

Voluntary Report – Voluntary - Public Distribution

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

Country: Japan

Post: Tokyo

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

The Government of Japan has completed and published guidelines for handling food and agricultural products derived from genome editing technology. The Ministry of Health, Labour and Welfare developed and oversees the guidelines for genome edited food and food additives. The Ministry of Agriculture, Forestry and Fisheries developed and oversees the guidelines for both genome edited feed and feed additives as well as the impact of genome edited products on the biodiversity of products within its jurisdiction. The Consumer Affairs Agency has also finalized guidance on labeling genome edited products.

Disclaimer

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

Background

In February 2018, Japan's Ministry of Environment (MOE) finalized policies for regulating genome editing technologies based on Japan's Cartagena Act ([JA9024](#)). MOE's policy provided the guidance needed for the Ministry of Agriculture, Forestry and Fisheries (MAFF) to develop handling procedures for genome edited products to protect the biological diversity of products under MAFF's jurisdiction ([JA2019-0196](#)). MAFF also developed policies and handling procedures for genome edited feed and feed additive products based on MAFF's authority under the Act on Safety Assurance and Quality Improvement of Feeds ([JA2020-0060](#)). In parallel, the Ministry of Health, Labour and Welfare (MHLW) convened a Research Sub-Committee to review the treatment of genome edited food and food additives under Japan's Food Sanitation Act. In March 2019, MHLW finalized the regulatory policy for the handling of food and food additives derived from genome editing technology ([JA9050](#)). MHLW then developed and finalized the guidelines for handling organisms derived from genome editing technology for food and food additives in September 2019 ([JA2019-0011](#)).

The three handling procedures, for biological diversity, feed products, and food products, developed by MAFF and MHLW provide a pathway to commercial distribution in Japan for developers of genome edited products. MAFF and MHLW expect developers of genome edited products to follow the relevant guidelines before commercializing a product derived from genome editing technology.

Consultation and Notification Process for Genome Edited Products

The three handling procedures 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 have the opportunity to determine if the product in question is required 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 are required to undergo the appropriate GE safety reviews because each procedure has a different legal basis. This could mean a genome edited product is required to undergo the GE safety review for one or a combination of either food, feed, or biological diversity approval.

The first step for all three procedures is to undergo an initial consultation with the relevant authorities to determine if the product must undergo a GE safety review. If through this consultation, MHLW or MAFF determine the product is not required to undergo the GE safety review, then the developer is requested to complete a notification process defined in each of the guidelines. For each process, much of the information requested is similar to what was requested during the initial consultation. When the notification process is complete, MAFF and MHLW will publish a portion of the information provided by the developer with appropriate consideration to confidential business.

Guidelines for Genome Edited Food and Food Additives	
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 Summary (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)	Required preliminary consultation for all crossbred progeny products for the time being. MHLW could revise the handling of crossbred progeny.
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 (from overseas, international access code +81-3-5253-2341) Fax: 03-3501-4868 (from overseas, international access code +81-3-3501-4868) Email: ISESHINKAI@mhlw.go.jp

Guidelines for Genome Edited Feed and Feed Additives	
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)
Translation of Guidelines	JA2020-0060
Non-GE Product Definition Summary (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)	<p>Notification required if:</p> <ul style="list-style-type: none"> • Organism has no GE safety review history <p>Notification <u>not</u> required if:</p> <ul style="list-style-type: none"> • Trait quality does not change by cross breeding; • no cross breeding between subspecies; and • no change in intake amount, portion of plant to be used as feed, processing method, etc.
Official Contact Point	<p>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 (from outside Japan, international access code + 81-3-6744-1708) Fax: 03-3502-8275 (from outside Japan, international access code + 81-3-3502-8275) Email: feed@maff.go.jp</p>

Guidelines for Impact to Biodiversity	
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 Summary (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

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. Many of the domestic research and crop development genome edited projects have been fully or partially funded through the SIP. 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 ([2019-02190](#)).

Attachments:

No Attachments.