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Japan's approval remains a key for commercial release of GE crops

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Report Highlights:
This report provides the latest status of consumption, regulation, public perception, research 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 between the Fall of 2012 and Spring of 2013, largely due to limited U.S. supply as a result of drought, and Brazil's corn exports to Japan exceeded the United States from December 2012 to March 2013. 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 would be 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. To date, over 160 events have been approved for food use. The GOJ completed the review of more than 20 events last year, a strong indication that the regulatory system is, in fact, functioning. 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. 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 120 events in 8 crops have been approved for environmental release, which includes cultivation. Recent approval of insect resistant soybean, MON87701, as "import only" was a significant breakthrough, considering the presence in Japan of *Glycine soja*, a wild ancestor of soybeans (*Glycine max*).

So far, 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.

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.

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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 eight million dogs in Japan suffers 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 much as 10 percent lower than costs associated with conventional production methods. 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)

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

d) IMPORTS:

Processed Products
In CY2012, Japan imported 15 million metric tons (MMT) of corn. The major supplier was the United States (12 MMT, 81 percent market share), followed by Ukraine (1 MMT), Brazil (0.8 MMT), and Argentina (0.6 MMT). Except for Ukraine, which does not have commercial production of GE crops (GAIN report, UP1222), all the top corn suppliers to Japan are also leading countries in the adoption of GE crop technology. Of the 15 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 industry sources report very few recent inquiries from consumers regarding the use of this term.

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 a previous report (JA2013), 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). In a current 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 ingredient (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: The mark in the red square indicates ‘minor ingredient(s) of the product (less than 5 percent) may be GMO non-segregated’ (left) and ‘the sauce may contain GMO non-segregated ingredients’ (right).

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

Figure: JCCU's private brand salad dressing. Underlined section indicates 'canola oil (GMO-non-segregated)'.

<u>Grains</u>

Japan remains one of the world's largest per capita importers of GE crops, such as corn and soybeans. 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. Though the U.S. is still the largest supplier of corn to Japan, the U.S. share decreased significantly in the fourth quarter of CY2012 due to lack of availability brought on by drought. As a result, the U.S. share in corn exports to Japan decreased to 81 percent in MY2012 from 90 percent in MY2011.

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). There is limited demand for non-GE feed corn for the specific non-GE fed dairy market. 'Concerned' consumer groups and some members of JCCU are potential customers of such specialized products. However, the March 2011 earthquake and tsunami disrupted port, storage, and processed feed manufacturing facilities, as well as distribution channels. Before the earthquake, feed manufacturers produced various types of feed based on customer demand. However, the circumstances after the earthquake forced feed manufacturers to limit inventory. On April 7, 2011, Seikatsu Club, a branch of JCCU with 350,000 members, announced that it was unable to offer 'non-GE feed from contracted feed manufacturers, and instead only sold 'GE non-segregated' material (http://www.seikatsuclub.coop/coop/news/20110407.html). It wasn't until June 29, 2011, that Seikatsu Club announced that the 'non GMO' feed supply had been partially resumed (http://seikatsuclub.coop/coop/news/20110628h2.html). The club's website introduced their activities to keep using non GE feed (http://www.seikatsuclub.coop/activity/20120912.html) and feed rice (http://www.seikatsuclub.coop/coop/news/20130311t.html); however, as of July 2013, there are no 'non GMO' fed livestock products available on its website (http://www.seikatsuclub.coop/item/).

There is a separate market for food-use corn in Japan, which until 2008 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. 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).

Japanese Corn Imports	
(1,000 MT – 2012) (Year Ending: September)	
Corn for feed	
United States	7,648
Ukraine	844
Brazil	739
Argentina	540
Romania	148
Serbia	96
Hungary	68
Bulgaria	38
South Africa	10
Slovakia	8
Others	7
Total Feed	10,145
Corn for food, starch, manufacturing	

United States	4,436
Ukraine	117
Brazil	105
Argentina	47
Australia	16
Serbia	12
Hungary	5
Others	9
Total Food & Other	4,745
Total	**14,890**
Source: Ministry of Finance	

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 that performs food and feed safety risk assessments for MHLW and MAFF.

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.

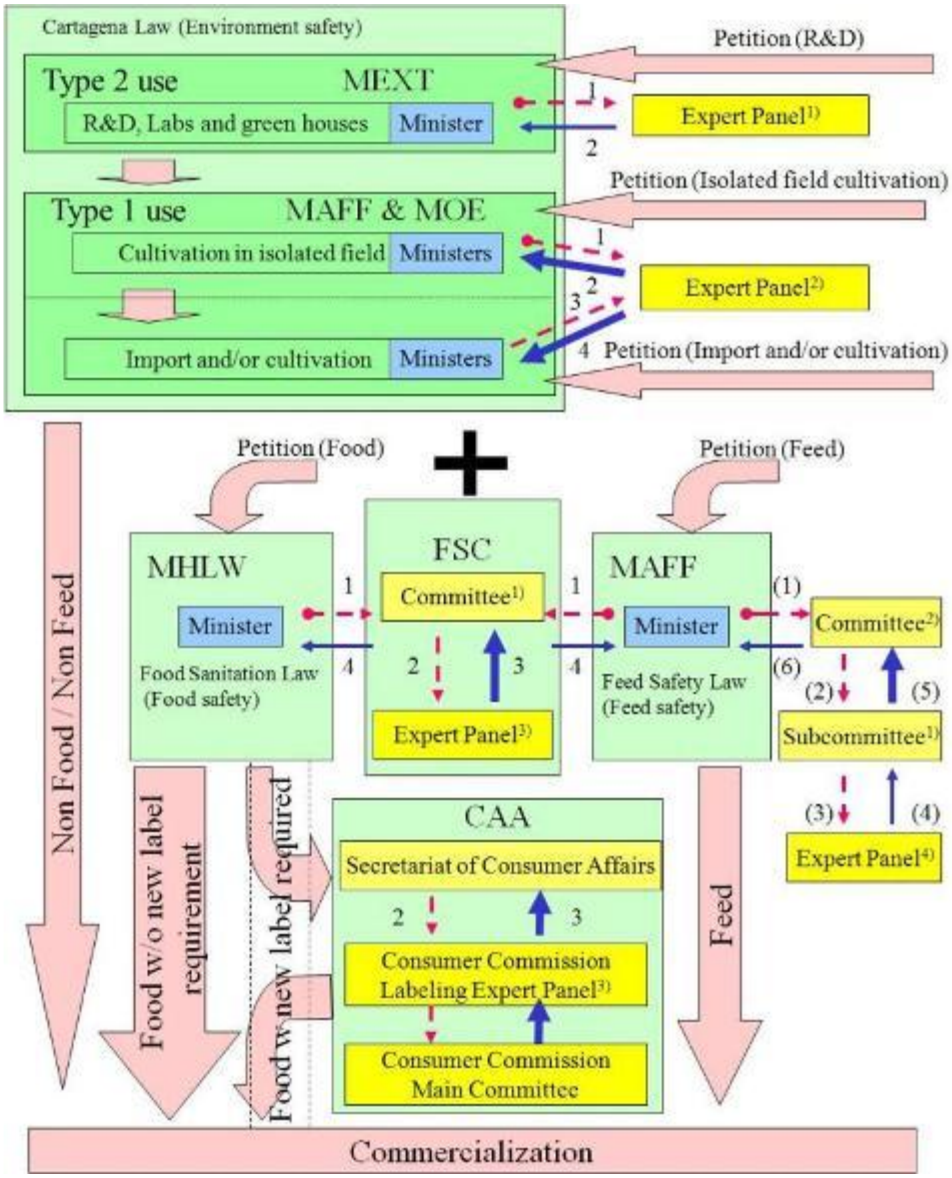
GE plants that are used for food must obtain food safety approvals from the MHLW Minister. Based on the Food Sanitation Law, upon receiving a petition for review from an interested party (usually a biotechnology provider), the MHLW Minister will request that the FSC conduct a food safety review. The FSC is an independent government organization under the Cabinet Office that was established in order to perform food safety risk assessments using expert committees. 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 also 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 new 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 hosted several additional public meetings from August 2008 to March 2009 in order to seek input on whether the biotechnology regulations should be revised; however, no change was made to the regulation. The HFSSC advised that the regulation be reviewed after three years, but no additional meetings have been held. Later, this was changed to five years.

A new household survey on GE crops taken by the Hokkaido government in 2008 mirrored the results of the 2004 and 2005 surveys. The survey showed that while 80 percent of respondents remained concerned about consuming GE crops, nearly 70 percent of respondents continued to support further research testing on GE crops for medical and industrial use.

The HFSSC decided in March 2009 to leave the ordinance unchanged. The committee also agreed that Hokkaido Prefecture should:

• hold additional meetings with a wider variety of participants to increase public understanding about GE foods and crops;

• urge the Government of Japan to improve labeling for GE food products and secure a stable supply of non-GE seeds; and

• re-examine the GE crops ordinance as well as current cross-pollen prevention methods after three years in order to take into account new approaches to GE crop management.

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 2013, 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 guideline was established, there seems to have been no attempt to grow GE crops (http://www.pref.iwate.jp/view.rbz?cd=44664).

5. Miyagi (Guidelines) - Following a series of public meetings on GE crop cultivation in 2007 and 2008, the Miyagi Prefectural Government determined that local regulations were necessary. 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 adopted guidelines 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 pollinating 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 (Guidelines) - It is not Ehime Prefecture, but rather one of its municipalities, that has drawn up ordinances on GE crops. These ordinances entered into force in April 2007 and require any producer of genetically modified products to first receive permission from the mayor. The ordinance also prohibits genetically modified foods from being served in school lunches.

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

13. 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.’

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 2, 2013, Japan has approved over 180 GE events for food, 170 for feed and 120 for environmental release, including commercial planting for most events.

Attachment A – Approved commercial GE events.

Attachment B – Approved additives derived from GE

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.

Path of Rainbow Papaya (55-1) to full approval in Japan

On December 1, 2011, the GOJ finally issued final approval for the importation of GE papaya from Hawaii, 12 years after its official submission. This approval was long sought, and is significant, as it is the first direct-to-consumer GE product, and first GE horticultural product, available in Japan. Industry analysts are watching Rainbow papaya's public acceptance keenly, as many consider it a leading indicator of how other GM products may fare in Japan's fickle food market.

Rainbow papaya has been grown in Hawaii since 1999 to cope with papaya ringspot virus. Because of the prevalence of the virus, papaya farmers have widely adopted the GE variety. In 2009 approximately 80 percent of papaya grown in Hawaii was GE (http://www.nass.usda.gov/Statistics_by_State/Hawaii/Publications/Fruits_and_Nuts/papaya.pdf). Further details can be found in the 2012 Agricultural Biotechnology Annual report (JA2013).

The case with Rainbow papaya highlighted an important issue that the GOJ and other countries will be forced to deal with in the near future. Most other GE events are submitted for approval by major biotechnology providers based in the United States or Europe. However, the application for approval of Rainbow papaya was submitted by a relatively small industry group, and as such, did not have the resources or personnel needed to answer the many questions, and respond to the many requests for additional data, from the GOJ. It is reasonable to expect that, with the price of genome sequencing coming down so significantly in recent years, many applications for novel GE events in the future will come from the public sector and smaller firms, which have fewer resources for application and regulatory compliance. GE papaya 55-1 showed that regulatory approval by the GOJ will require not only that the product's development be well documented, but also that the applicant have significant resources for attaining regulatory approval. If smaller firms and ventures start to petition for regulatory approval, the current system will become further strained. Logically, if a developer considers the hurdle to get the GOJ's regulatory approval to be too high, they may simply ignore regulatory requirements, creating the possibility of low level presence of unapproved events in the food supply. In fact, the Chinese Government announced in November of 2009 that they are developing GE rice and corn, with the intention of wide-scale cultivation in 2012 or 2013 (Bloomberg, December 1, 2009). Though media reported that the progress of GE corn in China slowed down (March 7, 2011, Reuters), as a country that relies heavily on imported food, Japan may need to make significant investments in its capacity to review and regulate new GE events in the very near future.

Other countries in Asia and even Latin America are expected to start to release commercial GE events developed by their own institutions, most likely the public sector. So far, there is no indication that any of these "new players" in agricultural biotechnology are seeking regulatory approval in Japan. The adoption of GE crops developed by Asian countries may not be primarily used for the export market, because the crops as such have been developed for the countries' own food supply. However, it is very likely that even crops developed for domestic consumption will be comingled and trace levels will be involuntarily distributed globally. Many food manufacturers, including Japanese, have processing plants in Asian countries and face a greater chance that unapproved GE events will be commingled into their products in the near future.

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 than Rainbow papaya (55-1), and suspected to be a locally developed PRSV resistant event from Taiwan which was comingled 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 unknown GE papaya has been found on the farms of local papaya growers in Okinawa. Unknown 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. Under the regulatory guidance of Okinawa Prefecture, farmers "voluntarily" cut down all unapproved papaya plants (http://www.maff.go.jp/j/press/syouan/nouan/130326.html). In addition, 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 (http://www.maff.go.jp/j/press/syouan/nouan/130326.html).

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. 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. So far there are only two countries, Japan and China, who require domestic field trials for GE crops intended only for import.

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). The new 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 has 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://www.fsc.go.jp/fsciis/attachedFile/download?retrievalId=kai20110721sfc&fileId=310). 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.

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 labeling requirements (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 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 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.

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

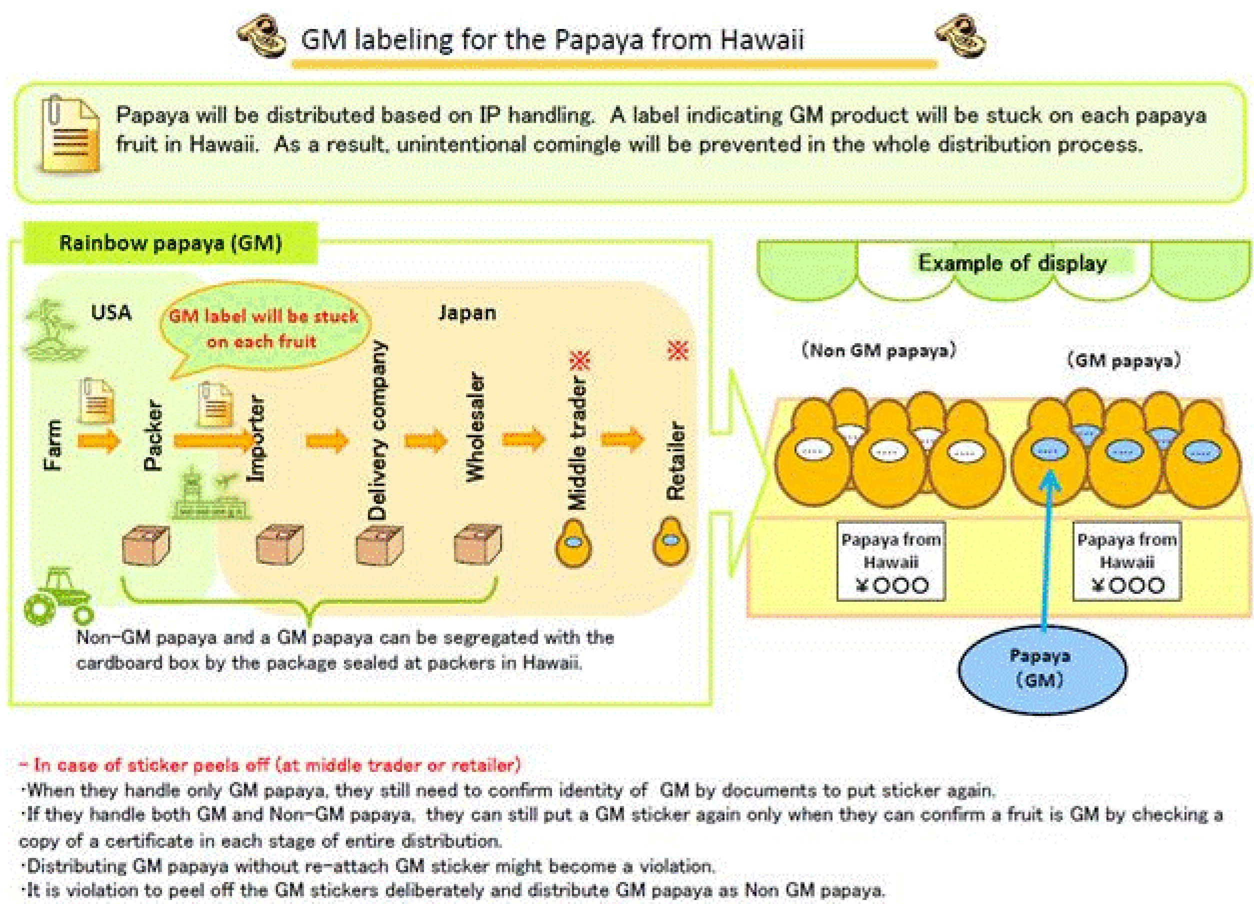
10. Item containing food of items 1 to 9 as a main ingredient	Soybean
11. Item containing soybean (for cooking) as a main ingredient	Soybean
12. Item containing soybean flour as a main ingredient	Soybean
13. Item containing soybean protein as a main ingredient	Soybean
14. Item containing edamame (green 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.



Figure; Diagram of labeling procedure to individual papaya fruit (prepared by CAA after consultation with HPIA and HDOA).
http://www.caa.go.jp/foods/pdf/syokuhin736.pdf

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.

<u>"5 percent rule" for non-GE labeling</u>

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 the new procedure, imported grain is initially tested by the conventional method. 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 new 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), the shipment is judged to be non-segregated. If the number of GE positive grains from the first and second single-grain-based test is 10 or more (10 out of 180), the shipment is also considered to be non-segregated.

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://www.ustr.gov/sites/default/files/2013%20NTE%20Japan%20Final.pdf). 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 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. As of the COP11MOP6 meetings in Hyderabad, India, held from October 1 to 19, 2012, only three countries had ratified the Supplementary Protocol.

South Korea will host the next meeting (COP12MOP7) in 2014.

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.

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.

On January 21, 2013, MHLW discussed the regulatory aspects of products created through NBTs in its Subcommittee for Newly Developed Food. Currently there is no clear criteria to determine whether NBTs should be regulated as "genetically engineered" or not. Consequently, the technology providers have faced difficulty in judging if a specific product needs to be reviewed under the GE Regulatory framework or not. The GOJ's approach is the same as the US, which is to review based on the nature of product, not the process (http://www.mhlw.go.jp/stf/shingi/2r9852000002tccm.html).

On May 14, 2013, the Science Council of Japan (SCJ) held a symposium on NBTs (http://www.scj.go.jp/ja/event/pdf2/148-s-2-2.pdf, in Japanese). The symposium covered various NBTs, such as the application of RNA virus vector for plant breeding, artificial nuclease for animal genome editing, RNA directed DNA methylation (aka RdDM), and grafting of GE and non-GE plants. The presentation also included the questions regarding the regulation of NBTs if the product cannot be distinguished from "natural occurring" products, whether or not it should be regulated, and the difficulty in developing an internationally harmonized approach.

MAFF 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. MAFF pays close attention to EU and US 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:
On September 12, 2012, MAFF announced the summary of its investigation of canola and Chinese colza (*Brassica campestris* L.), a domestic canola. The report covered a survey conducted between 2009 and 2011 in the vicinity of 16 ports where canola was unloaded from carrying vessels. Of the 1,753 plants subjected to analysis, the results showed that 108 plants, or 21 percent, had a tolerant gene for herbicide.

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 voluntary growth of GE plants in the environment. Voluntary growth *per se* is not of primary importance in most cases, as voluntary growth 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. 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.

In addition to MOE and MAFF's monitoring, citizen's groups sometimes operate their own monitoring. On July 7, 2012, Seikatsu Club, a division of JCCU, released the results of its investigation on voluntary growth of GE canola in 19 prefectures in Japan. They collected 419 canola plants voluntarily grown along the road between the ports and the manufacturing facility. The result showed five plants had the gene tolerant to glyphosate, 49 to glufosinate, and one to both glyphosate and glufosinate. As there is no commercial canola event tolerant both to glyphosate and glufosinate, they speculated the field cross of two events would have created the event tolerant to two herbicides. Seikatsu Club also reported voluntary growth of GE canola was observed inland as well, in locations where GE plant voluntary growth has not been found in the past.

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 LLRICE601 in bulk rice and some rice-containing processed food products (such as French fries), and MON71800 in bulk wheat. MHLW has phased out testing for LLP corn events, such as StarLink, Bt10 and Event 32.

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. According to the report by the Joint Research Centre of the European Commission, the number of GE events commercially grown will quadruple between 2008 and 2015 (http://ftp.jrc.es/EURdoc/JRC51799.pdf). Fifty percent of GE crops will be developed and released in Asia and Latin America. Crops other than soybeans, corn, canola and cotton will become a third of all newly developed crops entering the market. 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.

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"), and corn (StarLink, Bt10, E32) have, at some point in time, all been subject to testing or segregation, or have been temporarily banned. As of July 2013, there is no testing of U.S. potatoes and corn, 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/topics/yunyu/keikaku/dl/11_en.pdf), 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 4, 2013, MHLW monitors the following items:
- PRSV-YK
- 63Bt, NNBt, and CpTI
- LLRICE601
- RT73, B. rapa
- MON71800

<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 1 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 1 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).

<u>Ministry of Environment (MOE) and MAFF Policies on LLP in environment</u>
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.

<u>CODEX LLP Supported but Not Implemented</u>
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.

<u>**PART C: Marketing**</u>

a) MARKET ACCEPTANCE:
Based on the FSC's annual survey of consumers' opinions on food safety, 49 percent of those polled

indicated they have high or some concern regarding GE foods (http://www.fsc.go.jp/monitor/2407moni-kadai-kekka-yoyaku.pdf). At the same time, Japan is 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.

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. As indicated in the case of GE papaya 55-1, 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 U.S., 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 5 - 12, 2012 - FAS Tokyo collaborated with US Grains Council Tokyo to organize a Biotechnology Study Tour for eight GOJ regulators from MAFF, MHLW and FSC 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 16-20, 2012 – FSN Suguru Sato attended the International Symposium for Biosafety of Genetically Modified Organisms (ISBGMO) in St. Lois, Missouri. Seven Japanese scientists who are active and highly involved in the risk assessment of GE plants for biodiversity also attended the meeting. One of the key topics in the meeting was the problem formulation in regulatory science and risk assessment of GE products. Compared to academic science, which often focuses on the pursuit of truth in nature, regulatory science requires that one draw conclusions as to if the risk associated with the GE trait in question is scientifically justifiable. Therefore, it is important to formulate the problem and set a clear end point in GE risk assessment. Other agenda items included, but were not limited to, GE plants with RNA interference and GE animals. During the symposium, Post organized informal meeting for USDA/APHIS and Japanese scientists to exchange views.

March 25 and 26, 2013 - 'Informal Meeting for the Implementation of Article 19 and 20 of the Nagoya Protocol' was organized by Global Environment Division, MOFA and United Nation University in Tokyo. The discussion was focused on sharing views and experiences of each delegate on Access and Benefit Sharing (ABS), difficulties in separating 'commercial' versus 'non-commercial' use, and different understanding of language such as 'mutually agreed term'. FSN Suguru Sato attended as an observer and shared the experience with USG stakeholders.

Post has regular discussions with government officials and stakeholders regarding such issues as 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 May 28, 2013, Japan had approved 97 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_130528.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. On May 24, 2011, IBL and Nippon Flour Mills Co., Ltd. (http://www.nippn.co.jp/) made the world's first production of human fibrinogen by GE silkworm (http://www.ibl-japan.co.jp/news_img/PR_20110524.pdf). Fibrinogen has been used as hemostat, but the contamination of pathogenic elements has been an issue of concern. GE silkworm would enable the production of pathogenic element-free fibrinogen. On January 10, 2012, IBL, in conjunction with Gunma Prefecture's Agriculture Department, initiated large-scale GE silkworm production. A total of 48,000 GE silkworms were commercially grown in a closed culture environment to produce antibodies for medical diagnosis agents (http://www.pref.gunma.jp/houdou/f2300096.html). However, NIAS stopped the research of GE silkworm for commercial production in the summer of 2012.

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, 2013, Japan has produced 622 cows by fertilized egg cell cloning, 411 cows by somatic nuclear transfer (SCNT), 467 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. Currently, there is only one cloned livestock animal, produced by SCNT, existing in Japan (http://www.s.affrc.go.jp/docs/clone/kenkyu/20130331.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, the 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/food/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

'Trends and Public Acceptance of Genetically Modified Crops in Japan' (in Japanese), Nikkei Biotechnology Annual, 2011, Yoshiko SASSA
Life Bio Plaza 21, non-profit organization to increase science literacy of general public with emphasis on agricultural biotechnology.
http://www.life-bio.or.jp/

ATTACHMENTS

Attachment A - Approved events for commercial use (as of July 1, 2013)

Plant	Name of event	Applicant/ Developer	Characteristics	Approvals		
				BSP (OECD UI)	Feed	Food
Alfalfa (3)	J101	Monsanto Japan	Herbicide tolerant	2006 (MON-00101-8)	2006	2005
	J163	Monsanto Japan	Herbicide tolerant	2006 (MON-00163-7)	2006	2005
	J101 x J163	Monsanto Japan	Herbicide tolerant	2006 (MON-00101-8 × MON-00163-7)	2006	2005

Canola (16)	RT73	Monsanto Japan	Herbicide tolerant	2006 (MON-00073-7)	2003	2001
	HCN92	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN007-1)	2003	2001
	HCN10	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN007-1)	2003	2001
	PGS1	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN004-7 x ACS-BN001-4)	2003	2001
	PHY14	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN004-7 x ACS-BN001-4)	2003	2001
	PHY35	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN004-7 x ACS-BN001-4)	2003	2001
	T45	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN008-2)	2003	2001
	PGS2	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7xACS-BN002-5)	2003	2001
	PHY36	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7 x ACS-BN002-5)	2003	2001
	PHY23	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7 x ACS-BN002-5)	2003	2001
	Oxy-235	Bayer Crop Science	Herbicide tolerant	2008 (ACS-BN001-5)	2003	2001
	MS8RF3	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN005-8xACS-BN003-6)	2003	2001
	MS8	Bayer Crop Science	Herbicide tolerant, male sterile	2006 (ACS-BN005-8)	2003	2001
	RF3	Bayer Crop Science	Herbicide tolerant, sterility recovery	2007S(ACS-BN003-6)	2003	2001
	RT200	Monsanto Japan	Herbicide tolerant	2006 (MON-89249-2)	2003	2001
	MS8 x RF3 x RT73	Bayer Crop Science	Herbicide tolerant (glyphosate and glufosinate), male sterile, sterility recovery	2012 (ACS-BN005-8 x ACS-BN003-6 x MON-00073-7)	2010	2011
Carnation (8)	11	Suntory Holdings	Color change	2004 (FLO-07442-4)	N/A	N/A
	123.2.38	Suntory Holdings	Color change	2004 (FLO-40644-4)	N/A	N/A
	123.8.8	Suntory Holdings	Color change	2004 (FLO-40685-1)	N/A	N/A
	123.2.2	Suntory Holdings	Color change	2004 (FLO-40619-7)	N/A	N/A
	11363	Suntory Holdings	Color change	2004 (FLO-11363-1)	N/A	N/A
	123.8.12	Suntory Holdings	Color change	2009 (FLO-40689-6)	N/A	N/A
	25958	Suntory Holdings	Color change and herbicide tolerance	2013 (IFD-25958-3)	N/A	N/A
	26407	Suntory Holdings	Color change and herbicide tolerance	2013 (IFD-26407-2)	N/A	N/A
Corn (115)	T-14	Bayer Crop	Herbicide tolerant	2006 (ACS-ZM-	2005	2001

		Science		002-1)		
	T-25	Bayer Crop Science	Herbicide tolerant	2004 (ACS-ZM003-2)	2003	2001
	MON810	Monsanto Japan	Insect resistant	2004 (MON-00810-6)	2003	2001
	Bt11	Syngenta Seeds	Insect resistant	2007 (SYN-BT011-1)	2003	2001
	Sweet corn, Bt11	Syngenta Seeds	Insect resistant, herbicide tolerant	2007 (SYN-BT011-1)	-	2001
	Event176	Syngenta Seeds	Insect resistant	2007 (SYN-EV176-9)	2003	2003
	GA21	Monsanto Japan	Herbicide tolerant	2005 (MON-00021-9)	2003	2001
	DLL25	Monsanto Japan	Herbicide tolerant	2006 (DKB-89790-5)	2003	2001
	DBT418	Monsanto Japan	Insect resistant, herbicide tolerant	2007 (DKB-89614-9)	2003	2001
	NK603	Monsanto Japan	Herbicide tolerant	2004 (MON-00603-6)	2003	2001
	MON863	Monsanto Japan	Insect resistant	2004 (MON-00863-5)	2003	2002
	1507	Dow Chemical	Insect resistant and herbicide tolerant	2005 (DAS-01507-1)	2002	2002
	MON88017	Monsanto Japan	Insect resistant, herbicide tolerant	2006 (MON-88017-3)	2006	2005
	Mon863 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00863-5xMON-00603-6)	2003	2003
	GA21 x MON810	Monsanto Japan	Herbicide tolerant, Insect resistant	2005 (MON-00021-9xMON-00810-6)	2001	2003
	NK603 x Mon810	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00603-6xMON-00810-6)	2002	2003
	T25 x MON810	DuPont	Herbicide tolerant, Insect resistant	2005 (ACS-ZM003-2xMON-00810-6)	2001	2003
	1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2005 (DAS-01507-1xMON-00603-6)	2003	2004
	Mon810 x Mon863	Monsanto Japan	Insect resistant	2004 (MON-00810-6xMON-00863-5)	2004	2004
	Mon863 x MON810 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00863-5xMON-00810-6xMON-00603-6)	2004	2004
	59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7)	2006	2005
	MON88017 x MON810	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88017-3 x MON-00810-6)	2006	2005
	1507 x 59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-01507-1 x DAS-59122-7)	2006	2005
	59122 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x MON-00603-6)	2006	2005

59122 x 1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x DAS-01507-1 x MON-00603-6)	2006	2005
LY038	Monsanto Japan	High lysine content	2007 (REN-00038-3)	2007	2007
TC6275	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2008 (DAS-06275-8)	2007	2007
MIR604	Syngenta Seeds	Insect resistant	2007 (SYN-IR604-5)	2007	2007
MON89034	Monsanto Japan	Insect resistant	2008 (MON-89034-3)	2007	2007
Bt11 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-BT011-1 x MON-00021-9)	2007	2007
Bt11 x MIR604	Syngenta Seeds	Herbicide tolerant, Insect resistant	2008 (SYN-BT011-1 x SYN-IR604-5)	2007	2007
MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-IR604-5 x MON-00021-9)	2007	2007
Bt11 x MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2008 (SYN-BT011-1 x SYN-IR604-5 x MON-00021-9)	2007	2007
LY038 x MON810	Monsanto Japan	High lysine content, Insect resistant	2007 (REN-00038-3 x MON-00810-6)	2007	2007
MON89034 x MON88017	Monsanto Japan	Herbicide tolerant, Insect resistant	2008 (MON-89034-3 x MON-88017-3)	2007	2008
MON89034 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2008 (MON-89034-3 x MON-00603-6)	2007	2008
MON89034 x 1507	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
MON89034 x B.t.Cry34/35Ab1 Event DAS-59122-7	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
1507 x MON8017	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
B.t.Cry34/35Ab1 Event DAS-59122-7 x MON88017	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
MON89034 x 1507 x MON88017	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
MON89034 x 1507 x B.t.Cry34/35Ab1 Event DAS-59122-7	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
MON89034 x	Dow Chemical	Herbicide tolerant,	-	2008	2008

B.t.Cry34/35Ab1 Event DAS-59122-7 x MON88017	Japan and Monsanto Japan	Insect resistant			
1507 x B.t.Cry34/35Ab1 Event DAS-59122-7 x MON88017	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
MON89034 x 1507 x MON89017 x B.t.Cry34/35Ab1 Event DAS-59122-7	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	2009 (MON-89034-3×DAS-01507-1×MON-88017-3×DAS-59122-7)	2008	2008
NK603 x T25	Monsanto Japan	Herbicide tolerant	2010 (MON-00603-6 x ACS-ZM003-2)	2009	2009
MIR162	Syngenta Seeds	Insect resistant	2010 (SYN-IR162-4)	2010	2010
Bt11 x MIR162	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
MIR162 x MIR604	Syngenta Seeds	Insect resistant	-	2010	2010
MIR162 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
Bt11 x MIR162 x MIR604	Syngenta Seeds	Herbicide tolerant, Insect resistant	2010 (SYN-BT011-1 x SYN-IR162-4 x MON-00021-9)	2010	2010
Bt11 x MIR162 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
MIR162 x MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
Bt11 x MIR162 x MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
Bt11 x 1507	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
MIR162 x 1507	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
1507 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
Bt11 x MIR162 x 1507	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
Bt11 x 1507 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
MIR162 x 1507 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	-	2010	2010
3272	Syngenta Seeds	Heat-resistant alpha-amylase production	2010 (SYN-E3272-5)	2010	2010
3272 x Bt11	Syngenta Seeds	Heat-resistant alpha-amylase producing, Insect resistant, herbicide tolerant	-	2010	2010
3272 x MIR604	Syngenta Seeds	Heat-resistant alpha-amylase producing, Insect resistant	-	2010	2010
3272 x GA21	Syngenta Seeds	Heat-resistant alpha-amylase producing, herbicide tolerant	-	2010	2010
3272 x Bt11 x MIR604	Syngenta Seeds	Heat-resistant alpha-amylase producing, Insect resistant,	-	2010	2010

		herbicide tolerant			
3272 x Bt11 x GA21	Syngenta Seeds	Heat-resistant alpha-amylase producing, Insect resistant, herbicide tolerant	-	2010	2010
3272 x MIR604 x GA21	Syngenta Seeds	Heat-resistant alpha-amylase producing, Insect resistant, herbicide tolerant	-	2010	2010
3272 x Bt11 x MIR604 x GA21	Syngenta Seeds	Heat-resistant alpha-amylase producing, Insect resistant, herbicide tolerant	2010 (SYNE3272-5 × SYN-BT011-1 × SYN-IR604-5 × MON-00021-9)	2010	2010
MON89034× B.t. Cry1F maize line 1507 × NK603	Dow Chemical Japan and Monsanto Japan	Insect resistant, herbicide tolerant	2010 (MON-89034-3 × DAS-01507-1 × MON-00603-6)	2010	2010
Bt11 × MIR162 × B.t. Cry1F maize line 1507 × GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	2011 (SYN-BT011-1 × SYN-IR162-4 × DAS-01507-1 × MON-00021-9)	2010	2010
1507× MON810×NK603	DuPont	Insect resistant, herbicide tolerant	2011 (DAS-01507-1× MON-00810-6×MON-00603-6)	2011	2009
DAS-59122 -7 × MON810	DuPont	Insect resistant, herbicide tolerant	-	2011	2009
1507 x MON810	DuPont	Insect resistant, herbicide tolerant	-	2011	2009
1507 x 59122-7 x MON810	DuPont	Insect resistant, herbicide tolerant	-	2011	2009
59122-1 x MON810 x NK603	DuPont	Insect resistant, herbicide tolerant	-	2011	2009
1507 × 59122 -7× MON810 × NK603	DuPont	Insect resistant, herbicide tolerant	2011 (DAS-01507-1 × DAS-59122-7 × MON-00810-6 × MON-00603-6)	2011	2009
MIR604 x B.t.Cry1F maize line 1507	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
B.t.Cry34/35Ab1 Event DAS-59122-7 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
B.t.Cry34/35Ab1 Event DAS-59122-7 x B.t.Cry1F maize line 1507 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant		2010	2011
B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604 x B.t.Cry1F maize line	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011

	1507					
	Bt11x MIR604 x B.t.Cry1F maize line 1507	Syngenta Seeds	Insect resistant, herbicide tolerant		2010	2011
	Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7 x B.t.Cry1F maize line 1507	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604 x B.t.Cry1F maize line 1507 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	Bt11 x MIR604 x B.t.Cry1F maize line 1507 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7 x B.t.Cry1F maize line 1507 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604 x B.t.Cry1F maize line 1507	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	Bt11 x B.t.Cry34/35Ab1 Event DAS-59122-7 x MIR604 x B.t.Cry1F maize line 1507 x GA21	Syngenta Seeds	Insect resistant, herbicide tolerant	2011 (SYN-BT01-1 x DAS59122-7 x SYN-IR604-5 x DAS01507-1 x MON-00021-9)	2010	2011
	MIR604 x NK603	Dupont	Insect resistant, herbicide tolerant	-	2011	2011
	1507 x MIR604 x NK603	Dupont	Insect resistant, herbicide tolerant	2011 (DAS01507-1 x SYN-IR604-5 x MON-00603-6)	2011	2011
	Bt11 x MIR162 x GA21 (sweet corn)	Syngenta Seeds	Insect resistant, herbicide tolerant	-	-	2012
	Bt11 x GA21 (sweet corn)	Syngenta Seeds	Insect resistant, herbicide tolerant	-	-	2012
	Bt11 x MIR162 (sweet corn)	Syngenta Seeds	Insect resistant, herbicide tolerant	-	-	2012
	MIR162 x GA21 (sweet corn)	Syngenta Seeds	Insect resistant, herbicide tolerant	-	-	2012
	MIR162 (sweet corn)	Syngenta Seeds	Insect resistant	-	-	2012
	GA21 (sweet corn)	Syngenta Seeds	Herbicide tolerant	-	-	2012
	MON87460	Monsanto Japan	Drought tolerant	2012 (MON-87460-4)	2011	2011
	1507 x 59122 x MON810 x NK603 x MIR604	Dupont	Insect resistant, herbicide tolerant	2012 (DAS-01507-1 x DAS-59122-7 x MON-00810-6 x	2012	2012

				MON-00603-6 x SYN-IR604-5)		
	MON87460 x NK603	Monsanto Japan	Insect resistant, herbicide tolerant	2012 (MON-87460-4 x MON-00603-6)	2011	2011
	MON87460 x MON89034 x MON88017	Monsanto Japan	Drought tolerant, insect resistant, herbicide tolerant	2012 (MON-87460-4 x MON-89034-3 x MON-88017-3)	2011	2011
	MON87460 x MON89034 x NK603	Monsanto Japan	Drought tolerant, insect resistant, herbicide tolerant	2012 (MON-87460-4 x MON-89034-3 x MON-00603-6)	2011	2011
	DAS40278	Dow Chemical Japan	Herbicide tolerant	2012 (DAS-40278-9)	2012	2012
	MON89034 x 1507 x NK603 x DAS40278	Dow Chemical Japan	Insect resistant, herbicide tolerant	2013 (MON-89034-3 x DAS-01507-1 x MON-00603-6 x DAS-40278-9)	2013	2013
	MON89034 x 1507 x MON88017 x DAS5912-7 x DAS40278	Dow Chemical Japan	Insect resistant, herbicide tolerant	2013 (MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7 x DAS-40278-9)	2013	2013
	1507 x MON810 x MIR162 x NK603	Dupont	Insect resistant, herbicide tolerant	2013 (DAS-01507-1 x MON-00810-6 x SYN-IR162-4 x MON-00603-6)	2013	2013
	NK603 x DAS40278	Dow Chemical Japan	Herbicide tolerant	2013 (MON-00603-6 x DAS-40278-9)	2013	2013
	MON87427	Monsanto Japan	Herbicide-induced male sterility and herbicide tolerant	2013 (MON-87427-7)	2013	2013
	Event 5307	Syngenta Japan	Insect resistant	2013 (SYN-05307-1)	2013	2013
Cotton (22)	531	Monsanto Japan	Insect resistant	2004 (MON-00531-6)	1997	2001
	757	Monsanto Japan	Insect resistant	2005 (MON-00757-7)	2003	2001
	1445	Monsanto Japan	Herbicide tolerant	2004 (MON-01445-2)	1998	2001
	10211	Stoneville Pedigreed Seed	Herbicide tolerant	-	-	2001
	10215	Stoneville Pedigreed Seed	Herbicide tolerant	-	1998	2001
	10222	Stoneville Pedigreed Seed	Herbicide tolerant	-	1998	2001
	15985	Monsanto Japan	Insect resistant	2004 (MON-15985-7)	2003	2002
	1445 x 531	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-01445-2xMON-00531-6)	2003	2003
	15985 x 1445	Monsanto	Herbicide tolerant,	2005 (MON-	2003	2003

		Japan	Insect resistant	16985-7xMON-01445-2)		
	LLCotton25	Bayer Crop Science	Herbicide tolerant	2006 (ACS-GH001-3)	2006	2004
	MON88913	Monsanto Japan	Herbicide tolerant	2006 (MON-88913-8)	2006	2005
	MON88913 x 15985	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88913-8 × MON-15985-7)	2006	2005
	281	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	-	2005	2005
	3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	-	2005	2005
	281 x 3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 (DAS-24236-5×DAS-21023-5)	2006	2005
	281 x 3006 x 1445	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 DAS-24236-5×DAS-21023-5×MON-01445-2)	2006	2006
	281 x 3006 x MON88913	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006(DAS-24236-5×DAS-21023-5×MON-88913-8))	2006	2006
	LLCotton 25 x 15985	Bayer Crop Science	Herbicide tolerant, Insect resistant	2007 (ACS-GH001-3×MON-15985-7)	2006	2006
	GHB614	Bayer Crop Science	Herbicide tolerant	2010 (BCS-GH002-5)	2010	2010
	GHB614 x LLCotton25	Bayer Crop Science	Herbicide tolerant	2010 (BCS-GH002-5 x ACS-GH001-3)	2010	2010
	GHB614 x 15985	Bayer Crop Science	Herbicide tolerant, insect resistant		2010	2010
	GHB614×LLCotton25 ×15985	Bayer Crop Science	Herbicide tolerant, insect resistant	2011 (BCS-GH002-5 × ACSGH001-3 × MON-15985-7)	2010	2010
	MON88913	Monsanto Japan	Herbicide tolerant	2011 (MON-88913-8)	2011	2010
	COT67B	Syngenta Japan	Insect resistant	2012 (SYN-IR67B-1)	2012	2012
	COT102	Syngenta Japan	Insect resistant	2012 (SYN-IR102-7)	2012	2012
	GHB119	Bayer Cropscience	Herbicide tolerant, insect resistant	2013 (BCS-GH005-8)	2012	2012
Potato (8)	BT6	Monsanto Japan	Insect resistant	Not needed	N/A	2001
	SPBT02-05	Monsanto Japan	Insect resistant	Not needed	N/A	2001
	RBMT21-129 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	RBMT21-350 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001

	RBMT22-82 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	SEMT15-15 (NLY)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
	RBMT15-101	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
	New Leaf Y Potato SEMT15-02	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
Rose (2)	WKS82/130-4-1	Suntory	Alteration of flavonoid synthesis pathway	2008 (IFD-52401-4)	N/A	N/A
	WKS82/130-9-1	Suntory	Alteration of flavonoid synthesis pathway	2008 (IFD-52901-9)	N/A	N/A
Soybean (8)	40-3-2	Monsanto Japan	Herbicide tolerant	2005 (MON-04032-6)	2003	2001
	260-05	DuPont	High oleic acid	2007 (DD-026005-3)	2003	2001
	A2704-12	Bayer Crop Science	Herbicide tolerant	2006 (ACS-GM005-3)	2003	2001
	A5547-127	Bayer Crop Science	Herbicide tolerant	2006 (ACS-GM006-4)	2003	2001
	MON89788	Monsanto Japan	Herbicide tolerant	2008 (MON-89788-1)	2007	2007
	DP-356043-5	DuPont	Herbicide (glyphosate and acetolactate synthase (ALS)-inhibitor) tolerant	2009 (DP-356043-5)	2009	2009
	DP-305423-1	DuPont	High oleic acid	2010 (DP-305423-1)	2010	2010
	DP-305423 x 40-3-2	DuPont	High oleic acid, Herbicide tolerant	2012 (DP-305423-1 x MON-04032-6)	2010	2012
	MON87701*	Monsanto Japan	Insect resistant	2013 (MON-87701-2)	2011	2011
	CV127	BASF Japan	Herbicide tolerant	2013 (BPS-CV127-9)	2013	2012
	MON87705	Monsanto Japan	Low saturated fat, high oleic acid, and herbicide tolerant	2013 (MON-87705-6)	2013	2012
	MON87701 x MON89788	Monsanto Japan	Insect resistant and herbicide tolerant	2013 (MON-87701-2 x MON-89788-1)	2011	2011
Sugar beet (3)	T120-7	Bayer Crop Science	Herbicide tolerant	Not needed	1999	2001
	77	Monsanto Japan	Herbicide tolerant	Not needed	2003	2003
	H7-1	Monsanto Japan	Herbicide tolerant	2007 (KM-000H71-4)	2005	2003
Papaya	55-1	HPIA	Virus resistant	2011 (CUH-CP551-8)	-	2011
Total approval numbers	BSP	Feed	Food	128	176	186
For each biotechnology variety, the years safety approvals were granted are shown for BSP environmental (import and planting), feed and food safety. Potato and sugar beet are imported to Japan only as processed foods, thus indicated as 'Not needed' for import and planting. 'N/A' means not applicable.						

Attachment B - Approved biotech additives (as of July 1, 2013).

Products	Name	Characteristics	Developer	Public announcement
alpha-amylase	TS-25	Improved productivity	Novozymes A/S	2001
	BSG-amylase	Improved productivity	Novozymes A/S	2001
	TMG-amylase	Improved productivity	Novozymes A/S	2001
	SP961	Improved productivity	Novozymes A/S	2002
	LE399	Improved productivity	Novozymes A/S	2005
	SPEZYME FRED	Improved heat tolerance	Genencor International, Inc.	2007
Chymosin	Maxiren	Improved productivity	DMS	2001
	CHY-MAX	Improved productivity	CHR HANSEN A/S	2003
Pullulanase	Optimax	Improved productivity	Genencor International, Inc.	2001
	SP962	Improved productivity	Novozymes A/S	2002
Lipase	SP388	Improved productivity	Novozymes A/S	2001
	NOVOZYM677	Improved productivity	Novozymes A/S	2003
Riboflavin	Riboflavin (Vitamin B2)	Improved productivity	F. Hoffmann-La Roche	2001
Glucoamylase	AMG-E	Improved productivity	Novozymes A/S	2002
α-glucosyltrans-ferase	6-α-glucanotransferase (BR151(pUAQ2))	Improved productivity, property change	EZAKI GLICO CO., LTD	2012
	4-α-glucanotransferase (BR151(pUMQ1))	Improved productivity	EZAKI GLICO CO., LTD	2012