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Report Highlights:
This report provides the latest status of consumption, regulation, public perception, research, development, production, and use of genetically engineered crops and animals in Japan.

Executive Summary:

Japan remains one of the world's largest per-capita importers of food and feed produced using modern biotechnologies. In general, the United States has historically been the dominant supplier of corn to Japan, accounting for 89 percent of Japanese corn imports in Marketing Year (MY) 2016/17[1] (October 2016 – September 2017). Regardless of some shifts in suppliers during certain marketing years, the regulatory approval of genetically engineered (GE) crops by the Government of Japan (GOJ) continues to be important for U.S. agriculture and global food production and distribution, as harvested GE crops not approved in Japan could result in significant trade disruption. Therefore, regulatory approval by the GOJ is essential to delivering the latest technologies to growers, regardless of the country of production. Annually, Japan imports about 15.2 million metric tons (MT) of corn, 3.2 million MT of soybeans and 2.4 million MT of canola from around the world, in which genetic engineering is predominantly used. Japan also imports billions of dollars of processed foods that contain GE crop-derived oils, sugars, yeasts, enzymes, and/or other ingredients.

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 October 5, 2018, 319 events had been approved for food use. In addition to managing the review process more efficiently than in the past (e.g., exempting breeding-stacked GE events that use pre-approved single events from scientific review), Japan's increased familiarity with events using popular transgenes has contributed to more prompt reviews. Nevertheless, Japan, like many other countries, may encounter regulatory challenges, because some developers may not have the resources to obtain regulatory approval in countries other than the country of production. As one of the world's largest per-capita importers of GE crops, improvement to the Japanese GE regulatory system, focused on long-term trends in biotechnology, and risk-based management will benefit all stakeholders.

Thus far, 183 events have been approved for environmental safety, which include 139 approvals for commercial cultivation. However, there is still no commercial cultivation of GE food crops in Japan. The GE rose released by Suntory in 2009 is still the only GE crop commercially cultivated in Japan.

There is very little applied research and development of animal biotechnology in Japan, and most activities remain in the area of basic research. The genetically engineered silkworm for veterinary drug production is one of the few examples of commercial application of animal biotechnology in Japan.

[1] MY2017 data is the most current finalized data published by the GOJ at the time of this report.

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CHAPTER I: PLANT BIOTECHNOLOGY

PART A: Trade and Production

a) PRODUCT DEVELOPMENT

Most agricultural research and development (R&D) in Japan is conducted by the public sector, government research institutes and universities. Recently, however, innovative technologies, such as genome editing, have received attention from researchers, and experimental cultivation trials have been increasing (for detail, note PART B: Policy - e) INNOVATIVE BIOTECHNOLOGIES).

Compared with the R&D in the United States, which is driven by the private sector, Japanese R&D seems to progress at a comparatively slow pace due to multiple factors. One reason is a very cautious attitude towards consumer acceptance of GE crops. Because of unforeseeable consumer acceptance, even for GE crops with high value added or consumer benefit, Japanese retailers and food manufactures are taking a very conservative approach towards the use of GE crops in products which require labeling. Therefore, even a farmer interested in the cultivation of GE crops might not actually be able to introduce it because of opposition from neighboring farmers (for detail, note PART C: MARKETING a) PUBLIC/PRIVATE OPINIONS). Other factors, such as regulations by local governments (for detail, note PART B: POLICY a) REGULATORY FRAMEWORK) and Japan's mandatory GE labeling requirements, which are currently under review, in effect discourage farmers from being the first to cultivate GE food/feed in a country where social "harmonization" is highly respected.

Nevertheless, there are some Japanese researchers and pro-science citizens' that are eager to reap the benefits of GE crops. For example, in December 2017, the "Food Communication Roundtable Council," a consumer organization for science-based risk communication, held a town hall meeting to discuss the future of GE rice that produces a therapeutic vaccine against Japanese cedar pollen allergy. The GE rice has been seeking regulatory approval for more than 10 years. Although researchers collaborated with medical institutions and reported the successful mitigation of the pollen allergy by the GE rice, they cannot find a way to move forward in the regulatory process because the GE rice could not be reviewed as a "food" due to its medical efficacy. As a pharmaceutical product, limited regulatory resources coupled with strict pharmaceutical manufacturing standards could be a significant hurdle for the agricultural crop developed by this public institution (for additional information, see http://www.naro.affrc.go.jp/publicity_report/press/laboratory/nias/077693.html, in Japanese).

Japanese researchers are demonstrating an increased interest in genome editing technologies for commercial production, particularly those targeting specialty crops with direct consumer benefits. For example, as an alternative to GE rice, Japan's Forestry and Forest Products Institute has attempted to produce a genome edited cedar that does not produce pollen. The GoJ's national project for science and

technology innovation, the "Cross-ministerial Strategic Innovation Promotion Program (SIP)", has also encouraged more research of genome editing technology.
For additional details, please see JA6050 (for R&D of existing conventional GE and SIP) and PART B: POLICY, e) INNOVATIVE BIOTECHNOLOGIES.

b) COMMERCIAL PRODUCTION
As previously noted, there is still no commercial production of GE food crops in Japan. The only commercial GE crop produced is a blue GE rose developed by Suntory (http://www.suntorybluerose.com/, in Japanese), but the volume of production has not been publicly released. Suntory also developed and distributed a blue GE carnation (http://moondust.co.jp/, in Japanese), but the carnation is cultivated in Columbia.

A GE strawberry producing a modified interferon has been grown commercially by Hokusan (http://www.hokusan-kk.jp/product/interberry/index.html, in Japanese) in a contained environment since 2014. However, the volume of production has not been publicly released.

Although there are still consumer groups actively campaigning against GE crops, the public risk perception to GE crops has been decreasing (see, e.g., http://www.fsc.go.jp/monitor/monitor_report.html, in Japanese), possibly due to lower levels of negative media coverage and the widely known fact that Japan is reliant on imported GE grain and oilseeds. For details, see PART C: MARKETING, b) MARKET ACCEPTANCE/STUDIES.

c) EXPORTS
There are no GE food crops exported from Japan. However, Japan exported 801 billion yen (7.2 billion USD[2], up 7.6 percent in Japanese yen from previous year) of food and agricultural products in CY2017, which includes processed products (264 billion yen or 2.4 billion USD) and livestock products (63 billion yen or 558 million USD). For additional detail, see the Ministry of Agriculture, Forestry and Fisheries' (MAFF's) website, in Japanese). Processed products may contain GE crops as ingredients and/or raw materials. Also, as Japanese livestock relies on imported feed, they are raised on GE or "non-segregated" feed corn.

d) IMPORTS
Grains
Japan remains a country which receives major benefits from agricultural biotechnology for its food security. Japan relies on imports for almost 100 percent of its corn supply and 95 percent of its soybean supply.

In Marketing Year (MY) 2016/2017 (October to September), Japan imported 15.2 million metric tons (MMT) of corn, which is dominantly supplied by the United States, with a market share of 89 percent (13.5 MMT). Of the 15.2 MMT of corn that Japan imported, approximately one-third was for food use. The grain price hike in 2008 forced Japanese food manufacturers to switch some imports to more cost-effective GE corn, since manufacturers were loath to pass along higher prices to consumers. Although

[2] $1USD = 112.13 Japanese yen based on the Bank of Japan's average exchange rate in CY2017 (see https://www.boj.or.jp/statistics/market/forex/fxdaily/ex2017.pdf, in Japanese).

there are no official statistics, based on information from various sources, FAS/Tokyo estimates nearly half to two-thirds of food corn imported by Japan may now be non-segregated or GE.

Table 1: Japanese Total Corn Imports (1,000 MT – MY2016/2017) (Year Ending: September)

Corn for Food and Feed	
United States	13,487
Brazil	930
Russia	310
Ukraine	215
South Africa	180
Others	46
Total	15,167

Source: Global Trade Atlas

Fresh Produce

There has been a very limited volume of 55-1 or "Rainbow Papaya", a GE papaya event grown in Hawaii, exported to Japan since its approval in 2011. Despite limited volumes, imports have increased in recent years as Rainbow Papaya has been increasingly served by several operations in the food service industry (for additional information, see, e.g., JA4519).

e) FOOD AID

Japan is not a recipient of food aid.

f) TRADE BARRIERS

Although there is a reluctance to accept GE food and food crops among some consumer groups, Japan remains one of the world's largest per-capita importers of GE crops and has no significant trade barriers.

PART B: Policy

a) REGULATORY FRAMEWORK

Regulatory Process

In Japan, the commercialization of GE plant products requires food, feed and environmental approvals. Four ministries are involved in the regulatory framework: MAFF, the Ministry of Health, Labour and Welfare (MHLW), the 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 trials. 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 assessment (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	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
Safety as animal feed	Agricultural Materials Council	Ministry of Agriculture, Forestry, and Fisheries	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 for the production of toxic substances (especially with regard to interactions between the transformation and the metabolic system of the animal)
Impact on biodiversity	Biodiversity Impact Assessment Group	Ministry of Agriculture, Forestry, and Fisheries Ministry of the Environment	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 as 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. The 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 Minister of Health, Labour and Welfare. Based on Japan's Food Sanitation Act, upon receiving a petition for review from an applicant, the Minister of Health, Labour and Welfare will request that the FSC conduct a food safety review. Within the FSC, there is a 'Genetically Modified Foods Expert Committee' consisting of scientists from universities and public research institutes. The Expert Committee conducts the actual scientific review. Upon completion, the FSC provides its conclusions for the Minister of Health, Labour

and Welfare. The FSC then publishes results of its food risk assessments of GE foods in English on its website (see http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf, 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.

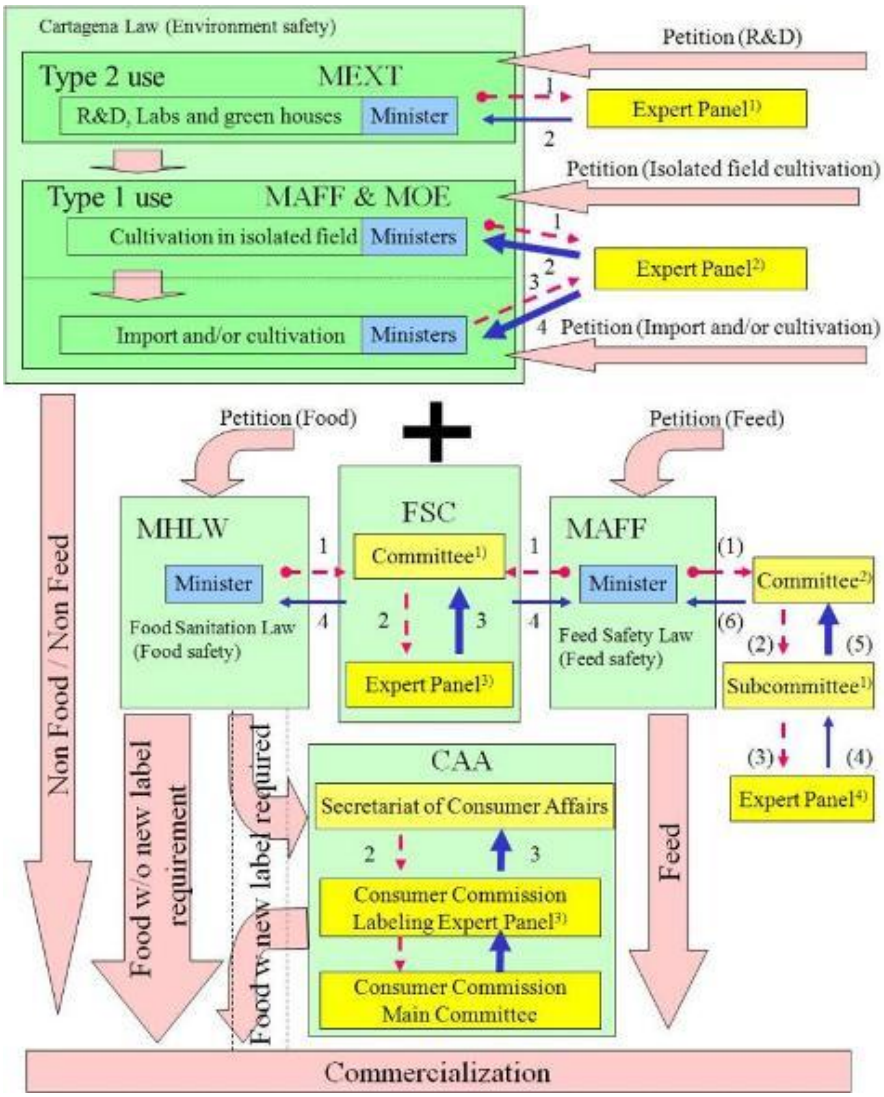
Under the Feed Safety Act, GE products that are used as feed must obtain approvals from the Minister of Agriculture, Forestry and Fisheries. Based on a petitioner's request, MAFF asks the Expert Panel on Recombinant DNA Organisms, which is part of the MAFF-affiliated Agricultural Materials Committee (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 Minister of Agriculture, Forestry and Fisheries also asks the FSC's Genetically Modified Foods Expert Committee to review any possible 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 Minister of Agriculture, Forestry and Fisheries approves the feed safety of the GE events.

Japan ratified the Cartagena Protocol on Biosafety in 2003. To implement the Protocol, 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." Under the law, MEXT requires Minister-level approval before performing early stage agricultural biotechnology experiments 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. After the necessary scientific data is collected through isolated field trials, with permission from the Minister of Agriculture, Forestry and Fisheries and Minister of the Environment, an environmental risk assessment for the event, which includes 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 reception of dossier to approval as 6 months (in Japanese, see http://www.maff.go.jp/j/kokuji_tuti/tuti/t0000824.html). However, when the applicant revises the dossier, receives questions from MAFF, and prepares the response, the "clock" for the standard processing time stops. Also, it takes a considerable amount of time to complete the preliminary consultation, confined field trial[3], and administrative handling for an official notification. Furthermore, it is customary for approval to first be given for food, followed by feed and environment. Therefore, a delay in food and/or feed approval will delay the environmental approval. In reality, the actual time required for full approval varies significantly from one event to another depending on the familiarity of the crop and trait. The official approval is generally given within 18 months of formal acceptance of the dossier for food, feed and environmental release if the event is a combination of familiar crops and genes.

Finally, GE products that require new 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). The CAA is currently reviewing Japan's current regulations for GE labeling. For details of the CAA's GE labeling review, see PART B) POLICY, g) LABELING. The 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 crops. There are no processing fees charged by any GoJ Ministry for the review.

[3] Please note PART B: Policy, b) APROVAL for recent management improvement initiated by the GoJ.



• 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.

In 2018, the GoJ started a public discussion on the handling of genome editing technology. For environmental safety, after an MOE Advisory Panel on Genetically Modified Organisms discussed the handling of genome editing technology under the Cartagena Protocol on Biosafety, the advisory panel concluded that any living organism with foreign nucleotide(s) remained in the host genome should be regulated regardless of whether the foreign nucleotide(s) is detectable. MOE opened a public comment period from September 20 to October 19, 2018. For additional information, see, e.g., JA8048, JA8064 and JA8075.

In September 2018, MHLW also started a public discussion on genome editing technology under the Research Sub-Committee for Genetically Modified Food. The sub-committee members discussed the handling of food products derived from genome editing technology. In its first meeting, the Sub-Committee concluded that product that does not contain a foreign gene should be exempted from the regulation of genetically engineered food. For additional detail, see, e.g., JA8077.

The MOE and MHLW discussions are expected to continue through Japanese Fiscal Year 2018 and conclude by the end of March 2019.

b) APPROVALS

As of October 16, 2017, Japan has approved over 319 GE events for food, 172 for feed and 183 for environment which include 139 for environmental release, including commercial planting for most events. 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 21 stacks, which, as previously noted, no longer go through the regulatory approval process (see Note "c) STACKED or PYRAMIDED EVENT APPROVALS" for details).

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 events using pre-approved single events from review as long as the crossing of single events does not affect the metabolic pathway of the host plant (for additional information, see JA4005). Furthermore, on December 22, 2017, the FSC's Expert Panel agreed to exempt stacked event using single events with the modified metabolic pathway from review (http://www.fsc.go.jp/senmon/idensi/index.data/gm_taisha_kaihen_kakeawase.pdf, in Japanese). The position was taken after the Expert Panel reviewed six cases of stacked events and found no rationale for a food safety concern. As of October 8, 2018, 30 stacked events (4 soybean, 18 corn, 2 canola, and 6 cotton) have been exempted from review (https://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/0000210015.pdf). 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, since 2014, MAFF has excluded crops that do not have wild relatives in Japan, such as corn, with traits of sufficient familiarity, such as herbicide tolerance and insect resistance, from mandatory field trail requirements. In September 2018, MAFF's Expert Committee proposed to add two more

traits, *DvSnf7* and *dmo*, to the list of familiar traits for corn to be exempted from domestic field trails, and a subsequent proposal to exempt cotton plants with familiar traits was also made. The recommendation was based on: 1) no sexually compatible wild relatives for cotton in Japan, 2) no characteristics of competitive superiority in cotton, and 3) the committee's empirical familiarity from previous reviews on GE cotton. The committee's recommendations for cotton's familiar traits are as follows:

Insect resistance: *cry1Ab, cry1Ac, cry1F, cry2Ab2, cry2Ae, vip3A*
Herbicide tolerance: *cp4 epsps, 2mepsps, bar, pat, aad-12, dmo*

The references and minutes of the meeting are expected to be uploaded to MAFF's website (http://www.affrc.maff.go.jp/docs/commitee/diversity/top.htm, in Japanese) in the near future. MAFF will continue to work on administrative procedures, which may include a public comment period. For additional information on field trials, see JA6050.

e) INNOVATIVE TECHNOLOGIES

Like many other countries, the GoJ has been handling products derived from innovative technologies on a case-by-case basis. Consequently, researchers have been taking a relatively conservative and cautious position towards R&D. However, the GoJ's "Cross-Ministerial Strategic Innovation Promotion Program (SIP)[4] has encouraged researchers to work on new agricultural technologies including genome editing technology. SIP has provided financial support not only to the researchers in the field of biology but also to researchers and organization in social sciences to increase public understanding of technology. After SIP began in 2014, more progress in research and field trials of products derived from innovative technologies has been observed in the past year (for additional information on SIP, please see JA6050). A few examples of genome edited research are listed below:

- 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). They planted genome edited rice in May and June 2018, and plan to harvest in late October 2018 (http://www.naro.affrc.go.jp/nias/gmo/news/083362.html, 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, they achieved the potato of SGA free (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 (https://www.nature.com/articles/s41598-017-00501-4).

Based on a survey conducted by the University of Notre Dame, Japan finished in third in CRISPR-based genome editing research after the United States and China, and in fourth for TALENs-based research. For additional detail, see its report: "The Global State of Genome Editing". As is the case in many other

[4] The Cross-Ministerial Strategic Innovation Promotion Program is a national project under the auspices of the Council for Science, Technology and Innovation to promote advancements of science, technology and innovation. The program began in April 2014 as a five-year project. GoJ proposed "Second Term" SIP in August 2018 which does not seem to give priority to genome editing technology. For additional information, see http://www8.cao.go.jp/cstp/panhu/sip_english/sip_en.html.

countries, legal classification of plants developed with innovative technologies in Japan has not yet been formulated.

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 (in Japanese).

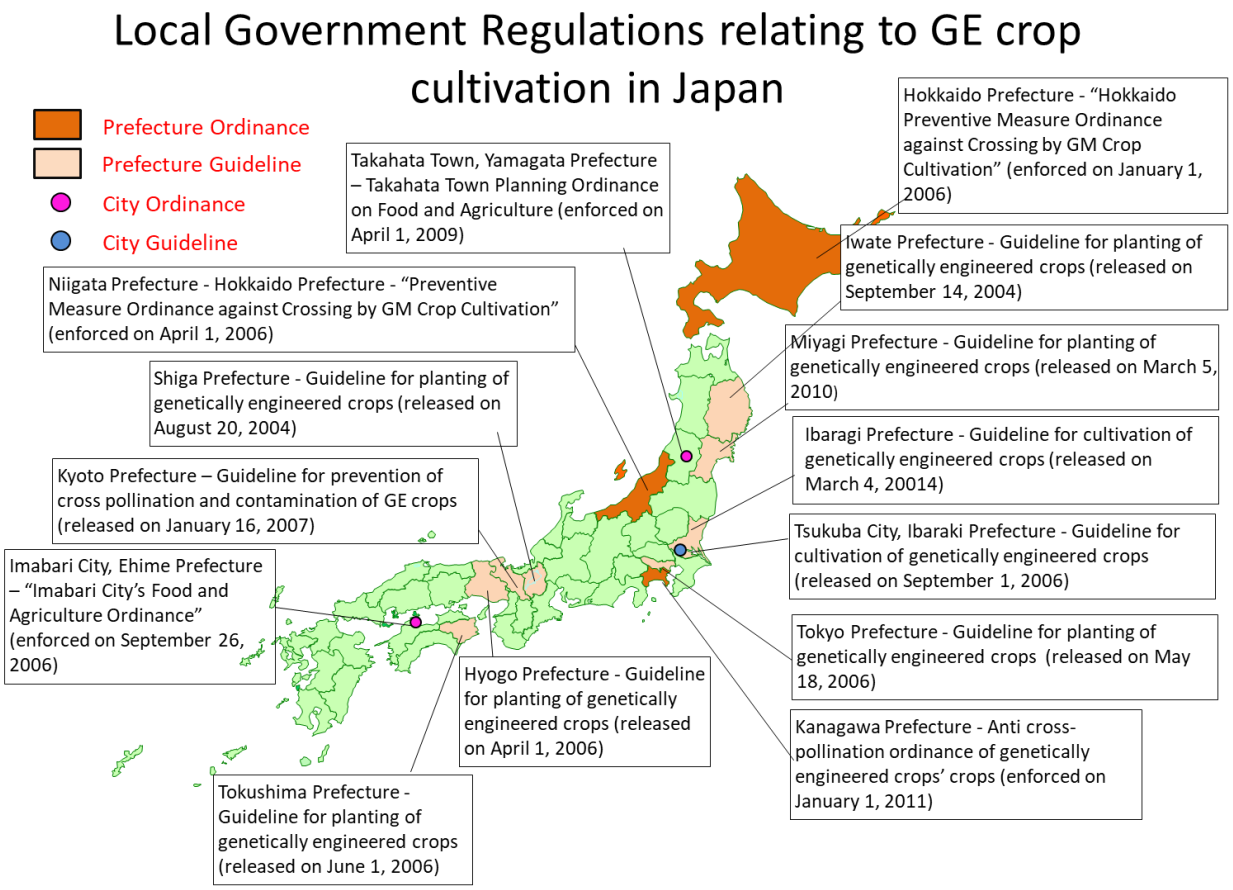
In theory, non-GE crops and GE crops can co-exist. However in reality, because of restrictive local regulations and public resistance, the planting of GE crops co-existing with non-GE crops is extremely difficult in Japan.

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

Local Government Regulations

There are 15 local governments with regulations for the planting of GE crops for research and/or commercial purpose. Many local rules were established between 2004 and 2009.



Source: Dr. Yoshiko Sassa, Life and BioPlaza 21 (with modification)

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 (which 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-IPed products (currently described as "non-segregated") should have a different description to more precisely represent the products. For additional information, see 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 make revisions to its GE labeling requirements. The majority of the discussion to validate the proposed changes from the Expert Committee review will occur after the

public comment period for interested parties closes, and after the comments submitted are reviewed by the CAA. FAS/Tokyo has submitted multiple reports on the review process (see, e.g., JA7067, JA7093, JA7121, JA8014, and JA8017).

h) MONITORING AND TESTING

Environmental Monitoring

The GoJ has been monitoring volunteer plants to assess the effect of a GE crops' environmental release on biodiversity. 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, in Japanese). Monitoring results have remain relatively unchanged: there have been limited findings of voluntary growth of GE canola, soybean, corn and cotton plants dropped during the unloading process from arriving vessels. However, there were no instances of GE plants affecting biodiversity or sustainably surviving through multiple generations.

Testing for the "5 percent rule" for non-GE labeling

For the purpose of detecting GE events in food products, the GoJ has been using 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. As the use of stacked events in corn production is increasingly important for management against pests, there was once a concern that non-GM corn being exported to Japan could be tested and mistakenly judged as 'GE' or 'not-segregated' if the test result indicates more than five percent GE grains in the shipment. However, current standards and specifications for the testing of GE grain in non-GE shipments, which MHLW first implemented in November 2009, allayed these concerns. For additional detail, please see JA6050.

i) LOW-LEVEL PRESENCE (LLP) POLICY

There have been no changes to Japan's LLP policies. For additional detail, please see JA6050.

As of November 2017, 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}, 299 cases per year);
- 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}, 299 cases per year);
- RT73 *B. rapa* (canola and its processed products, 29 cases per year);
- MON71700 and MON71800 (U.S. wheat, 59 case per year);
- MON71200 (Canadian wheat, 59 cases per year. 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., 59 cases per year); and,
- AquAdvantage (salmon and its processed products, such as salmon flakes, from Canada, Panama and the United States, 59 cases per year).

Ministry of Agriculture (MAFF) Policies on LLP in Feed Grain and Environment

MAFF monitors the quality and safety of imported feed ingredients and planting seeds at port. However, there have been no changes to Japan's policies this year. For additional detail, please see JA6050.

Following the detection of GE petunia by the Finnish Government in 2017, MAFF announced its intention to collect all unapproved GE petunia distributed in the Japanese market (see http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/petunia.html {in Japanese}) and continues to monitor for the presence of unapproved GE petunia.

For the import of planting seeds and seedlings of papaya and cotton from specific countries, MAFF requires advance notification and testing before approving imports. This requirement is based on the finding of unapproved GE papaya plants in Okinawa in 2011. The unapproved GE papaya was commingled in seedlings and/or seeds exported from Taiwan. Regarding cotton, although a number of GE crops are approved for food safety, the approval of environmental safety is limited to "import only" in which only the risk of drop during import was reviewed. As of October 12, 2018, MAFF requires 10-days advance reporting and testing for planting seeds and seedlings of papaya from Taiwan and cotton from India or Greece. For additional information, please see http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/index.html#3 (in Japanese).

CODEX LLP Supported but Not Implemented

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 with regard to food, as the Codex Annex allows for more than a 'zero' tolerance.

j) ADDITIONAL REGURATORY REQUIREMENT

Although GE crops receive regulatory approval for commercial planting, GE events with herbicide resistance may need to have the relevant chemical registered in Japan. As there is little expectation of domestic commercial cultivation of GE food crops in Japan, relevant chemical registration might not be completed even when an event's approval is completed.

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 the responsible agency for IPR.

A provisional translation of the "Implementing Guidelines for Inventions in Specific Fields - Chapter 2 Biological Inventions" can be found online at http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pdf/tt1303-061_41.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
Approval in Japan is Important to U.S. Farmers
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. To address this issue, the Biotechnology Innovation Organization's (BIO), a group of major biotechnology developers, released a statement on Product Launch Stewardship.

b) MARKET ACCEPTANCE/STUDIES
As previously noted, Japan remains one of the world's largest per-capita importers of GE products, even though the country has a labeling requirement for products containing GE materials. Because of the labeling requirement, the food industry has been taking a very cautious approach towards the use of GE ingredients when labeling is required. However, in a recent survey, concerns related to GE food continue to drop. In the FSC's Food Safety Monitor survey, 75 percent of participants responded they were "highly concerned" or "concerned" with GE food in JFY2006. However, in the JFY2016 survey, only 34.3 percent responded that they were "highly concerned" or "concerned." For more information, please see JA6050, JA7093 and JA7138.

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, e.g., the development of cancer immunotherapy from Dr. Tasuku Honjo, winner of the Nobel Prize in Medicine). Similar to 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 with regard to the genetic

transformation of animals. That being said, in traditional biotechnology, GE silkworm became the first commercial application of animal biotechnology in Japan. Also, Japan's National Institute of Agrobiological Sciences (NIAS) has been working on the development of GE silkworm for the production of spider (*Araneus ventricosus*) dragline silk protein, which could be threefold stronger than aramid fibers and fivefold stronger than steel (http://www.naro.affrc.go.jp/archive/nias/seika/nias/h26/nias02612.html).

Interest in animal cloning appears to have waned in Japan, and the 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_20180331.htm, in Japanese).

b) COMMERCIAL PRODUCTION
Currently, there is no commercial production of GE animals or cloned animals for the purpose of agricultural production, save for GE silk. As a result of collaboration between the Gunma Prefecture Silkworm Technology Center (http://www.pref.gunma.jp/06/f01g_00025.html, in Japanese) and Japan's National Agriculture and Food Research Organization (NARO), farmers in Gunma Prefecture continue to grow GE silkworm producing green fluorescent protein (HC-EGFP, *Bombyx mori*). In January 2018, 176 kilogram of GE silk was harvested and sold to a textile manufacturer in Kyoto (https://www.nikkei.com/article/DGKKZO25861710Y8A110C1L60000/, in Japanese).

Silkworm have also been genetically engineered for medical and pharmaceutical purposes including, but not limited to, production of antibodies for diagnosis, human collagen for cosmetic material (http://www.ibl-japan.co.jp/en/business/silkworm/), etc.

c) EXPORTS
None.

d) IMPORTS
None.

e) TRADE BARRIERS
None at this time.

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. Also 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, developing silkworm and tuna with reduced aggressiveness for culture, has been covered extensively by the media. However, all of this research remains in the basic research stage of development, based on available information. Much of the research is supported by the GoJ's Cross-ministerial Strategic Innovation Promotion Program (see http://www8.cao.go.jp/cstp/panhu/sip_english/sip_en.html).

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 has to be handled based on this regulation.

f) RELATED ISSUES
The GoJ implemented monitoring for GE salmon and processed salmon products (such as salmon flakes) in September 2017. For additional details, please see JA7112.

PART F: Marketing

a) PUBLIC/PRIVATE OPINIONS
At this moment, there is no commercial distribution of livestock GE animals in Japan, except GE 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 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
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