLW notification process. |
| Notification Requirements (Section 5 of Guidelines) | <p><u>Food</u>: 1) Name, Breed, Summary of Use; 2) Technology Used, Details of Modification; 3) No Remaining Foreign Genes or Parts Confirmation; 4) Allergens and Toxic Substances Information; 5) Metabolic Systems Information; 6) Month/Year of Marketing</p> <p><u>Food Additives</u>: 1) Name, Summary of Use; 2) Technology Used, Details of Modification; 3) No Remaining Foreign Genes or Parts Confirmation; 4) Complies with Compositional Standards; 5) Month/Year of Marketing</p> |
| Information Made Public by MHLW (Section 5 of Guidelines) | <p><u>Food</u>: 1) Name of Developer; Date of Notification; 2) Name, Breed, Summary of Use; 3) Technology Used, Modification; 4) Allergen and Toxic Substances Confirmation; 5) Summary of Metabolic System Changes; 6) Month/Year of Marketing</p> <p><u>Food Additives</u>: 1) Name of Developer; Date of Notification; 2) Name; 3) Technology Used, Modification; 4) Complies with Compositional Standards; 5) Month/Year of Marketing</p> |
| Crossbred Progeny (Section 6 of Guidelines, revised in December 2020) | Not expected to undergo MHLW's consultation process. |
| Official Contact Point | 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 1-2-2, Kasumigaseki, Chiyoda-ku Tokyo 100-8916, Japan Tel: 03-5253-2341 (+81-3-5253-2341) Fax: 03-3501-4868 (+81-3-3501-4868) Email: ISESHINKAI@mhlw.go.jp |

| Summary of Guidelines for Genome Edited Feed and Feed Additives | |
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| Competent Authority | Ministry of Agriculture, Forestry and Fisheries |
| Legal Basis | Act on Safety Assurance and Quality Improvement of Feeds (English and Japanese) |
| Official Guidelines | Feed Safety Guidelines on the Handling of Genome Edited Feed and Feed Additives (Japanese and English) |
| Non-GE Product Definition (Sections 2 and 3 of the Guidelines) | Does not contain foreign genes and/or a part of foreign genes. |
| If Determined by MAFF to be GE | Product must undergo MAFF safety review for feed products (JA2020-0219). |
| If Determined by MAFF to not be GE | Developer requested to complete MAFF notification process. |
| Notification Requirements (Section 5 of Guidelines) | <p><u>Feed</u>: 1) name, variety, and summary of product; 2) Technology Used, Details of Modification; 3) No Remaining Foreign Genes or Parts Confirmation; 4) Toxic Substances Information; 5) Metabolic Systems Information; 6) Month/Year of Marketing.</p> <p><u>Feed Additives</u>: 1) name, variety, and summary of product; 2) Technology Used, Details of Modification; 3) No Remaining Foreign Genes or Parts Confirmation; 4) Conformance with Specifications and Standards; 5) Month/Year of Marketing.</p> |
| Information Made Public by MAFF (Section 5 of Guidelines) | <p><u>Food</u>: 1) Name of Developer; Date of Notification; 2) Name, Breed, Summary of Use; 3) Technology Used, Modification; 4) Allergen and Toxic Substances Confirmation; 5) Summary of Metabolic System Changes; 6) Month/Year of Marketing</p> <p><u>Food Additives</u>: 1) Name of Developer; Date of Notification; 2) Name; 3) Technology Used, Modification; 4) Complies with Compositional Standards; 5) Month/Year of Marketing</p> |
| Crossbred Progeny (Section 6 of Guidelines, revised in April 2021) | Not expected to undergo consultation process. |
| Official Contact Point | Animal Products Safety Division Food Safety and Consumer Affairs Bureau Ministry of Agriculture, Forestry and Fisheries 1-2-1, Kasumigaseki, Chiyoda-ku Tokyo 100-8950, Japan Phone: 03-6744-1708 (+81-3-6744-1708) Fax: 03-3502-8275 (+81-3-3502-8275) Email: feed@maff.go.jp |

| Summary of Guidelines for Impact to Biodiversity | |
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| Competent Authority | Ministry of Agriculture, Forestry, and Fisheries |
| Legal Basis | Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act) (English and Japanese) |
| Official Guidelines | Specific Procedures for Providing Information on the Adverse Effects on Biological Diversity of Organisms Obtained by Using Genome Editing Technology in the Field of Agriculture, Forestry, and Fisheries (Japanese) |
| Translation of Guidelines | JA2019-0196 |
| Non-GE Product Definition (Section 2 of the Guidelines) | No incorporation of extracellularly processed nucleic acids, or no remaining extracellularly processed nucleic acids and/or their copies. |
| If Determined by MAFF to be GE | Product must undergo MAFF safety review for impact on biodiversity (JA2020-0219). |
| If Determined by MAFF to not be GE | Developer requested to complete MAFF notification unless use of the product is within a containment system approved within the Cartagena Act or by the relevant ministry. |
| Notification Requirements (Section 3.1.(1)* of Guidelines) | 1) Name and summary of the organism; 2) Application/purpose; 3) Facility where used; 4) Confirmation that no extracellularly processed nucleic acid or any replicated product remains; 5) Taxonomic species of the modified organism; 6) Genome editing technology used; 7) Modified gene and function of the corresponding gene; 8) Trait changes; 9) Other trait changes; 10) Adverse effect on biodiversity. |
| Information Made Public by MAFF (Section 3.1.(2) ii) of Guidelines) | All notified information excluding confidential business information that may create an unreasonable advantage or disadvantage. |
| Crossbred Progeny (Section 3.1. (3) of Guidelines) | Contact MAFF to check if further information should be provided. |
| Official Contact Point | Plant Products Safety Division Food Safety and Consumer Affairs Bureau Ministry of Agriculture, Forestry and Fisheries 1-2-1, Kasumigaseki, Chiyoda-ku Tokyo 100-8950, Japan Phone: 03-6744-2102 Fax: 03-3580-8592 Email: nbt_tetsuzuki@maff.go.jp |

Genome Edited Aquaculture Decision

On February 10, 2021, MHLW convened the Research Committee for Genetically Engineered Foods to discuss food safety aspects in the handling of fish derived from genome editing technology. After four additional meetings, on June 25, MHLW finalized a draft report titled the “[Notes on the Handling of Fishes Obtained via Genome Editing Technology](#)” (Japanese Only). MHLW convened the committee and published the report because they determined that aquaculture breeding is distinct from farm crop cultivation, including a shorter history of breeding and more genetic diversity in some fish species. Developers of genome edited aquaculture products are advised to reference the finalized note when released by MHLW.

Labelling Genome Edited Products

On September 19, 2019, the Consumer Affairs Agency (CAA) released guidance documents that encourage stakeholders to disclose genome edited food products or products that contain genome edited ingredients ([JA2019-0174](#)). Similarly, food manufacturers may also disclose that their products are not derived from genome edited ingredients. CAA encourages manufacturers to monitor their product’s supply chain to identify genome edited ingredients since there is no way to distinguish between genome edited and conventionally bred products. More on CAA’s food labeling guidance can be found on their [website](#) (link in Japanese).

Genome Editing Research in Japan

Genome editing research accelerated in Japan in 2015 when the Government of Japan (GOJ) initiated the Cross-Ministerial Strategic Innovation Promotion Program (SIP), a national project for science, technology, and innovation that identifies key areas for revitalization of the Japanese economy. In 2015, 3.3 billion yen was allocated through SIP for, Technologies for Creating Next-Generation Agriculture, Forestry and Fisheries. In 2016, through SIP, 2.66 billion yen was allocated for Next-Generation Agriculture. Plant breeding with genome editing technologies such as CRISPR/Cas9 was a key focal point of the 2016 program. The SIP has fully or partially funded many of the domestic research and crop development genome edited projects in Japan. SIP also provides support to researchers and organizations specializing in social sciences in order to increase public understanding of the technology.

[The second phase of SIP](#) (link in Japanese) provides funding for applied research and public acceptance of genome editing technology in agriculture.

Japanese researchers have developed a number of genome edited plant and animal products including, vegetables, grains, and aquaculture species.

In December 2020, MHLW and MAFF announced their determination that a genome edited tomato will not be required to undergo the food and feed safety approval process as a genetically engineered (GE) product. The tomato was nutritionally enhanced with CRISPR-Cas9 technology and the first product to complete either ministry’s voluntary notification process for verification of whether a genome edited product should be regulated as a GE product ([JA2020-0200](#)).

Attachments:

No Attachments.