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# Japan

# Agricultural Biotechnology Annual

# 2017 Agricultural Biotechnology Annual

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**Report Highlights:**
This report provides the latest status of consumption, regulation, public perception, research, development, production, and use of 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 70 percent of Japanese corn imports in Marketing Year 2016[1] (October 2015 – September 2016). For additional information, see JA7127. 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 roughly 15 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 16, 2017, 313 events had been approved for food use. However, the number of approved events in the past three years has fallen. This reduction in the number of approved events is the result of an improvement to the Japanese review process implemented by MHLW in calendar year (CY) 2015. Prior to CY2015, developers had to submit an application for intermediate stack combinations in order to obtain approval for the highest stack. Now, however, developers can report the highest stack combination if there is no recognized change in the metabolic system. As reported stacks are listed in a separate list from the list of approved events, the number of approved events per year has declined since CY2015.

So far, 176 events for 9 crops have been approved for environmental release, 133 events of which include approval for commercial cultivation. However, there is 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. For details on the approved events, please see the links contained in the REFERENCE section at the end of this report.

Additionally, there has been very little applied research and development of animal biotechnology in Japan after the end of the "biotechnology boom" in the early 1990's. Since then, most activities remain in the area of basic research. However, in the past year, new breeding techniques (e.g., CRISPR-Cas9) have reportedly drawn the attention of Japanese researchers for their potential for market release. The genetically engineered silkworm for veterinary drug production is one of the few examples of a commercial application of animal biotechnology in Japan.

[1] MY2016 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
Research and development (R&D) in agricultural biotechnology was very active in both the public and private sectors until the early 1990's. However, due to a combination of economic instability and the unpredictability of public acceptance, most private companies closed or decreased the scale of operations significantly by the end of the 1990's. Since then, most agricultural R&D is operated by the public sector, government research institutes and universities. Recently, however, innovative technologies, such as CRISPR/Cas9, have received attention from researchers, and experimental cultivation trials have begun (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, farmers are not opting to grow GE crops, even when they understand the benefits to be gained. Although Japanese consumer concerns towards GE products still exists, these concerns have been waning, based on the results of a government survey (Note Part C: Marketing). A second factor is regulatory clearance. In addition to central government regulation, many local governments set additional regulatory requirements, even for the planting of events approved by the central government. The situation is extremely inauspicious for agricultural biotechnology R&D. Lastly, the use of voluntary "non-GE" labeling has cultured a somewhat negative perception and misunderstanding of the safety of GE foods. Although the majority of consumers pay less attention to GE labeling in food packages, some food industries tend to use "non-GE" labeling to promote the appeal of a product when applicable and avoid the labeling of "GE" when ingredients are required to be mandatorily labeled.

As a result, even for rice, one of the most important agricultural crops in Japan (both in dietary and cultural aspects), the research of modern biotechnology at the applied level (aiming for product development) is not particularly active. Although there are a number of reports published in academic

journals by Japanese researchers, who mostly come from public institutes, only one field trial has been approved since 2009. The single trial was for a GE rice line (OsCr11) that expresses a seed-based edible vaccine against Japanese cedar pollen allergy. The National Institute of Agricultural Sciences (NIAS), a government research institute, developed a genetically engineered rice that produces a therapeutic vaccine against Japanese cedar pollen allergy. NIAS has also collaborated with medical institutions (see, e.g., Jikei University School of Medicine, http://www.jikei.ac.jp/eng/index.html) and has been conducting clinical trials, including in CY2017, to accumulate safety and efficacy data for regulatory approval (for additional information, see http://www.naro.affrc.go.jp/publicity_report/press/laboratory/nias/077693.html (in Japanese)).

Some Japanese research in agricultural biotechnology is unique in the way that it is targeting specialty crops with direct consumer benefits. Because grains, except rice and oilseeds, are largely supplied by imports, technologies targeting specialty crops are more likely to be appealing to Japanese farmers and consumers. Additionally, the direct consumer benefit might receive more support from the general public. As a result, a group at Tsukuba University has been working for several years on developing a GE tomato with a gene producing miraculin. Miraculin is a protein accumulated in the fruit commonly referred to as "miracle fruit" (*Richardella dulcifica*), a native of West Africa. When individuals consume a small amount of miraculin protein, it binds to the taste buds, and changes acidic tastes to sweet. The GE tomato with miraculin protein could be used for individuals who need to reduce sugar consumption, such as diabetics. Though the GE tomato is completely safe to be consumed as it is, the intention of researchers at Tsukuba University seems to be to extract the miraculin protein from the GE tomato in order to market a purified protein (see, e.g., http://asia.nikkei.com/magazine/20150409-The-big-tax-squeeze/Tech-Science/Deceiving-the-mind-for-a-better-diet-without-sacrifices). Tsukuba has been working with Inplanta Innovations Inc., which is a biotech venture spun out from RIKEN, the largest national science research institute, to obtain safety approval from the GOJ.

To avoid negative public reactions, some R&D is trying to find a path for the application of modern agricultural biotechnology by moving into non-food crops. For example, in addition to GE cyclamen with doubled flowers (CpAG2SRDX, *Cyclamen persicum* Mill) in CY2016 (note JA6050), a group of scientists from Japan's National Agriculture and Food Research Organization and Suntory (inventor of the GE blue rose) developed a GE blue chrysanthemum (http://www.sciencemag.org/news/2017/07/scientists-genetically-engineer-world-s-first-blue-chrysanthemum). As chrysanthemums have close relatives which may cross pollinate, it is expected take time to receive full safety approval for the products commercial production.

The Ministry of Economy, Trade and Industry (METI) has also been promoting research into commercial plant cultivation for the production of high value ingredients such as pharmaceuticals. Examples of research funds include, but are not limited to, the production of malaria transmission-blocking oral vaccine for Hokusan (http://www.hokusan-kk.jp), the production of combination vaccine protein for Idemitsu Kosan Co., Ltd. (http://www.idemitsu.com/company/profile/index.html) and vaccine ingredient production in GE soybean for Hokko Chemical Industry Co., Ltd. (https://www.hokkochem.co.jp/english). Although these research projects have been funded by METI, information on the current phase of research development has not been publicly released.

Additionally, in April 2017, Tsukuba University opened the Tsukuba-Plant Innovation Research Center (T-PIRC). T-PIRC was created from the integration of two of the University's divisions: the "Gene

Research Center" and the "Agriculture and Forestry Technology Center" (http://www.nourin.tsukuba.ac.jp/T-PIRC/introduce.html). One of T-PIRC's main goals is to act as a "one-stop shop" for plant biotechnology research. The center plans to provide a laboratory facility for basic and applied research, field plots for confined field trials, as well as assistance in data generation for regulatory clearance.

Please note Part B), e) for research activities with innovative biotechnologies led by GOJ.

b) COMMERCIAL PRODUCTION

There is still no commercial production of GE food crops in Japan. The only commercial GE crop produced is a GE rose developed by Suntory (http://www.suntorybluerose.com/). The volume of production is not publicly released.

Although there is no commercial production of GE food crops, Hokusan has been producing a modified interferon for canines from a GE strawberry (http://www.hokusan-kk.jp/product/interberry/index.html). Its distribution has reached all over Japan, with no apparent objection from dog owners. The GE strawberry is cultivated in a closed system facilitated with controlled light, temperature, and nutrient solution. The scale of production and distribution, however, has not been publicly released.

Additionally, there are a limited number of professional farmers, academia and citizens' groups who have expressed interest in GE crop production, especially GE soybeans and sugar beets. Hokkaido is the northernmost and largest prefecture in Japan, where the agricultural industry is relatively more important (e.g., the agricultural share of Hokkaido's Gross Domestic Product (GDP) is 2.7 percent, compared to a national GDP share of 1 percent). Hokkaido also has a size advantage -- the average farm size in Hokkaido (25.8 hectares {ha}) far exceeds Japan's national average (2.4 ha), but local government regulations for GE crop cultivation (see JA6050 and Part B): POLICY - f) COEXISTENCE) and an aversion to GE crops from the general public have prevented cultivation to date. On March 1, 2017, the Agricultural Academy of Japan released a recommendation to demonstratively cultivate GE crops in Japan so the advantages of GE crops can be made more apparent to the public. The recommendation paper specifically pointed out the potential benefits of glyphosate resistant sugar beets for farmers in Hokkaido (see, e.g., http://www.academy.nougaku.jp/pdf/20170301agriculturalacademyofjapan_suggestion.pdf and https://www.jba.or.jp/jba/osirase/002507.php).

c) EXPORTS

There are no GE food crops exported from Japan. However, Japan exported 750 billion yen (6.9 billion USD[2]) of food and agricultural products in CY2016, which includes processed products (236 billion yen or 2.2 billion USD) and livestock products (51 billion yen or 469 million USD). Processed products

[2] 1 USD = 108.77 Japanese yen based on the average bank of Japan exchange rate in CY2016 (see https://www.boj.or.jp/statistics/market/forex/fxdaily/index.htm/).

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, October to September) 2015/2016, Japan imported 15.2 million metric tons (MMT) of corn. The largest supplier was the United States, with a market share of 69.3 percent (10.6 MMT). The rest of the market was taken by Brazil (29.5percent, 4.5 MMT). Supplies from other countries (Argentina, Ukraine, Russia, etc.) accounted for less than one percent (see JA7127 for additional information). The two major corn suppliers to Japan, the United States and Brazil, are also leading countries in the adoption of GE crop technologies.

Of the 15.2 MMT of corn that Japan imports, approximately one-third is for food use. Prior to the increase in grain prices in CY2008, most food corn imported into Japan was non-GE, which is more expensive than non-segregated corn. The 2008 price spikes 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 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 non-segregated or GE.

| **Table 1: Japanese Total Corn Imports**<br>(1,000 MT – 2015/2016)<br>(Year Ending: September) | |
|---|---|
| **Corn for food and feed** | |
| United States | 10,586 |
| Brazil | 4,483 |
| Argentina | 76 |
| Ukraine | 35 |
| Russia | 13 |
| Others | 9 |
| Total | 15,202 |

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 and feed safety risk assessment for MHLW and 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<br>• Safety of proteins produced as a result of genetic modification, particularly their allergenicity.<br>• Potential for unexpected transformations as the result of genetic modification<br>• Potential for significant changes in the nutrient content of food |
| 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<br>• 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<br>Ministry of the Environment | Law Concerning Securing of Biological Diversity (Regulation of the Use of Genetically Modified Organisms) | • Competitive superiority<br>• Potential production of toxic substances<br>• Cross-pollination |

Note: MHLW and MEXT are not involved in conducting risk assessments 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 the expert panels are reviewed by the 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 the Food Sanitation Law, upon receiving a petition for review from an interested party (usually a biotechnology provider), 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 to 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). FSC sets the standard processing time from the reception of dossier to approval as 12 months.

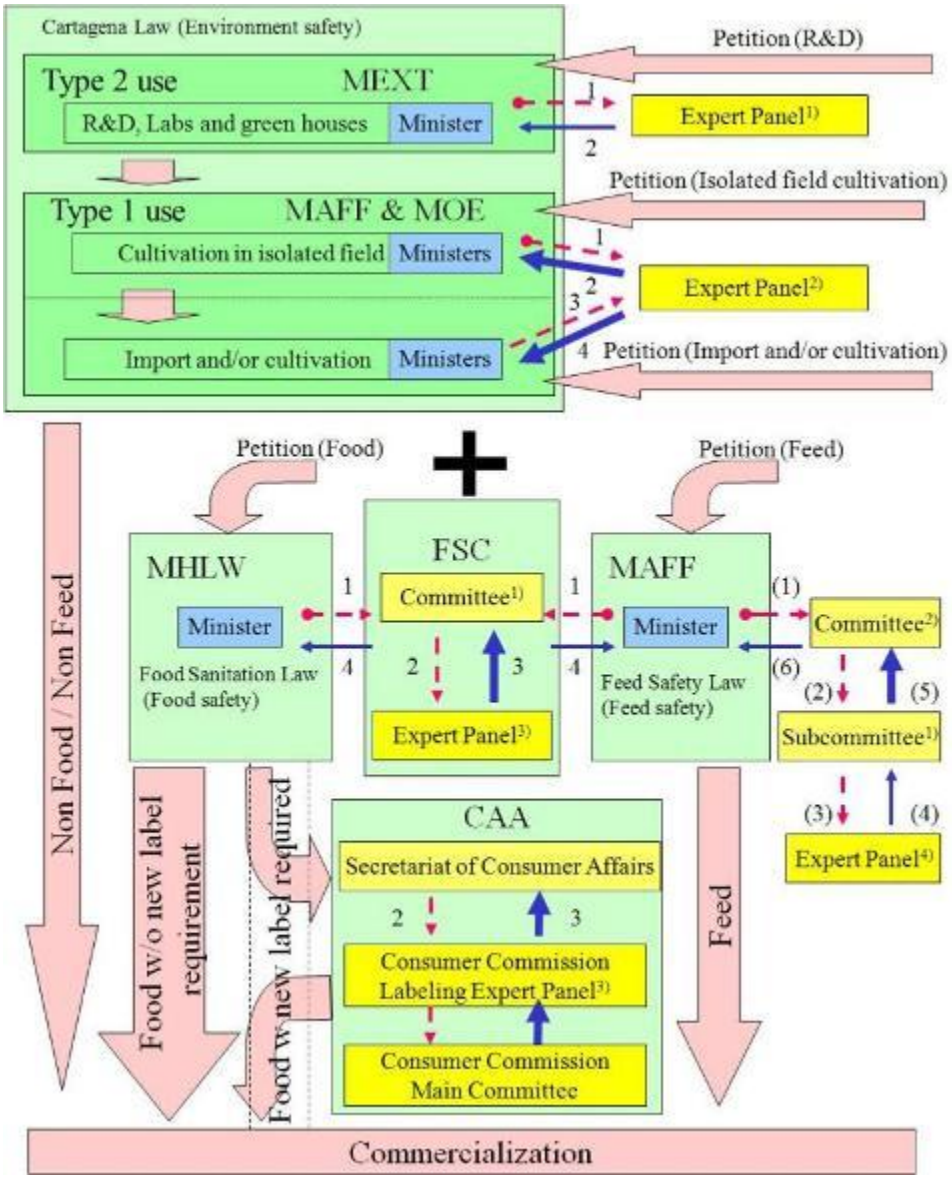
Under the Feed Safety Law, GE products that are used as feed must obtain approvals from the Minister of Agriculture, Forestry and Fisheries. Based on a petitioner's request, MAFF asks the Expert Panel on Recombinant DNA Organisms, which is part of the MAFF-affiliated Agricultural Materials Committee (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 experiments, 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 for the preliminary consultation, confined field trial, and administrative handling for an official notification. Furthermore, it is customary for approval to be given for food first, followed by feed and environment. Therefore, a delay in food and/or feed approval will delay the environmental approval. In reality, actual time required for full approval varies significantly from one event to the other, but the official approval is generally given within18 months after 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 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. There are no processing fees charged by any GOJ ministry for the review of GE crops.




• 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 October 16, 2017, Japan has approved over 313 GE events for food, 167 for feed and 133 for environmental release, including commercial planting for most events. Please note the reference section at the end of report for the 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 made improvements in the approval process for stacked events. In 2014, MHLW exempted the review of GE events using pre-approved single events as long as the crossing of single events does not affect the metabolic pathway of the host plant (for additional information, see JA4005). As of November 8, 2017, 21 stacked events (3 soybean, 10 corn, 2 canola, and 6 cotton) have been exempted from review (http://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/0000069329.pdf). For details on the approved stacks, please see the links contained in the REFERENCE section at the end of this report.

In the past, when three approved single events, trait A, B and C, were available, and if the developer planned to commercialize three doubled stacks, the developer had to submit three separate applications for the stacks, A x B, B x C, and A x C. Now, the developer can submit all possible combinations (A x B, B x C, A x C, and A x B x C), including possible triple stacks for future release, in one application. Since this change was introduced, 19 events have been granted approval with the benefit of improved stack handling.

For feed safety of stacked events, MAFF requires approvals from the Expert Panel on Recombinant DNA Organisms of the Agricultural Material Committee (AMC). Unlike the full feed safety review, approval by the Expert Panel is neither subject to MAFF Ministerial notification nor public comment.

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. The list of qualifying crops and traits has not changed since last year. For additional information, see JA6050.

e) INNOVATIVE TECHNOLOGIES

Like many other countries, the GOJ handles 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. At the same time, with support of the GOJ's "Cross-Ministerial Strategic

Innovation Promotion Program (SIP), more progress in research and field trials of products derived from innovative technologies have been observed in the past year (for additional information on SIP, please see JA6050).

A potato with reduced amylose and acrylamide developed by Hirosaki University utilizing epi-genomic modification and grafting (previously reported on in JA6050) was cultivated in April 2017 at the confined field of National Agricultural Research Organization (NARO). It was the first instance of open field experimental cultivation of plants with innovative technology in Japan. Also in May 2017, NARO began experimental cultivation of rice with a higher yield trait developed by CRISPR technology. Moreover, a research team in Tsukuba University used CRISPR/Cas9 to develop a tomato with higher content of γ-aminobutyric acid (GABA) which is reported to lower blood pressure (https://www.nature.com/articles/s41598-017-06400-y).

As is the case in many other 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 details, 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 a number of local rules relating to agricultural biotechnology in Japan. Many, if not all, of these rules are non-scientific responses to limited concerns of local residents but are not based on science. As a result, these local regulations make it extremely difficult for farmers to adopt GE crops which are already approved by the GOJ. There have been no changes in local cultivation regulations in the last year. For additional information, please see JA6050 and JA7121.

g) LABELING

Food labeling issues, including GE labeling, are handled by the Consumer Affairs Agency (CAA). In April 2017, CAA initiated a review of Japan's GE labeling requirements. Three specific topics for reivew include: 1) the types of foods to be labeled, 2) the threshold for requiring GE labeling, and the 3) the appropriateness of "non-GE" labeling its. For additional details, please see JA7093 and JA7121. The CAA is expected to conclude the review by the end of JFY2018 (i.e., March 31, 2018).

h) MONITORING AND TESTING

Environmental Monitoring

The GOJ has been monitoring volunteer plants to assess the effect of 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/attach/pdf/index-42.pdf). 2017 monitoring results were similar to past reports. There were findings of voluntary growth of GE canola and soybean plants dropped during the unloading process from arriving vessels. There were no instances of cross pollination with domestic plants: mustard (*Brassica juncea*), Chinese colza (*Brassica campestris* L.), a domestic canola, and *Glycine soja*, a domestic wild relative of soybean.

*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 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, 299 cases per year)
- 63Bt, NNBt, and CpTI (rice and its processed product with rice as a main ingredient, 299 cases per year)
- RT73 B. rapa (canola and its processed products, five cases per year)
- MON71700 and MON71800 (U.S. wheat, 59 case per year)
- F10 and J3 (potato and its processed products (of potato as a main ingredient, such as French fries and potato chips, 59 cases per year)
- 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 policy this year. For additional detail, please see JA6050.

Following the detection of GE petunia by the Finnish Government, 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).

CODEX LLP Supported but Not Implemented

International guidelines on food safety assessments for LLP for genetically modified 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 "Implementing Guidelines for Inventions in Specific Fields - Chapter 2 Biological Inventions" can be found 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". This, and other laws implementing the protocol, may be found on the Japan Biosafety Clearing House (J-BCH) website (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 (http://www.mabs.jp/eng/index.html). Their target, however, is more geared towards the pharmaceutical and medical industries rather than agriculture.

At the Organization for Economic Co-operation and Development (OECD), Japan is 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 the production technologies available to U.S. farmers. Moreover, the presence of an unapproved GE crops in shipments to Japan can lead to costly export testing requirements and trade disruptions. To address this issue, the Biotechnology Industry Organization's (BIO), a group of major biotechnology developers, has called for new GE crops to be approved in Japan before they are commercialized in the United States.

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. However, the FSC's survey conducted in recent years showed that the Japanese consumer concern about GE food has been gradually decreasing and is the lowest among 18 items surveyed (food poisoning microorganisms, agricultural chemical residues, food additives, mycotoxins, chemicals eluted from food containers, dioxins, heavy metals such as cadmium, natural toxins such as ones in puffy fish and wild mushrooms, and others). Similarly, decreasing concerns among Japanese consumers were demonstrated by data in a recent survey conducted by the CAA (see http://www.caa.go.jp/policies/policy/food_labeling/other/genetically_modified_food.html) and FSC (http://www.fsc.go.jp/monitor/monitor_report.html). In the FSC's Food Safety Monitor's survey, 75 percent responded "highly concerned" or "concerned" with regard to GE food in JFY2006. In the JFY2016 survey, only 35.4 percent responded that they were "highly concerned" or "concerned". Despite these developments, there are still some consumers who are concerned with the current regulations that allow for the inclusion of less than five percent of approved GE content in a product that is not labeled as GE. A consumer's right to know if food contains GE ingredients is reportedly one of the driving factors for the CAA's review of the current GE labeling requirements. For more details, please see previous report JA6050 and JA7093.

*CHAPTER 2: ANIMAL BIOTECHNOLOGY*

**PART D: Production and Trade**

a) PRODUCT DEVELOPMENT
Most research in genetic transformation in animals is focused on human medical and pharmaceutical purposes. Similarly with plant biotechnology, this research is mostly operated by university and government/public research institutions, with limited involvement by the private sector in Japan. 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, GE

silkworm remains relatively close to the commercial application stage in Japan. Please note commercial production of genetically engineered silk in the section b) COMMERCIAL PRODUCTION..

Additionally, interest in animal cloning appears to have waned in Japan. As of March 2017 (most recent data available), Japan had produced 626 cows by fertilized egg cell cloning, 415 cows by somatic nuclear transfer (SCNT), 647 swine by SCNT, and 5 goats by SCNT. All production has been done in public research institutions. 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_20170331.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. In October 2017, GE silkworm producing green fluorescent protein (HC-EGFP, *Bombyx mori*) were cultured by local farmers in Gunma Prefecture (http://www.pref.gunma.jp/houdou/p148_00001.html). The GE silk worm was developed by NARO and propagated by the Gunma Prefecture Silkworm Technology Center. The center propagated 120,000 GE silkworm and distributed them to farmers in the prefecture. Based on media reports, this was the world's first example of commercial production of GE silk by farmers. The silk was harvested and shipped to a textile company in November for interior design use (see http://www.sankei.com/region/news/171102/rgn1711020029-n1.html).

c) EXPORTS
None.

d) IMPORTS
None.

e) TRADE BARRIERS
None at this time.

**PART E: Policy**

a) REGULATORY FRAMEWORK
The same regulation as for GE plants will be applied for commercialization of GE livestock animals and insects. For production or environmental release of GE animals, the 'Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms' under MAFF will be applied as Japan ratified the Cartagena Protocol on Biosafety in 2003. The Food Sanitation Law, with 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. As innovative biotechnologies are one of the key agenda items in the aforementioned SIP, some research programs and results started to be released to the public. Examples of programs include, but are not limited to, am application for red seabream (*Pagrus major*, CRISPR/Cas9) and Japanese anchovy (*Engraulis japonica*, CRISPR/Cas9 and TALEN). However, like the tuna with reduced aggressiveness, which can be developed as a more suitable fish for culture by

CRISPR/Cas9, all SIP research is still in the basic research stage of development, based on available information.

c) LABELING AND TRACEABILITY
The labeling requirement for GE animals will be the same as for plants. For products 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 the same 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. Moreover, 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

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.bch.biodic.go.jp/english/e_index.html

As of October 17, 2017, the GOJ had reviewed and approved 313 events for food, 167 events for feed, and 133 events for environmental release (i.e., cultivation) (taking stacked events into account).

Approved events for commercial use:

Approved events for food use:
http://www.mhlw.go.jp/english/topics/food/pdf/sec01-2.pdf

Approved stacked events for food use in which the metabolic pathway is not affected by stacking:
http://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/0000069329.pdf

Approved events for feed use:
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-97.pdf

Approved for environmental release under the Cartagena Protocol domestic Law:
http://www.biodic.go.jp/bch/english/e_index.html (in Japanese)