Required Report: Required - Public Distribution **Date:** March 30,2020

Report Number: JA2019-0219

Report Name: Agricultural Biotechnology Annual

Country: Japan

Post: Tokyo

Report Category: Biotechnology and Other New Production Technologies

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. The Government of Japan has completed and published guidelines for the handling of genome edited food and agricultural products in Japan.

Executive Summary

Japan remains one of the world's largest per-capita importers of food and feed produced using modern biotechnologies. In 2019, Japan imported 16 million metric tons of corn, 3.2 million tons of soybeans, and 2.4 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/or other ingredients. As such a significant buyer of GE food and agricultural goods, regulatory approval of genetically engineered products by the Government of Japan (GOJ) is important for U.S. agriculture as well as global food production and distribution. GE exports not approved in Japan could result in significant trade disruptions.

The GOJ's regulations for GE products are science-based and generally transparent, and new events are generally reviewed and approved for market release within anticipated time periods that mostly align with industry expectations. As of March 27, 2020, Japan has approved 322 GE products for food. In addition to managing the review process more efficiently than in previous years (e.g., exempting breeding-stacked GE events that use pre-approved single events from scientific review), Japan's increased familiarity with products using common transgenes has contributed to more prompt reviews. Nevertheless, Japan, may encounter self-imposed regulatory challenges because some developers may not have the resources to obtain regulatory approval in countries other than the country of production. This could limit Japan's ability to purchase from a country where a new product or technology has been commercialized. As one of the world's largest per-capita importers of GE crops, improvement to the Japanese GE regulatory system that are focused on long-term trends in biotechnology and risk-based management will benefit all stakeholders.

Thus far, 186 events have been approved for environmental safety, which include 141 approvals for commercial cultivation. However, there is still no commercial cultivation of GE food products in Japan. A GE rose, released by Suntory in 2009, is the only GE crop commercially cultivated in Japan.

Throughout 2019 and early 2020, Japanese regulators completed the handling guidelines for genome edited food and agricultural products. These guidelines provide the commercialization pathway for developers who wish to commercialize their products in Japan. The Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Agriculture, Forestry, and Fisheries (MAFF) convened committees of technical experts to provide guidance throughout development of the guidelines, held public comment periods, and published their respective guidelines for genome edited food and agricultural products. Researchers in Japan have developed a few genome edited plant products, but none are commercially available.

There is limited applied research and development of animal biotechnology in Japan, and most activities remain in the area of basic research. The GE silkworm for veterinary drug production is one of the few examples of commercial application of GE animals in Japan. Researches are developing a genome edited seabream, but it is not yet commercially available.

Table of Contents

CHAPTER I: PLANT BIOTECHNOLOGY

PART A: Trade and Production

a) PRODUCT DEVELOPMENT

Japanese biotechnology research and development (R&D) progresses at a slower pace than in the United States. Most agricultural biotechnology R&D in Japan is conducted by the public sector through government research institutes and universities. One reason for the slower pace is the cautious attitude towards consumer acceptance of GE products. Japanese retailers and food manufactures take a conservative approach towards the use of products which require GE labeling, even for products with consumer-facing benefits. Another factor limiting adoption is peer to peer pressure in the agricultural community. For example, a farmer interested in the cultivation of GE crops might not plant GE products due to perceived opposition from neighboring farmers. Japan's mandatory GE labeling requirements, updated and released in April 2019, can also discourage manufacturers and retailers from developing products with GE ingredients (see JA2019-2551). Another hurdle are the regulations by local governments that discourage farmers from being the first to cultivate GE food or feed in a country where social "harmonization" is highly respected.

Nevertheless, there are Japanese researchers, members of the media, and pro-science citizens that understand the benefits of GE products. For example, in February 2019, the "Food Communication Roundtable Council", a consumer organization for science-based risk communication, held a meeting to discuss the future of a GE rice product that produces a therapeutic vaccine against Japanese Cedar pollen allergy (http://food-entaku.org/, link in Japanese). The product has been seeking regulatory approval in Japan for more than ten years. Although researchers collaborated with medical institutions and reported the successful mitigation of the allergy, the product was not reviewed as a "food" due to its medical efficacy.

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 include a nutritionally enhanced tomato, a potato with reduced toxin, a less aggressive mackerel for aquaculture, and high yield rice (https://www.nhk.or.jp/gendai/articles/4331/index.html, link in Japanese).

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. A GE strawberry that produces a modified interferon has been grown commercially by Hokusan in a contained environment since 2014, but the volume of production has also not been publicly released (http://www.hokusan-kk.jp/product/interberry/index.html, link in Japanese). The strawberries are not harvested for consumption as food.

Although there are still consumer groups actively campaigning against GE products, the public's perception of the risk posed by GE products is decreasing, possibly due to less negative media coverage and a better understanding of Japan's reliance on imported GE grain and oilseeds (http://www.fsc.go.jp/monitor/monitor_report.html, link in Japanese). The increased media coverage of genome editing technology over the past 12 months has the capacity to create renewed consumer anxiety for agricultural biotechnology products.

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) and livestock products ($598 million). Exported processed products may contain GE ingredients. Japanese livestock production relies on imported feed, which includes GE or "non-segregated" feed corn.

d) IMPORTS

Grains and Oilseeds

Japan imports of almost 100 percent of its corn and 94 percent of its soybean supply, most of which are GE. In 2019, Japan imported 16 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 may now be non-segregated or GE, but there are no official statistics available. For more information on the import of grains and oilseeds see JA2020-0058 and JA9033.

Table 1: Japanese Total Corn Imports

(1,000 MT – 2019)	
Corn for food and feed	
United States	10,957
Brazil	4,682
Argentina	238
Russia	92
India	7
All others	11
Total	15,986

Source: Trade Data Monitor

Fresh Produce
Since 2011, there has been a limited volume of "Rainbow Papaya," a GE papaya grown in Hawaii and exported to Japan. Rainbow papaya imports have increased in recent years as its popularity within the food service industry has grown.

e) FOOD AID
Japan is not a recipient of food aid.

In JFY2017, Japan provided approximately $54 million of food aid. Rice accounts for the majority of food aid donated by Japan (https://www.mofa.go.jp/policy/oda/page_000029.html).

f) TRADE BARRIERS
Japan remains one of the world's largest per-capita importers of GE products and has no significant trade barriers.

PART B: Policy

a) REGULATORY FRAMEWORK
In Japan, the commercialization of GE plant products requires food, feed and environmental approvals. Four ministries are involved in the regulatory framework: MAFF, MHLW, 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 assessment for MHLW and feed safety risk assessments (in terms of human consumption of livestock products grown with GE feed) for MAFF.

Table 2: Ministries Responsible for Safety Review of GE Products

Type of Approval	**Examining body**	**Jurisdiction**	**Legal Basis**	**Main Points Considered**
Safety as food	Genetically Modified Foods Expert Committee	FSC, 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
Safety as animal feed	Agricultural Materials Council	Animal Product Safety	Law Concerning the Safety and Quality	• Any significant changes in feed use compared with existing traditional crops

		Division, MAFF	Improvement of Feed (the Feed Safety Law)	• 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	Plant Product Safety Division, MAFF	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 (http://www.japaneselawtranslation.go.jp/law/detail_main?id=12&vm=2&re), 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 (http://www.fsc.go.jp/english/evaluationreports/newfoods_gm_e1.html). 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.

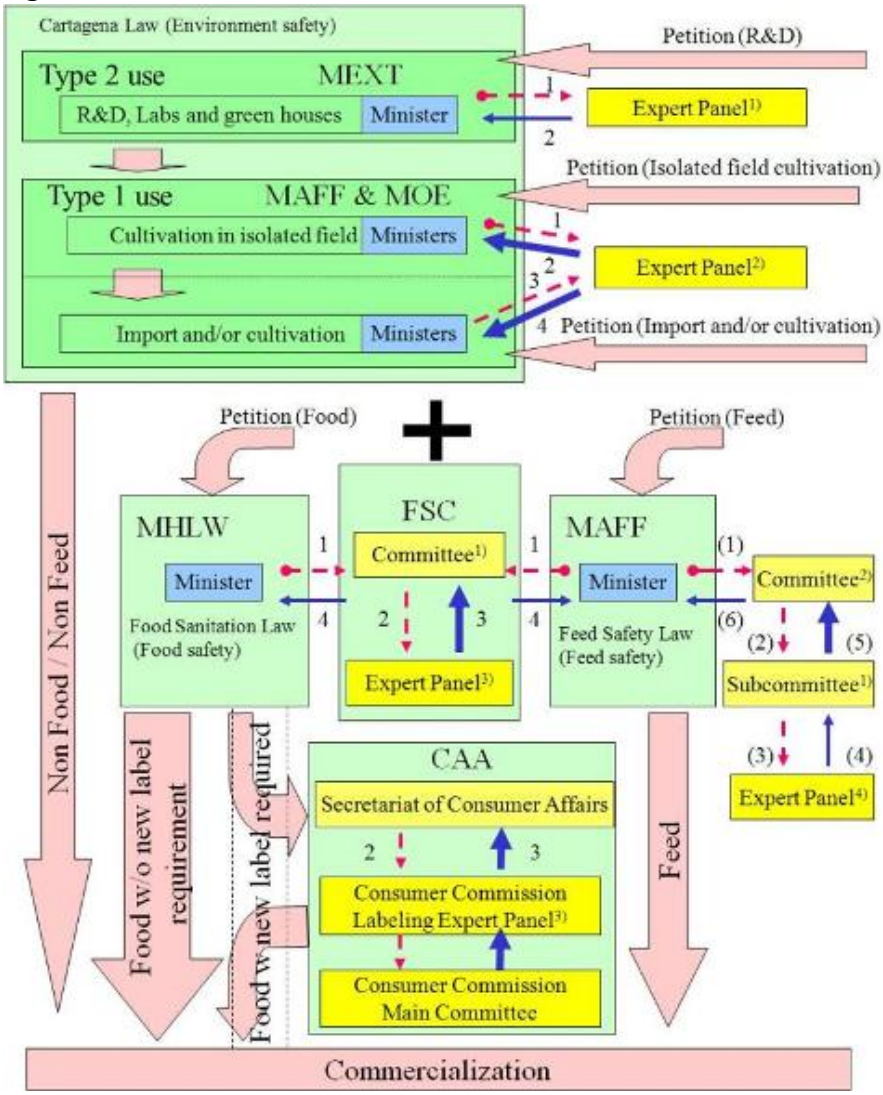
The necessary scientific data is collected through isolated field trials. With permission from the MAFF and MOE Ministers, an environmental risk assessment for the event, including field trials, is conducted. A joint MAFF and MOE expert panel carries out the environmental safety evaluations. MAFF sets the standard processing time from the receipt of dossier to approval as six months (for more information, see http://www.maff.go.jp/j/syouan/nouan/carta/c_about/attach/pdf/reg_2-27.pdf, 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.

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 (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: GOJ's Review 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 March 27, 2020, Japan has approved over 322 GE products for food, 179 for feed, and 185 for environment, which include 141 for environmental release, including commercial planting for most products. Please see the reference section at the end of this report for a list of approved events. The number of events approved for food does not include 28 stacks, which no longer go through the regulatory approval process.

c) STACKED or PYRAMIDED EVENT APPROVALS

As a basic principle, Japan requires separate environmental approvals for stacked events. However, Japan has made improvements to the approval process for some stacked events. In 2014, MHLW exempted 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 plant. Furthermore, on December 22, 2017, the FSC's Expert Panel agreed to exempt stacked products using single events with the modified metabolic pathway from review (http://www.fsc.go.jp/senmon/idensi/index.data/gm_taisha_kaihen_kakeawase.pdf, link in Japanese). The update was made after the Expert Panel reviewed six cases of stacked events and found no rationale for a food safety concern. As of March 27, 2020, a total of 28 stacked events have been exempted from review; four soybean, 15 corn[1], two canola, and seven cotton (https://www.mhlw.go.jp/content/11130500/000513500.pdf, link in Japanese). 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 event approvals, see JA7138.

d) FIELD TESTING

Japan's basic rule requiring 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, such as corn, with traits of sufficient familiarity, such as herbicide tolerance or 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 (http://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/plant_proced.html#2, link in Japanese[2]). For additional information on field trials, see GAIN Report JA6050.

e) INNOVATIVE TECHNOLOGIES

In August 2018, MOE held an Environmental Safety Advisory Panel meeting on "GMOs" to discuss the handling of genome editing technology under the Cartagena Protocol on Biosafety (see JA8048). The advisory panel concluded that any living organism with foreign nucleotide(s) remaining in the host genome should be regulated. In February 2019, MOE concluded that when an organism is not obtained by inserting nucleic acid that was processed extracellularly,

[1] The total decreased from last year because an applicant retracted a notification.

[2] It says "Regarding GE corn and cotton with known mode of action from past review, MAFF will compare the structure and mode of action of the recombined gene with what has been approved in the past and determine whether the review is possible based on past data or data obtained outside of Japan. Then, the decision can be made from past review, the isolated field test would be exempted".

the organism is not considered a living modified organism (LMO), as specified in the Cartagena Act (see JA9024). This decision provided the framework policy for the handling of living organisms derived from genome editing technology.

Regulatory agencies where charged with developing the necessary policies and procedures for handling genome edited products that fall within their purview. MHLW developed guidelines for organisms derived from genome editing technology for food and food additives. MAFF developed guidelines for genome edited products for use as feed and feed additives. MAFF also developed separate guidelines to prevent adverse effects to biological diversity by genome edited food and agricultural products. Product developers are requested to follow the relevant guidelines before commercializing genome edited products in Japan. Developers should consider addressing all three commercialization pathways for their product, depending on how it might be used in Japan. See Attachment 1 for a summary table of the GOJ's genome edited product policies and procedures.

In October 2019, MAFF's Plant Products Safety Division published final guidelines on the "Specific Information Disclosure Procedures of Living Organisms Obtained through Use of Genome Editing Technology in Agriculture, Forestry and Fishery Fields" (JA2019-0196). The guidelines detail the process for disclosing information regarding adverse effects on biological diversity for products under MAFF's jurisdiction with respect to productions and distribution, prior to commercialization in Japan. Developers are requested to initially submit information for a "Pre-consultation" for MAFF to determine if the product is or is not an LMO and should undergo either the required LMO safety review or further notification to MAFF. If the product is determined to not be an LMO, then the guidelines provide detailed instruction for the notification process. LMOs will be required to undergo the relevant review detailed in the Policy section of this report.

In February 2020, MAFF's Animal Products Safety Division released the final guidelines for the handling of genome edited feed and feed additives (JA2020-0034). These guidelines provide guidance to developers seeking to commercialize genome edited feed and additives. Like the biological diversity guidelines, developers are requested to provide preliminary information for MAFF to make a determination on if the product should be handled as an LMO or not. If the product is determined to not be an LMO, the developer is requested to follow the notification requirements detailed in the guidelines.

In October 2019, MHLW released the final guidelines for the handling of genome edited food and food additives (JA2019-0011). Like both sets of guidelines from MAFF, developers are requested to provide initial information for MHLW to determine if the product should be handled as a genetically engineered product or not. MHLW, with consideration from academic experts as needed, determines if the product should undergo the food safety approval process required of GE food products. If this is not required, then developers are requested to complete the notification process detailed in the guidelines.

MAFF and MHLW's guidelines are largely in alignment and based on science. However, there are key differences in how the regulators determine if a product is eligible for notification or if it must undergo a more significant safety review required of GE products. A lengthier, GE product safety review required of one, but not all, of the genome edited guidelines could lead to confusion for developers and delay commercialization of new genome edited technologies. Neither MAFF nor MHLW have expressed how long developers should expect the consultation response or publication of information gathered through the notification process to take.

The handling of crossbred progeny in each of the guidelines is different and the requirements are not completely science based. Each of the three genome editing guidelines indicate the developers of products derived from crossbred progeny (products with at least one non-GE genome edited parent and one conventional or GE parent) must undertake a separate consultation or notification process for each product derived from crossbred progeny. This is not consistent with the science-based protocols for GE crossbred progeny products, which do not require separate notifications. This is likely to create considerably more consultations and notifications as developers begin to license genome edited products for the express purpose of crossbreeding products to fit their production needs.

In September 2019, CAA published guidance that stipulates 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 (JA2019-0174).

The GOJ's "Cross-Ministerial Strategic Innovation Promotion Program (SIP) has encouraged researchers to work on new agricultural technologies, including genome editing technology. SIP has provided financial support to the researchers in the field of biology but also to researchers and organizations specializing in social sciences in order to increase public understanding of the technology.

Examples of genome edited research in Japan:

- High yield rice – Researchers "knocked out" the function of the specific gene and achieved yield increase by increasing grain size and number (http://science.sciencemag.org/content/353/6305/aaf8729.long). Researchers planted genome edited rice in May 2019 and harvested in November 2019 (https://www.naro.affrc.go.jp/laboratory/nias/gmo/news/gene_recombination/132911.html, link in Japanese).
- Potato without production of toxic substance – Researchers "knocked out" a gene in biosynthesis pathway of toxic substances, steroidal glycoalkaloids (SGAs) alpha-solanine, and alpha-chaconine, achieving a potato with reduced SGA (https://www.sciencedirect.com/science/article/abs/pii/S0981942818301840).

- Parthenocarpic (seedless) tomato – Researchers made a mutation to a hormone related gene influencing fruit set and created a tomato plant, which can set fruit without pollination under environmental stress condition.
- Nutritionally enhanced tomato – Researchers deleted a domain for glutamate decarboxylase, a key enzyme in γ-Aminobutyric acid (GABA) biosynthesis in tomato. A conventional tomato contains GABA at lower concentration. Enhanced levels of GABA shows blood-pressure-lowing function(https://www.ncbi.nlm.nih.gov/pubmed/28765632).

The second phase of SIP provides funding for translation research and public acceptance of genome editing technology in agriculture (https://bio-sta.jp/, link in Japanese).

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 in order to prevent related plant species in the surrounding environment from cross-pollinating (see Table 3). For additional detail, please see the guidelines for cultivation of GE crops provided by MAFF at www.naro.affrc.go.jp/archive/nias/gmo/indicator20080731.pdf, link in Japanese.

In theory, conventional and GE crops can co-exist. However, restrictive local regulations and public resistance has made the planting of GE crops extremely difficult in Japan.

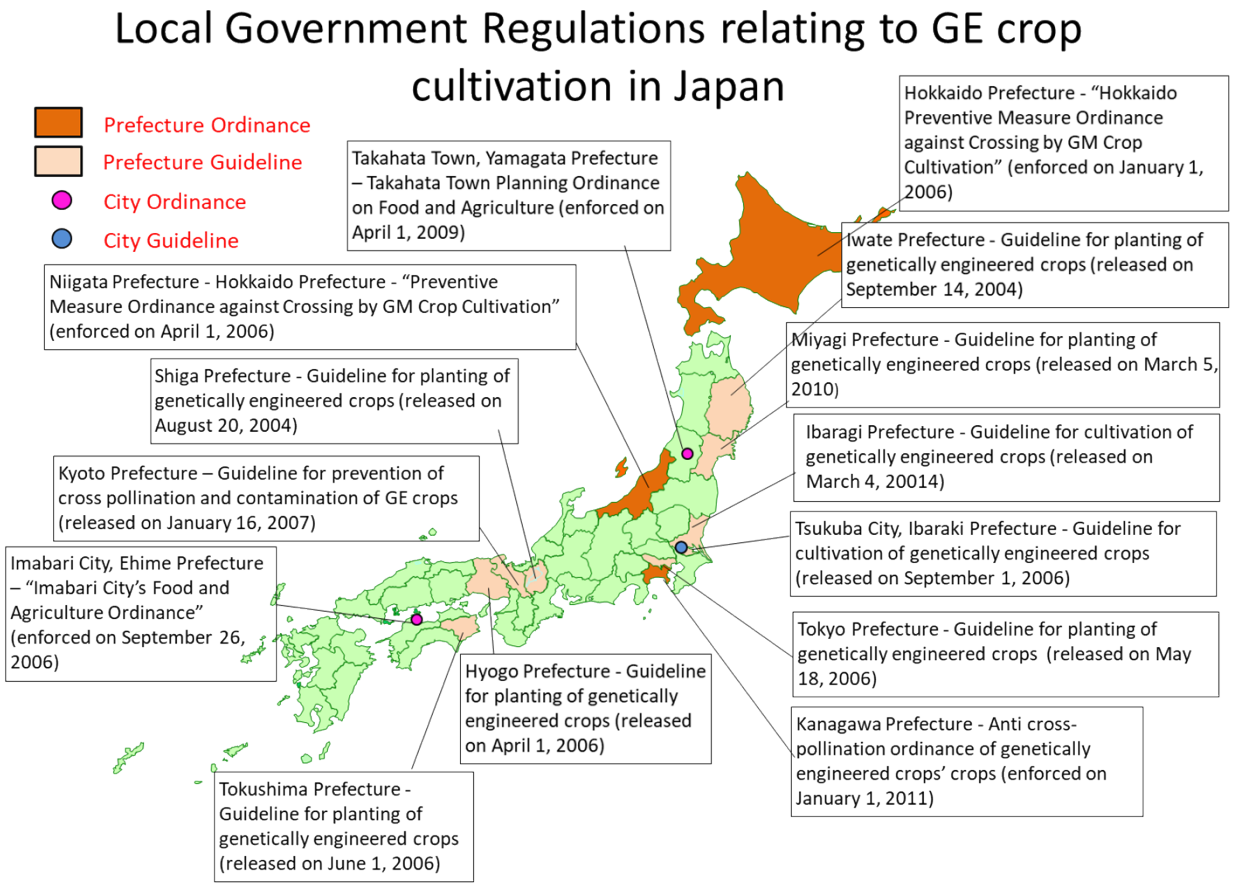
Table 3: Required buffer zone to GE crops in open fields

Name of the field-tested plant	**Minimum isolation distance**
Rice	30 meters
Soybeans	10 meters
Corn (applicable only on those with food and feed safety approvals)	600 meters or 300 meters with the presence of a windbreak
Rapeseed (applicable only on those with 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

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 even argue that foods containing GE ingredients should not be used in local school lunch (Imabari City's Food and Agriculture Ordinance

https://www.city.imabari.ehime.jp/reikishu/reiki_honbun/r059RG00000848.html, link in Japanese).

Figure 2: Local Government GE Crop Regulations



Source: Dr. Yoshiko Sassa, Life and BioPlaza 21 (http://www.life-bio.or.jp/, link in Japanese)

For additional information on local government regulations, please see JA6050.

g) LABELING

As previously noted, food labeling requirements, including GE labeling, are handled by the CAA. In April 2017, the CAA initiated a review of Japan's GE labeling requirements and focused on three specific topics for review: 1) the types of foods to be labeled, 2) the threshold for requiring GE labeling, and the 3) the appropriateness of "non-GE" labeling. On March 14, 2018, the CAA's Expert Committee concluded its review and proposed: 1) "Non-GE" labeling will be allowed only when there is no detection of GE, 2) identity preserved (IP) products with inadvertent GE content of up to five percent (had been permitted to be labeled as "non-GE") should have a new description, such as "Identity preserved to avoid commingling of GE ingredient," to more precisely represent the products, and 3) non-IP-ed products (currently described as "non-segregated") should have a different description to more precisely represent the products. For additional information, see GAIN Report JA8017.

On October 20, 2018, the CAA's Food Labeling Committee initiated a discussion to validate the proposals from its Expert Committee. Simultaneously, Japan established a public comment period for domestic interested parties and notified foreign trading partners via the World Trade Organization (see G/TBT/N/JPN/608) of its intention to revise its GE labeling requirements. Most of the discussion to validate the proposed changes from the Expert Committee review will occur after the public comment period closes and after the comments submitted are reviewed by the CAA.

In March 2019, CAA finalized the revised labeling policy for GE foods (see JA9055). 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 foreign DNA content is detectable, effectively establishing a zero tolerance for GE components. The new GE labeling regulations will be effective on April 1, 2023 (https://www.caa.go.jp/policies/policy/food_labeling/other/review_meeting_010/, link in Japanese).

h) MONITORING AND TESTING

The GOJ monitors volunteer plants to assess the effect on biodiversity of environmental release of a GE crop. MAFF's annual report includes a survey conducted in the vicinity of ports where canola and soybeans were unloaded from carrying vessels (see http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/index.html#2, link in Japanese). Monitoring results have remained relatively unchanged, and there have been some findings of voluntary growth of GE canola, soybean, corn, and cotton plants dropped during the unloading process from arriving vessels. However, there no evidence of the GE plants harming biodiversity or sustainably surviving through multiple generations.

For the purpose of detecting 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. There was once a concern that non-GE corn being exported to Japan could be tested and mistakenly determined as being GE or non-segregated if the test result indicates more than five percent GE product in the shipment. However, current standards and specifications for the testing of GE product in conventional shipments that MHLW first implemented in November 2009 allayed these concerns (JA6050).

i) LOW-LEVEL PRESENCE (LLP) POLICY

There have been no changes to Japan's LLP policies (JA6050).As of March 2020, 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. 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. However, 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. A provisional translation of the "Implementing Guidelines for Inventions in Specific Fields - Chapter 2 Biological Inventions" can be found online at https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/document/tukujitu_kijun_0930/7_2.pdf.

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" (the Supplemental Protocol, see JA8007). This and other laws implementing the protocol may be found on the Japan Biosafety Clearing House (J-BCH) website (see http://www.biodic.go.jp/bch/english/e_index.html).

m) INTERNATIONAL TREATIES/FORA
Japan is also active in the area of Access and Benefit Sharing (ABS). The Japan Bioindustry Association has provided seminars to the industry and prepared guidelines on ABS (http://www.mabs.jp/eng/index.html). Their target, however, is geared more towards the pharmaceutical and medical industries rather than agriculture.

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

n) RELATED ISSUES
None at this time.

PART C: Marketing

a) PUBLIC/PRIVATE OPINIONS
In a very real sense, Japanese regulators can act as 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 (https://www.bio.org/articles/product-launch-stewardship-food-and-agriculture-section).

b) MARKET ACCEPTANCE/STUDIES
Recent survey results indicate that concerns related to GE food have diminished. In the 2006 Japan Fiscal Year (JFY), FSC's Food Safety Monitor survey found 75 percent of participants were "highly concerned" or "concerned" with GE food. However, in the JFY2018 survey, only 12.1 percent responded that they were "highly concerned" and 28.2 percent responded "concerned", marking a significant change in public acceptance of GE products (http://www.fsc.go.jp/monitor/monitor_report.html, link in Japanese).

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

a) PRODUCT DEVELOPMENT
Most research in molecular biology in animals is focused on human medical and pharmaceutical purposes in Japan (see the development of cancer immunotherapy from Dr. Tasuku Honjo, winner of the Nobel Prize in Medicine). Like plant biotechnology, this research is mostly operated by universities and government/public research institutions, with limited involvement by the private sector in Japan. Again, like crop agriculture, the non-involvement of the private sector seems to be partially related to the public reaction towards modern biotechnology, especially regarding the genetic transformation of animals.

In traditional biotechnology, GE silkworm was the first commercial application of animal biotechnology in Japan. Japan's National Institute of Agrobiological Sciences (NIAS) has been working on the development of GE silkworm for the production that creates a high-staining, fluorescent, glowing silk. In September 2019, NIAS received another approval to grow GE silkworm in an open environment (http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-200.pdf, link in Japanese).

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 (see http://www.affrc.maff.go.jp/docs/clone/kenkyu/clone_20190331.html , 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 GE silkworms. The Gunma Prefecture Silkworm Technology Center, Japan's National Agriculture and Food Research Organization, and farmers in Gunma Prefecture continue to grow GE silkworms that produce green fluorescent protein (HC-EGFP, *Bombyx mori*). For more information, https://www.pref.gunma.jp/07/p14710007.html and http://www.naro.affrc.go.jp/laboratory/nias/introduction/chart/0202/index.html (links in Japanese).

c) EXPORTS
None.

d) IMPORTS
None.

e) TRADE BARRIERS
None.

PART E: Policy

a) REGULATORY FRAMEWORK
The same regulation for GE plants will be applied for 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, and animal biotechnology researchers have shifted their interest to the application of genome editing technologies. Research to increase

skeletal muscle in red sea bream, reduce production time for pufferfish, and to reduce aggressiveness in aquaculture tuna has been covered extensively by Japanese media. However, research remains in the early stages of development. Much of the research is supported by SIP, http://www8.cao.go.jp/cstp/panhu/sip_english/sip_en.html.

The regulatory policies and guidelines developed by MHLW for food and environmental safety explained in CHAPTER I: PLANT BIOTECHNOLOGY 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 (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 (https://www.naro.affrc.go.jp/collab/cllab_report/docu/report24.html, link in Japanese). 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 significant marketing activity in livestock animal biotechnology.

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

Food Labeling Law, Government Ordinance, Ministerial Ordinance and Notifications
http://www.caa.go.jp/foods/index18.html (in Japanese only)

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
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

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

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

Attachment 1: Genome Editing Policy and Procedures Summary Table

	Regulatory Oversight	Genome Edited Products/Organisms Subject to GE Regulations	Genome Edited Products/Organisms Not Subject to GE Regulation	Handling of Crossbred Progeny (Non-GE)
MOE	Biodiversity	Transfer of extracellularly processed nucleic acids and extracellularly processed nucleic acids and/or their copies remain in the host.	No incorporation of extracellularly processed nucleic acids or no extracellularly processed nucleic acids and/or their copies remaining in host.	N/A
MHLW	Food and Food Additives	Foreign genes and/or their copies remain in the host.	No foreign genes or fragments of such genes remain, and those of which results in deletion of base(s), substitution and insertion of a few bases caused by cleavage by an enzyme recognizing specific base sequences, and the consequent insertion of mutations of one to several bases due to failure of repair at the cleavage site of an artificial restriction enzyme.	Required preliminary consultation for all crossbred progeny products for the time being.
MAFF (Plant Product Safety Division)	Biodiversity for Products Under MAFF Jurisdiction	Transfer of extracellularly processed nucleic acids and extracellularly processed nucleic acids and/or their copies remain in the host.	No incorporation of extracellularly processed nucleic acids, or no remaining of extracellularly processed nucleic acids and/or their copies.	Contact MAFF to check if further information needs to be provided.
MAFF (Animal Product Safety Division)	Feed and Feed Additives	Foreign genes and/or a part of foreign genes remain in the host.	Not containing foreign genes and/or a part of foreign genes.	Notification required if: • Organism has no GE safety review history • Product does not meet below conditions: Trait quality does not change by cross breeding; no cross breeding between subspecies; or, no change in intake amount, portion of plant to be used as feed, processing method, etc.
CAA	Food Labeling	Mandatory GE labeling regulation.	Voluntary labeling encouraged.	N/A

Attachments:

No Attachments