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# **Report Name:** Agricultural Biotechnology Annual

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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. Three genome edited products developed by Japanese companies have completed the necessary consultation and notification processes and are cleared for production and distribution in the domestic market.

**Executive Summary**

Japan is a major per-capita importer 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 Marketing Year (MY) 2020/2021, Japan imported 15.5 million metric tons of corn, 3.1 million tons of soybeans, and 3.4 million tons of canola. Japan also imports billions of dollars of processed foods that contain GE-derived oils, sugars, yeasts, enzymes, and additives. Conversely, Japanese farmers do not cultivate any genetically engineered food or feed products, despite broad regulatory approval. As of September 2022, the Government of Japan (GOJ) has approved 198 products for environmental safety, including 149 approvals for domestic cultivation. The GOJ requires domestic field trials for the approval of GE grains and oilseeds.

The GOJ's regulatory approval of GE crops is important for U.S. agriculture and global food production and distribution. As a significant importer of agricultural products, GE exports not approved by the GOJ could result in significant trade disruption. The GOJ's GE regulations are largely science-based and transparent, and regulators generally review and approve new events within expected time periods that align with industry expectations for market release. As of September 2022, regulators have approved 331 products for food use.

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. 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. As of September 2022, two companies have notified the GOJ about three non-GE genome edited food products and all are commercially available in Japan.

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## CHAPTER I: PLANT BIOTECHNOLOGY

PART A: Production and Trade

*a) PRODUCT DEVELOPMENT*

In Japan, government research institutes and public universities conduct much of the agricultural biotechnology research and development. Research progresses at a slower pace than in the United States as there is limited demand for domestic application. Japanese farmers and food companies are reluctant to handle GE varieties as many GE food products come with mandatory labeling requirements and concerns over public perception persist. Annual GOJ polling shows public concern about GE products has fallen significantly over the last 10 years. However, without a demand signal for commercial GE products, product developers have little reason to seek commercialization of GE varieties developed for cultivation in Japan.

The GOJ's national project for science and technology innovation, the Cross-Ministerial Strategic Innovation Promotion Program (SIP), encouraged research of genome editing technology (JA6050). In December 2020, Sanatech Seed, an agricultural biotechnology company founded in 2018, was the first organization to complete the GOJ's voluntary notification and consultation process for genome edited products. The product, a nutritionally enhanced tomato, is now commercially available in Japan. USDA Animal Plant Health Inspection Service (APHIS) has also determined that the tomato product is not regulated under 7 CFR part 340. Public and private sector researchers, as well as joint public-private research, continue to develop genome edited products in Japan. For example, researchers at Osaka University are developing a gene edited potato to reduce toxicity levels.

Hokusan, a Japanese agrochemical manufacturer, developed a GE strawberry that produces a modified interferon for the treatment of gingivitis in dogs. The strawberries are grown commercially in a contained environment and are not harvested for consumption as food.

*b) COMMERCIAL PRODUCTION*

There is no commercial production of GE food or feed products in Japan, despite MAFF approval for the cultivation of 149 GE agricultural products. A lack of GE products developed for the Japan market and burdensome federal and local GE cultivation regulations make it almost impossible for Japanese farmers to cultivate GE agricultural products. There is a limited domestic cultivation of GE ornamental and pharmaceutical crops, however, neither the government nor the private sector release information on the scale of production.

Sanatech Seed began online sales of its nutritionally enhanced, genome edited fresh tomato after completing Japan's voluntary consultation and notification process in 2020. They also sell tomato puree made from the genome edited tomato as well as home gardening kits with six seedlings, fertilizers, and a gardening handbook.

*c) EXPORTS*

There are no GE agricultural products exported from Japan. In CY2021, Japan exported $8.6 billion of food and agricultural products, including processed products ($3.2 billion). Exported processed products may contain GE ingredients (USD=144 JPY, Link to MAFF's home page, in Japanese).

*d) IMPORTS*

Grains and Oilseeds

Japan imports almost 100 percent of its corn and over 95 percent of its oilseeds supply, much of which is GE soybean and canola. In CY2021, Japan imported 15.5 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 JA2022-0024 and JA2022-0028.

Fresh Produce

The "Rainbow Papaya," a GE papaya grown in Hawaii, is the only fresh GE product exported from the United States to Japan (JA1048).

*e) FOOD AID*

In 2021, Japan provided approximately $51 million food aid, mainly with Japanese Government reserve rice, to 25 countries and regions. 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

The GOJ requires regulatory approval prior to the commercialization of GE plant products for use as food, feed and/or environmental release depending on the nature and use of product. Four ministries play a role 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.

It is customary for regulators to first approve products for food, followed by feed, and then environment. The actual time needed for full approval varies significantly depending on each event and 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 characterize the product as familiar. For a detailed diagram of the food, feed, and biodiversity approval process, see Figure 1.

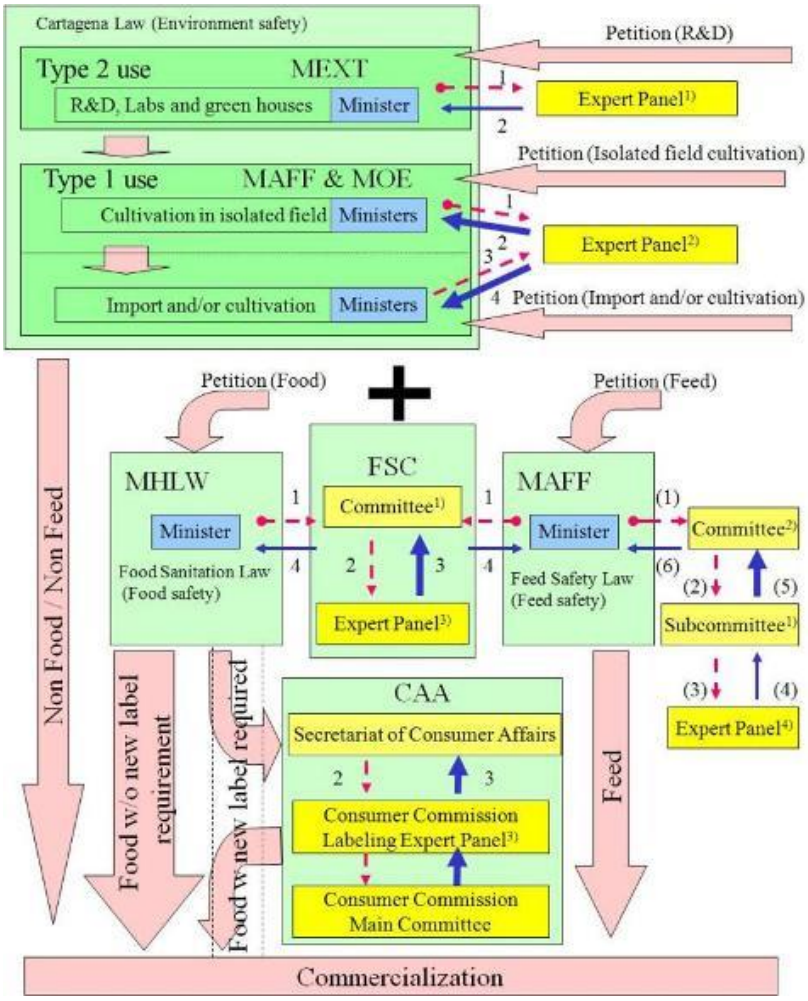
Responsible ministries use external advisors to provide scientific review and risk assessment of GE products for which developers seek approval in Japan. The advisory committees and expert panels primarily consist of researchers, academics, and representatives from public research universities, and they report their findings and recommendations to the responsible ministries for final approval.

**Table 1: GE Product Safety Review by Approval Type**

| Type of Approval | Examining body | Jurisdiction | Legal Basis | Main Points Considered |
|---|---|---|---|---|
| Food Safety | FSC | Cabinet Office | Food Safety Basic Law | • Safety of host plants, genes used in the modification, and the vectors<br>• Safety of proteins produced because of genetic modification, particularly their allergenicity<br>• Potential for unexpected transformations as the result of genetic modification<br>• Potential for significant changes in the nutrient content of food |
| Feed Safety | Agricultural Materials Council | MAFF Animal Product Safety Division | Law Concerning the Safety and Quality Improvement of Feed (the Feed Safety Law) | • Any significant changes in feed use compared with existing traditional crops<br>• Potential to produce toxic substances (especially with regard to interactions between the transformation and the metabolic system of the animal) |
| Environment/ Impact on Biodiversity | Biodiversity Impact Assessment Group | MAFF Plant Product Safety Division | Law Concerning Securing of Biological Diversity (Regulation of the Use of Genetically Modified Organisms) | • Competitive superiority<br>• Potential production of toxic substances<br>• Cross-pollination |

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

**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.

*Food Safety*
The MHLW Minister must approve GE plants intended for food use prior to commercialization in Japan. Upon receiving a petition for review from an applicant, MHLW will undertake a preliminary check of the application then request FSC complete a food safety risk assessment. Within the FSC, there is a "Genetically Modified Foods Expert Committee" that consists of scientists from universities and public research institutes who 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 set the standard processing time from the receipt of dossier to the completion of review at 12 months.

*Feed Safety*
Under the Feed Safety Act, the MAFF Minister must approve all GE products intended for feed use prior to commercialization. When MAFF receives a petition, 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 fed the GE crops under review. Based on the AMC and FSC reviews, the MAFF Minister approves the feed safety of the GE events.

*Impact on Biodiversity*
In 2003, Japan ratified the Cartagena Protocol on Biosafety. In 2004, Japan adopted the "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms," commonly referred to as 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 product developers to perform isolated field trials in Japan to collect scientific data as part of the approval process for biodiversity. MAFF and MOE must give developers permission to begin field trials required for the environmental risk assessment for the event. A joint MAFF and MOE expert panel conducts the environmental safety evaluations. MAFF set the standard processing time from the receipt of the dossier to approval to begin field trials at 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.

*Labeling*
Finally, the Food Labeling Division of the Consumer Affairs Agency (CAA) is responsible for standards or regulations not related to food safety, such as GE labeling and identify preserved (IP) handling protocols for GE products. CAA finalized the most recent revision of regulations for GE labeling in March 2019, for more see JA2019-0174.

CAA is responsible for protecting and enhancing consumer rights. MHLW is responsible for risk management procedures, such as the establishment of a detection method for GE products in food. The GOJ does not charge fees for the review of GE products.

**Table 2: Relevant Terminology**

| Legal Term (in local language) | Legal Term (in English) | Laws and Regulations where Term is Used | Legal Definition (in English) |
|---|---|---|---|
| 遺伝子組換え技術<br>(Idenshi Kumikae) | Genetic engineering | Law Concerning Securing of Biological Diversity | Technology for processing nucleic acids outside the cell Technology to fuse cells of organisms belonging to different taxonomic families |
| 組換えDNA技術<br>(Kumikae Di Enu Ei Gijyutsu) | Recombinant DNA technique | Standards for the Safety Assessment of Genetically Modified Foods | Technique that recombinant DNA molecules prepared by cleavage and recombination of DNA using enzymes or other methods are transferred to living cells for proliferation (the term refers to the techniques that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection) |
| 遺伝子組換え生物<br>(Idenshi Kumikae Seibutsu) | Living Modified Organism (LMO) | Law Concerning Securing of Biological Diversity | Living organisms created by genetic engineering |
| 第二種使用<br>(Dai Nishu Sihyou) | Type 2 Use | Law Concerning Securing of Biological Diversity | Use with the intention of preventing the spread of the LMO into the air, water, or soil outside of facilities, equipment, or other structures |
| 第一種使用<br>(Dai Isshu Shiyou) | Type 1 Use | Law Concerning Securing of Biological Diversity | Use of LMO without measures in Type 2 use (e.g., open field cultivation) |
| 宿主<br>(Shukushu) | Host | Standards for the Safety Assessment of Genetically Modified Foods | A living cell or individual organism into which DNA is transferred through recombinant DNA techniques |

| | | | |
|---|---|---|---|
| ベクター<br>(Bekuta) | Vector | Standards for the Safety Assessment of Genetically Modified Foods | A carrier DNA that transfers the target genes or DNA fragment into the host for its proliferation or gene expression |
| ドナー<br>(Donah) | Donor | Standards for the Safety Assessment of Genetically Modified Foods | A microbe, animal or plant that supplies the inserted DNA |
| ゲノム編集技術<br>(Genomu Henshuu Gijyutsu) | Genome Editing Technology | Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology | 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 |

*b) APPROVALS*

As of September 2022, Japan has approved over 331 GE products for food, 194 for feed, and 198 for environment, including 149 for environmental release, including cultivation. The 331 products approved for food does not include 35 stacked events, which are no longer subject to the safety review 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*

The GOJ requires separate environmental approvals for stacked products. MHLW exempts from review GE stacked products that use previously approved single events if the crossing of single events does not affect the metabolic pathway of the host, for more details see the FCS website (in Japanese). As of September 2022, MHLW has exempted 35 stacked products (5 soybean, 14 corn, 4 canola, and 12 cotton) 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*

The GOJ requires domestic field trials for GE products, even those with no foreseeable opportunity for environmental release or commercial cultivation. In December 2014, MAFF excluded crops that do not have wild relatives in Japan, like corn, with traits of sufficient familiarity (i.e., herbicide tolerance, insect resistance) from mandatory field trail 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 GOJ 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.

MHLW and MAFF amended procedures regarding pre-market consultations and notifications for products derived from genome edited crossbred progeny in December 2020 and April 2021, see JA2020-0214 and JA2021-0073 for more information.

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 product's authenticity of ingredients throughout supply chain. For more on CAA's labeling guidance, see JA2019-0174.

*f) COEXISTENCE*

A 2004 MAFF guideline requires that before product developers can begin a field trial, they publicly disclose detailed information about the field trial online and host meetings with nearby 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 perceived public resistance has made the planting of GE crops difficult. For additional detail, please see the guidelines for cultivation of GE crops on the MAFF website (link in Japanese).

**Table 3: Required Buffer Zone for GE Crops in Open Fields**

| **Plant** | **Minimum Isolation Distance** |
|---|---|
| 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 purposes. Local governments established many of these rules between 2004 and 2009 with limited changes since then. In addition, 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.

In July 2022, the Hokkaido Prefectural Government (HPG) amended a rule that requires prefectural approval before planting GE products for pot-grown ornamental plants. The HPG amended the ordinance and exempted ornamental plants following MAFFs approval of a GE phalaenopsis orchid developed by Ishihara Sangyo (link in Japanese). In March, MAFF completed the biodiversity risk assessment for the orchid, with enhanced blue color (OECD UI: ISK-311NR-4), and commercial distribution began in June 2022. HPG's ordinance requires prospective farmers and gardeners apply for permission from the HPG to cultivate approved GE products. The application process includes requirements to host explanatory community meetings and establish measures to prevent crossbreeding.

The HPG has never granted prefectural level approvals for GE cultivation. See JA2019-0219 for more information on other local regulations.

*g) LABELING*
Processed product manufacturers, importers, and/or retailers can make three types of GE claims on food labels in Japan: GE, non-segregated (i.e., without identity preservation), and non-GE. CAA requires GE and non-segregated product labeling. If a product is GE IP, CAA requires the food label contain a GE label. If a retailer distributes a non-IP product for which approved GE varieties exist (e.g., grains, oilseeds), CAA requires the food label to contain a non-segregated label (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 show more than five percent of GE components are contained therein, the product must be labeled as non-segregated.

CAA requires food labels to identify GE products and/or ingredients when the GE ingredient is among the top three ingredients and accounts for at least five percent of the product.

In March 2019, CAA revised labeling policy for GE foods that will come into effect on April 1, 2023. CAA will continue to recognize the current IP system used by Japanese industry but will require product labels 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. For more information please see CAA website (in Japanese). 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.

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

*i) LOW-LEVEL PRESENCE (LLP) POLICY*
Japan has a zero-tolerance policy for unapproved GE events in food and the environment, and it is explicitly illegal to import GE-derived foods that MHLW has not approved, regardless of the amount, form, or their known safety outside of Japan. For this reason, LLP of unapproved GE crops has the potential to disrupt agricultural trade with Japan. For more on Japan's LLP policy, see JA6050.

As of October 2022, MHLW monitors imported foods 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).

*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 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*
The Japan Bioindustry Association has prepared guidelines on Access and Benefit Sharing. Their target, however, are the pharmaceutical and medical industries and not agriculture.

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

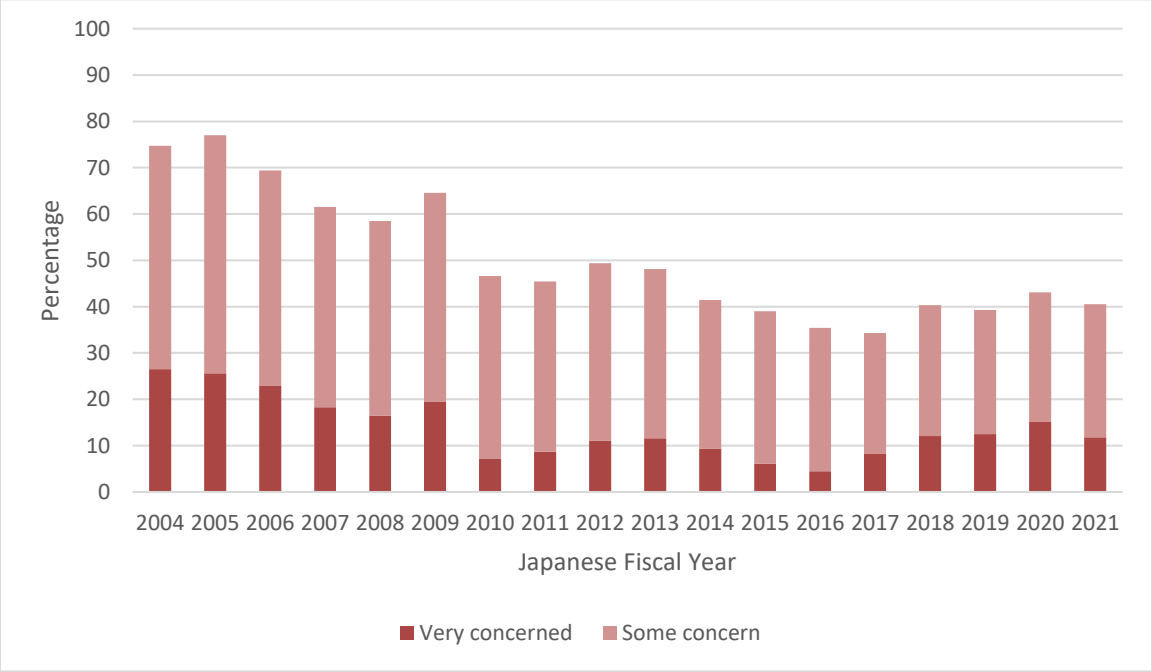
*n) RELATED ISSUES*
None.

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, through the Biotechnology Innovation Organization's (BIO), 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 perception of GE-derived products has changed. Recent GOJ survey results show that consumers concerned with GE food are now in the minority in Japan. 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 JFY2021 survey, only 41 percent of respondents were "highly concerned" or "concerned," marking a notable change in the public's concern about GE products. GE foods last appeared in the top seven food safety concerns for survey respondents in 2009. For non-GE, genome edited food products, 13 percent responded that they are "highly concerned," and 32 percent did "concerned." For more information on the FSC's annual survey, see Appendix 1 in this report.

**Figure 2: Japan Consumer Acceptance of GE Foods (2004-2021)**




Source: FSC Food Safety Monitoring (in Japanese)

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

*a) RESEARCH AND PRODUCT DEVELOPMENT*
In Japan, most molecular biology researchers focus on medical and pharmaceutical applications. As with plants, universities and public research institutions conduct much of the limited animal biotechnology research for use in food and agriculture.

In 2019, a largely academic research team behind a genome edited sea bream and pufferfish founded a startup company called Regional Fish, with private sector financial support. Regional Fish aims to revive the Japanese aquaculture industry and address a shortage of protein sources through the commercialization of genome edited aquaculture products. For more scientific and technical information on the new genome edited products, see their publication. Regional Fish also recently announced a partnership with JETRO, a quasi-governmental export assistance organization, and an Indonesian company to bring their genome editing technology to Indonesia.

Kyushu University and the Karatsu City Government are partnering to develop a genome edited mackerel grown in open water aquaculture facilities.

Japan's National Institute of Agrobiological Sciences (NIAS) continues to develop GE silkworm varieties for value-added silk production; however, its commercial application remains limited. As of October, 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. There have been no new births since 2018, and currently there is only one cattle from a fertilized-egg clone and five cattle from somatic cell cloning in Japan. For more details, see the MAFF website (link in Japanese).

*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.

As of September 2022, one company, Regional Fish, has notified MHLW of two animal food products from genome editing technology A sea bream with increased edible skeletal muscle and a fast-growing puffer fish. More details in MHLW website (in Japanese).

*c) EXPORTS*
None.

*d) IMPORTS*
None.

*e) TRADE BARRIERS*
None.

PART E: Policy

*a) REGULATORY FRAMEWORK*

GOJ 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 will apply its "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms." The Food Sanitation Act, under MHLW's supervision, covers the food safety aspect of GE animals.

In general, the technical terms used in animal are the same as plants.

*b) APPROVALS/AUTHORIZATIONS*

**Table 4: GE Animals for Commercial Use in Open Environment**

| Organisms | Product | Developer | Date of Approval |
|---|---|---|---|
| Silkworm | Green fluorescent emitting protein producing silkworm (HC-EGFP, *Bombyx mor)* (HC-EGFP Gunma, HC-EGFP 200, HC-EGFP Gunma x HC-EGFP 200, and their progenies) | National Agriculture and Food Research Organization | September 22, 2017 |
| Silkworm | Green fluorescent emitting protein producing silkworm (HC-EGFP, *Bombyx mor*) (HC-EGFP Gunma (including progeny with Gunma), HC-EGFP 200 (including progeny with 200, HC-EGFP Gunma x HC-EGFP 200, HC-EGFP Gunma x 200, Gunma x HC-EGFP 200) | National Agriculture and Food Research Organization | September 12, 2019 |
| Silkworm | Blue Fluorescent emitting protein producing silkworm (HC-Sirius, *Bombyx mori*), (GN13, GCS13, GN13 x GCS13, GN13 x MCS4, GN13 x Shi 146, Nichi 137 x GCS13) | National Agriculture and Food Research Organization | August 21, 2020 |
| Silkworm | Highi staining property silkworm (modified Fibroin H, *Bombyx mori), (*GCS500, GCS508, Chu515 x GCS500, CHu 517 x GCS508) | National Agriculture and Food Research Organization | August 21, 2020 |

*c) INNOVATIVE BIOTECHNOLOGIES*
The regulatory policies and guidelines developed by MHLW for food and MAFF for biodiversity explained in Chapter 1 apply to animals derived from genome editing technology with some exceptions.

MHLW decided that due to differences between fish raised for aquaculture versus crops and livestock, such as a shorter breeding history, greater genetic variation in species, and genetic mosaicism with CRISPR/Cas9, it would change its genome edited product consultation and notification process for fish. MHLW finalized a report titled "Note on the Handling of Fishes Obtained via Genome Editing Technology." For more detail, please see JA2021-0132.

*d) LABELING AND TRACEABILITY*
The labeling requirement for GE animals is the same as for plants. There is no mandatory labeling requirement for non-GE, genome edited products. For products derived from a cloned animal, CAA requires products to carry a cloned label. FAS/Tokyo is not aware of any commercial product with a "cloned" label.

*e) INTELLECTUAL PROPERTY RIGHTS (IPR)*
Same as for plants.

*f) INTERNATIONAL TREATIES/FORA*
Japan ratified the Cartagena Protocol on Biosafety in 2003.

*g) 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.

*b) MARKET ACCEPTANCE/STUDIES*
There are no marketing acceptance studies specific to animal 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). Other products common in the modern Japanese diet that use fermentation include yogurt, cheese, and bread. Despite widespread use, there is little public information on the scale of production of products derived from microbial biotechnology in Japan. The food industry in Japan is sensitive to consumer reaction to the use of biotechnology and labeling rules exempt the products in this category from required GE labeling, so there is little incentive to indicate if a product uses microbial biotechnology.

Industry values Japan's 2021 enzyme and yeast markets at approximately 49 billion yen (340 million USD) but there is no specific value available for enzyme and yeast derived from biotechnology.

Manufacturers of products that use microbial biotechnology (e.g., GE enzymes) are a mix of international and domestic companies. MHLW has given approval to a number of companies to use microbial biotechnology, including, Novozyme, Danisco U.S., Ezaki Glico and several other domestic companies. Lists of approved products and applicants can be found on MHLW's website.

Japanese companies make up most applicants for self-cloning, natural occurrence, and highly purified products (e.g., L-glutamine). See MHLW's website (link in Japanese) for a list of approved products and applicants.

Product developers have introduced limited alternative meat products in the Japan market. Most alternative meat products currently available on the Japanese market are soybean based. So far, meat analogue products from bacteria or single cell-based proteins are not in commercial distribution in Japan. In October 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. The Center for Rule-Making Strategies at Tama University established Japan Association of Cellular Agriculture in 2020 to promote activities and communication among stakeholders in industry, regulators, policy makers, and academia toward commercial application of cellular agriculture for medical/pharmaceutical, food, material industry, etc.

*b) EXPORTS*

In 2021, Japan exported 4,582 MT of enzymes (HS code 3507), valued at $257 million, which may include products derived from microbial biotechnology.

**Table 5: Japan Enzyme Exports (HS3507, CY2021)**

| Country | Volume (Metric Ton) | Value (Million USD) |
|---|---|---|
| Denmark | 1,422 | 18 |
| United States | 1,083 | 87 |
| China | 836 | 48 |
| Germany | 389 | 18 |
| France | 349 | 15 |
| Others | 1,720 | 117 |
| **Total** | **5,799** | **303** |

Source: Trade Data Monitor Inc.

*c) IMPORTS*

In 2021, Japan imported 4,805 MT of enzymes (HS code 3507), valued at $95 million, which may contain products derived from microbial biotechnology.

**Table 6: Japan Enzyme Imports (HS3507, CY2021)**

| Country | Volume (Metric Ton) | Value (Million USD) |
|---|---|---|
| China | 1,721 | 13 |
| Denmark | 1,324 | 27 |
| United States | 645 | 23 |
| Finland | 432 | 3 |
| Germany | 250 | 19 |
| Others | 433 | 24 |
| **Total** | **4,805** | **109** |

Source: Trade Data Monitor Inc.

*d) TRADE BARRIERS*

None.

PART H: Policy

*a) REGULATORY FRAMEWORK*

Japan's Food Sanitation Act defines food additives as (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. The GOJ considers most microbial biotechnology products as food additives. More information can be found on MHLW's website.

If product manufacturers only use the GE microorganism and its products in a contained environment for food production, the manufacturer must only seek food safety approval from MHLW. The approval process is the same as the GE food safety review process for plant and animal products. After MHLW completes a preliminary review it sends the application to FSC for the safety risk assessment. For more information on the process, please see FSC's website.

MHLW exempts food additives from the safety review when they are highly purified and do not contain foreign GE material. MHLW and FSC can exempt microorganisms from the safety review if they agree that they are self-cloning or natural occurrence. FSC has published their Safety Assessment Standards for microorganisms, food additives, food additives, and highly purified end products. More information can be found on MHLW's website (in Japanese).

In general, the technical terms used in microprobes are same as plants.

*b) APPROVALS*
As of September 2022, 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: 17 products
- Rennet: 5
- Pullulanase: 4
- Lipase: 3
- Riboflavin: 2
- Glucoamylase: 5
- Alpha-glucosyltransferase: 4
- CGTase: 1
- Asparaginase: 1
- Phospholipase: 6
- Beta-amylase: 1
- Exomalt tetraohydrolase: 2
- Acid phosphatase: 1
- Glucose oxidase: 2
- Protease: 3
- Hemicellulaze: 2
- Xylanase:5
- Beta-galactosidase: 1
- Psicose epimerase: 1
- Terpene hydrocarbons: 1
- Aminopeptidase: 1
- Alpha-Glucsosidase: 1
- Carboxypeptidase: 1
- Pectinase: 1

As of September 2022, MHLW has approved 87 products as highly purified substance, product of natural occurrence, or self-cloning. MHLW's website (link in Japanese) has the complete list of products.

*c) LABELING and TRACEABILITY*
CAA requires food labels to identify GE products and/or ingredients when the GE ingredient is among the top three ingredients and accounts for at least five percent of the product.

CAA does not require food labels to contain GE labeling for food additives. CAA does have other food additive labeling requirements, for more see JA2019-0216.

*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

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

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-Shokuhinanzenbu/0000210015.pdf

Approved events for feed use (in English):
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

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

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/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

CAA – Information for the labeling of genome edited foods (in Japanese)
https://www.caa.go.jp/policies/policy/food_labeling/quality/genome/

## Appendix

**Table: Degree of Concern for Each Hazard Perceived in Terms of Food Safety (Top 7 responses, by percentage, answering "very anxious" and "somewhat anxious") (Provisional Translation)**

| | #1 | #2 | #3 | #4 | #5 | #6 | #7 |
|---|---|---|---|---|---|---|---|
| 2004 | Contaminants (cadmium, methylmercury, arsenic, etc.) (91.7%) | Pesticide Residue (89.7%) | Antibiotics for livestock (83.5%) | Food poisoning from harmful microorganisms, viruses (80.9%) | Food Additives (76.4%) | Genetically Modified (74.7%) | BSE (74.5%) |
| 2009 | Food poisoning from harmful microorganisms, viruses (82.8%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (78.1%) | Pesticide Residue (73.1%) | Antibiotics for livestock (68.2%) | Elution of chemicals from utensils, containers and packaging (67.5%) | Genetically Modified (64.6%) | Food Additives (62.5%) |
| 2014 | Food poisoning from harmful microorganisms, viruses (82.8%) | Radioactive material (64.1%) | Health food claims (64.1%) | Pesticide Residue (58.8%) | Antibiotics for livestock (55.4%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (53.6%) | Food Additives (50.4%) |
| 2016 | Food poisoning from harmful microorganisms, viruses (82.8%) | Health food claims (61.7%) | Mold toxicity (61.5%) | Drug-resistant bacteria by antibiotics for livestock (59.1%) | Radioactive material (56.5%) | Foods containing allergenic substances (55.7%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (51.9%) |
| 2017 | Food poisoning from harmful microorganisms, viruses (82.8%) | Health food claims (63.6%) | Mold toxicity (62.0%) | Drug-resistant bacteria by antibiotics for livestock (59.1%) | Foods containing allergenic substances (57.5%) | Radioactive material (51.5%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (49.9%) |
| 2018 | Food poisoning from harmful microorganisms, viruses (82.8%) | Drug-resistant bacteria by antibiotics for livestock (66.9%) | Health food claims (64.9%) | Mold toxicity (64.6%) | Foods containing allergenic substances (61.8%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (60.9%) | Radioactive material (54.0%) |
| 2019 | Food poisoning from harmful microorganisms, viruses (82.8%) | Drug-resistant bacteria by antibiotics for livestock (66.1%) | Health food claims (62.6%) | Mold toxicity (61.9%) | Foods containing allergens (59.9%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (53.9%) | Elution of chemicals from utensils, containers and packaging (52.8%) |
| 2020 | Food poisoning from harmful microorganisms, viruses (82.8%) | Mold toxicity (72.5%) | Health food claims (60.5%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (59.4%) | Drug-resistant bacteria by antibiotics for livestock (57.4%) | Pesticide Residue (56.3%) | Elution of chemicals from utensils, containers and packaging (55.5%) |
| 2021 | Food poisoning from harmful microorganisms, viruses (82.8%) | Mold toxicity (64.1%) | Drug-resistant bacteria by antibiotics for livestock (63.9%) | Health food claims (62.9%) | Contaminants (cadmium, methylmercury, arsenic, etc.) (61.4%) | Foods containing allergens (60.5%) | Radioactive material (54.9%) |

Source: Food Safety Commission of Japan

## Attachments:

No Attachments

**Attachments:**

No Attachments