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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.

Section I. 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 86 percent of Japanese corn imports in MY2015* (October 2014 – September 2015). 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 million metric tons (MT) of corn, three 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.

* MY2015 data is the most current finalized data published by the GOJ at the time of this report.

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 19, 2016, 307 events had been approved for food use. However, the number of approved events in the past two 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 CY2015. This improvement exempts from scientific review breeding-stacked GE events that use pre-approved single events, provided the cross pollination does not affect the metabolic system of the host. In addition to managing the review process more efficiently, Japan's increased familiarity with events using popular transgenes has contributed to more prompt reviews. At the same time, various sources expect an increase over the next decade in the number and type of GE events released to the market, emergence of new transformation technology, as well as releases from venture capitals and emerging economy countries. Japan, like many other countries, may encounter regulatory challenges, because some of 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.

So far, over 160 events for 9 crops have been approved for environmental release, most 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. Suntory also has approval for environmental release (i.e., commercial cultivation) of eight GE carnations; however, they are cultivated in Colombia and exported to Japan, the United States and Europe.

There is very little applied research and development of animal biotechnology in Japan. 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.

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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 public and private sectors until the early 1990s. 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 90'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/Cas, has received attention both from public and private sectors, and may influence the future course of biotechnology applications in agriculture in Japan (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 of 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 stepping forward to grow GE crops, even when they know the benefits to be gained (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.

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 very active. Although there are a number of reports published in academic journals by Japanese researchers, who are mostly from public institutes, only one field trial has been approved since 2009. In March 2016, the Ministry of Agriculture, Forestry and Fishery (MAFF)'s approved a domestic confined field trial for OSCR11, a GE rice line that expresses a seed-based edible vaccine

against Japanese cedar pollen allergy. The National Institute of Agricultural Sciences (NIAS), a government research institute, has been working on the development of a genetically engineered rice that produces a therapeutic vaccine against Japanese cedar pollen allergy. Researchers modified and deconstructed antigen genes of Japanese cedar pollen and used them for the rice transformation. The transgenic rice grain containing the modified Japanese cedar pollen antigen was then fed to mice in clinical trials and successfully suppressed pollinosis symptoms such as sneezing and nasal tissue inflammation (see, e.g., http://www.ncbi.nlm.nih.gov/pubmed/23066780).
After a preliminary clinical trial between 2012 and 2014 at Jikei University School of Medicine (see, e.g., http://www.jikei.ac.jp/eng/index.html), researchers will start a clinical trial in November 2016 at Osaka Prefectural Medical Center for Respiratory and Allergenic Diseases (in Japanese only, see http://www.ra.opho.jp/). In the trial, ten patients with cider pollen allergy will eat a conventional Japanese diet with rice containing 5 grams of GE rice for one year. As the product may ultimately claim a medicinal benefit, the developers reportedly plan to release the pollen allergy mitigating GE rice as a pharmaceutical product.

Some Japanese research in agricultural biotechnology is unique in the way that it is targeting specialty crops with direct consumer benefits. A group at Tsukuba University has genetically engineered a tomato with a gene producing miraculin. Miraculin is a protein accumulated in the fruit called "miracle fruit" (*Richardella dulcifica*), a native of West Africa. When people 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 people 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 extracting miraculin protein from the GE tomato in order to market its 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). In November, 2015, Tsukuba University announced a joint research project with Inplanta Innovations Inc., which is a biotech venture spun out from RIKEN, the largest national science research institute. One of the services Inplanta Innovations provides is joint R&D and consultation for launching GE products.

Besides edible crops, Tsukuba University and Hokko Chemical Co. Ltd jointly received the permission on October 14, 2016 for a confined field trial for GE cyclamen with doubled flowers (CpAG2SRDX, *Cyclamen persicum* Mill). As the permission is only for a confined field trial to allow for the accumulation of data for further regulatory clearance (e.g., application for the deregulation), it will still take time to obtain legal approval for domestic production. Furthermore, depending on the location and types of products, growers may need clearance of local regulation, if they plan to grow the flowers domestically (see Part B: Policy, (f) Coexistence, for details of local regulations).

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.

b) COMMERCIAL PRODUCTION

There is no commercial production of GE food crops in Japan. The only commercial GE crop produced is a GE rose developed by Suntory, the third largest beer brewery in Japan. The GE rose is the world's first 'blue' rose. Suntory developed the GE rose by silencing the dihydroflavonol reductase gene, which is responsible for the red pigment in a rose, with RNA interference. The volume of production and sales is not publically released. Suntory also has several genetically engineered blue carnations approved for

cultivation in Japan. However, these carnations are not cultivated in Japan but rather in Colombia and then exported to Japan. Some GE carnations from Suntory have received regulatory approval in other countries such as Malaysia and in the European Union. The volume of trade, however, is not publically released.

Although there is no commercial production of GE food crops, on April 24, 2014, a company named "Hokusan" started producing the world's first pharmaceutical product, modified interferon, for canines from a GE strawberry. Hokusan (http://www.hokusan-kk.jp/product/interberry/index.html) is a private Japanese company founded in 1951 by Sankyo (currently Daiichi-Sankyo, a pharmaceutical company) and Hokkoren (currently Hokuren Federation of Agricultural Cooperatives). 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, as was the practice in the R&D phase. The system enables the optimal growth of the strawberry. As a result of using closed system cultivation, the manufacturer likely avoids anti-GE claims by environmentally concerned groups. As industry and manufacturers in Japan are very sensitive to the voice of the consumer, the closed cultivation system of high valued crops, such as a pharmaceutical ingredient, could be a way to increase the adoption of commercial production of GE crops in Japan.

Although there are no growers cultivating GE food crops, there are a limited number of professional farmers 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). As some farmers in Hokkaido have more than 100 ha of farmland, the advantage of GE adoption could be significant. One of the arguments against GE crops in Japanese agriculture, however, is the fitness of currently available events and crops to Japanese agricultural practice and farm size. However, the benefit of GE crops (soybeans and sugar beets) was clearly demonstrated in an estimate by two professional growers in Hokkaido. A grower cultivating soybeans and wheat on 100 hectares estimated the benefit of using glyphosate tolerant soybeans instead of non-GE cultivars to be a 41 percent reduction in operating hours and a 41 percent increase in profit (per unit acreage) due to lower herbicide costs. The most notable (potential) benefit of using GE soybeans is the potential to expand the operation size, i.e., farm size, because of the reduction in operating hours. An increase in farm size will not only benefit the growers, but also Japanese food security and rescuing farmland being abandoned as growers retire. Another grower estimated the benefit of growing GE sugar beets to result in as much as a 58 percent reduction in operating hours and a 72 percent increase in profit (per unit acreage). Japan's self-sufficiency rate in soybeans and sugar is approximately seven and 35 percent, respectively. Furthermore, approximately 70 percent of soybean used for crushing and feed is almost all "non-segregated". As "non-segregated" soybeans as well as sugar and food containing sugar from GE sugar beets are utilized by the Japanese food industry, it is expected that there would be an advantage for local growers to adopt GE soybean and sugar beets.

However, there are a few significant obstacles for local growers to engage in commercial GE crop cultivation. For example, farmers must pay a processing fee of 314,760 yen (approximately $3,150) to the Hokkaido Governor's office in order to cover the costs of reviewing their application. See 'Local Government Regulations' for more details. Other hurdles include securing a buyer who will accept

harvested GE products and making sure that the crop has the relevant chemical registration in Japan if the farmer plans to utilize a herbicide tolerant trait such as glyphosate resistance.

c) EXPORTS

There are no GE food crops exported from Japan. However, Japan exported 745 billion yen (7.2 billion USD*) of food and agricultural products in JFY2015, which includes processed products (222 billion yen or 2.1 billion USD) and livestock products (47 billion yen, 450 million USD). Processed products may contain GE crops as ingredients and/or raw material. Also, as Japanese livestock relies on imported feed, they are raised on GE or "non-segregated" feed corn.
(*1 USD = 104 Japanese yen)

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) 2014/2015, Japan imported 14.7 million metric tons (MMT) of corn. The major supplier was the United States, with a market share of 86 percent (12.6 MMT). The rest of the market was taken by Brazil (14.5 percent, 2.2 MMT) and Ukraine (8.0 percent, 1.2 MMT). Among these countries exporting to Japan, Ukraine is only the country which does not have official commercial production of GE crops; all major corn suppliers to Japan are also leading countries in the adoption of GE crop technology.

Of the 14.7 MMT of corn that Japan imports, approximately 4.5 MMT 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. Though there are no official statistics, based on information from various sources, Post estimates nearly a half to two-thirds of food corn imported by Japan is non-segregated or GE. The share of GE/non-segregated corn for food use started to increase in CY2015, after major manufacturers of 'happoshu', also known as "third category beer" or low malt beer, which is a beer-like drink brewed with non-malt material, increased their use of GE and non-segregated grains. The gradual increase of GE/non-segregated corn for happoshu reportedly caused the shift from non-GE corn to GE/non-segregated corn.

Genetic engineering and other new agricultural sciences for crop production remain important for Japan's importing needs. For example, in 2008, U.S. corn production was adversely affected by severe weather. Although Japan's top foreign supplier was unable to meet Japan's needs, production in South American countries, which relied on GE, was able to help bolster Japan's import shortfalls. After the United States, Brazil -- which is concurrently and actively adopting GE technology for its corn production -- was the largest corn exporter to Japan in 2014/2015. To cope with global climate change, reduce the environmental footprint, and save natural resources, the role of agricultural biotechnology will continue to be valuable, and its compliance with global regulatory standards will remain important under the expectation of increasing global food trade.

Table 1: Japanese Corn Imports (1,000 MT – 2014/2015) (Year Ending: September)	
Corn for feed	
United States	8,149
Brazil	1,297
Ukraine	316
South Africa	113
Argentina	111
Others	0
Total Feed	10,006
Corn for food, starch, manufacturing	
United States	4,489
Ukraine	75
Brazil	42
South Africa	29
Argentina	7
India	5
Indonesia	2
Peru	1
Others	>1
Total Food & Other	4,649
Total	**14,655**
Source: Ministry of Finance	

Fresh Produce

There has been a very limited volume of 55-1 or "Rainbow Papaya", a GE papaya event grown in Hawaii, and exported to Japan since its approval. Papayas are a niche product in Japan. Due to the lack of popularity of papaya compared with other tropical fruit, such as mango, Japanese consumers are not well informed about the proper handling, ripeness, and varietal characteristics. In addition, American (or more precisely, Hawaiian) papaya has to compete with Philippine papaya, which has a price advantage. There also seems to be reluctance among retailers to handle GE papaya due to the fear of losing their customers to non-GE papaya. Accordingly, there is currently no GE papaya sold in retail stores in Japan. However, several hotel restaurants and chain restaurants introduced GE papaya to their customers (See, e.g., JA4519) and the use of GE papaya in food service has gradually increased. In past 12 months, several franchised and independent restaurants and cafés have also started to use GE papaya in their foodstuffs.

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 • 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 risk assessment as they are risk management bodies and/or contact point for application.

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 consumers and industry. The advisory committees report their findings and recommendations to the responsible ministries. The minister of each ministry then typically approves the product.

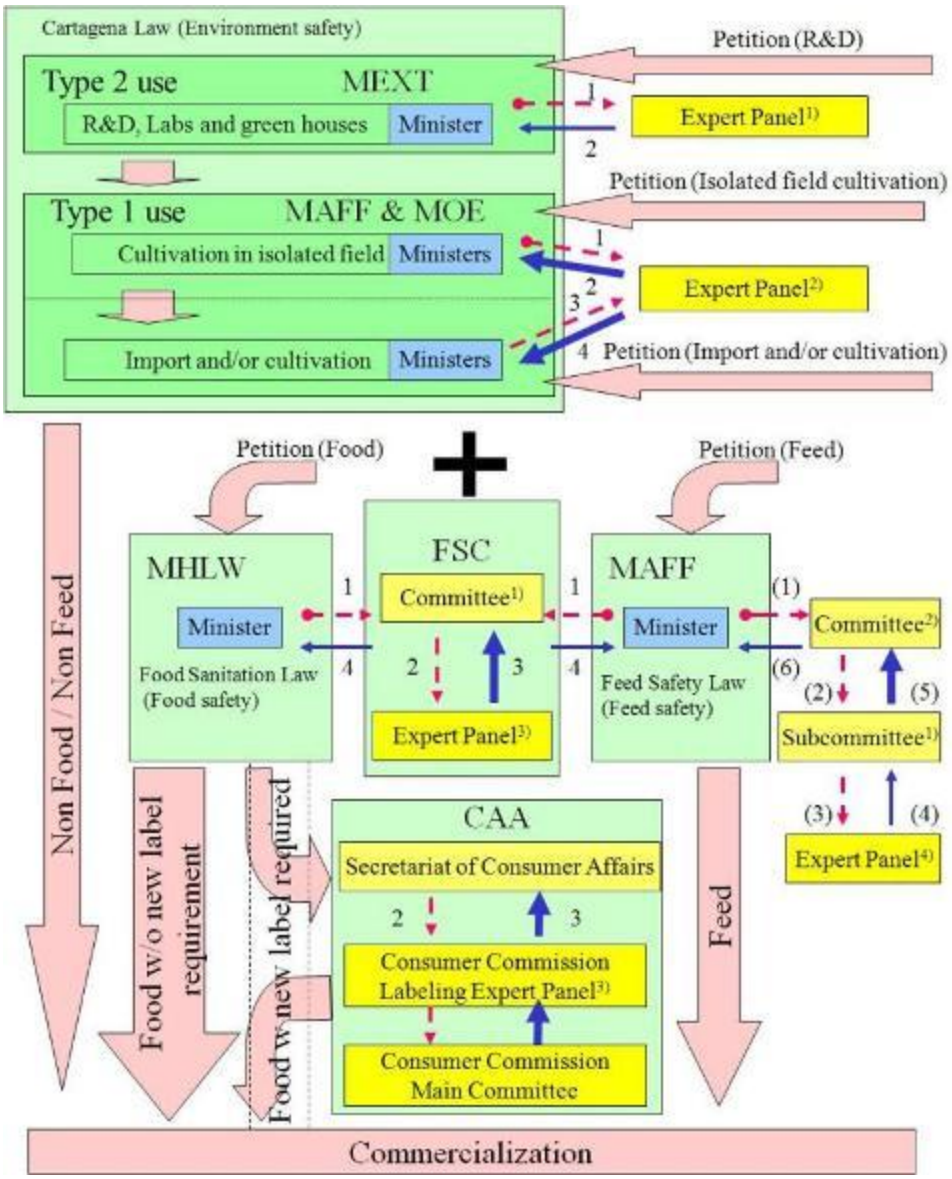
GE plants that are used for food must obtain food safety approvals from the MHLW Minister. Based on the Food Sanitation Law, upon receiving a petition for review from an interested party (usually a biotechnology provider), the MHLW Minister will request that the FSC conduct a food safety review. Within 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 MHLW Minister. 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 MAFF Minister. 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 MAFF Minister 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 MAFF Minister 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 MAFF and MOE Ministers, 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 26, 2016, Japan has approved over 309 GE events for food, 150 for feed and 120 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 18 stacks, which 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 recently made an improvement in the approval process for stacked events.

For food safety approvals, a 2004 FSC opinion paper categorized GE events into three categories (http://www.fsc.go.jp/senmon/idensi/gm_kangaekata.pdf):

1. Introduced genes which do not influence host metabolism, and mainly endow the host with insect resistance, herbicide tolerance or virus resistance;

2. Introduced genes which alter host metabolism and endow the host with enhanced nutritional components or suppression of cell wall degradation by promoting or inhibiting specific metabolic pathways; and

3. Introduced genes that synthesize new metabolites not common to the original host plant.

As reported in JA4005, Japan proposed an exemption from the review for 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. The proposal later became official. Similar to the efficient handling of S3-FT to be exempted for crops with no domestic wild relatives, this regulatory handling of stacked events in food safety review is remarkably positive in multiple aspects: saving regulatory resources for Japanese regulators and technical providers and reducing the risk of asynchronous approval. After this measure, the number of approved events listed as approved since 2014 was no longer as large as previous years. Stacked events exempted from review are now identified in a different table. As of October 27, 2016, eighteen stacked events (2 soybean, 8 corn, 2 canola, and 6 cotton) have been exempted from review (http://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/0000069329.pdf).

The safety approvals for stacked events between GE events in categories 1 and 2, 1 and 3, 2 and 2, 3 and 3, and 2 and 3 will still be required.

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

Although Japan has provided for the option of seeking "import only" approvals, the level of data required for such an approval (e.g., for food, feed and processing) is practically the same as for intentional release into the environment (e.g., planting as a commercial crop), because MAFF still reviews the effect on biodiversity in case of spillage during transportation.

Also, in principle, Japan requires field trials in domestic soil to assess the effect of GE crop "release" to local biodiversity, and is one of only two countries (with China) that requires domestic field trials for GE crops intended only for import. Therefore, seed companies seeking approval must conduct at least two field tests in an isolated plot on domestic soil – a so-called 'Stage 3 Field Trial' (S3-FT) - regardless of the fact that the seed will not be commercially planted in Japan. Within the commercial sector, this policy is widely viewed as unnecessary to protecting Japanese biodiversity. It is also considered to be a costly aspect of Japan's regulatory system for biotechnology providers in terms of time, intellectual resources, and finances. Another aspect of S3-FT is that the availability of resources, i.e., isolated field plots, is extremely limited. All major technology providers either own their own fields for S3-FT or have secured long-term contracts on trial facilities. Japanese regulation requires detailed specification of the 'isolated field' for the trial and constantly monitors the management of the Stage 3 Trial. As only limited technology providers can afford to use such facilities, this requirement creates a barrier to entry into the market for many agricultural biotechnology providers. International standard-setting bodies for agricultural biotechnology generally do not consider domestic field trials as a necessary step for food safety or environmental risk assessments.

At the same time, Japan has been continuously reviewing its regulatory efficiency. One potential significant modification in the near future could be the flexible handling of the requirement for S3-FT. Instead of lifting the requirement for all crops, the GOJ started to lift the exemption for crops that do not have wild relatives in Japan, such as corn, with traits of sufficient familiarity, such as herbicide tolerance and insect resistance. The GOJ and its academic members have been discussing the issue internally, as well as in a publically held expert meeting in June, 2014. The effect of S3-FT exemptions for GE corn events would be tremendously positive, not only for technical providers, but also for Japanese regulators, and indirectly for Japanese food security, because it will reduce the possibility of asynchronous approval.
(in Japanese, http://www.s.affrc.go.jp/docs/commitee/diversity/140203/pdf/shiryou4.pdf).

As of October 27, 2016, traits of "sufficient familiarity" are listed as below.

Insect resistance
- *Lepidoptera* Resistance - *cry1Ab, cry1F, cry1A.105, cry2Ab2, cry1Ac, vip3A*
- *Coleoptera* Resistance - *cry3Bb1, cry3Aa2, ecry3.1Ab, cry34Ab1/cry35Ab1*

Herbicide resistance
- Glyphosate resistance - *cp4 epsps, mEPSPS*
- Glufosinate resistance - *pat, bar*

Allyloxymethyl alkanoate resistance - *aad-1*

Other traits
Heat-stable alpha amylase - *amy797E*
High lysine - *cordapA*
Drought tolerance - *cspB*

The improvement, i.e., the exemption of field trial, that MAFF-Environment has made is a significant time saver, and is a practice of data transportability although crops and traits for the practice are limited. Currently, MAFF does not accept data generated from non-domestic field trials for environmental risk assessment, except for the combinations listed above, the discussion of data transportability is active (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4639567/pdf/11248_2015_Article_9892.pdf).

e) INNOVATIVE TECHNOLOGIES
Like many other countries, the GOJ handles products derived from innovative technologies on a case-by-case basis. Consequently, researchers are taking a relatively conservative and cautious position towards R&D. Although some products and/or approaches of innovative technologies may not fall under the current definition of "genetic engineering", the Tohoku University Gene Research Center announced that they would manage all "genome-editing technology" in the center in the same manner as "genetic engineering", and will seek regulatory authorization for experimental operations (http://www.cgr.tohoku.ac.jp/genome/) .

In September 2015, MAFF released a report summarizing its perspective, current status of domestic and international research, possible application, and regulatory consideration of innovative technologies, (or new plant breeding techniques, NPBTs, in MAFF's terminology,). In the report, MAFF does not provide a regulatory definition of "NPBTs" or the complete criteria for whether or not NPBT-derived products should be regulated. However, the report illustrates the direction in which MAFF is moving. In short, MAFF will make a decision in light of existing regulations for genetically engineered crops on a case-by-case basis. Two major points of consideration are: 1) if transgenes were used for recombination or their copies still remain in the final product, and 2) comparison with conventional breeding and the possibility of unintended mutagenesis.

Japan is also actively involved in the research and development of innovative biotechnologies, such as CRISPR/Cas9. Because of the advantages in cost and time required for development, Japanese researchers in public institutes and universities have been actively engaged in the development of agricultural crops with novel traits. Under current regulatory ambiguity is whether or not CRISPR/Cas9 products fall under the category of "GE crops." MAFF recommends researchers receive approval from the relevant authority for field trials in order to avoid accidental regulatory incompliance.

The first trial case of an agricultural crop with innovative technologies in Japan was a potato event with reduced amylose and acrylamide developed by Hirosaki University and utilizing epi-genomic modification and grafting. The genes for low amylose and acrylamide were introduced to the plant for shoot. Then, genetic suppression, which will prevent accumulation of novel genes, was made to the plant for root. Therefore, when these two plants were grafted, the tuber will have lower amylose and acrylamide but also no genetic material of the introduced "foreign genes. Therefore, the harvested tuber can be technically considered non-GE.

Hirosaki University also developed a novel apple event in which GE rootstock was grafted with a non-GE shoot. Because the rootstock has been genetically engineered with resistance to soil disease, the apple tree will be regarded as a GE plant when cultivated. However, the regulatory classification for the fruit remains unclear.

In terms of R&D promotion, the GOJ has made a significant commitment to promote innovative technology, such as genome editing technologies, in agriculture. In CY2015, the GOJ initiated the "Cross-ministerial Strategic Innovation Promotion Program (SIP)", a national project for science, technology and innovation, identifying the ten most important areas for revitalization of the Japanese economy. One of the ten areas identified is agriculture with the program name "Technologies for Creating Next-Generation Agriculture, Forestry and Fisheries," which received 3.32 billion yen among 50 billion yen SIP budget in JFY2015. In JFY2016, "Next-Generation Agriculture" received 2.66 billion yen among 32.5 billion yen SIP budget.
Plant breeding with genome editing technologies such as CRISPR/Cas9 is one of main topics in "Next-Generation Agriculture". As a result, basic research in various crops have been partially or fully supported with the SIP budget and published in journals. However, none of the research has yet reached the phase of regulatory clearance or consultation for commercial release.

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.

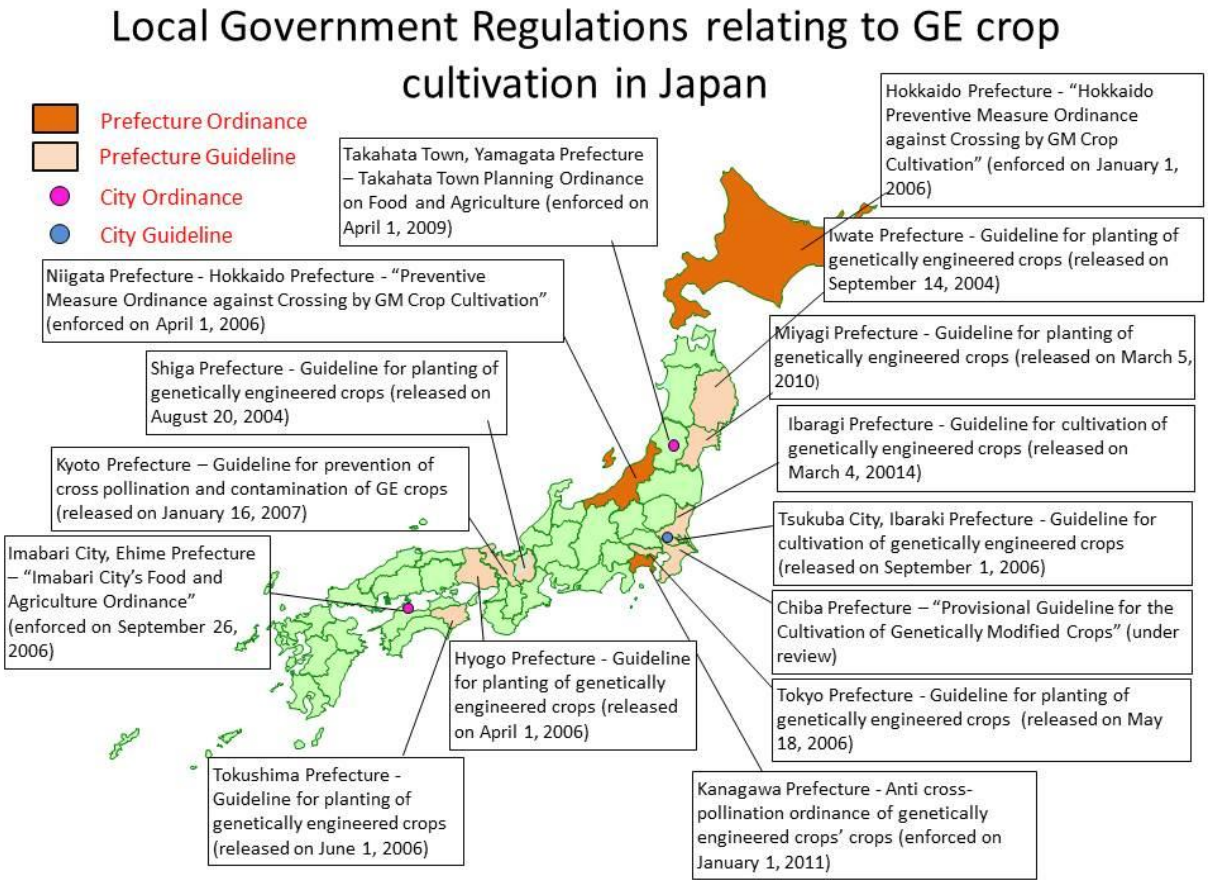
In addition to MAFF's guidance, local governments often have strict "regulations" and/or guidance which may contain the requirement of risk communication with neighboring farmers and the community to have consent to grow GE crops. Local government regulations are often the most difficult obstacles to farmers growing GE crops.

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

As previously noted, there are a number of local rules relating to agricultural biotechnology in Japan. Many, if not all, of these rules are political responses to popular concerns and are not based on science.



Source: Dr. Yoshiko Sassa, Life and BioPlaza 21.

Note: Hokkaido is the largest agricultural producing prefecture in Japan, followed by Ibaragi and Chiba

1. Hokkaido (Ordinance) - Japan's northernmost island of Hokkaido is the country's bread basket, and, in many instances, leads the country on agricultural policy issues. The prefecture's rules effectively

discourage the commercial cultivation of GE crops, even though there is demand from some growers who would like to grow GE crops (e.g., herbicide resistant sugar beets).

On January 1, 2006, Hokkaido became the first prefecture in the country to implement strict local regulations governing the open-air cultivation of GE crops. Hokkaido's rules set minimum distances between GE crop fields and other crops (e.g., at least 300 meters for rice, 1.2 kilometers for corn, and 2 km for sugar beets). The distances, however, are nearly twice as large as those set at the national level for research purposes.

Under the current regulations, individual farmers wishing to plant open-air GE crops must complete a series of complicated steps to request approval from the Hokkaido Governor's office. For farmers, failure to follow these procedures could result in up to one year imprisonment and a fine of as much as 500,000 yen (approximately $4,808). In order to apply, farmers must first host public meetings at their own expense with neighboring farmers, agricultural cooperative members, regional officials, and other stakeholders. At these meetings, farmers must announce their intention to plant GE crops and explain how they will ensure that their crops do not mix with non-GE crops. Afterwards, the farmers must draft complete minutes of these meetings to submit to the Governor's office. Additionally, farmers must complete a detailed application for submission to the Governor's office that explains their plans for growing GE crops. The application requires precise information on the methods that will be used to monitor the crops, as well as measures for preventing cross-pollination, testing for GE 'contamination,' and procedures for responding to emergencies. Finally, farmers must pay a processing fee of 314,760 yen (approximately $3,026) to the Hokkaido Governor's office in order to cover the cost of reviewing their application. If approval is initially granted but major changes to the application are made later, then farmers must pay an additional reprocessing fee of 210,980 yen (about $2,028).

Institutions that wish to conduct research using open-air GE farming are subject to a regulatory process similar to that imposed upon farmers. After receiving government designation as qualified research institutions, these organizations must then give formal notification of their biotechnology research activities and submit extensive paperwork to the Hokkaido Governor's office for approval. They must also provide detailed test cultivation plans to a local government panel for review. However, unlike individual farmers, research institutions are not required to hold explanatory meetings with neighbors or pay application processing fees to the Hokkaido government. Furthermore, while subject to fines as large as 500,000 yen (approximately $4,808) for non-compliance, employees of research institutions are not subject to imprisonment if they fail to comply with GE regulations like farmers would be.

For both individual farmers and research institutions, the Hokkaido Governor's office decides whether to approve the applications based on the recommendations of the Hokkaido Food Safety and Security Committee (HFSSC). The HFSCC serves as an advisory board to the governor and consists of fifteen members representing academia, consumers, and food producers with a knowledge of food safety. Within HFSCC, there is also a separate subcommittee made up of six professional researchers who study the application from a scientific point of view. The HFSSC is authorized by the governor to order applicants to change their cultivation plans if they feel it is necessary.

Since the 2006 implementation of Hokkaido's GE regulatory regime, no farmers or research institutions have submitted any requests to the Hokkaido governor's office to grow open-air GE crops. Difficulties in complying with the Hokkaido GE regulations, along with continued consumer anxiety about the

safety of GE products and a shift towards conducting GE crop research inside enclosed environments, effectively halted attempts at open-air cultivation of GE crops. Therefore, the HFSSC has not yet had the opportunity to review, let alone approve or reject, applications. It remains to be seen how strictly the committee will evaluate individual applications.

As Hokkaido farmers are secluded from the latest agricultural technology – despite a 20-year history of efficacy and safety - 50 professional farmers formed the Hokkaido Farmers Association and submitted a petition requesting field tests of GE crops, including soybeans, maize, and sugar beets, to the Hokkaido Research Organization in April 2015. As of October, 2016, there is no reported response by the Hokkaido Research Organization.

2. Ibaragi (Guidelines) - The Ibaragi GE crop guidelines were established in March 2004. The guidelines state that a person who plans to grow GE crops in open-air fields must provide information to the prefectural government before planting the crops. The person must make sure that s/he gets acknowledgement from local governments, nearby farmers, and farm cooperatives in the region. The person must take measures to prevent the pollination of conventional crops and commingling with ordinary foods. The guidelines became effective on September 1, 2006.

3. Chiba (Provisional Guidelines) - Based on food safety ordinances that came into force in April 2006, the government is in the process of drawing up guidelines on GE crops. The last discussion of the 'Provisional Guideline for the Cultivation of Genetically Modified Crops' was in March 2008. As of October 2016, the guideline is still just a draft and has not yet been finalized.

4. Iwate (Guidelines) - Iwate GE crop guidelines were established in September 2004. The guidelines state that the prefectural government, in cooperation with local governments and local agricultural cooperatives, request that farmers not grow GE crops. For research institutes, the prefectural government requests that they strictly follow the experimental guidelines when they grow GE crops. Since the guidelines were established, there seems to have been no attempt to grow GE crops.

5. Miyagi (Guidelines) - On March 5, 2010, Miyagi Prefecture implemented the 'Guideline for planting of genetically modified crops in Miyagi'. The applicant has to submit the experimental plan in January or June of the year of the experiment and at least three months prior to the experiment. The requirement for the experiment is basically to observe MAFF's Cartagena Law for isolated field trial. However, the hardest part for applicants is to hold a briefing for neighbors of the experimental sites and concerned citizens in order to receive agreement for the GE crop planting. The Center of Gene Research at Tohoku University is one of the few universities that operates an isolated field trial for GE crops on a regular basis in Japan. The activity focuses on the basic research of UV sensitivity in rice.

6. Niigata (Ordinance) - Niigata put a stringent ordinance into effect in May 2006. It obliges farmers to get permission from the Governor to grow GE crops, while research institutes must file reports on open-air experiments. Violators face up to a year in prison or fines of up to 500,000 yen.

7. Shiga (Guidelines) - The Shiga Prefectural government is reportedly eager to promote biotechnology but worries about a consumer backlash if crops are planted in the region. Thus, the guidelines adopted in 2004 request farmers to refrain from commercial planting of GE crops. For test plots, the government

requests farmers take measures to prevent cross pollination and commingling. The guidelines do not apply to research institutions.

8. Kyoto (Guidelines) - In January 2007, the Kyoto government published detailed guidelines for growing GE crops based on a 2006 food safety ordinance. The guidelines state that a person who is going to grow GE crops is obliged to take measures to prevent cross pollinating and commingling. GE crops addressed by the guidelines are rice, soybeans, corn and rapeseed.

9. Hyogo (Guidelines) - Coexistence guidelines were enacted on April 1, 2006. The basic policy of the guidelines is twofold: one aspect provides guidance to farmers concerning production, distribution and marketing of GE crops; the other deals with the labeling of GE products in order to address consumer concerns.

10. Tokushima (Guidelines) - Tokushima Prefecture published guidelines on GE crops in 2006. The guidelines state that a person who grows GE crops in open-air fields must first notify the governor. The fields must then incorporate signage indicating that GE crops are being grown. The GE crop guidelines are stressed as a part of its "farm brand strategy" to compete with other production centers.

11. Imabari City in Ehime Prefecture (Ordinance) - This municipality-led ordinance entered into force in April 2007 and requires any producer of genetically engineered products to first receive permission from the mayor. The application fee is 216,400 yen. The ordinance also prohibits genetically modified foods from being served in school lunches.

12. Tokyo (Guidelines) - Guidelines were enacted in May 2006 requiring growers of GE crops to provide information to the Tokyo Metropolitan government . Tokyo is primarily urban, but the local government is known for being a vanguard of new food safety rules.

13. Kanagawa – On January 1, 2011, Kanagawa Prefecture implemented the “Anti cross-pollination ordinance of genetically engineered crops” and requires growers to submit an application for the planting of GE crops (except rose and carnation) due to the possibility of cross pollination with domestic plants. There is no charge for the submission for planting of GE crops.

14. Takahata Town, Yamagata Prefecture – On April 1, 2009, Takahata Town implemented the “Takahata Town Planning Ordinance on Food and Agriculture”, which includes a series of requirements (like Hokkaido Prefecture) including obtaining agreement from local residents for commercial planting of GE crops.

15. Tsukuba City, Ibaraki Prefecture – On September 1, 2006, Tsukuba City released a guideline for cultivation of GE crops. There are just a few public entities, including Tsukuba University and the National Institute of Agricultural Sciences, where GE crops are grown in confined field plots.

g) LABELING

Food labeling issues, including GE labeling, are handled by the Consumer Affairs Agency (CAA). Recently, the CAA reviewed the laws related to food labeling, with a vision of unifying the Food Sanitation Law, the Japan Agricultural Standard (JAS) Law, and the Health Promotion Law. The new “Food Labeling Law” was implemented on April 1, 2015. The regulations for GE labeling, such as

items to be labeled, the three types of labeling categories, and the “5 percent rule” for the non-GE category, are unchanged. For more details about this Food Labeling Law, please note GAIN reports on Japan's New Food Labeling Law, JA3054 and JA4043.

Table 4: Processed products of mandatory GE labeling

Items subject to labeling	**Ingredient to be labeled**
1. Tofu (soybean curd) and fried tofu	Soybean
2. Dried soybean curd, soybean refuse, yuba	Soybean
3. Natto (fermented soybean)	Soybean
4. Soy milk	Soybean
5. Miso (soybean paste)	Soybean
6. Cooked soybean	Soybean
7. Canned soybean, bottled soybean	Soybean
8. Kinako (roasted soybean flour)	Soybean
9. Roasted soybean	Soybean
10. Item containing food of items 1 to 9 as a main ingredient	Soybean
11. Item containing soybean (for cooking) as a main ingredient	Soybean
12. Item containing soybean flour as a main ingredient	Soybean
13. Item containing soybean protein as a main ingredient	Soybean
14. Item containing edamame (green soybean) as a main ingredient	Edamame
15. Item containing soybean sprouts as a main ingredient	Soybean sprouts
16. Corn snacks	Corn
17. Corn starch	Corn
18. Popcorn	Corn
19. Frozen corn	Corn
20. Canned or bottled corn	Corn
21. Item containing corn flour as a main ingredient	Corn
22. Item containing corn grits as a main ingredient	Corn
23. Item containing corn (for processing) as a main ingredient	Corn
24. Item containing food if items 16 to 20 as a main ingredient	Corn
25. Frozen potato	Potato
26. Dried potato	Potato
27. Potato starch	Potato
28. Potato snacks	Potato
29. Item containing food items 25 to 28 as a main ingredient	Potato
30. Item containing potato (for processing) as a main ingredient	Potato
31. Item containing alfalfa as a main ingredient	Alfalfa
32. Item containing sugar beet (for processing) as a main ingredient	Sugar beet
33. Item containing papaya as a main ingredient	Papaya

In addition to the 33 food items in the table, Japan applies GE labeling requirements to high oleic acid soybean products, even though the oil extracted from the soybean does not contain traces of the introduced genes or proteins.

In the case of GE papaya, the Hawaii Papaya Industry Association voluntarily agreed to apply labeling to individual GE papaya as the product is a consumer-ready fruit. By placing labels on each fruit to

segregate GE fruit from non-GE fruit, the label functions as an identity preservation program (IPP). As such, the industry is not required to prepare special documentation for each shipment.

It is important to note that the labeling of GE and non-GE fruit is done voluntarily by the Hawaii papaya industry, and is unique to Hawaiian papaya. The industry agreed on the use of individual fruit labeling instead of IPP paperwork. As such, this case cannot be considered as a general labeling practice applicable to other GE specialty crops which may be released in the future.

The use of 'non-segregated' ingredients in processed products has been widespread for several years, and established its "specific" position, where labeling is not required, in the food industry.

Table 5: Processed products exempted from GE labeling

Source GE Crop	**Processed product (ingredient) from GE crop**	**Examples of final processed products**
Corn	Corn oil	processed seafood, dressing, oil.
	Corn starch	ice-cream, chocolate, cakes, frozen foods
	Dextrin	bean snacks
	Starch syrup	candy, cooked beans, jelly, condiments, processed fish
	Hydrolyzed protein	potato chips
Soybean	Soy sauce	dressing, rice crackers
	Soybean sprout	Supplements
	Margarine	snacks, supplements
	Hydrolyzed protein	pre-cooked eggs, past, beef jerky, potato chips
Canola	Canola oil	fried snacks, chocolate, mayonnaise
Sugar beet	Sugar	various processed products

In previous reports (JA2013 and JA3027 Post reported on the increasing use of ingredients from GE crops. This trend, which is not subject to a mandatory labeling requirement, continues to be popular. Based on an estimate by a consumer group concerned with GE crops, the top ten food manufactures' total sales of processed products containing ingredient(s) from GE crops could be as much as 5 trillion yen (approximately $4.8 billion). The group's list of products covers a wide variety of processed foods, including snacks, ice cream, soda, soy milk, vegetable oil, and ready-to-eat foods. Even though most of the ingredients are highly processed and do not contain traces of DNA or protein from the gene inserted to create the novel trait of GE crops, some food manufacturers have continued to make labels indicating the source of the ingredient could be GE. Although there has been no explicit public acceptance of GE food crops, negative campaigns, such as boycotts of GE crops, appear to be decreasing, which could be a sign that the use of ingredients from GE crops has been passively accepted.

The Japanese Consumers' Co-operative Union (JCCU), a co-op organization with 25 million members and 346 billion yen ($3.3 billion) in sales, frequently uses GE/non-segregated ingredients in its store brands and identifies that fact on the ingredient label (JA9046). In their catalog, JCCU (provided an explanation of why they use GE ingredients, focusing on the difficulties of segregating products during distribution. In their report, JCCU explained global status of GE crop's adoption, cultivation, benefit, and use in various food products. The report indicates that GE crops passed through Japanese safety

reviews and, as such, there is no safety concern. Accordingly, JCCU will not exclude products containing GE materials as long as they are regulatory approved, possess qualities they should have, and are appropriately priced.

The use of inappropriate, inaccurate, or misleading food labels is also a concern in Japan. As an example, in December 2008, MAFF ordered a bean trader in Fukuoka to stop using the "Non-GMO" label on red kidney and adzuki beans. This label was deemed a violation of the Japan Agricultural Standards Law, because there is currently no commercial production of GE adzuki and red kidney beans.

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/pdf/h26_houkoku.pdf).

Of the 303 volunteer canola plants in 15 ports subjected to analysis, the results showed that 70 plants, or 23 percent, had a transgene for herbicide tolerance. They also tested mustard (*Brassica juncea*) and Chinese colza (*Brassica campestris* L.), a domestic canola, to see if there was "gene flow" from cross pollination. Of the 1072 mustard and 205 Chinese colza plants, no foreign gene was detected, indicating there was no cross pollination leading to gene flow. Of the 7 volunteer soybean plants found in two ports among ten invested ports, the results showed that six plants had a transgene. Though soybean is mostly self-pollinating, they also tested 16 *Glycine soja*, a domestic wild relative of soybean to detect cross pollination. No transgene was found in *Glycine soja*.

Testing for "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 pest pressure, there has been an increasing 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.

In November 2009, MHLW implemented a new standard and specification for testing for GE grain in non-GE bulk shipments. With this procedure, imported grain is initially tested by the conventional method, quantifying GE specific regions in the bulk sample. If the result from the conventional method indicates that the shipment contains more than five percent GE grain in a non-GE shipment, a new single grain based test is performed. In this test, 90 grains are used and each grain is tested individually. This methodology enables the determination of GE or non-GE for each grain, regardless of whether it is non-GE, incorporates a single GE event, or is a stacked GE event. If the results demonstrate that two or less of the 90 grains are GE varieties, the shipment is considered 'non-GE' because it contains less than five percent GE by bulk. If the test results indicate three to nine grains are GE varieties, a second single-grain-based test is run with a new set of 90 grains. If the sum of GE grains from the first and second run is nine or less of the 180 tested grains, the shipment is considered 'non-GE'. If the number of GE

positive grains from the first single-grain-based test is 10 or more (i.e., 10 out of 90), or if the number of GE positive grains from the first and second single-grain-based test is 10 or more (i.e., 10 out of 180), the shipment is considered to be non-segregated.

i) LOW-LEVEL PRESENCE (LLP) POLICY

In 2001, Japan began legally requiring safety assessments of GE foods. This was done under the broad authority contained in Article 11 of the Food Sanitation Law as follows:

> 'Article 11: The Minister of Health, Labour and Welfare, from the viewpoint of public health, may establish standards of manufacturing, processing, using, preparing, or preserving food or food additives intended for sale or may establish specifications for components of food or food additives intended for sale, based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

Where specifications or standards have been established pursuant to provisions of the preceding text, any person shall be prohibited from manufacturing, processing, using, preparing, or preserving any food or food additive by a method not complying with established standards; or from manufacturing, importing, processing, using, preparing, preserving, or selling any food or food additive not complying with established specifications.'

MHLW's zero tolerance Low Level Presence (LLP) policy is implemented through the Ministry of Health and Welfare Announcement that states in Section A - "Standards Regarding Composition of Foods in General" of Part 1- "Foods":

> 'When foods are all or part of organisms produced by recombinant DNA techniques, or include organisms produced by recombinant DNA techniques either partially or entirely, such organisms shall undergo examination procedures for safety assessment made by the Minister for Health and Welfare and shall be announced to the public in the Official Gazette.'

Japan has a zero tolerance for unapproved GE events in food and the environment, and it is explicitly illegal to import GE-derived foods that have not been approved, regardless of the amount, form, or their known safety outside of Japan. For this reason, LLP of unapproved GE crops has the potential to disrupt agricultural trade with Japan. Since the late 1990's, potatoes (NewLeaf), papayas (55-1, aka "Rainbow"), corn (StarLink, Bt10, E32), and rice (LLRICE601) have, at some point in time, all been subject to testing or segregation, or have been temporarily banned. As of October 2016, there is no testing of U.S. corn or rice, since the presence of unapproved events was confirmed to be negligible or below the detection limit. After the discovery of unapproved GE wheat in Oregon in May 2013 and in Washington in July 2016, the GOJ introduced testing of wheat exported from the United States. As wheat is a state traded commodity in Japan, MAFF tests shipments prior to export, while MHLW monitors a percentage of shipments on arrival at Japanese ports.

To assure compliance, monitoring is in place for both imported shipments and, at the retail level, processed food products. As a part of the monitoring program for imported foods, testing at ports is handled by MHLW directly, while local health authorities handle testing for processed foods at the retail level. All testing is performed according to sampling and testing criteria set by MHLW. If the detection

is at the port, the shipment must be re-exported or destroyed. If the detection is at the retail level, the manufacturer of the product must issue an immediate recall.

As of June 29, 2015, MHLW monitors for the following items:

- PRSV-YK, PRSV-SC and PRSV-HN (papaya and its processed products)
- 63Bt, NNBt, and CpTI (rice and its processed product with rice as a main ingredient)
- RT73 B. rapa (canola and its processed products)
- MON71700 and MON71800 (U.S. wheat)
- E12, F10 and J3 (potato and its processed products (of potato as a main ingredient, such as French fries and potato chips)

Ministry of Agriculture (MAFF) Policies on LLP in feed grain

Under the Feed Safety Law, MAFF monitors the quality and safety of imported feed ingredients at the ports. All GE-derived plant materials to be used as feed in Japan must obtain approvals for feed safety from MAFF. However, as an exemption, MAFF may set a one percent tolerance for the unintentional commingling of GE products in feed that are approved in other countries but not yet approved in Japan. To apply the exemption, the exporting country must be recognized by the MAFF Minister as having a safety assessment program that is equivalent to or stricter than that of Japan. In practice, MAFF would consult with its Experts Panel on Recombinant DNA Organisms on any decision concerning a one percent exemption for feed. This exemption has applied to the United States since 2003. In December 2014, MAFF announced that the exemption would also be applied to Australia, Canada, Brazil and European Union.

Ministry of Environment (MOE) and MAFF Policies on LLP in environment

Japan's environmental rules also have a zero tolerance for unapproved living modified organisms (LMOs). These rules are specific to planting seeds, and not relevant to products that are not intended for release into the environment, such as feed grains.

CODEX LLP Supported but Not Implemented

International guidelines on food safety assessments for the low-level presence of genetically modified foods were adopted by the 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 especially 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 the 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.bch.biodic.go.jp/).

The thirteenth meeting of the Conference of the Parties to the Convention on Biological Diversity, will be held in Cancun, Mexico, from December 4 to 17, 2016. Since COP12, focus of discussion seems to be shifted toward synthetic Biology.

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). The target is more geared towards the pharmaceutical and medical industries rather than agriculture.

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 crop 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 latest survey done in JFY2014 showed that the concern about GE food is the lowest among 18 items (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). This might be an indication of consumers' familiarity with GE foods and/or the effect from reduced negative media coverage and campaigns from consumer groups and correlates with the JCCU members' acceptance of food products containing GE materials (note "PART B: Policy, e) LABELING").

Food manufacturers avoided GE crops for the products requiring 'GE' or 'non-segregated' labeling until 2008. After the hike in grain prices in 2008, some companies, including JCCU, started to use cheaper, non-IP products (non-segregated), which are mostly GE. JCCU even began voluntarily labeling products which did not have a legal requirement for labeling. Since then, there has been no significant public backlash or no-buy movement in the organization of JCCU, which has 25 million members.
In fact, the acceptance of GE ingredients by the food processing industry seems to have been stable in the past few years. Industry sources estimate that approximately 70 percent of food corn is either non-segregated or GE. Although most food corn that falls under the GE or non-segregated category is still consumed in food that does not require labeling under Japanese law (e.g. starch, sweeteners, etc.), the non-segregated category has begun to be used more widely.

Intriguingly, an industry survey indicated that consumers' acceptance and confidence in food products containing GE crops increased when appropriate information was conveyed and labeling of GE was practiced. Prior to learning about GE technology opportunities, 40 percent of those interviewed accepted food products containing GE products. Then, interviewees were exposed to "key messages" regarding crop GE technology, namely that (1) only GE products with stringent scientific review will be marketed, (2) no adverse health effect has been proved after 20 years of GE crop production, (3) Japan consumes more GE products for food and feed than domestic rice consumption, and (4) GE crops are widely used in food oil, corn starch, sweetener and feed in Japan, and contribute to Japanese food security. After learning the key messages, the acceptance of food products containing GE crops increased to 60 percent. The result indicates that continuing risk communication on the importance of agricultural biotechnology for food production and security, environmental protection, and consumer benefit is a necessity for gaining consumer acceptance.

Although not all consumers would be fully convinced by scientific information to accept GE food, the adoption of GE labeling in a proactive manner could be a way to increase market acceptance among certain consumers. (Note "PART B: Policy, e) LABELING" for related information.)

Feed use accounts for about 68 percent of Japan's corn consumption, and nearly all feed-use corn contains GE. In the past, there was limited demand for non-GE feed corn for a specific non-GE fed dairy market. However, sources indicate that the non-GE feed corn market is extremely small.

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 negative public reaction to modern biotechnology, especially with regard to the genetic transformation of animals.
That being said, the GE silkworm remains relatively close to the commercial application stage in Japan, see JA5024 for more information.

Additionally, interest in animal cloning appears to have waned in Japan. As of March 2016, Japan had produced 625 cows by fertilized egg cell cloning, 415 cows by somatic nuclear transfer (SCNT), 638 swine by SCNT, and 5 goats by SCNT. All production has been done in public research institutions. The activity has been steadily decreasing since late 90's when 461 of the 625 cows to date were produced by fertilized egg cell cloning in 1998 alone, and 98 of the 415 cows to date were produced by SCNT in 1999 alone.

b) COMMERCIAL PRODUCTION
Currently, there is no commercial production of GE animals or cloned animals for the purpose of agricultural production.

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 public sector, which receives financial support from the government. As innovative biotechnologies are one of the key agenda in the aforementioned SIP, program "Technologies for Creating Next-Generation Agriculture, Forestry and Fisheries". In animal biotechnology, MAFF is promoting research into the CRISPR/Cas9 application for the breeding of tuna with reduced aggressiveness and as a more suitable for fish culture.

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. Post is not aware of any commercial product with "cloned" labeling available 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

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

Consumer Affairs Agency (the agency responsible for labeling regulations, including GE)
http://www.caa.go.jp/en/index.html (English)

Food Labeling Law (in Japanese only)
http://www.caa.go.jp/foods/index18.html
Currently, the information on the new Food Labeling Law is not available in English. Please refer to GAIN report "An Overview of the New Food Labeling Standard" JA4043 (http://goo.gl/FbyfVu) for details on new law. In short, there is no substantial change on the regulatory requirement of GE labeling.

Useful resources on agricultural biotechnology by Japan Biosafety Clearing House (Japan)
http://www.bch.biodic.go.jp/english/e_index.html

As of June 29, 2015, the GOJ had reviewed and approved 302 events for food (taking stacked events into account), 140 events for feed, and 113 events for food (taking stacked events into account). Also, 17 food additives derived from GE have been approved for commercial use.

Approved events for commercial use

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

Approved events for feed use:
http://www.famic.go.jp/ffis/feed/obj/sub3_gmoe.pdf

Approved for environmental release under the Cartagena Protocol domestic Law;
http://www.bch.biodic.go.jp/english/lmo.html