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Japan's regulatory system for GE crops continues to improve

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Report Highlights:
This report provides the latest status of consumption, regulation, public perception, research, development and production 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 that have been produced using modern biotechnology. Though the United States has historically been the dominant supplier of corn to Japan, the U.S. share dropped significantly following the U.S. drought in 2012. The U.S. share of global corn exports to Japan fell to 23 percent in February 2013, but recovered to 90 percent in the latter half of MY2013/14. Regardless of the shift in supplies, the regulatory approval of genetically engineered (GE) crops by the Government of Japan (GOJ) continues to be important for the U.S. industry and global food production, 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 and three million MT of soybeans from around the world, approximately three-quarters of which are produced using biotechnology. Japan also imports billions of dollars worth of processed foods that contain GE crop-derived oils, sugars, yeasts, enzymes, and other ingredients.

GE regulations in Japan are science-based and transparent, and new events are generally reviewed and approved within acceptable time periods that mostly align with industry expectations. As of June 29, 2015, 302 events, including stacked events, had been approved for food use. The number of approved events in the past 12 months fell from over 100 to 12. However, this reduction in the number of approved events is because of an improvement in the review process that MHLW implemented in CY2015, exempting from scientific review those stacked GE events that use pre-approved single events, provided the cross does not affect the metabolic system of the host. In addition to managing the review process more efficiently, increased familiarity with events with popular transgenes contributes to a prompt review. At the same time, assuming 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. As one of the world's largest per capita importers of GE crops, improvement of the Japanese GE regulatory system, focused on long-term trends in biotechnology, will benefit all stakeholders.

So far, over 148 events in 9 crops have been approved for environmental release, most of which includes 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.

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

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 the economy crash and the unpredictability of public acceptance, most private companies closed or decreased the scale of operations significantly. Currently, most agricultural R&D is operated by the public sector, government research institutes and universities. There are a few R&D operations in the private sector, but most of them are supported by government funds, with the exception of food additives.

Compared with the R&D in the United States which is private driven, Japanese R&D seems to progress at a comparatively slow pace due to multiple factors. One reason is a very cautious attitude towards consumer's acceptance of GE crops. Because of unforeseeable consumer acceptance even of GE crops with high value added or consumer benefit, retailers and food manufactures are taking a very conservative position to the use of GE crops in the products which require labeling. Therefore, farmers will not step forward to grow GE crops, even when they know the benefits to be gained. A second factor is regulatory clearance. In addition to central government regulation, many local governments set additional regulations even for the planting of events approved by the central government. The situation is extremely discouraging for R&D of agricultural biotechnology. Even with these restrictions, however, there is R&D worth to mentioning.

The Forest and Forest Product Research Institute (FFPRI), a public research institute, has developed a pollen free Japanese cedar (*Cryptomeria japonica*) using genetic engineering

(http://tinyurl.com/qgkbp7o). According to some estimates, twenty to thirty percent of the Japanese population suffers from pollen allergies, and economic loss due to increased pollen release as a result of high temperatures can reach 5 billion USD or more (http://tinyurl.com/plo87hr). By suppressing the genes expressed specifically in male flowering or pollen development, the FFPRI team produced pollen free Japanese cedar. On April 8, 2015, FFPRI received a two-year approval for an open field trial for GE "pollen free" Japanese cedar.

The National Institute of Agricultural Sciences (NIAS), another government research institute, has taken a different approach to pollen allergies – 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 rice transformation. The transgenic rice grain containing modified Japanese cedar pollen antigen was used to feed mice in clinical trials and successfully suppressed pollinosis symptoms such as sneezing and nasal tissue inflammation (http://tinyurl.com/p5kdzd3). Researchers started clinical human trials in February 2015, a step toward to commercial production in the near future.

Some Japanese research in agricultural biotechnology is unique in the way that it is targeting specialty crops with direct consumer benefit. 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*), native of West Africa. When people take 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 (http://tinyurl.com/qyc4oak).

b) COMMERCIAL PRODUCTION

There is no commercial production of GE food crops in Japan. The only commercial GE crop production 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 red pigment in rose, with RNA interference. The volume of production and sales is not publically released (http://tinyurl.com/oof29qt). 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 have received regulatory approval in other countries such as Malaysia and European Union (http://bch.cbd.int/database/organisms/). The volume of export is unknown.

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 for canines from GE plants (http://www.hokusan-kk.jp/info/). Hokusan is a private company founded in 1951 by Sankyo (currently Daiichi-Sankyo, a pharmaceutical company, http://www.daiichisankyo.com/) and Hokkoren (currently Hokuren Federation of Agricultural Cooperatives, http://www.hokuren.or.jp/). Its distribution has reached all over Japan, with no rejection by 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 significant interest in GE crop production, especially GE soybeans and sugar beets (http://tinyurl.com/m2z9g5q). Hokkaido is the northernmost and largest prefecture in Japan, where the agricultural industry is relatively more important; the agricultural share of Hokkaido's Gross Domestic Product (GDP) is 2.7 percent, compared to the national GDP share of 1 percent (http://tinyurl.com/pwojsej). Hokkaido also has a size advantage. The average farm size in Hokkaido and Japan's national average are 25.8 hectares (ha) and 2.4 ha, respectively. 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 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 cost. 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. As with GE soybeans, the benefit of cultivating glyphosate-resistant sugar beets can be as much as a 58 percent reduction in operating hours and a 72 percent increase in profit (per unit acreage) (http://www.foodwatch.jp/science/readwritebio2). 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 have been utilized by the Japanese food industry for the past two decades, it is expected that there would be a demand for domestic non-segregated soybean.

However, there are a few significant obstacles for local growers to engage in commercial GE crop cultivation. One of those is local regulations. 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 they plan to utilize a herbicide tolerant trait such as glyphosate resistance (http://www.roundupjp.com/pdf/maxroad.pdf).

Though Suntory's blue rose is the only "intentional" commercial GE crop production in Japan, there have been "accidental" environmental releases of GE cotton. On December 25, 2014, MAFF announced that non-GE cotton planting seed imported from China between April 2010 and July 2012 contained GE cotton seed. The GE cotton events found were both approved by the GOJ for food and feed use, but the approval for environmental release was limited to "import-only". As such, spill-off during transport and distribution is allowed but intentional planting is a violation of the "Cartagena Law". MAFF instructed the importer and distributors to recall the "contaminated" cotton seed (http://www.maff.go.jp/j/press/syouan/nouan/141225.html).

c) EXPORTS
There are no GE food crops exported from Japan.

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. For corn, the United States has been the dominant supplier for decades.

In Marketing Year (MY, October to September) 2013/2014, Japan imported 15.1 million metric tons (MMT) of corn. The major supplier was the United States, with a market share of 72.9 percent (11.0 MMT), a significant increase from the previous market year (6.9 MMT, 48.1 percent market share). 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 (GAIN report, UP1421, http://fasintranetapps-gain.fas.usda.gov/Applications/FileDownLoad.aspx?FileID=15588); all major corn suppliers to Japan are also leading countries in the adoption of GE crop technology.

Of the 15.1 MMT of corn that Japan imports, approximately 5.1 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. Post estimates nearly half of food corn imported by Japan is non-segregated or GE. Much to the surprise of industry watchers, there was no significant media attention or negative consumer reaction to the introduction of GE corn by the Japanese food industry. Though there are no official statistics, based on information from various sources, although the use of GE food corn has increased by almost 50 percent, costly non-GE corn still holds a majority of the market. One of the reasons for this is that major manufacturers of 'happoshu', aka "third category beer" or low malt beer, which is a beer-like drink brewed with non-malt material, still insist on using non-GE corn. All four major 'happoshu' manufacturers in Japan claim that they are using non-GE corn, possibly out of fear of consumer rejection. (See "Marketing" section for the activities of consumer groups).

Although the market share fluctuates due to the production, yield and market demands, the importance of genetic engineering and other agricultural science in crop production has remained the same, if not increased. The second largest corn exporting country to Japan in 2014 was Brazil, which is concurrently and actively adopting GE technology for its corn production. Eighty-two percent of corn production in Brazil depends on GE technology (GAIN Report BR0938, http://goo.gl/ki2iZe). 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 – 2013/2014) (Year Ending: September)	
Corn for feed	
United States	6,456
Brazil	1,908
Ukraine	1,088
Argentina	287
South Africa	126
Romania	98
Russia	9
India	>1
France	>1
Paraguay	>1
Others	0
Total Feed	9,971
Corn for food, starch, manufacturing	
United States	4,561
Brazil	287
Ukraine	132
South Africa	46
Russia	41
Australia	35
France	21
Argentina	14
India	5
Total Food & Other	5,147
Total	**15,118**
Source: Ministry of Finance	

Fresh Produce

There has been a very limited volume of GE papaya 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 aware of 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. Currently there is no GE papaya sold in retail stores in Japan, but several hotel restaurants and chain restaurants introduced GE papaya to their customers (GAIN Report JA4519, http://goo.gl/LsmGCV).

e) FOOD AID RECIPIENT COUNTRIES

Japan is not a recipient of food aid.

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, 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

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 by the expert panels are reviewed by the advisory committees, whose members include technical experts and opinion leaders from a broad scope of interested parties such as 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 publishes results of its food risk assessments of GE foods in English on its website (http://tinyurl.com/q7nlc53). FSC sets the standard processing time from the reception of dossier to approval as 12 months (http://tinyurl.com/pdy9adq).

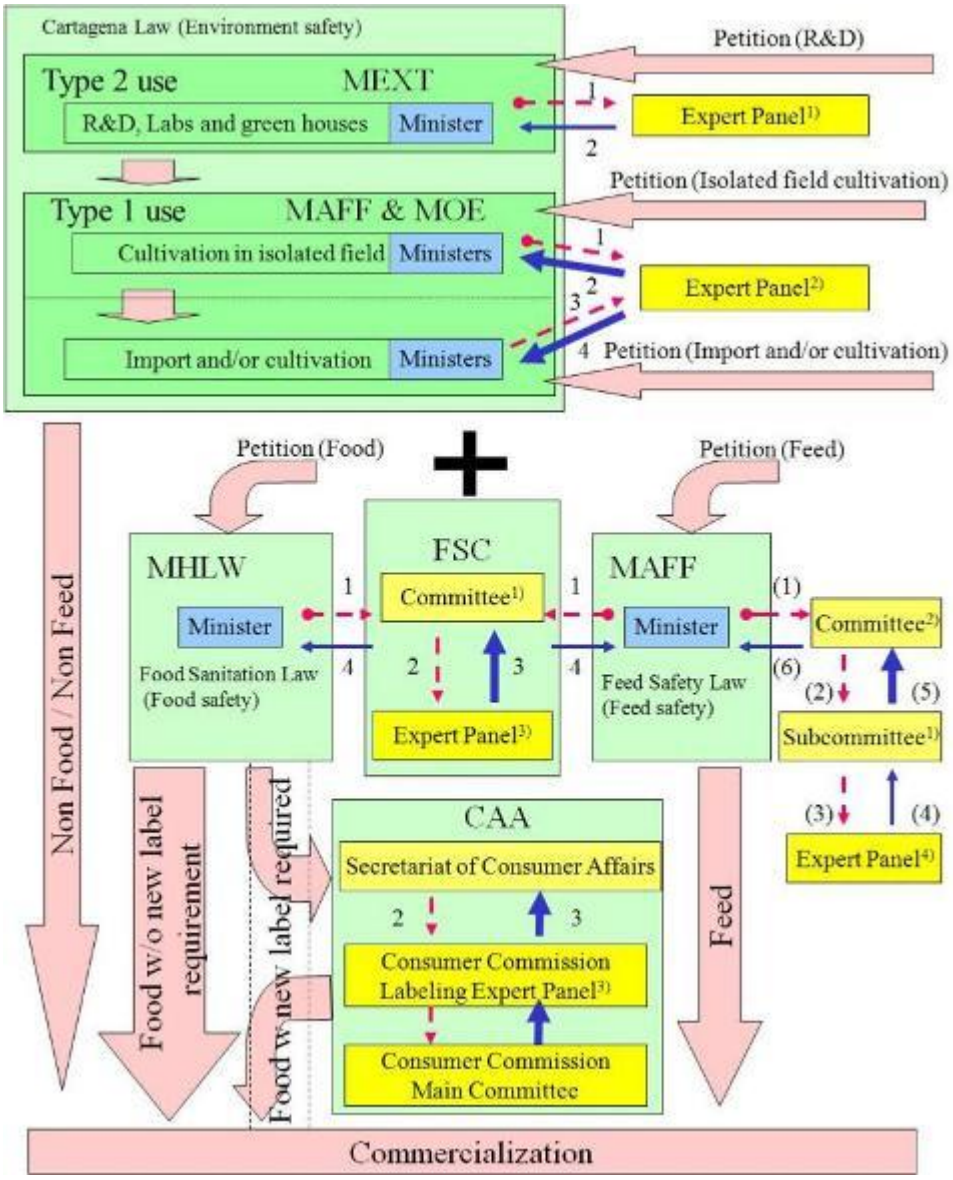
Under the Feed Safety Law, GE products that are used as feed must obtain approvals from the MAFF Minister. Based on a petitioner's request, MAFF asks the Expert Panel on Recombinant DNA Organisms, which is part of the MAFF-affiliated Agricultural Materials Committee (AMC), to review the GE crops for 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' (http://tinyurl.com/njgkdnf), 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 the 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 (http://tinyurl.com/q3j8kvm). However, when the applicant revises the dossier, receives questions from MAFF and prepares the response, the "clock" to count standard processing time stops.

Also, it takes a considerable amount of time for preliminary consultation, confined field trial, and administrative handling for official notification. Furthermore, it is customary for approval to be given for food first, followed by feed and environment. Therefore, the 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 dossier for food, feed and environmental release of the event with familiar genes.

Finally, GE products that require new standards or regulations not related to food safety, such as 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. Consequently, food labeling, including GE labeling, falls under the authority of CAA. 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. No GOJ ministry charges a regulatory processing fee 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 June 29, 2015, Japan has approved over 302 GE events for food, 140 for feed and 113 for environmental release, including commercial planting for most events. Please note the reference section for the list of approved events. The number of events approved for food do not include 12 stacks, which are no longer go through the regulatory approval process (Note "d) STACKED EVENTS" for details).

Rainbow Papaya (55-1)
On December 1, 2011, the GOJ finally issued final approval for the importation of GE papaya from Hawaii, 12 years after its official submission. For more information, please refer to previous GAIN report, JA3027 (http://goo.gl/XhZOSd).

c) FIELD TESTING
Though Japan has provided for the option of seeking "import only" approval, the level of data required for such approval (e.g., for food, feed and processing) is practically the same as the one 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.

Furthermore, Japan is one of the few countries requiring field trials in domestic soil to assess the effect of GE crop "release" to local biodiversity, and one of only two countries (with China) that require 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 leases on land. 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 this 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 assessment.

At the same time, Japan has been continuously reviewing its regulatory efficiency. One potential significant modification in the near future could be a flexible handling of the requirement of S3-FT 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 on June 30, 2014. The effect of S3-FT exemption 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. As of June 29, 2015, sources indicate that a few dossiers of new corn events have entered the regulatory pipeline under this new regulatory handling, receiving the benefit of S3-FT exemption (http://tinyurl.com/q275z34).

Regarding cultivation for isolated trials (Type 1 use), on December 5, 2014, MAFF announced an improved application process, simplifying the information required in the dossier, if the host plant is corn, the inserted genes are familiar and have scientifically well-illustrated functions, and the effect of bi-products from inserted genes to biodiversity are nothing more than that with the corn events which have been already approved (http://tinyurl.com/q2gxate). Though the simplification of the dossier is limited only to specific corn events, the merit and importance is significant in terms of the increase in efficiency, including better allocation of limited resources for both technical providers and regulators.

d) STACKED EVENTS

As a basic principle, Japan requires separate environmental approvals for stacked events. However, Japan recently made an improvement in the approval process of stacked events.

For food safety approvals, a 2004 FSC opinion paper categorized GE events into three categories (http://tinyurl.com/orfp4gz):

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 (http://goo.gl/vtggJl), Japan proposed 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 became official on June 27, 2014 (http://tinyurl.com/nnb967z). 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 will be remarkably positive in multiple aspects; saving regulatory resources for Japanese regulators and technical providers, and reducing the risk of asynchronous approval. Due to this exemption, the number of approved events listed as approved since 2014 is not as large as the number of approved events between 2013 and 2014. Stacked events exempted from review are indicated in a different table. As of June 28, 2015, twelve stacked events (1 soybean, 4 corn, 2 canola, and 5 cotton) have been exempted from review (http://tinyurl.com/ppfp9ak).

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 be still 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. However, since June 30, 2014, MAFF has consolidated the applications for stacked events. 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. (http://tinyurl.com/q275z34)

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

e) ADDITIONAL REQUIREMENTS

If any farmer tries to commercially grow a GE crop with the trait of herbicide tolerance, the farmer needs to make sure that the herbicide has appropriate registration for the cultivation of the GE crop. As there has never been commercial GE crop production in an open field in Japan, the registrants may not consider the chemical being applied to GE crops, which will have different crop management from non-GE crops.

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 through 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

There are a number of local rules relating to agricultural biotechnology in Japan. Most, if not all, of these rules are political responses to popular concerns and are not based on science. 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).

In January 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. The distance is at least 300 meters for rice, 1.2 kilometers for corn, and 2 km for sugar beets. The distances are about 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 $4,065). 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, they 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. Secondly, 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 $2,560) 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 $1,715).

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 legitimate 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 $4,065) 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 as a whole 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 on 7 April, 2015. (http://tinyurl.com/oqtfmmn) As of July 8, 2015, 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 on March 2008. As of June 2015, the guideline is still in draft and has not yet been finalized (http://tinyurl.com/o4hkgzu).

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 (http://www.pref.iwate.jp).

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 (http://www.cgr.tohoku.ac.jp/) 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

(http://www.pref.niigata.lg.jp/nogyosomu/1222970561636.html).

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 (http://tinyurl.com/po9janj). 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) - It is not Ehime Prefecture, but rather one of its municipalities, that has drawn up an ordinance on GE crops. This ordinance entered into force in April 2007 and requires any producer of genetically modified 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 (http://tinyurl.com/oxhsvgd).

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. Aichi - There are no specific guidelines that regulate GE crop production in Aichi. No specific GE crops are being produced in Aichi, but Aichi Prefecture has its own R&D laboratory that, due to consumer concerns, limits research to non-edible GE crops.

14. Gifu - Gifu Prefecture has no guidelines regulating GE crops, but local government officials have reportedly taken steps to limit the introduction of GE crops, primarily out of concern over cross pollination. Gifu Prefecture does not have an R&D facility for GE crops.

15. Mie - Mie Prefecture has no local guidelines or ordinances that regulate GE crop production. There is an R&D laboratory studying agricultural biotechnology and GE traits.

16. Kanagawa – On January 1, 2011, Kanagawa Prefecture implemented the ‘Anti cross-pollination

ordinance of genetically engineered crops' (http://www.pref.kanagawa.jp/cnt/f7227/) and requires the submission for 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.

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 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 recent GAIN report on Japan's New Food Labeling Law, JA3054 (http://goo.gl/x5M38i).

In Japan, three types of GE claims may be made on food labels: non-GE, GE, and non-segregated. To make labeling claims about foods or ingredients in the first category, the commodities must be handled under an identity preservation system and segregated. All 'GE' and non-segregated products must be labeled. Products in the 'non-segregated' category are assumed to be primarily from GE varieties. Manufacturers using non-segregated ingredients in processed products in many instances are not required to label under Japanese rules, but may do so voluntarily.

GE labeling schemes for non-GE products are based on IP handling of non-GE ingredients from production to final processing. Suppliers and distributors are responsible for supplying IP certification to exporters, who in turn supply certification to Japan's food importers or manufacturers. The manuals for the IP handling of corn and soybeans are available on CAA's website (in Japanese only, http://tinyurl.com/o6xu63s).

As shown in Table 4 below, the 33 products currently subject to labeling requirements were selected because they are made from ingredients that could include GE products and because traces of introduced DNA or protein can be identified in the foods. Generally, if the raw ingredient does not have certificates of IP handling, and if the weight content of the ingredient to be labeled exceeds five percent of the total weight of the food and is one of the top three ingredients by weight, it must be labeled with either the phrase "GE Ingredients Used" or "GE Ingredient Not Segregated". In order to be labeled "Non-GE," the processor must be able to show that the ingredient to be labeled was IP handled from production through processing.

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 product is a consumer-ready fruit. The Hawaii Papaya Industry Association agreed to apply labeling to individual 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.

Figure: An example of GE labeling. Japanese language indicates 'Hawaii Papaya (Genetically Modified).

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 does not face a mandatory labeling requirement, continues to be popular. Based on an estimate by a relatively conservative consumer group, 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 $4.06billion). 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 (http://www.mynewsjapan.com/reports/1158). 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 positive public reaction to 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 ($2.8 billion) in sales, frequently uses GE/non-segregated ingredients in its store brands and identifies that fact on the ingredient label (JA9046, http://goo.gl/9nGNIv). In their catalog, JCCU (http://jccu.coop/eng/jccu/summary.php) provided an explanation of why they use GE ingredients, focusing on the difficulties of segregating products during distribution. The co-op claims that it chooses non-GE ingredients whenever possible and gives several reasons the organization is opposed to the use of GE crops, including the novelty of the technology, unspecified possible negative effects on the environment, and economic concentration in the commercial seed industry.

At the same time, JCCU has increased the number of product offerings which use GE ingredients, and applies the label of 'non-segregated' to products even when there is no legal requirement for labeling, such as on cooking oil. Tokai Co-op, one of JCCU's branches in central Japan covering three prefectures with 28 retail stores and 73 billion yen per year business volume ($595 million per year), shares the information of two different types of canola oil, non-segregated (basically GE) and non-GE in their newsletter. In addition to voluntary labeling "non-segregated" in order to meet consumer demands to know the source, the newsletter explains the breeding history to lower glucosinolates and erucic acid, 100 percent reliance of canola on import, as well as the cost of IP handling for non-GE canola oil, which is 1.6 times more expensive than non-segregated. (http://www2.tcoop.or.jp/security/library/b79ln30000000t8u-att/b79ln30000004n95.pdf) Also, the majority of processed foods contain non-segregated ingredients amongst their major ingredients (more than 5 percent of the product) and/or minor ingredients (less than 5 percent of the product). Examples of GE ingredients are shown below.

Figure: The mark in the red square indicates 'major ingredient(s) of the product (5 percent or more by weight) may be GMO non-segregated'.

Figure: JCCU's frozen food (chicken rice). Underlined section states, 'corn (GMO non-segregated).

The use of inappropriate, inaccurate, or misleading food labels is a major 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) TRADE BARRIERS

There is no significant trade barrier in Japan to hinder the export of GE products from the United States. In fact, Japan is one of the world's largest per capita importers of GE products.

i) INTELLECTUAL PROPERTY RIGHTS (IPR)

Japan generally provides strong IPR protection and enforcement (http://goo.gl/qwYCk8). Japanese IPR covers the field related to 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.

Provisional translation of "Implementing Guidelines for Inventions in Specific Fields - Chapter 2 Biological Inventions" can be found at http://tinyurl.com/oyb6x5z.

j) 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 tenth Conference of the Parties (COP10) to the Convention on Bio Diversity (CBD, http://tinyurl.com/pps2vf3) and the fifth Member of the Party (MOP5) to the Cartagena Protocol took place in Nagoya, Japan from October 11 to 29, 2010. Japan took a lead role in a non-binding approach to Liability and Redress in the Cartagena Protocol on Biosafety negotiations, demonstrating positive leadership on this issue. Japan and seven other countries signed the Nagoya Protocol on May 11, 2011.

Japan signed the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety on March 2, 2012 (http://tinyurl.com/oqcfx8c). It requires ratification, acceptance, approval or accession by 40 countries for Liability and Redress (L & R) to be effective.

Japan attended the COP12/MOP7 meeting from September 29 to October 17, 2014, in Pyeongchang, the Republic of Korea (South Korea), where there was serious and substantial discussion about synthetic biology. Member states such as Indonesia and Bolivia took a conservative position that the Cartagena Protocol needs to be applied to living organisms resulting from synthetic biology, but some others, such as the European Union, Japan, and Brazil took the position that the decision of regulatory requirement should be made by each member state, not the CBD. The Ad Hoc Technical Expert Group will discuss the issue to set a baseline prior to COP13 at Los Cabos, Mexico in November, 2016.

k) INTERNATIONAL TREATIES/FORA

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 on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food (http://tinyurl.com/osaepm6). Japan played a very constructive role in setting the guidelines by hosting meetings and facilitating discussions among Codex members. However, Japan does not fully apply this internationally-recognized approach to its own LLP policies.

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.

l) RELATED ISSUES

<u>New Breeding Technology (NBT)</u>

New Breeding Technology (NBT, also known as New Breeding Techniques) is increasingly receiving attention as a new tool for plant transformation, as well as an issue of regulatory difficulty.

Like many other countries, the GOJ handles NBT products on a case-by-case basis. Consequently, researchers are taking a relatively conservative and cautious position towards R&D with NBTs. On March 27, 2015, although some products and/or approaches of NBTs may not fall under the current definition of "genetic engineering", Tohoku University Gene Research Center announced that they would manage all "genome-editing technology" in the center as the same as "genetic engineering", and will seek regulatory authorization for experimental operations (http://www.cgr.tohoku.ac.jp/genome/).

m) MONITORING AND TESTING

Environmental Monitoring

The GOJ has been monitoring volunteer plants to assess the effect of GE crops' environmental release on biodiversity. On November 21, 2014, MAFF announced the summary of its investigation of canola and soybean (http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/pdf/h25_kekka.pdf). The report covered a survey conducted in JFY2013 in the vicinity of ports where canola and soybeans were unloaded from carrying vessels.

Of the 403 volunteer canola plants in 14 ports subjected to analysis, the results showed that 126 plants, or 31 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 880 mustard and 190 Chinese colza plants, no foreign gene was detected, indicating there was no cross pollination leading to gene flow. Of the 112 volunteer soybean plants in four ports, the results showed that 11 plants had a transgene. Though soybean is mostly self-pollinating, they also tested 15 *Glycine soja*, a domestic wild relative of soybean to detect cross pollination. No transgene was found in *Glycine soja*.

In addition, MAFF also surveyed spill-off and voluntary growth of corn in seven ports where corn was unloaded, and three major routes from ports to inland feed mills. During a survey conducted from mid-August to early October 2013, MAFF observed spill off of corn in all seven ports and three distribution routes, but no voluntary growth was found (http://tinyurl.com/pszntcq). The survey showed the difficulty of domesticated crops growing voluntarily under "wild" conditions. Though further research is necessary, the findings and the fact that there are no wild relatives of cross capability with corn in Japan could be an indication that environmental release of corn is unlikely to affect Japanese domestic biodiversity.

MAFF also monitors for the presence of voluntary growth of unapproved GE papaya in Okinawa Prefecture. In December 2010, GE papaya with viral resistance was detected from papaya seedlings sold in a local garden store in Okinawa Prefecture. The virus resistant papaya is a different strain from Rainbow papaya (55-1), and suspected to be a locally developed PRSV resistant event from Taiwan which was commingled with a local conventional papaya variety, Tainoh #5. Tainoh #5 was developed in Taiwan as a conventional cross in 1987, and has been sold in Japan since 2005. The unapproved GE papaya has been found on the farms of local papaya growers in Okinawa. The unapproved GE papaya plants were cut down, as it violates the Cartagena Protocol on Biosafety. By the end of CY2011, MAFF identified over 8,000 farm-grown unapproved GE papaya plants, occupying almost 20 percent of all papaya farm fields in Okinawa Prefecture. Also between February and September of 2012, MAFF investigated 696 papaya plants grown on the roadside, in open fields and in gardens in Okinawa Prefecture and found 59 unapproved GE papaya plants. MAFF continued monitoring in JFY2013 and 2014, but did not find any additional unapproved GE papaya plants. As its influence to Japanese local biodiversity is most likely to be negligible, MAFF decided to end the monitoring for unapproved GE papaya at the end of JFY2014 (http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/pdf/h26_kekka.pdf).

As a country that is a party to the Cartagena Protocol on Biosafety, it is important for Japan to monitor

the effect of GE crop release on the environment in order to assess the effect on regional biodiversity. However, one unfortunate side-effect is that citizens groups, and even scientists, sometimes misunderstand the meaning of finding volunteer GE plants in the environment. Voluntary growth *per se* is not of primary importance in most cases, as volunteers of GE plants in the environment are not a risk. The novel gene of voluntary GE plants was herbicide tolerance, and herbicides cannot be a selection pressure in the natural environment. Therefore, the voluntary growth of herbicide tolerant GE canola will not receive any survival advantage from genetic engineering in a natural environment and most likely will be wiped out by competition with other wild plants. In the case of soybeans, by considering the crop's nature of self-pollination and the status of no commercial GE soybean cultivation in Japan, the exposure factor is extremely small. The activities of science literacy and risk communication on GE technology and its meaning under the Cartagena Protocol on Biosafety is necessary for the general public to understand the true meaning of finding GE plants in the environment.

Food Safety Monitoring

Cases of LLP monitoring in food

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 July 2014, there is no testing of U.S. potatoes, 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, 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 (http://www.mhlw.go.jp/english/topics/importedfoods/15/notice-2015-0330-01.html), 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)
- MON71800 (U. S. wheat)

Except MON71800, the export country is not specified in the monitoring program, because MHLW has not received sufficient information regarding the scope of the incident from the relevant governments and stakeholders. Sources indicate that monitoring of papaya (PRSV-YK and PRSV-SC) is mostly targeting China and Thailand. The rice testing mostly targets China and Vietnam. Canola is mostly sampled from the shipments from Canada. Since June 2014, there were seven detections of unapproved

GE food in imported products – four cases of processed papaya products (frozen or preserved in syrup from Thailand or China) and three cases of rice noodles from China (http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/ihan/index.html).

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.

On November 12, 2009, MHLW implemented a new standard and specification for testing for GE grain in non-GE bulk shipments (http://tinyurl.com/olyctrf). With this procedure, imported grain is initially tested by the conventional method, quantifying GE specific regions in 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 out 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 in three to nine grains being 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 out of 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.

n) LOW-LEVEL PRESENCE POLICY (LLP)

MHLW Policy on LLP in food

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 (http://www.mhlw.go.jp/english/topics/foodsafety/dna/01.html):

'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 Paragraph, 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 (http://www.mhlw.go.jp/english/topics/food/3-2.html) 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.'

For products from the United States, MHLW-mandated testing is currently being enforced for MON71800 in bulk wheat.

MHLW has phased out testing for LLP (and adventitious presence (AP)) corn events, such as StarLink, Bt10 and Event 32, as well as the rice event LLRICE601. In July 2014, MAFF, the state trader of MA rice, also removed LLIRCE601 from the testing requirement in its contract.

In the past, testing for LLP/AP in Japan has been focused on bulk products (e.g., corn and rice) and processed products manufactured by non-Japanese companies (e.g., rice noodles). In the near future, Japan and other countries could be forced to expand the scope of testing because of an increasing number in traits, crops and developers of GE crops. As the application for regulatory approval requires resources, asynchronous approval and/or a lack of regulatory approval in countries other than the production countries may occur with growing frequency. Global food manufacturers, including Japanese firms, are diversifying their production facilities and supply sources of ingredients worldwide. When food manufacturers have facilities overseas, it would be increasingly difficult to test all ingredients, since the information system to notify of LLP/AP occurrence to stakeholders might not be transparent and systematic enough to prevent unapproved events commingled into commercial distribution.

Japan participated in the LLP Workshop organized by the Food and Agricultural Organization, United Nations, between March 19 and 21, 2014 in Rome, Italy. In the past, the GOJ handled some corn LLP cases reasonably, when the appropriate and sufficient information was provided the responsible technical providers and the USG. However, the situation could be different if the incidence of LLP happened in products from countries where regulatory resources in industry and government are relatively limited. Therefore, from an international trade viewpoint, the enforcement of LLP regulations need to be case-by-case and practical. Based on the precedent of LLP occurrences in Japan and the GOJ's handling, it is expected that Japan will continue to handle LLP cases in a practical manner, as long as government-to-government communication regarding scientific rationale is well established.

<u>Ministry of Agriculture (MAFF) Policies on LLP in feed grain</u>

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. On December 16, 2014, MAFF announced that the exemption would also be applied to Australia, Canada, Brazil and European Union (http://www.famic.go.jp/ffis/feed/tuti/26_3706.html).

On December 25, 2008, MAFF published a risk management plan addressing the low level presence of unapproved GE feeds. MAFF believes this risk management policy helps prevent LLP incidents from happening, but also establishes procedures for when an LLP incident does occur by providing a mechanism for ending testing requirements when they are no longer needed (e.g., StarLink). (https://www.famic.go.jp/ffis/feed/tuti/20_8829.html)

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 (ftp://ftp.fao.org/codex/Alinorm08/al3103Ae.pdf)). Japan played a very constructive role in setting the guidelines by hosting meetings and facilitating discussions among Codex members. 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.

PART C: Marketing

a) MARKET ACCEPTANCE

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 surveys have often shown relatively high concern regarding GE foods. For instance, the FSC's annual survey in JFY2013 showed 48 percent of those polled indicated they have high or some concern regarding GE foods. The difference between the poll and actual consumption could be a sign that consumers passively accept GE products even though the system does not require labeling of products, such as oil and sugar, which do not contain genetic material from the novel trait. Interestingly, 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). (http://www.fsc.go.jp/osirase/risk_questionnaire.data/risk_questionnaire_20150513.pdf) 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. For instance, when the International Organization for Research on Cancer, a part of the WHO, announced that glyphosate, the active ingredient of one of the most popular herbicides named Roundup, was "classified as probably carcinogenic to humans" (which was denied by the majority of the scientific community), there was

very limited media coverage in Japan.(http://tinyurl.com/noa3fpz; http://tinyurl.com/mqpbvxr)

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 40 to 50 percent of food corn is either non-segregated or GE. Though 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 (http://tinyurl.com/lm25vwf). Prior to learning opportunities about GE technology, 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 17 years of GE crop production, (3) Japan consumes more GE products for food and feed than its domestic rice production, and (4) GE crops are widely used in food oil, corn starch, sweetener and feed in Japan, and support 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 pro-active manner could be a way to increase market acceptance among certain consumers. (Note the section "PART B: Policy, g) LABELING" for related information.)

Feed use accounts for about 66 percent of Japan's corn consumption, and nearly all feed-use corn contains GE (roughly 93 percent of all U.S. corn planted in 2014 was GE, http://goo.gl/zDG4dO). In the past, there was limited demand for non-GE feed corn for the specific non-GE fed dairy market. However, sources indicate that the non-GE feed corn market is extremely small.

b) 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) Product Launch Stewardship Policy calls for new GE crops to be approved in Japan before they are commercialized in the United States (https://www.bio.org/media/press-release/biotechnology-industry-approves-product-launch-stewardship-policy).

c) MARKETING STUDIES

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 do 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. This could be a positive indication that the Japanese market has flexibility to accept GE products.

On the other hand, a few consumer groups still maintain activities to refuse non-GE ingredients. The "No GMO Campaign" (http://gmo-iranai.lolipop.jp/) questioned four major beer breweries and one major soy sauce manufacturer in Japan regarding their use of "GE ingredients". In the past, the same group asked Costco Japan not to handle Rainbow papaya (http://gmo-iranai.lolipop.jp/archives/1337/). Similarly they asked the Flour Millers Association, MAFF and MHLW not to handle U.S. wheat because of an incident of unapproved GE wheat (http://gmo-iranai.lolipop.jp/archives/1055/).

PART D: Capacity Building and Outreach

a) ACTIVITIES
August 24 - 30, 2014 - FAS Tokyo collaborated with US Grains Council Tokyo to organize a Biotechnology Study Tour for eight GOJ regulators from MAFF and MHLW to visit US farms, grain distribution facilities, and technical providers. It was also their first time to discuss biotechnology issues directly with U.S. regulators in USDA/APHIS, FDA, and EPA.

September 24, 2014 – FAS Tokyo collaborated with DuPont Japan and Hawaii Papaya Industry Association to organize an Agricultural Biotechnology Media Study Session at Tokyo Prince Tower Hotel for local media representatives. Information was shared on the current status and advantage of agricultural biotechnology. Approximately 25 local media representatives attended.

December 3 and 4, 2014 – FAS Tokyo worked with ILSI, CBIJ and MAFF for a NBT seminar where USDA/APHIS's Sally McCammon, the chair of the OECD's NBT Working Group, gave two presentations and exchanged views with Japanese regulators.

Post has regular discussions with government officials and stakeholders regarding such issues as streamlining GE regulations, LLP and regulation of NBTs.

b) STRATEGIES AND NEEDS
As Japan is not only an important partner for U.S. agricultural trade and importer of GE crops, but also a key country for the industry's GE crop product launch stewardship, it is extremely vital to maintain the close communication and information sharing with regulators in all relevant agencies. Therefore, with the cooperation of the grain industry, since 2007, Post has organized a tour for GOJ regulators to visit the United States and be exposed to the latest status of technology, production, distribution and regulation. The result has been enormously positive and increased the communication, understanding and trust between the GOJ, USG, and industry.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: 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.

Though they are not livestock animals, laboratory animals, such as mice with gene knockout, are commonly used for medical and pharmaceutical purposes. As of July 1, 2015, Japan had approved 107 GE animals for Type 2 use under the Cartagena Protocol on Biosafety (note Regulatory Process in Section III; http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/pdf/type2_animal_table_150330.pdf).

That being said, the GE silkworm is relatively close to the commercial application stage in Japan. The National Institute of Agrobiological Sciences (NIAS) launched The Silkworm Genome Research Program (SGP) in 1994. Silk protein is already used as the sticking fiber for surgery. The research will expand the use of silk for medical materials such as artificial skin, contact lenses, etc. On November 16, 2010, a joint project by NIAS (http://www.nias.affrc.go.jp/index_e.html), Gunma Prefecture, and Immuno - Biological Laboratories Co., Ltd. (IBL, http://www.ibl-japan.co.jp/eng/index.htm) started the test-run of the world's first case of industrial GE silkworm production. The GE silkworm is modified to produce "protein A", a protein used for medical diagnostic agent. Since then, GE silkworms have been grown by six farmers in Gunma Prefecture at least. Silkworms are domesticated from the wild silkworm *Bombyx mandarina*, and are entirely dependent on humans for its reproduction and feeding. Therefore, in terms of risk management for accidental release to the environment, the chance of affecting biological diversity and environment is practically nil.

On May 25, 2015, MAFF announced the second case of Type 1 approval of genetically engineered animals for silkworms producing green fluorescent silk. Gunma Sericultural Technology Center, a local research center in Gunma Prefecture (http://tinyurl.com/ovzlkrk), worked with local farmers to grow 210,000 GE silkworm to produce green fluorescent silk. They plan to harvest in October 2015 (http://www3.nhk.or.jp/shutoken-news/20150627/5846421.html).

After the world's first production of human fibrinogen by GE silkworms (http://tinyurl.com/nuce9av) in 2011, IBL expanded its products to include human collagen produced by GE silkworms (http://tinyurl.com/pnfvavq). Neosilk, IBL's wholly-owned company, started to sell a cosmetic containing human collagen from GE silkworms on June 13, 2013 (http://www.neosilk.jp/).

On May 2, 2014, the first application for a GE animal under an open system in Japan was approved. MAFF approved NIAS's GE silkworm applied, which produces a fluorescent protein, for Type 1 use (for conveyance, cultivation, food and feed use). Type 1 Use approval is given only when the event is considered not to cause adverse effects on biological diversity.

NIAS also conducts research into GE swine (http://www.nias.affrc.go.jp/org/GMO/Pig/). The purpose of producing GE swine is to study medical organ transplantation oncology in human beings. Swine are used simply because of the similarities of metabolism and organ size with humans.

Animal cloning is becoming less active in Japan. As of December 19, 2014, Japan had produced 623 cows by fertilized egg cell cloning, 414 cows by somatic nuclear transfer (SCNT), 559 swine by SCNT, and 5 goats. All production has been done in public research institutions. The activity has been steadily decreasing since the peak in 1999. (http://www.s.affrc.go.jp/docs/clone/kenkyu/20140930.htm).

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.

PART F: Policy

a) REGULATION
The same regulation as for GE plants will be applied for commercialization of GE livestock animals. 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) LABELING AND TRACEABILITY
The labeling requirement for GE animals will be the same as for plants. For the products from a cloned animal, Japan has a specific labeling requirement that it be labeled as a cloned product.

c) TRADE BARRIERS
None at this time.

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.

PART G: Marketing

a) MARKET ACCEPTANCE
There is no significant marketing activity in livestock animal biotechnology.

b) PUBLIC/PRIVATE OPINIONS

At this moment, there is no commercial distribution of livestock GE animals in Japan; however, Post expects public opinion of GE and cloned livestock products would be conservative and/or negative, as observed in GE food crops.

c) MARKET STUDIES
None at this time.

PART H: Capacity Building and Outreach

a) ACTIVITIES
March 9, 2015 – FAS Tokyo organized the courtesy visit of U.S. Ambassador to Japan, Caroline Kennedy, to NIAS, where she learned about the history of silk production and the advantages of using silkworms for genetically engineered (GE) applications. While there, she also had the opportunity to see a fluorescent silk wedding dress, observe silk worms, and operate laboratory equipment that inserts genes into a silkworm egg.

b) STRATEGIES AND NEEDS
None at this time.

REFERENCE

Risk assessment standards of genetically engineered food
Food Safety Commission
http://tinyurl.com/pchpyju

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