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Prepared By: Suguru Sato

Approved By: Zeke Spears

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. Japan has finalized handling procedures and labeling requirements for genome edited food and agricultural products. This report now contains a chapter on microbial biotechnology.

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 marketing year (MY)2018/2019, Japan imported 16.1 million metric tons (MT) of corn, 3.3 million MT of soybeans and 2.4 million MT 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/or other ingredients. Conversely, no genetically engineered feed or food products are produced in Japan, despite broad regulatory approval. Thus far, 187 products have been approved for environmental safety, including 141 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 disruptions. GE regulations in Japan are science-based and transparent, and new events are generally reviewed and approved within anticipated time periods that mostly align with industry expectations for market release. As of December 21, 2020, 323 products had been approved 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 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 procedures for food products. In the fall of 2020, after initial completion of its handling procedures in the fall of 2019, MHLW undertook a review of the handling guidelines for products that are derived from the crossbreeding of genome edited varieties which have already been notified to MHLW. On December 7, the Research Committee for Newly Developed Foods recommended MHLW adjust the procedures so that developers of these products are not expected to consult or notify MHLW of those products prior to commercialization in Japan. As of December 23, MHLW has not updated its handling procedures to reflect this change.

Multiple private sector entities have been established in Japan to produce and market products derived from genome editing. On December 11, MHLW and MAFF announced their determination that a genome edited tomato will not be regulated as a GE product. This is the first product to complete either ministry's consultation and notification process for verification of whether a genome edited product should be regulated as GE, for more see JA2020-0200. 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. R&D often progresses at a slower pace than in the United States because 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 varied. Without a demand signal for commercial GE products, product developers have little reason to push for the commercialization of GE varieties.

Despite this, there are some notable shifts in Japan's agricultural biotechnology private sector. Kaneka Corporation, a large chemical manufacturing company, recently announced the acquisition of Japan Tobacco Inc's plant biotechnology assets. The press release indicates the objective of the acquisition is to accelerate research and development of genome editing and conventional crop breeding.

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 levels, a less aggressive mackerel for aquaculture, and high-yield rice. Using GOJ funded research, several companies have been founded to focus on the development and marketing of products derived from genome editing. Sanatech Seed, founded in 2018, hopes to begin the commercial distribution of a genome edited, nutritionally enhanced tomato by the end March 2021, after completing Japan's notification process for genome edited products. USDA's Animal and Plant Health Inspection Agency has also 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 reported to be cultivated in Colombia. A GE strawberry that produces a modified interferon for the treatment of gingivitis in dogs has been grown commercially by Hokusan (link in Japanese) in a contained environment since 2014, but the volume of production has also not been publicly released. The strawberries are not harvested for consumption as food.

c) EXPORTS

There are no GE agricultural products exported from Japan. In 2019, Japan exported $8.4 billion of food and agricultural products, including processed products ($2.8 billion). Exported processed products may contain GE ingredients.

d) IMPORTS

Grains and Oilseeds

Japan imports almost 100 percent of its corn and 94 percent of its soybean supply, which are largely GE. In 2019, Japan imported 16.1 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 see JA2020-0163.

Fresh Produce

Since 2011, Japan has imported a limited volume of "Rainbow Papaya," a GE papaya grown in Hawaii. Rainbow papaya imports have increased in recent years as its popularity with the food service industry has grown, for more information see JA4519.

e) FOOD AID

In JFY2018, Japan provided approximately $48 million of food aid. Rice accounts for most of the food aid donated by Japan.

f) TRADE BARRIERS

Japan is one of the 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	Food Safety Commission	Cabinet Office	Food Safety Basic Law	• Safety of host plants, genes used in the modification, and the vectors • Safety of proteins produced as a result of genetic modification, particularly their allergenicity • Potential for unexpected transformations as the result of genetic modification • 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 • Potential to produce toxic substances (especially with regard to interactions between the transformation and the metabolic system of the animal)

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 • Potential production of toxic substances • Cross-pollination

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. Decisions made by these expert panels are reviewed by advisory committees, 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 that are used for food 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. The risk assessment results of GE foods are also published in English on FSC's website. FSC sets the standard processing time from the receipt of dossier to approval as 12 months.

Under the Feed Safety Act, GE products that are used as feed must obtain approvals from the MAFF Minister. 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 its evaluation is then reviewed by the AMC. 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.

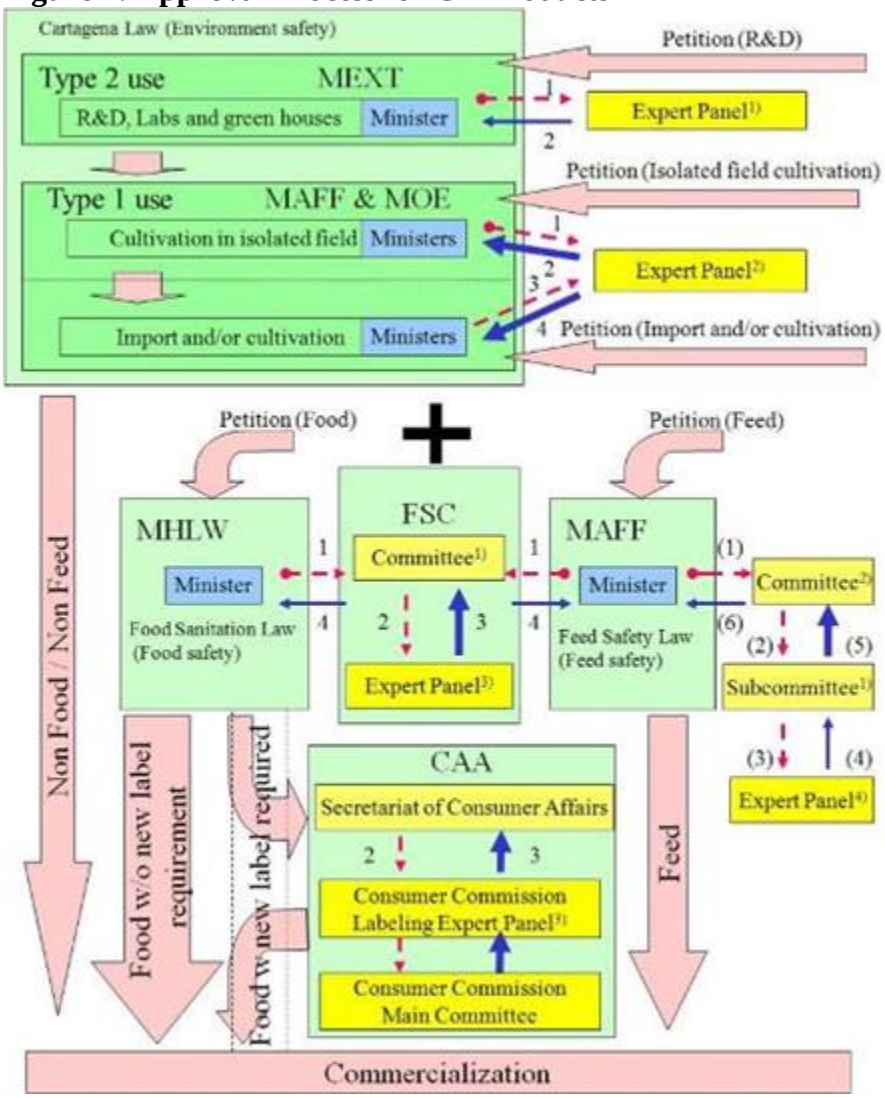
Japan ratified the Cartagena Protocol on Biosafety in 2003. In 2004, Japan adopted the "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms," also called the "Cartagena Law," to implement the Protocol. Under this law, 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. The necessary scientific data is collected through isolated field trials. With permission from the MAFF and MOE

Ministers, an environmental risk assessment for the event, including field trials, is conducted. 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 approval to first be given 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 18 months of formal acceptance of the dossier for food, feed, and environmental release if the product can be characterized as familiar.

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. The following is a schematic chart of the flow of the approval process for GE products. There are no processing fees charged by any GOJ ministry for the review.

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.

b) APPROVALS
As of December 2020, Japan has approved over 323 GE products for food, 185 for feed, and 188 for environment, which include 141 for environmental release, including commercial planting for most products. The number of products approved for food does not include 34 stacked events, 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 as long as 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. As of December, 2020, 34 stacked products 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's requirement for 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 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. 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. Developers who wish to commercialize their products in Japan are strongly encouraged to adhere to relevant handling producers. For more on genome editing handling procedures in Japan, see JA2020-0184. For details on the development of Japan's genome editing handling procedures, see JA2019-0219.

On September 15, MHLW commenced a series of expert panel meetings to review possible updates to its handling procedures, particularly the section on crossbred progeny. On December 7, the Research Committee for Newly Developed Foods recommended that MHLW adjust the procedures so that developers of products that are derived from the crossbreeding of genome edited varieties which have already been notified to MHLW are not expected to consult or notify MHLW of these products prior to commercialization in Japan. As of December 23, MHLW has not updated its handling procedures to reflect this change.

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 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

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 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 "5 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. Tests results are published annually on MAFF's website.

i) LOW-LEVEL PRESENCE (LLP) POLICY

There have been no changes to Japan's LLP policies (JA6050). As of March 2020, MHLW monitors for the following items:

- PRSV-YK, PRSV-SC and PRSV-HN (papaya and its processed products, if papaya can be isolated for analysis. Monitored 299 cases in JFY2019.)
- 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. Monitored 299 cases in JFY2019.)
- RT73 B. rapa (canola and its processed products. Monitored 29 cases in JFY2019.)
- MON71100/MON71300, MON71700 and MON71800 (U.S. wheat. Monitored 59 cases in JFY2019. Also, regulatory authority, MHLW and/or port officials, may request inspection of specific shipments.)
- MON71200 (Canadian wheat. Monitored 59 cases in JFY2019. 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. Monitored 59 cases in JFY2019)
- AquAdvantage (salmon and its processed products, such as salmon flakes, from Canada, Panama and the United States. Monitored 59 cases in JFY2019).

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 (JBCH) 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.

There are many Japanese researchers, members of the media, and pro-science citizens that understand the benefits of GE products. Throughout 2019 and 2020, a group of scientists and risk communicators hosted viewings of Food Evolution (link in Japanese), with subsequent discussions and Q&A sessions with the audience about the documentary. The events have been well attended and covered by multiple domestic media outlets, including Japan Agriculture.

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 2006, a survey conducted by FSC (in Japanese) found 75 percent of participants were "highly concerned" or "concerned" with GE food. However, in the 2019 survey, 12.5 percent responded that they were "highly concerned" and 26.8 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 is focused on human medical and pharmaceutical purposes. Like with plants, the limited food and agricultural biotechnology research is mostly done by universities and public research institutions, 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.

A team of researchers, representing multiple Japanese universities, have developed a genome edited sea bream and puffer fish that are expected to undergo Japan's new genome edited product notification process. The research team 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 September 2020, Japan has approved 10 GE silk worms.

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 production.

c) EXPORTS
None.

d) IMPORTS
None.

e) TRADE BARRIERS
None.

PART E: Policy

a) REGULATORY FRAMEWORK
The same regulation for GE plants is applied for 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
Like plant biotechnology, the major player in animal biotechnology is the public sector, which receives financial support from the government. Like plant biotechnology, the interest of animal biotechnology researchers has shifted to the application of genome editing technologies. Research to increase skeletal muscle in red sea bream, grow pufferfish faster, and developing a tuna with reduced aggressiveness for aquaculture has been covered extensively by the media.

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.

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. 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 is no marketing activity specific for livestock animal biotechnology.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY
PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION
Japan has a number of traditional foods that rely on fermentation including soy sauce, *natto* (fermented soybeans), *miso* (soybean paste), and *sake* (or *nihonshu*, 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 the products in this category are exempted from the mandatory GE labeling requirement. Therefore, there is little incentive to indicate if your product uses microbial biotechnology.

Based on industry reports, Japan's enzyme and yeast markets in 2019 was approximately 50.5 billion yen ($468 million). Manufacturers of direct products of microbial biotechnology (e.g., GE enzymes) are mix of international and domestic companies. Major international companies, including Novozymes, Danisco U.S., and Ezaki Gulico, and several domestic companies have received approval for their microbial biotechnology products. Lists of approved products and applicants can be found on MHLW's website (link in Japanese).

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

Limited alternative meat products have been introduced in Japan. 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 "Joint Food Technology Conference by Public and Private Sectors" (link in Japanese) for the promotion of cross-sectorial collaboration, but the conference was not open to the general public.

b) EXPORTS
In CY2019, 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, CY2019)

Country	Volume (Metric Ton)	Value (million USD)
United States	919	76
Denmark	709	14
China	438	33
Netherlands	420	7
Germany	305	13
Others	1,791	114
Total	**4,582**	**257**

Source: Trade Data Monitor Inc.

Japan also exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived products.

c) IMPORTS
In CY2019, 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, CY2019)

Country	Volume (Metric Ton)	Value (million USD)
China	2,030	15
Denmark	1,129	22
Finland	893	7
United States	556	8
Germany	163	18
Others	437	25
Total	**5,208**	**95**

Source: Trade Data Monitor Inc.

Microbial biotech-derived products for food are likely in imports of alcoholic beverages, dairy products, and processed products, where these products are commonly used in food production.

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, the dossier is accepted by MHLW and then proceeds to FSC for the safety risk assessment. More for information on the process, please see FSC's website.

When the products are highly refined or purified and do not contain GE materials, Japan has a separate review system. Also, when the microorganisms producing food and food ingredients are considered to be self-cloning or natural occurrence, the scientific safety review is exempted, for more see JA4005.

FSC has published their Safety Assessment Standards for microorganisms, food additives, and highly purified end products.

b) APPROVALS

As of November 2020, Japan has approved 47 food additive ingredients derived from GE technologies. Approved products can be found on MHLW's website and are listed below:

- Alpha amylase: 10 products
- Rennet: 4
- Pullulanase: 4
- Lipase: 3
- Riboflavin: 2
- Glucoamylase: 3
- Alpha-glucosyltransferase: 3
- CGTase: 1
- Asparaginase: 1
- Phospholipase: 4
- Beta-amylase: 1
- Exomalt tetraohydrolase: 2
- Acid phosphatase: 1
- Glucose oxidase: 1
- Protease: 2
- Hemicellulaze: 1
- Xylanase:1
- Beta-galactosidase: 1
- Psicose epimerase: 1
- Terpene hydrocarbons: 1

As of September 2020, 84 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 ingredients 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

Information related to GE food regulations
Ministry of Health, Labor and Welfare
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.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/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html
Error! Hyperlink reference not valid.
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):
https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/index.html#1
Error! Hyperlink reference not valid.
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/

Attachments:

No Attachments