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### **Report Highlights:**

This report provides the latest status of consumption, regulation, public perception, research, development, production, and use of agricultural biotechnology in Japan. Japan uses a science-based process for evaluating and granting approval for import and production of genetically engineered products. Japan is a major importer and consumer of crops derived from biotechnology, but domestic production remains extremely limited. Japanese regulators have established handling procedures for genome edited food and agricultural products. Two gene edited products developed by Japanese companies have completed the necessary consultation and notification processes and were cleared for production and distribution in the domestic market without undergoing the food safety review for genetically engineered products.

## Executive Summary

Japan is one of the world's largest per-capita importers of food and feed produced using modern biotechnologies. The United States is the top exporter of genetically engineered (GE) products, namely grains and oilseeds, to Japan, but other major suppliers include Canada, Brazil, and Argentina. In MY2019/2020, Japan imported 15.9 million metric tons (MT) of corn, 3.3 million tons of soybeans, and 2.2 million tons of canola, products that are predominately genetically engineered (GE). Japan also imports billions of dollars of processed foods that contain GE-derived oils, sugars, yeasts, enzymes, and additives. Conversely, no genetically engineered feed or food products are cultivated in Japan, despite broad regulatory approval. Thus far, as of September 2021, 194 products have been approved for environmental safety, which include 145 approvals for domestic cultivation.

The regulatory approval of GE crops by the Government of Japan (GOJ) is important for U.S. agriculture and global food production and distribution. GE exports not approved in Japan could result in significant trade disruption. GE regulations in Japan are largely science-based and transparent, and regulators generally review and approve new events within anticipated time periods that mostly align with industry expectations for market release. As of September 2021, regulators have approved 326 products for food use. Japan's improved product review process and increased familiarity with products using common transgenes has contributed to more prompt reviews. As one of the world's largest per-capita importers of GE crops, continued improvements of the Japanese GE regulatory system that are focused on long-term trends in biotechnology and risk-based management will benefit all stakeholders. While unable to meet in person due to COVID-19 restrictions, GOJ regulators held GE product safety review meetings online to avoid delays to the regulatory review process.

In 2020, Japanese regulators completed the handling guidelines and product labeling policies for genome edited food and agricultural products. The Ministry of Agriculture, Forestry, and Fisheries (MAFF) is the competent authority for overseeing the animal feed and biodiversity handling procedures and the Ministry of Health, Labour, and Welfare (MHLW) oversees the handling producers for food products. During Japanese Fiscal Year (JFY) 2020, MAFF and MHLW undertook a review of its handling of crossbred progeny and adjusted the handling producers. In December 2021, MHLW added the first item, a nutritionally enhanced tomato, to its list of products that have completed the voluntary notification process for (non-GE) genome edited products. Multiple private sector entities have been established in Japan to produce and market products derived from genome editing. The GOJ supports genome editing research for food and agricultural applications through grants, public research institutions, and universities.

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## CHAPTER I: PLANT BIOTECHNOLOGY

### PART A: Production and Trade

#### *a) PRODUCT DEVELOPMENT*

In Japan, most agricultural research and development (R&D) is conducted by the public sector at government research institutes and universities and often progresses at a slower pace than in the United States. Agricultural producers in Japan are reluctant to plant GE varieties, GE food products come with mandatory labeling requirements, and public perception of GE crops and products remains mixed. Without a demand signal for commercial GE products, product developers have little reason to push for the commercialization of GE varieties.

The GOJ's national project for science and technology innovation, the Cross-ministerial Strategic Innovation Promotion Program (SIP), has encouraged research of genome editing technology. Projects funded by the GOJ include a nutritionally enhanced tomato, a potato with reduced toxin, a less aggressive mackerel for aquaculture, and high-yield rice. Product developers, using GOJ funded research, along with investment from private sector, have started companies to focus on the development and marketing of products derived from genome editing. Sanatech Seed, founded in 2018, completed GOJ's voluntary notification and consultation process for the nutritionally enhanced tomato in December 2020 and made the product available to the public, the first genome edited agricultural food product available in Japan. USDA Animal Plant Health Inspection Service (APHIS) has already [determined](#) that the tomato product is not regulated under 7 CFR part 340. For additional details on SIP, see [JA6050](#).

#### *b) COMMERCIAL PRODUCTION*

There is no commercial production of GE food products in Japan. The only commercial GE product produced is a rose developed by Suntory and the volume of production has not been made public. Suntory also developed and distributes a blue GE carnation, but it is cultivated in Colombia.

Sanatech Seed began distribution of seedlings of its nutritionally enhanced, genome edited tomato after completing Japan's voluntary consultation and notification process in December 2020. In September, Sanatech Seed, started online sales of genome edited tomatoes (Link to [newspaper article](#), in Japanese).

#### *c) EXPORTS*

There are no GE agricultural products exported from Japan. In 2020, Japan exported \$8.7 billion of food and agricultural products, including processed products (\$3.4 billion). Exported processed products may contain GE ingredients (USD=110 JPY, Link to MAFF's [home page](#), in Japanese).

#### *d) IMPORTS*

##### Grains and Oilseeds

Japan imports almost 100 percent of its corn and over 96 percent of its oilseeds supply, which are largely GE soybean and canola. In CY2020, Japan imported 15.8 million tons of corn, approximately a third of which was for food use. FAS/Tokyo estimates nearly half to two-thirds of corn for food use imported by Japan is non-segregated or GE, but there are no official statistics available. For more information on the import of grains and oilseeds see [JA2021-0035](#) and [JA2021-0043](#).

### Fresh Produce

A limited volume of “Rainbow Papaya,” a GE papaya grown in Hawaii, is the only fresh GE product exported by the United States to Japan ([JA1048](#)).

#### *e) FOOD AID*

In JFY2019, Japan provided approximately \$37million for 680,000 tons rice and wheat of food aid. Rice accounts for most of the food aid donated by Japan. For more, see [Ministry of Foreign Affairs](#) (in Japanese).

#### *f) TRADE BARRIERS*

Japan is one of the world’s largest per-capita importers of GE products and has no significant trade barriers.

### PART B: Policy

#### *a) REGULATORY FRAMEWORK*

##### Regulatory Process

In Japan, the commercialization of GE plant products requires regulatory approvals of food, feed and/or environment depending on the nature and use of product. Four ministries are involved in the regulatory framework: MAFF, MHLW, Ministry of Environment (MOE), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). These ministries are also involved in environmental protection and regulating lab studies. The Food Safety Commission (FSC), an independent risk assessment body under the Cabinet Office, performs food safety risk assessments for MHLW and feed safety risk assessments (in terms of human consumption of livestock products grown with GE feed) for MAFF.

**Table 1: Ministries Responsible for GE Product Safety Reviews**

Type of Approval	Examining body	Jurisdiction	Legal Basis	Main Points Considered
Food Safety	FSC	Cabinet Office	Food Safety Basic Law	<ul style="list-style-type: none"> <li>• Safety of host plants, genes used in the modification, and the vectors</li> <li>• Safety of proteins produced as a result of genetic modification, particularly their allergenicity</li> <li>• Potential for unexpected transformations as the result of genetic modification</li> <li>• Potential for significant changes in the nutrient content of food</li> </ul>
Feed Safety	Agricultural Materials Council	MAFF	Law Concerning the Safety and Quality Improvement of Feed (the Feed Safety Law)	<ul style="list-style-type: none"> <li>• Any significant changes in feed use compared with existing traditional crops</li> <li>• Potential to produce toxic substances (especially with regard to interactions between the transformation and the metabolic system of the animal)</li> </ul>
Impact on biodiversity	Biodiversity Impact Assessment Group	MAFF of the Environment	Law Concerning Securing of Biological Diversity (Regulation of the Use of Genetically Modified Organisms)	<ul style="list-style-type: none"> <li>• Competitive superiority</li> <li>• Potential production of toxic substances</li> <li>• Cross-pollination</li> </ul>

Note: MHLW and MEXT are not involved in conducting risk assessments; they are risk management bodies and/or contact points for applications.

Risk assessments and safety evaluations are performed by advisory committees and scientific expert panels, which primarily consist of researchers, academics, and representatives from public research institutions. Upper committees then review these decisions, whose members include technical experts and opinion leaders from a broad range of interested parties, including consumer groups and industry. The advisory committees report their findings and recommendations to the responsible Ministries. The Minister of each ministry then typically approves the product.

GE plants intended for food use must obtain food safety approvals from the MHLW Minister. Based on Japan's [Food Sanitation Act](#), upon receiving a petition for review from an applicant, the MHLW

Minister will request a food safety review by the FSC. Within the FSC, there is a ‘Genetically Modified Foods Expert Committee’ consisting of scientists from universities and public research institutes that conducts the scientific review. Upon completion, the FSC provides its conclusions to the MHLW Minister for the official announcement of review completion. FCS publishes the risk assessment results of GE foods in English on [its website](#). FSC sets the standard processing time from the receipt of dossier to the completion of review at 12 months.

Under the Feed Safety Act, the MAFF Minister must approve all GE products that are intended for feed use. Based on a petitioner’s request, MAFF asks the Expert Panel on Recombinant DNA Organisms, part of the MAFF-affiliated Agricultural Materials Committee (AMC), to review the GE crops for feed use. The Expert Panel evaluates feed safety for livestock animals and then the AMC reviews the evaluation. The MAFF Minister also asks the FSC’s Genetically Modified Foods Expert Committee to review human health effects from consuming livestock products from animals that have been fed the GE crops under review. Based on the AMC and FSC reviews, the MAFF Minister approves the feed safety of the GE events.

Japan ratified the Cartagena Protocol on Biosafety in 2003. In 2004, Japan adopted the “Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms”, also called the “Cartagena Law”, to implement the Protocol. Under this law, MEXT requires Minister-level approval before performing early stage agricultural biotechnology studies in laboratories and greenhouses. MAFF and MOE require joint approvals for the use of GE plants in greenhouses or labs as part of their assessment on biodiversity.

MAFF requires the developers to perform isolated field trials in Japan to collect necessary scientific data. Developers need to receive the permission from the MAFF and MOE Ministers for field trial to data for environmental risk assessment for the event. A joint MAFF and MOE expert panel carries out the environmental safety evaluations. MAFF sets the standard processing time from the receipt of dossier to approval as six months, more information can be found on [MAFF’s website](#) (link in Japanese).

However, the “clock” for the standard processing time stops when the applicant revises the dossier, receives questions from MAFF, and prepares the response. Additionally, the preliminary consultation, confined field trial, and administrative handling for an official notification is a prolonged process. Furthermore, it is customary for regulators to first approve products for food, followed by feed, and then environment. Therefore, a delay in food and/or feed approval will delay the environmental approval. The actual time required for full approval varies significantly depending on the familiarity of the product and trait. Approval is generally within eighteen months of formal acceptance of the dossier for food, feed, and environmental release if regulators can be characterize the product as familiar.

Finally, GE products that require standards or regulations not related to food safety, such as GE labeling and IP handling protocols, are addressed by the Food Labeling Division of the Consumer Affairs Agency (CAA). CAA finalized the revision of regulations for GE labeling in March 2019, for more see [JA2019-0174](#).



CAA is responsible for protecting and enhancing consumer rights. Risk management procedures, such as the establishment of a detection method for GE products in food, are addressed by MHLW. There are no processing fees charged by any GOJ ministry for the review. See appendix Figure 1 for a schematic chart of the flow of the approval process for GE products.

#### *b) APPROVALS*

As of September 2021, Japan has approved over 326 GE products for food, 190 for feed, and 194 for environment, which include 145 for environmental release, including commercial planting for most products. The number of products approved for food does not include 35 stacks, which no longer go through the regulatory approval process. See the reference section at the end of this report for the links to lists of approved products.

#### *c) STACKED or PYRAMIDED EVENT APPROVALS*

Japan requires separate environmental approvals for stacked products. Although, MHLW exempts GE products from review that use pre-approved single events if the crossing of single events does not affect the metabolic pathway of the host. FSC agreed to exempt stacked products using single events with the modified metabolic pathway from review, for more details see the FCS [website](#) (in Japanese). As of July 2021, 34 stacked products (5 soybean, 13 corn<sup>1</sup>, 4 canola, and 12 cotton) have been exempted from review, for more information see MHLW's [website](#). For details on the approved stacks, please see the links contained in the REFERENCE section at the end of this report. For additional details on previous improvements made in the handling of stacked product approvals, see [JA7138](#).

#### *d) FIELD TESTING*

Generally, MAFF requires domestic field trials to review the effect on biodiversity has not changed. However, in December 2014, MAFF excluded crops that do not have wild relatives in Japan (ex: corn) with traits of sufficient familiarity (ex: herbicide tolerance, insect resistance) from mandatory field trial requirements. In March 2019, MAFF added cotton with traits of sufficient familiarity to the list of products excluded from domestic field trials, for more information on this change see MAFF's [website](#) (in Japanese). For additional information on field trials, see [JA6050](#).

#### *e) INNOVATIVE TECHNOLOGIES*

The Government of Japan has three separate handling procedures for genome edited food and agricultural products that cover food, feed, and biodiversity safety. MHLW oversees the procedures for food and food additives, while MAFF is responsible for both feed and feed additives as well as biodiversity safety for products under its authority. For more on genome editing handling procedures in Japan, see [JA2021-0106](#). Developers of food and food additive as well as feed and feed additive products derived from genome edited crossbred progeny are no longer expected to submit their products to pre-market consultations and notifications with the relevant authority. MHLW and MAFF amended their procedures in December 2020 ([JA2020-0214](#)) and April 2021 ([JA2021-0073](#)), respectively. For details on the development of Japan's genome editing handling procedures, see JA2019-0219.

CAA determined that genome edited foods that do not contain foreign DNA are not subject to the Food Labeling Standard. However, CAA guidance recommends food manufacturers voluntarily label genome edited foods. Similarly, food manufacturers may also disclose that their products are not derived from genome edited ingredients, but CAA articulates that manufacturers should be able to verify their

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<sup>1</sup> The number decreased from last year because the applicant retracted the notification.

product’s authenticity of ingredients throughout supply chain. For more on CAA’s labeling guidance, see [JA2019-0174](#).

*f) COEXISTENCE*

A 2004 guideline issued by MAFF requires that before a field trial can be undertaken, detailed information on the trial must be made public via web pages and meetings with local residents. MAFF also requires the establishment of buffer zones to prevent related plant species in the surrounding environment from cross-pollinating (see Table 3). These requirements, restrictive local regulations, and public resistance has made the planting of GE crops with conventional crops difficult in Japan. For additional detail, please see the guidelines for cultivation of GE crops on the MAFF [website](#) (link in Japanese).

**Table 2: Required Buffer Zone for GE Crops in Open Fields**

<b>Plant</b>	<b>Minimum isolation distance</b>
Rice	30 meters
Soybeans	10 meters
Corn (applicable for food and feed safety approvals)	600 meters or 300 meters with the presence of a windbreak
Rapeseed (applicable for food and feed safety approvals)	600 meters or 400 meters if non-recombinant rapeseed is planted to flower at the same time of the field-tested rapeseed. A width of 1.5 meters surrounding field tested plants as a trap for pollens and pollinating insects

Local Government Regulations

There are 15 local governments with regulations for the planting of GE products for research and/or commercial purpose that create administrative hurdles for farmers who would like to plant approved GE products. Many local rules were established between 2004 and 2009; since then however, there is little update or pressure to change these regulations. Some local governments, for example [Imabari City](#) (link in Japanese), argue that foods containing GE ingredients should not be used in the school lunch program. See [JA2019-0219](#) for more information on local regulations.

*g) LABELING*

Currently, three types of GE claims may be made on food labels in Japan: GE, non-segregated (i.e. without identity preservation), and non-GE. GE and non-segregated product labeling is mandatory. If a product is identity-preserved as GE, it must be labeled as GE. If a product for which approved GE varieties exist (e.g. grains, oilseeds) is distributed without identity preservation, it must be labeled as non-segregated (regardless of the percentage of GE or non-GE in the product). Non-GE labeling is voluntary. To make non-GE labeling claims about foods or ingredients, the commodities must be handled under an identity preservation system and segregated from other GE and non-segregated products. A non-GE product cannot contain more than five percent of GE components. If test results demonstrate more than five percent of GE components are contained therein, the product must be labeled as non-segregated.

In March 2019, CAA finalized the revised labeling policy for GE foods. CAA maintained Japan's current IP system but will use new language to identify IP products in lieu of the previously acceptable "Non-GE" label. CAA also revised the definition of the term "Non-GE" to mean that no GE content is detectable, effectively establishing a zero tolerance for GE components. The new GE labeling regulations will be effective on April 1, 2023, for more information please see CAA website. FAS/Tokyo has submitted multiple reports on the review process (see, e.g., [JA7067](#), [JA7093](#), [JA7121](#), [JA8014](#), and [JA9055](#)).

#### *h) MONITORING AND TESTING*

The GOJ monitors volunteer plants to assess the effect on biodiversity of environmental release of a GE crop. MAFF's most recent [report](#) on environmental release includes a survey conducted in the vicinity of ports where canola and soybeans were unloaded from vessels and found no significant impact on biodiversity. MAFF looks for GE plants that are affecting biodiversity, such as by surviving through multiple generations, or crossbreeding of a GE soybean with *Glycine soja*, a Japanese domestic wild plant and the closest living relative of soybean.

To detect GE materials in food products, the GOJ uses the qPCR test. However, this method may not be the most accurate, as it detects and quantifies GE specific regions (e.g., 35S promoter, NOS terminator) in a single event with multiple promoters. The use of stacked events in corn production is increasingly important for management against pests. MHLW implemented a new testing method to avoid false detection in "five percent rule" in 2009. For additional detail, please see [JA6050](#).

MAFF, acting as a state trading enterprise, conducts tests for GE wheat and rice shipments from some export markets, including the United States. These tests are completed to ensure compliance with MHLW's low-level presence policy. MAFF publishes tests results annually on its [website](#).

#### *i) LOW-LEVEL PRESENCE (LLP) POLICY*

There have been no changes to Japan's LLP policies ([JA6050](#)). As of March 2021, MHLW monitored for the following items:

- PRSV-YK, PRSV-SC and PRSV-HN (papaya and its processed products, if papaya can be isolated for analysis. Monitors 299 cases annually.)
- 63Bt, NNBt, and CpTI (rice and its processed product with rice as a main ingredient, such as rice flour, rice noodle, etc., when products are unheated or mildly heated. Monitors 299 cases annually.)
- RT73 B. rapa (canola and its processed products. Monitored 29 cases annually.)
- MON71100/MON71300, MON71700 and MON71800 (U.S. wheat. Monitors 59 cases annually. Also, regulatory authority, MHLW and/or port officials, may request inspection of specific shipments.)
- MON71200 (Canadian wheat. Monitors 59 cases annually. Also, regulatory authority, MHLW and/or port officials, may request inspection to specific shipments);
- F10 and J3 (potato and its processed products, of potato as a main ingredient, such as French fries, potato chips, etc. Monitors 59 cases annually)
- AquAdvantage (salmon and its processed products, such as salmon flakes, from Canada, Panama and the United States. Monitors 59 cases annually).

International guidelines on food safety assessments for LLP for GE foods were adopted by the Codex Alimentarius (Codex) commission in July 2008, as an Annex to the Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food. Japan does not fully apply this internationally recognized approach to its own LLP policies. This is evident in MHLW's policies regarding food, as the Codex Annex allows for more than a 'zero' tolerance.

*j) ADDITIONAL REGULATORY REQUIREMENT*

Although GE products receive regulatory approval for commercial planting, GE products with herbicide resistance may need to have the relevant chemical registered in Japan.

*k) INTELLECTUAL PROPERTY RIGHTS (IPR)*

Japan generally provides strong IPR protection and enforcement. Japanese IPR covers genetic engineering of agricultural crops, including but not limited to, the gene, seeds, and name of varieties. Japan's Patent Office is responsible for IPR.

*l) CARTAGENA PROTOCOL RATIFICATION*

Japan ratified the Cartagena Protocol on Biosafety in November 2003 and implemented the "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms." In December 2017, Japan ratified the "Nagoya-Kuala Lumpur Supplemental Protocol on Liability and Redress to the Cartagena Protocol on Biodiversity." This and other laws implementing the protocol may be found on the Japan Biosafety Clearing House (J-BCH) [website](#).

*m) INTERNATIONAL TREATIES/FORA*

Japan is also active in Access and Benefit Sharing (ABS). The Japan Bioindustry Association has provided seminars to the industry and prepared [guidelines](#) on ABS. Their target, however, is geared more towards the pharmaceutical and medical industries rather than agriculture.

Japan is also actively involved in the harmonization of regulatory oversight in biotechnology at the Organization for Economic Co-operation and Development (OECD).

*n) RELATED ISSUES*

None.

PART C: Marketing

*a) PUBLIC/PRIVATE OPINIONS*

Japanese regulations can be a brake on production technologies available to U.S. farmers. Moreover, the presence of an unapproved GE crops in shipments to Japan and other major markets can lead to costly export testing requirements and trade disruptions. In 2007, the Biotechnology Innovation Organization's (BIO), a group of major biotechnology developers, released a statement on [Product Launch Stewardship](#) to address this issue.

*b) MARKET ACCEPTANCE/STUDIES*

Although there are still consumer groups actively campaigning against products derived biotechnology, the public's perception of the risk posed by these products is decreasing, possibly due to less negative media coverage and a better understanding of Japan's reliance on imported GE grain and oilseeds.

Recent survey results indicate that concerns related to GE food have diminished. In the 2006 Japan Fiscal Year (JFY), a [survey conducted by FSC](#) (in Japanese) found 75 percent of participants were "highly concerned" or "concerned" with GE food. However, in the JFY2020 survey, 15 percent responded that they were "highly concerned" and 28 percent responded "concerned", marking a significant change in public acceptance of GE products.

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: Production and Trade

#### *a) PRODUCT DEVELOPMENT*

Most of the research in molecular biology in Japan has been focused on human medical and pharmaceutical purposes. Like with plants, universities and public research institutions conduct much of the limited food and agricultural biotechnology research with limited involvement by the private sector. However, with the emergence of genome editing technology there seems to be a greater level of interest from Japan's private sector. Japanese media regularly covers the ongoing genome editing based research into increasing skeletal muscle in sea breams, faster growing pufferfish, and the development of aquaculture tuna with reduced aggressiveness.

The research team behind the sea bream founded a startup company called [Regional Fish](#), in 2019 with financial support from the private sector, which aims to revive the Japanese aquaculture industry and address a shortage of protein sources through the commercialization of genome edited aquaculture products. For more information on the new genome edited products, see their [publication](#).

Japan's National Institute of Agrobiological Sciences (NIAS) continues to develop GE silkworm varieties for the value-added silk production, however, its commercial application appears to remain limited. As of August 2021, Japan has approved [10 GE silkworms](#).

Interest in animal cloning appears to have waned in Japan and activity has been steadily decreasing since the late 1990's and [has been negligible in recent years](#).

#### *b) COMMERCIAL PRODUCTION*

Currently, there is no commercial production of GE animals or cloned animals for the purpose of agricultural production except for value added silk and protein production by GE silkworms.

#### *c) EXPORTS*

None.

#### *d) IMPORTS*

None.

*e) TRADE BARRIERS*

None.

PART E: Policy

*a) REGULATORY FRAMEWORK*

Japanese regulators apply the same regulation for GE plants to the commercialization of GE livestock animals and insects. For production or environmental release of GE animals, MAFF's "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" will be applied, as Japan ratified the Cartagena Protocol on Biosafety in 2003. The Food Sanitation Act, under MHLW's supervision, will cover the food safety aspect of GE animals.

*b) INNOVATIVE BIOTECHNOLOGIES*

The regulatory policies and guidelines developed by MHLW for food and environmental safety explained in Chapter 1 are applicable to animals derived from genome editing technology with a few exceptions.

MHLW determined that due to differences between fish raised for aquaculture and crops and livestock animals they, such as the shorter history of breeding, greater genetic variation in some species, and genetic mosaicism with CRISPR/Cas9, it would need to consider possible changes to its genome edited product consultation and notification process. To discuss these issues, MHLW commenced a series of expert discussions on possible changes and on June 25. MHLW finalized a report titled "Note on the Handling of Fishes Obtained via Genome Editing Technology." For detail, please see [JA2021-0132](#).

*c) LABELING AND TRACEABILITY*

The labeling requirement for GE animals is the same as for plants. For products derived from a cloned animal, Japan has a specific labeling requirement that it be labeled as a cloned product. FAS/Tokyo is not aware of any commercial product with a "cloned" label at this point.

*d) INTELLECTUAL PROPERTY RIGHTS (IPR)*

Same as for plants.

*e) INTERNATIONAL TREATIES/FORA*

As Japan ratified the Cartagena Protocol on Biosafety in 2003, the handling of animals developed with GE also must be handled based on this regulation.

*f) RELATED ISSUES*

In September 2017, the GOJ implemented monitoring for GE salmon and processed salmon products, such as salmon flakes. For additional details, please see [JA7112](#).

PART F: Marketing

*a) PUBLIC/PRIVATE OPINIONS*

At this moment, there is no commercial distribution of GE animals in Japan except for a few products, such as the silkworm used to make protein for medical diagnostic agent. It is not clear how much, if any,

public interest there would be in consuming meat from GE or cloned animals. However, some research has received public attention and private investment for potential future marketing.

#### *b) MARKET ACCEPTANCE/STUDIES*

There is no marketing activity specific for livestock animal and aquaculture biotechnology.

### **CHAPTER 3: MICROBIAL BIOTECHNOLOGY**

#### **PART G: Production and Trade**

##### *a) COMMERCIAL PRODUCTION*

Japan has several traditional foods that rely on fermentation including soy sauce, *natto* (fermented soybeans), *miso* (soybean paste), and *sake* (rice wine). Non-traditional food products that utilize fermentation have also become common in the modern Japanese diet, including yogurt, cheese, and bread. Despite widespread use in traditional and non-traditional foods, there is little public information on the scale of production of products derived from microbial biotechnology. The food industry in Japan is sensitive to consumer reaction to the use of biotechnology and CAA labeling rules exempt the products in this category from the GE labeling requirement, so there is little incentive to indicate if a product uses microbial biotechnology.

Japan's 2020 enzyme and yeast markets was approximately 48 billion yen (436 million USD).

Manufacturers of direct products of microbial biotechnology (e.g., GE enzymes) are mix of international and domestic companies. Major international companies that have received approval include, Novozyme, Danisco U.S., Ezaki Gulico and several other domestic companies have also received approval their microbial biotechnology products. Lists of approved products and applicants can be found on [MHLW's website](#).

For self-cloning (e.g., protease), natural occurrence (e.g., phospholipase A2), highly purified products (e.g., L-glutamine), and Japanese companies make up most applicants. A list of approved products and applicants can be found on [MHLW's website](#) (link in Japanese).

Product developers have introduced limited alternative meat products in the Japan market. The alternative meat products currently available on the Japanese market are mainly soybean based. So far, meat analogue products from bacteria or single cell-based proteins are not found in commercial distribution in Japan. On October 2, 2020, MAFF held its first "[Council for Public-Private Partnership in Food Technology](#)" (link in Japanese) for the promotion of cross-sectorial collaboration, but the conference was not open to the general public.

##### *b) EXPORTS*

In 2020, Japan exported 4,582 MT of enzymes (HS code 3507), valued at \$257 million, which may include products derived from microbial biotechnology.

**Table 3: Japan's Export of Enzymes (HS3507, CY2020)**

Country	Volume (Metric Ton)	Value (million USD)
United States	857	76
Denmark	637	13
China	491	35
Netherlands	394	6
France	361	15
Others	1,816	123
<b>Total</b>	<b>4,556</b>	<b>268</b>

Source: [Trade Data Monitor Inc.](#)

*c) IMPORTS*

In 2020, Japan imported 5,208 MT of enzymes (HS code 3507), valued at \$95 million, which may contain products derived from microbial biotechnology.

**Table 4: Japan's Import of Enzymes (HS3507, CY2020)**

Country	Volume (Metric Ton)	Value (million USD)
China	1,568	12
Denmark	1,321	27
Finland	824	6
United States	332	11
Germany	155	14
Others	361	22
<b>Total</b>	<b>4,561</b>	<b>92</b>

Source: [Trade Data Monitor Inc.](#)

*d) TRADE BARRIERS*

None.

PART H: Policy

*a) REGULATORY FRAMEWORK*

Most microbial biotechnology products will fall into the food additive category in Japan, where food additives are defined as below in Japan's Food Sanitation Act. More information can be found on [MHLW's website](#).

- (i) substances used in or on food in the process of manufacturing food, or
- (ii) substances used for the purpose of processing or preserving food.

As long as the GE microorganism and its products are only used in a contained environment for food production, the products must only receive food safety approval. The approval process is the same as the GE food safety review process for plant and animal products. After a preliminary review, MHLW accepts the dossier and then it goes to FSC for the safety risk assessment. More for information on the



process, please see [FSC's website](#).

When the products are highly defined additive ingredient and do not contain foreign GE materials, Japan has a separate review system. Also, when the microorganisms producing food and food additives are considered to be self-cloning or natural occurrence, the scientific safety review is exempted. FSC has published their Safety Assessment Standards for [microorganisms](#), food additives, [food additives](#), and [highly purified end products](#).

#### *b) APPROVALS*

As of August 2021, Japan has approved 58 food additive ingredients derived from GE technologies. Approved products can be found on [MHLW's website](#) and are list below:

- Alpha amylase: 11 products
- Rennet: 4
- Pullulanase: 4
- Lipase: 3
- Riboflavin: 2
- Glucoamylase: 4
- Alpha-glucosyltransferase: 3
- CGTase: 1
- Asparaginase: 1
- Phospholipase: 6
- Beta-amylase: 1
- Exomalt tetraohydrolase: 2
- Acid phosphatase: 1
- Glucose oxidase: 2
- Protease: 2
- Hemicellulaze: 2
- Xylanase:5
- Beta-galactosidase: 1
- Psicose epimerase: 1
- Terpene hydrocarbons: 1
- Beta- glucosidase: 1

As of August 2021, 86 products are approved as highly purified or a natural occurrence substance.

Approved products can be found on [MHLW's website](#) (link in Japanese).

#### *c) LABELING and TRACEABILITY*

As food ingredients, GE products and/or ingredients are required to be labeled as GE when it is among top three ingredients in the product and accounts for at least five percent of the product.

Japan has a labeling requirement for the use of food additives, for more see [JA2019-0216](#). However, there is no labeling or traceability requirement as GE element even when additive substances are GE.

#### *d) MONITORING AND TESTING*

No specific testing for products from microbial biotechnology.

*e) ADDITIONAL REGULATORY REQUIREMENTS*

None.

*f) INTELLECTUAL PROPERTY RIGHTS (IPR)*

Same as for plants and animals.

*g) RELATED ISSUES*

None.

**PART I: Marketing**

*a) PUBLIC/PRIVATE OPINIONS*

Public awareness of microbial biotechnology use by the food industry is limited.

*b) MARKET ACCEPTANCE/STUDIES*

There are no significant market acceptance or studies available.

**Reference**

Risk assessment standards of genetically engineered food

Food Safety Commission

[http://www.fsc.go.jp/english/standardsforriskassessment/gm\\_kijun\\_english.pdf](http://www.fsc.go.jp/english/standardsforriskassessment/gm_kijun_english.pdf)

Information related to GE food regulations

Ministry of Health, Labor and Welfare

<http://www.mhlw.go.jp/english/topics/foodsafety/dna/index.html>

Information on GE Food Labeling

Consumer Affairs Agency (the agency responsible for labeling regulations, including GE)

<http://www.caa.go.jp/en/> (English)

Food Labeling Law, Government Ordinance, Ministerial Ordinance and Notifications (in Japanese only)

<http://www.caa.go.jp/foods/index18.html>

The information on the Food Labeling Law is still not available in English. Please refer to [JA7078](#) for additional details on the law.

Useful resources on agricultural biotechnology by Japan Biosafety Clearing House (Japan)

[http://www.biodic.go.jp/bch/english/e\\_index.html](http://www.biodic.go.jp/bch/english/e_index.html)

Approved events for commercial use

Approved events for food use (in English):

<https://www.mhlw.go.jp/english/topics/food/pdf/sec01-2.pdf>

Approved stacked events for food use (exempted from review, in Japanese):

<https://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinzenbu/0000210015.pdf>

Approved events for feed use (in English):

[http://www.famic.go.jp/ffis/feed/r\\_safety/r\\_feeds\\_safety33.html](http://www.famic.go.jp/ffis/feed/r_safety/r_feeds_safety33.html)

Approved events for environmental release (in Japanese):

<http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-164.pdf>

Japan Biosafety Clearing House – List of approved living modified organisms under Cartagena Protocol domestic Law (in English):

[http://www.biodic.go.jp/bch/english/e\\_index.html](http://www.biodic.go.jp/bch/english/e_index.html)

Genome editing technology

MHLW – Foods derived from genome editing technology (in Japanese)

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryoushokuhin/bio/genomed/index\\_00012.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoushokuhin/bio/genomed/index_00012.html)

MAFF – Handling of living organisms derived from new breeding technique under Cartagena Law (in Japanese)

<http://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt.html>

MAFF – Safety of Feeds and Pet Foods (in English)

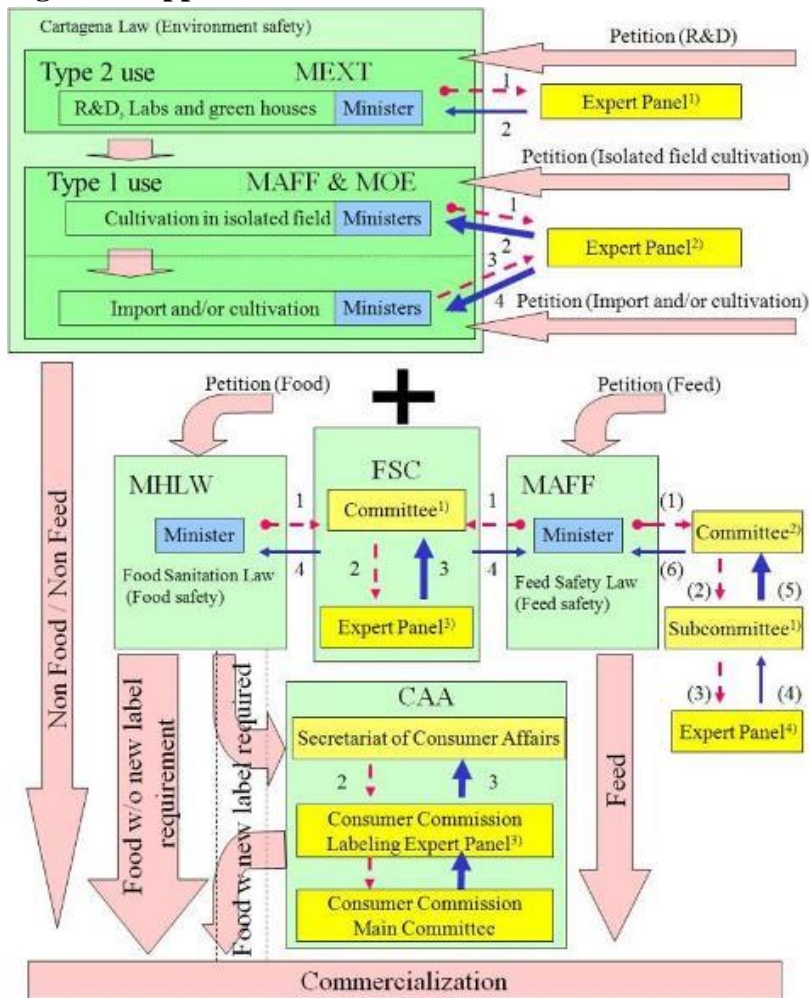
[https://www.maff.go.jp/e/policies/ap\\_health/petfood/index.html](https://www.maff.go.jp/e/policies/ap_health/petfood/index.html)

CAA – Information for the labeling of genome edited foods (in Japanese)

[https://www.caa.go.jp/policies/policy/food\\_labeling/quality/genome/](https://www.caa.go.jp/policies/policy/food_labeling/quality/genome/)

## Appendix

**Figure 1: Approval Process for GE Products**



- Type 1 Use: The use of living modified organisms (LMOs, therefore not limited to plants) outside facilities, equipment, or other constructions without containment measures
- Type 2 Use: The use of living modified organisms (LMOs, therefore not limited in plants) with containment measures
- Expert Panel 1: Expert Panel on Recombinant DNA Technology, Bioethics and Biosafety Commission, Council for Science and Technology, MEXT
- Expert Panel 2: Experts with special knowledge and experience concerning adverse effect on biological diversity selected by MAFF/MOE Ministers
- Expert Panel 3: Genetically Modified Foods Expert Committee, FSC
- Expert Panel 4: Expert Panel on Recombinant DNA Organisms, Agricultural Materials Council, MAFF
- Committee 1: Food Safety Commission
- Committee 2: Feed Committee, Agricultural Materials Council, MAFF
- Subcommittee 1: Safety Subcommittee, Feed Committee, Agricultural Materials Council, MAFF
- Red (broken) arrow: Request for review or risk assessment
- Blue (solid) arrow: Recommendation or risk assessment results (thick arrows: with public comment periods)
- Numbers beside the arrows indicate the order of requests/recommendations within the respective ministries.

**Attachments:**

No Attachments