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Japan's approval and regulatory approach affects commercial release of GE crops

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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 in Japan.

Section I. Executive Summary:

Japan remains one of the world's largest per capita importers of foods and feeds 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 since the Fall of 2012, largely due to limited U.S. supply as a result of drought. . The U.S. share of global corn exports to Japan ranged between 40 and 60 percent in past two years. 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 of corn and three million metric tons 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 expectation. As of July 1, 2014, 290 events, including stacked events, have been approved for food use. The GOJ completed reviews of more than 100 events in the last 12 months. This is a strong indication that the regulatory system is, in fact, functioning. In addition to managing the review process more efficiently, increased familiarity with events with popular transgenes contributes to a prompt review. However, it needs to be noted that the number includes the stacked events. At the same time, assuming an increase over the next decade in the number and types of GE events released to the market, emergence of new transformation technology, as well as releases from venture capitals and emerging economy countries, Japan may encounter regulatory challenges. As with other regulatory systems around the world, Japan's biotechnology review system contains some points which can be improved, and improvement has been made at technical levels by GOJ regulators. One significant improvement is a streamlining in the food safety review of stacked events which do not affect crops' metabolic pathway. 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 130 events in 8 crops have been approved for environmental release, which includes cultivation. 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 the approval of environmental release (i.e., commercial cultivation) for eight GE carnations; however, they are cultivated in Colombia and exported to Japan.

There is very little applied research activity of biotechnology for livestock animals. Most activities are for basic research. Commercial production is limited to experimental animals, such as the 'knockout' mouse.

Section II. Author Defined:

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CHAPTER I: PLANT BIOTECHNOLOGY

PART A: Trade and Production

a) PRODUCT DEVELOPMENT

Though the basic research in the area of plant molecular biology and genetics is very active, there are very few GE products in the commercial release phase. One of the few potential products for commercial production within the next five years is a GE strawberry for the production of vaccine material. Advanced Industrial Science and Technology (AIST) transformed a strawberry to accumulate interferon, which treats canine periodontal disease. Interferon production by biotech strawberries is more cost effective than conventional production with transgenic microorganisms. This is a potentially large market, as it is estimated that nearly 80 percent of the twelve million dogs in Japan suffer from periodontal disease. The extraction and purification process of interferon is simpler in biotech strawberries since it is a food crop. Therefore, production costs could be as little as 10 percent of conventional production methods. One reason for this low cost is simple post-harvest process. Using conventional methods with microorganisms, the interferon protein has to be purified; however, the fruit of interferon producing GE strawberry can be simply freeze dried and powdered for the products. The GE strawberry will be grown in a 291 square meters (3132 sq feet) confined facility with hydroponic and artificial lighting systems (http://www.aist.go.jp/aist_e/aist_laboratories/1lifescience/index.html).

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://www.suntory.com/business/research/index.html).

Although there is no commercial GE production of food crops, on April 24, 2014, a company named "Hokusan" started producing the world's first pharmaceutical product for canine from GE plants as described above (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/). It's distribution has reached all over Japan and no rejection by dog owners. The GE strawberry is cultivated in a closed system facilitated with controlled light, temperature, and nutrient solution, as it was practiced in the R&D phase. The system enables the optimal growth of the strawberry. As a result of using closed system cultivation, the manufacture 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 food GE crops, there are a limited number of professional farmers those have significant interest in GE crop production, especially GE soybean and sugar beet (http://www.foodwatch.jp/science/readwritebio2/47094). 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://www.pref.hokkaido.lg.jp/ns/nsi/seisakug/doukou/gaiyouban_h24.pdf). 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. Based on local growers' estimates, the adoption of GE soybean and sugar beet could increase profits between 40 and 70 percent. There a few obstacles for local growers to engage in commercial GE crop cultivation. The hurdle to pass is local regulation. 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. Another hurdle is securing a buyer who will accept harvested GE products. Growers also need to make sure that the crop has the relevant chemical registration in the Japanese regulation if they plan to utilize a herbicide tolerant trait such as glyphosate resistance (http://www.roundupjp.com/pdf/maxroad.pdf).

c) EXPORTS

There are no GE crops exported from Japan.

d) IMPORTS

Processed Products

In CY2013, Japan imported 14.4 million metric tons (MMT) of corn. The major supplier was the United States; however, the market share was 44.8 percent (6.4 MMT), a significant drop from the previous year (12 MMT, 81 percent market share). The rest of market was taken by Brazil 4.4 MMT, 30.4 percent), Argentina (13.3 percent, 1.9 MMT), Ukraine (4.7 percent, 1.0 MMT), and Spain (0.7 percent, 0.1 MMT).

Among these countries exporting to Japan, Ukraine is only the country which does not have commercial production of GE crops (GAIN report, UP1222), all major corn suppliers to Japan are also leading countries in the adoption of GE crop technology.

Of the 14.4 MMT of corn that Japan imports, 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 loathe to pass along higher prices to consumers. Post estimates nearly half of food corn imported by Japan is non-segregated or GE categories. Much to the surprise of industry watchers, there was no significant media attention or anti-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, the use of GE food corn has increased by almost 50 percent, but 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 on their websites, possibly out of fear of consumer rejection.

The use of 'non-segregated' ingredients has been widespread for several years, and established its specific position in food industry.

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 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 $50 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

(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 manufactures 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 ($3.5 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. In general, 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).

Other retailers also started to use non-IP ingredients which require the labeling of "GMO-non-segregated". Such examples are often found in voluntary labeling for degraded soy protein and powder including soybean and corn (http://www.topvalu.net/items/detail.php?id=12535).

Figure: AEON's private brand, TOPVALUE's stew saurce. Squared section indicates 'hydrolyzed protein (soybean): GE non-segregated (may contain GE soybean)'.

Figure: AEON's private brand, TOPVALUE's barbecue sauce. Squared section indicates 'high fructose corn syrup (corn) and starch syrup (corn): GE non-segregated (may contain GE corn)'.

Grains

Japan remains one of the countries which receive the major benefit of 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 corn, the U.S. has been the dominant supplier for decades.

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 and third largest corn exporting countries to Japan in 2013 were Brazil and Argentina, respectively, which were concurrently and actively adopting GE technology for their corn production. Sixty-eight and 85 percent of corn production in Brazil and Argentina, respectively, depend on GE technology. To cope with global climate changes, 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.

Feed use accounts for about 65 percent of Japan's corn consumption, and presumably all feed-use corn contains GE (roughly 88 percent of all U.S. corn is GE). In the past, there was limited demand for non-GE feed corn for the specific non-GE fed dairy market. However, sources indicate non-GE feed corn market is extremely small.

Until 2008, food-use corn in Japan was exclusively 'non-GE.' Due to high premiums for segregated non-GE corn and a lack of end-user opposition to GE ingredients, demand for non-GE food use corn has been declining. Industry sources estimate that approximately 40 to 50 percent of food corn is either non-segregated or GE. The acceptance of GE ingredients by the food processing industry seems to be stable in the past few years. 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 (see Processed Products).

Until a few years ago, the majority of consumer groups concerns were about GE food's purported negative effects on human health. Recently, however, the focus has been refocused on the suggested negative effect to biodiversity. One of these consumer groups, Japan Citizens' Network for Sustainable Food and Agriculture (http://fa-net-japan.org/) has been organizing seminars on GE crops, stating that they will contaminate the biodiversity of Japan and other Asian countries. Media reports on the overall concern about GE crops, especially regarding human health, seem to be decreasing.

Japanese Corn Imports	
(1,000 MT – 2012/2013) (Year Ending: September)	
Corn for feed	
Brazil	4,055
United States	3,305
Argentina	1569
South Africa	415
Ukraine	350
Thailand	10
France	8
Australia	2
South Africa	10
Slovakia	8
Others	7
Total Feed	9,714
Corn for food, starch, manufacturing	
United States	3,627
Brazil	566
South Africa	203
Argentina	188
France	73
Australia	29
India	4
Indonesia	3
Ukraine	2
Total Food & Other	4,696
Total	**14,410**
Source: Ministry of Finance	

Fresh Produce

There was a very limited volume of GE papaya exported to Japan. 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. Additionally, there seems to be reluctance among retailers to handle GE papaya due to the fear of losing their customers for non-GE papaya. As result, the commercial shipment of GE Rainbow papaya was limited to 6,240 pounds, valued at 19,032 USD in 2013.

e) FOOD AID RECIPIENT COUNTRIES

Japan is not a recipient of food aid.

PART B: Policy

a) REGULATORY FRAMEWORK

The Ministry of Health, Labor and Welfare (MHLW) is responsible for the food safety of GE products, while the Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for feed and environmental safety. The Food Safety Commission (FSC) is an independent risk assessment body under the Cabinet Office that performs food and feed safety risk assessments for MHLW (food) and MAFF (feed).

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

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 FSC, an independent risk assessment body, performs food and feed safety risk assessment for MHLW and MAFF.

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.

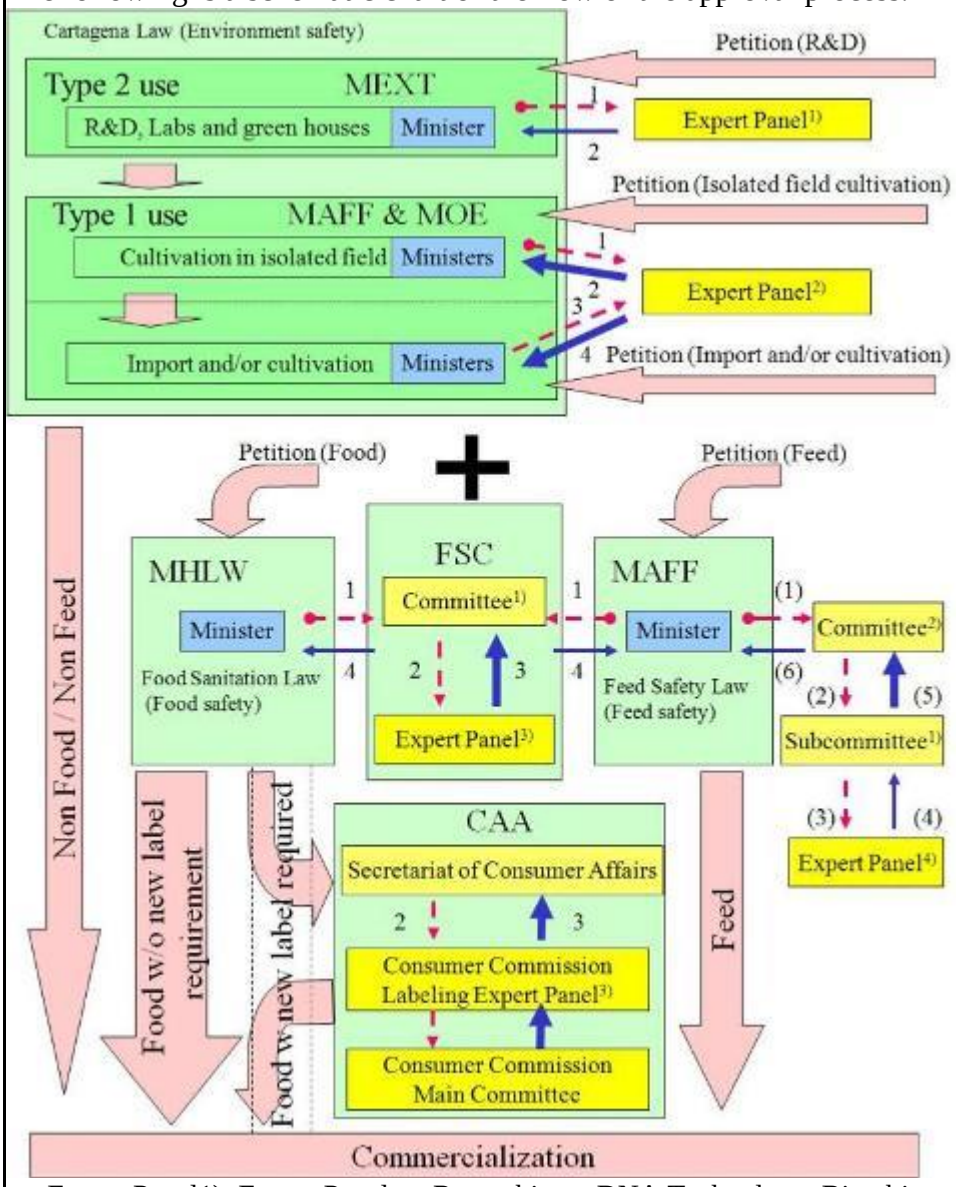
GE plants that are used for food must obtain food safety approvals from the MHLW Minister. Based on the Food Sanitation Law, upon receiving a petition for review from an interested party (usually a biotechnology provider), the MHLW Minister will request that the FSC conduct a food safety review. Within 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://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf).

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 feed. 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 product 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://www.bch.biodic.go.jp/download/en_law/en_regulation.doc), 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 influence on biodiversity. After the necessary scientific data are 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.

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. The Consumer Affairs Agency (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.



- Expert Panel1): Expert Panel on Recombinant DNA Technology, Bioethics and Biosafety Commission, Council for Science and Technology, MEXT
- Expert Panel2): Experts with special knowledge and experience concerning adverse effect on biological diversity selected by MAFF/MOE Ministers
- Expert Panel3): Genetically Modified Foods Expert Committee, FSC
- Expert Panel4): Expert Panel on Recombinant DNA Organisms, Agricultural Materials Council, MAFF
- Committee1): Food Safety Commission
- Committee2): Feed Committee, Agricultural Materials Council, MAFF
- Subcommittee1): 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.

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 biggest 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. The Hokkaido 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 $5,000). 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 $3,150) to the Hokkaido Governor's office in order to cover the costs 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 $2,100).

Institutions that wish to conduct research using open-air GE farming are also 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 for local government panel review. However, 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 $5,000) for non-compliance, employees of research institutions are not subject to imprisonment if they fail to comply with GE regulations.

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.

The Hokkaido prefectural government holds risk communication meetings on GE crops every year (http://www.pref.hokkaido.lg.jp/ns/shs/shokuan/risk-comu.htm); however, local anxiety about GE crops remains high.

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 July 2014, the guideline is still in draft and has not yet been finalized (http://www.pref.chiba.lg.jp/annou/jouhoukoukai/shingikai/idenshi/index.html).

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/view.rbz?cd=44664).

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 have briefing meetings for neighbors of the experimental sites and concerned citizens in order to receive agreement for the GE crop planting. Circumstances often require applicants have briefings and risk communication

sessions with the general public during and/or after the experiment. 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 of 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 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 requests farmers to refrain from commercial planting of GE crops (http://www.pref.shiga.lg.jp/g/nosei/idenshikumikae/idenshi_shishin040820.html). 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) - Coexistance 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 ordinances on GE crops. These ordinace entered into force in April 2007 and require 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://reikishu.city.imabari.ehime.jp/reiki_honbun/r059RG00000848.html).

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 researchers 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 concerns 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/). There is no charge for the application.

Unapproved food additives

On December 5, 2011, the GOJ announced that an unapproved food additive produced with biotechnology, Disodium 5'-Inosinate and Disodium 5'-guanylate, had been distributed in the Japanese market without regulatory clearance. Two substances were produced by the GE microorganisms and used as additives to increase 'umami' flavor in various processed foods. However, as the GE microorganisms are used for the production of the additives, Japan requires the microorganism undergoes regulatory clearance, even though the final products do not contain foreign genetic materials. After the incident was announced, MHLW requested the FSC review the safety of the substances (http://www.mhlw.go.jp/stf/houdou/2r9852000001wzcp.html). On March 1, 2012, the distribution of the additives resumed after FSC completed the review without any health risk concern. Subsequently, three more cases of unapproved additives were reported. Though the incidents did not compromise food safety, they did consume significant regulatory resources within the GOJ's food safety review system, to the detriment of a number of GE products in the regulatory pipeline.

b) APPROVALS

As of July 1, 2014, Japan has approved over 290 GE events for food, 121 for feed and 100 for environmental release, including commercial planting for most events. Please note the reference section for the list of approved events.

Import Only Approval of Insect Resistant Soybean

On February 25, 2013, MAFF released the "import-only" environmental approval for MON87701, the first import only approval for GE soybeans in Japan. Prior to the environmental approval, MHLW granted food safety approval on March 18, 2011. Because of the presence of *Glycine soja*, a wild ancestor of soybean (*Glycine max*), in Japan, the environmental risk assessment took significantly more time and discussion to complete the review. Gene flow of insect resistance could change the biological fitness of *Glycine soja*. However, soybean is a self-pollinating plant. Also, for gene flow to occur, the timing of flowering of *Glycine soja* and soybean has to match, and populations of two plant groups have to be dense and sufficiently close. Furthermore, for gene flow to affect the surrounding biodiversity, the progeny has to survive and dominate the environment, which is extremely unlikely. However, the review committee faced the technical difficulty of having to estimate the risk of gene flow and its effect on biodiversity, assuming the possibility that it could be planted commercially, and therefore the committee could not consider the risk to biodiversity as negligible. The review committee concluded that the Bt soybean could be approved

as 'import only' as its environmental exposure would be theoretically limited. There is no new soybean event with import only approval since MON87701.

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 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 grown in Japan. Within the commercial industry, 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 for 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 open expert meeting on June 30, 2014 (http://www.s.affrc.go.jp/docs/commitee/diversity/top.htm). 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. Another improvement proposed by MAFF Environment is to consolidate the applications for stacked events. For instance, when three approved single events, trait A, B and C, are available, and if the developer plans to commercialize three doubled stacks, the developer has to submit three separate applications for the stacks, A x B, B x C, and A x C. In the new proposed framework, 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.

d) STACKED EVENTS

Japan requires separate environmental approvals for stacked events - those that combine two prior approved traits, such as herbicide tolerance and insect resistance - though existing data and information on the parent lines may be used for the purpose of evaluation. It is generally unnecessary to carry out field trials for stacked events.

For food safety approvals, a 2004 FSC opinion paper categorized GE events into three groups: (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 component 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.

The FSC requires a safety approval for a stacked event if the crossing occurs above the subspecies level, or if the crossing involves GE events in category 1. The FSC also requires safety approvals on stacked events between those in category 1 if the amount consumed by humans, the edible part, or processing method is different from that of the parent's. The FSC also requires safety approvals on stacked events between GE events in categories 1 and 2, 1 and 3, 2 and 2, 3 and 3, and 2 and 3.

On July 21, 2011, the FSC proposed a new scheme regarding the review of stacked events (http://www.fsc.go.jp/senmon/idensi/gm_kakeawase_hinshu.pdf). This scheme is designed to review '1 x 1' stacked events without deliberation by the Novel Foods (Genetically Modified Foods) Expert Committee. Most likely, that proposal was based on the FSC's confidence that enough knowledge and experience in 1 x 1 stack reviews had been accumulated. On March 14, 2013, FSC's expert committee gave an efficient "bundled" approval to 35 stacked events which can be generated by crossing of six events (Bt11, MIR162, MIR604, 1507, Event5307, and GA21) whose reviews had all been completed, noting that there was no food safety concern with the stacks of these events (http://goo.gl/eueDKg). There are 57 stacked events from the combination of six events (15 doubles, 20 triples, 15 quads, 6 5-stacks, and one 6-stack); twenty-two of the 57 events had been approved previously. As MHLW requested FSC review the stacked events on February 20, 2013, it took less than a month to return the result from FSC to MHLW.

As reported in JA4005 (http://goo.gl/vtggJl), Japan proposed the exemption of GE events using pre-approved single events as long as the crossing of single events does not affect its metabolic pathway of host plant. The proposal became official on June 27, 2014 (http://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/0000049695.pdf). Similarly with the efficient handling of S3-FT to be exempted to crops with no domestic wild relatives, this new regulatory handling of stacked events in food safety review will be remarkably positive in multiple aspects; saving regulatory resource for Japanese regulators and technical providers, and reducing the risk of asynchronous approval.

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 approvals, the approvals by the Expert Panel are neither subject to MAFF Minister notification nor public comment.

e) ADDITIONAL REQUIRMENTS

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.

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

g) LABELING

Until August 31, 2009, GE labeling was handled by MAFF and MHLW under the Food Sanitation Law and the Japan Agricultural Standards (JAS) Law, respectively. Although the labeling requirements for the Ministries are listed separately, both sets of requirements are basically identical. When the Consumer Affairs Agency (CAA) was established in September of 2009, food labeling issues, including GE labeling, were transferred to this new agency. However, this transfer did not change the GOJ's GE labeling policies, which are available in English at http://www.maff.go.jp/e/jas/labeling/modified.html.

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 English version of the manuals for the IP handling of corn and soybeans are available on MAFF's website (http://www.maff.go.jp/e/jas/labeling/pdf/modi03.pdf).

As shown below, the 33 foods currently subject to JAS (and CAA) 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 weight content of the ingredient to be labeled in one of these 33 foods exceeds 5 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" if the raw ingredient does not accompany certificates of IP handling. 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.
Since September 2011, based on the Consumer Basic Plan, which promotes implementation of consumer policies and also evaluates the implementation of consumer policies (http://www.consumer.go.jp/english/cprj/index.html), CAA has been reviewing laws related to food labeling, with the vision of unifying the Food Sanitation Law, the JAS Law, and the Health Promotion Law. At this time, the regulations for GE labeling, such as items to be labeled and the "5 percent rule" for the non-GE category, are expected to remain same. For more details, please note recent GAIN report on Japan's New Food Labeling Law, JA3054 (http://goo.gl/x5M38i).

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. For shipment, several fruit will be packed into a box and the volume of trade will be significantly smaller compared with bulk products. In addition, the scale of specialty crop production is much smaller than grains, and it may be a financial burden for the industry to practice IP of non-GE and GE papaya based on laborious documentation. As a result of close communication between Japan's Consumer Affairs Agency, the Hawaii Papaya Industry Association, the Hawaii Department of Agriculture, and FAS Tokyo, the industry 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 general labeling practice applicable to other GE specialty crops which may be released in the future.

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.

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://www.foodwatch.jp/science/readwritebio2/32978). 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 have been already widely used in food oil, corn starch, sweetener and feed in Japan, and supported Japanese food security. After learning the key messages, the acceptance of food products containing GE crops increased to 60 percent from 40 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.

In 2004, the Japan Fair Trade Commission (JFTC) conducted a survey for the labeling of eggs. A growing number of egg suppliers have started using labels that make aesthetic or safety claims. After the survey, JFTC found that labeling such as "No GMO corn or soymeal is used" and "clean feed - without postharvest pesticides in main feed ingredients" are misleading consumers about adherence to higher standards and/or actual quality. As a result, JFTC issued recommendations to suppliers about the use of appropriate and objective labeling.

Figure: Example of an egg carton label claiming no GE feeds were used. (USDA/Tokyo Photo)

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 includes the area related to genetic engineering of agricultural crops, including, but not limited to, the gene, seeds, and name of varieties.
(http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/txt/bio-e-m.txt)
(http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pdf/tt1303-061_41.pdf).
Japan's Patent Office is the responsible agency for IPR.

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://www.env.go.jp/en/focus/070215.html) took place in Nagoya, Japan from October 18 to 29, 2010. Prior to COP10, the fifth Member of the Party (MOP5) to the Cartagena Protocol also took place in Nagoya from October 11 to 15, 2010. The main issue at the COP10MOP5 meeting was the implementation of the Cartagena Protocol on Biosafety article 18.2.a (documentation and compliance enforcement) and article 27 (Liability and Redress). Japan's support of a non-binding approach to Liability and Redress in the Cartagena Protocol on Biosafety negotiations demonstrated positive leadership on this issue.

The Nagoya Protocol became open for signature by Parties to the Convention from February 2, 2011 to February 1, 2012 at the United Nations Headquarters in New York, and Japan and seven other countries signed the Protocol on May 11, 2011.

The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was opened for signature from 7 March 2011 to 6 March 2012. On March 2, 2012, Japan signed the Supplementary Protocol
(http://www.env.go.jp/press/press.php?serial=14912). It requires ratification, acceptance, approval or accession by 40 countries for Liability and Redress (L & R) to be effective. On December 9, 2013, Hungary became 20th country of ratification of the Protocol
(http://www.cbd.int/doc/press/2013/pr-2013-12-17-bs-en.pdf).
The Republic of Korea (South Korea) will host the next meeting (COP12MOP7) from September 29 to October 17, 2014, in Pyeongchang.

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 (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, where the Codex Annex allows for more than a zero

tolerance.

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

New Breeding Technology (NBT)

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

The GOJ is also interested in NBTs and approached the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology in early 2013 to pursue global harmonization of NBT regulation. The OECD WG took place on February 10, 2014. MAFF pays close attention to EU and U.S. regulations by following government-released documents such as 'Regulated Letters of Inquiry' from USDA-APHIS (http://www.aphis.usda.gov/biotechnology/reg_loi.shtml).

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 September 24, 2013, MAFF announced the summary of its investigation of canola and soybean (http://www.maff.go.jp/j/syouan/nouan/carta/c_data/pdf/24_kekka.pdf). The report covered a survey conducted in JFY2012 in the vicinity of 15 ports for canola and 10 ports for soybean where canola and soybeans were unloaded from carrying vessels.

Of the 382 volunteer canola plants in 15 ports subjected to analysis, the results showed that 131 plants, or 34 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 a "gene flow" from cross pollination. Of the 823 mustard and 188 Chinese colza plants, no foreign gene was detected, indicating there was no cross pollination leading to gene flow. In the case of soybeans, of the 10 ports where surveys were conducted, only 3 ports had volunteer soybean plants, dropped from unloaded shipments. Of the 9 volunteer soybean plants in 3 ports, the results showed that 3 plants had a transgene. Though soybean is mostly self-pollinating, they also tested *Glycine soja*, a domestic wild relative of soybean to detect cross pollination. No transgene was found in *Glycine soja*.

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 volunteer of GE plants in the environment is not a risk. The novel gene of voluntary grown 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. Also 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.

To assure compliance, monitoring is in place for both imported shipments and processed food products at the retail level. As a part of the monitoring program for imported foods (http://www.mhlw.go.jp/english/topics/importedfoods/14/notice-2014-0328-01.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 July 1, 2014, MHLW monitors the following items:

- PRSV-YK and PRSV-SC (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. Based on sources, monitoring of the 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.

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 5 percent of 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://www.mhlw.go.jp/topics/yunyu/hassyutu/2009/index.html). 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 5 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 5 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 corn events, such as StarLink, Bt10 and Event 32, as well as the rice event, LLRICE601. In July 2014, the MAFF, state trader of MA rice, announced to delete LLIRCE601 from the testing requirement in its contract.

In the past, testing for LLP 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 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 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 GOJ's handling, it 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.

On December 25, 2008, MAFF published a new risk management plan addressing the low level presence of unapproved GE feeds. MAFF believes this risk management policy will help 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).

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, where the Codex Annex allows for more than a 'zero' tolerance.

PART C: Marketing

a) MARKET ACCEPTANCE
Based on the FSC's annual survey of consumers' opinions on food safety, 48 percent of those polled indicated they have high or some concern regarding GE foods ((http://www.fsc.go.jp/monitor/2508moni-kadai-kekka-yoyaku.pdf). There has been no significant change to this in the past five years. At the same time, Japan has remained as 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. 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. At the same time, it is curious to observe that an industry survey indicated that consumers' acceptance and confidence to GE foods increased after appropriate scientific information was provided. Though not all consumers would be fully convinced by science 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.

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 (http://www.bio.org/foodag/stewardship/20070521.asp). Similarly, the National Corn Growers Association's position on biotechnology states GE events must receive full approval by 'Japanese

regulatory agencies' (http://www.ncga.com/files/POLICYPOSITIONPAPER2-28-09.pdf).

The stewardship as above is possible only when the regulatory review system of the importing country is practical and functioning. The resources required for regulatory approval are rather significant. JRC reported in 2009 that increasingly GE crops will be developed by countries other than the United States., Canada, and Europe. Furthermore, the crops and traits to be developed for commercial production will be increasingly varied and complex. If any of these non-major players apply for regulatory review in Japan, the regulatory capacity in the country will have to be increased significantly. Otherwise, product launches for new crops, and dissemination of new technology to American farmers, will be severely slowed. If these new developers from emerging countries will not seek the regulatory approval, Japan has to consider a strategy to deal with low level presence of unapproved events in Japan. Hence, in addition to the resources of regulatory bodies, the approachability and openness for new entries will be equally important for Japan.

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 (note Part A: Trade and Production, d) IMPORTS). This could be a positive indication that the Japanese market has flexibility to accept GE products.

PART D: Capacity Building and Outreach

a) ACTIVITIES
August 25 - 31, 2013 - 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.

December 5, 2013 – "The 160th Committee on Plant Biotechnology for the Environment, Food and Resources", one of the committees in Japan Society for the Promotion of Science (http://www.jsps.go.jp/) organized the seminar "Path to Commercial Application of GE Crops". The seminar was open only to their members of industry and academia. At the seminar, Agricultural Specialist Suguru Sato introduced the U.S. GE regulatory framework.

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 animal model is focused on human medical and pharmaceutical purposes. In Japan, this research is mostly operated by university and government/public research institutions, with limited involvement by the private sector. 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, 2014, Japan had approved 98 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/c_list/pdf/type2_animal_table_140402.pdf).

That being said, the GE silkworm is relatively close to the commercial application stage in Japan. The National Institute of Agrobiological Science (NIAS, Tsukuba, Japan) launched The Silkworm Genome Research Program (SGP) in 1994. Silk protein is already used as the sticking fiber for surgery. The research is to expand the use of silk for expanded medical materials such as artificial skin, contact lenses, etc. In November 16, 2010, a joint project by National Institute of Agrobiological Sciences (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. Silkworm is domesticated from wild silkworm *Bombyx mandarina*, is entirely dependent on humans for its reproduction, and cannot survive without feeding from humans. Therefore, in terms of risk management for accidental release to the environment, the chance of affecting biological diversity and environment is practically nil.

After the world's first production of human fibrinogen by GE silkworm (http://www.ibl-japan.co.jp/news_img/PR_20110524.pdf) in 2011, IBL expanded their products to include human collagen produced by GE silkworm (http://www.ibl-japan.co.jp/news_img/20140613_neosiruku%20furevan.pdf). Neosilk, IBL's wholly-owned company, started to sell a cosmetics containing human collagen from GE silkworm 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 the GE silkworm applied for by NIAS, which produces a fluorescent protein, for Type 1 use (for conveyance and cultivation food, feed, etc.). Type 1 Use approval is given only

when the event is considered not to cause adverse effects on biological diversity. The fact that silkworms reportedly require constant human care, and therefore cannot survive in nature, could be a great advantage for commercial application with regards to environmental control.

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 March 31, 2014, Japan has produced 622 cows by fertilized egg cell cloning, 412 cows by somatic nuclear transfer (SCNT), 502 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/20140331.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
None.

b) STRATEGIES AND NEEDS
None at this time.

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
Ministry of Agriculture, Forestry and Fishery (Japan Agricultural Standard, base regulation of GE labeling)
http://www.maff.go.jp/e/jas/labeling/modified.html

Consumer Affairs Agency (the agency practicing GE labeling regulation)
http://www.caa.go.jp/en/index.html

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

As of July 1, 2014, GOJ reviewed and approved 290 events for food (taking stacked events into count), 121 events for feed, and 100 events for food (taking stacked events into count), feed, and environmental release, respectively.
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