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Japan's biotech approval process: slow but steady

Approved By:
Jeffrey Nawn

Prepared By:
Suguru Sato

Report Highlights:
This report provides the latest status of Japanese consumption, regulation, public perception, research and production of biotech crops.

Section I. Executive Summary:

Japan remains the world's largest per capita importer of foods and feeds that have been produced using modern biotechnology. Annually Japan imports about 15 million metric tons of corn and three million metric tons of soybeans, approximately three quarters of which are produced through biotechnology. Japan also imports billions of dollars worth of processed foods that contain biotech-derived oils, sugars, yeasts, enzymes, and other ingredients.

The biotech 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. GOJ completed the review of 29 events last year, a strong indication that the regulatory system is, in fact, functioning. However, assuming an increase over the next decade in the number and types of biotech events released to the market, the overall approval speed in Japan may become significantly slower. As with other regulatory systems around the world, Japan's biotech review system contains some points which can be improved. As one of the world's largest per capita importers of biotech crops, the improvement of biotech regulatory system, focused on long-term trends in biotechnology, will benefit all stakeholders.

So far, over 100 events in 8 crops have been approved for environmental release, which includes cultivation. Recently biotech papaya resistant to papaya ringspot virus was added to the approved list after 12 years since initial application. However, the biotech rose released by Suntory in 2009 is the only biotech crop commercially cultivated in Japan. So far, there is no commercial cultivation of biotech food crop in Japan.

Section II. Plant Biotechnology Trade and Production:

Processed Products

Japan imports 15 million metric ton (MMT) of corn annually exclusively from the United States. Of those 15 MMT of corn, 5 million metric ton of corn is for food use. Prior to the increase in grain prices in CY2008, most food corn imported into Japan was non-biotech, which is more expensive than non-segregated corn, which is practically all biotech. These spikes forced Japanese food manufacturer to switch to cost-effective biotech corn since manufacturers were loathe to pass along higher prices to consumers. Much to surprise of industry watchers, there was no significant media attention or anti-consumer reaction to the introduction of biotech corn to Japanese food industry. Though there is no official statistics, based on the information from various source, the use of biotech food corn has increased by almost 50 percent, but has not replaced the use of costly non-biotech corn. One of the reasons that non-biotech corn still holds the majority share of the market is that 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-biotech corn. All four major 'happoshu' manufacturers in Japan claim that they are using non-biotech corn in their websites, possibly out of fear of consumer rejection.

In Japan, three types of biotech claims may be made with regard to food; 1) Non-GMO, 2) GMO, and 3) non-segregated. To make labeling claims about foods or ingredients in the first category, the commodities must be handled under an identity preservation (IP) system and segregated from biotech commodities. Also, comingling of biotech products (which must also be approved by the Japanese regulatory authorities) must be less than 5% by volume in order to make the claim that the product is 'non-GMO'. 'GMO' products must be labeled as such. Lastly, products in the 'GMO non-segregated' category are ones in which identity was not preserved though the distribution channel, and therefore assumed to be primarily derived from biotech 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.

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 Biotech Crop	**Processed product (ingredient) from biotech 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 bans, 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

Source: Modified from the Nikkei Biotechnology Annual, 2009

Despite the widespread use of biotech ingredients, manufacturers and retailers still report a consumer bias against their use. A good example is the Japanese Consumers' Co-operative Union, a co-op organization with 25 million members and 346 billion yen ($3.5 billion) in sales. JCCU frequently uses biotech/non-segregated ingredients in their store brands and identifies that fact on the product's ingredient label (JA9046). In a current catalog JCCU (http://jccu.coop/eng/jccu/summary.php) provided an explanation of why they use biotech ingredients, focusing on the difficulties of segregating products during distribution. The coop claims that it chooses non-biotech ingredients whenever possible and gives several reasons the organization is opposed to the use of biotech crops, including the novelty of the technology, unspecified possible negative effects to the environment, and economic concentration in the commercial seed industry.

At the same time, CO-OP has increased the number of product offerings which use biotech ingredients, and applies the label of 'non-segregated' to products even when there is no legal requirement of labeling. In general, the majority of processed foods contain non-segregated (i.e., biotech) ingredients amongst their major ingredients (more than 5% of the product) and/or minor ingredient (less than 5% of product). In recent catalog of the CO-OP issued on July 7, 2011, approximately 40 % of processed products contained some form of ingredient from biotech crops, most likely corn and/or soybean.

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

Figure; The mark in red square indicates 'minor ingredient(s) of the product (less than 5%) may be GMO non-segregated' (left) and 'the sauce may contain GMO non-segregated ingredient' (right).

As an example, CO-OP offers a frozen chicken rice package which contains non-segregated corn. In past there were processed products containing biotech ingredient, however, never in the original form of corn or soybean. This chicken rice from CO-OP contains intact kernels of biotech corn, which may possibly be a first in Japan. The use of biotech soybeans for food has historically been primarily used for cooking oil. There is some biotech (non-segregated) soybean protein in processed food, however, the consumption in the form of whole biotech soybean has not been found yet.

Figure; CO-OP's frozen food (chicken rice). Underlined section describes that 'corn (GMO non-segregated).

CO-OP sells its own brand of salad dressings (figure below). More than 10 types of dressing are sold, and all of them use the labeling of 'GMO-non segregated' for oil ingredients. Vegetable oil is not subject to mandatory labeling for biotech, and the manufacturer is obviously using the label as a cost-saving strategy. Nonetheless, the general willingness of the retailer and manufacturer to use the label is indicative of a broad shift in thinking regarding biotech derived food products.

CO-OP sells at least 45 products with 'GMO non-segregated' label (Nikkei Biotechnology Annual, 2011). The benefit of using 'GMO-non segregated' ingredients is reflected directly in the price of the product; margarine (320g) with 'non-GMO' was 260 Japanese Yen (JY) but similar product with 'GMO non-segregated was 218 JY, 20% cheaper.

Figure; CO-OP's private brand salad dressing. Underlined section indicates 'canola oil (GMO-non-segregated).

AEON (http://www.aeon.info/en/) is one of major retailers in Japan with capital stock of 199,054 million yen and operates more than 10,000 retail stores of various formats in Japan and other Asian countries. AEON is also 'proactive' in the consumer education for the use of biotech origin ingredient. For instance, even though there is no legal requirement, AEON uses voluntary label of vegetable oil, e.g., soybean (biotech).

Among the inventory of AEON's private brand 'Top Value', the use of biotech ingredients has increased over the past several years. Among AEON's inventory, 51 products had the label of 'GMO non-segregated'. Some products contain non-segregated materials other than oil. The example shown below is a mixed snack package. Some snacks use hydrolyzed protein from non-segregated soybean and corn starch from non-segregated corn.

Figure; AEON's mixed snack packet. The underlined section of the label explains that 'corn starch, soybean oil, and hydrolyzed soy protein are non-segregated ingredients'.

<u>Grains</u>

The Great Eastern Japan Earthquake did not change the status of Japan as the largest export market for U.S. corn, expected to import over 15 million metric tons in the coming crop year. Feed use accounts for about 65 % of Japan's corn consumption, and presumably all feed-use corn contains biotech varieties (roughly 88 % of all U.S. corn is biotech). There is quite limited non-biotech feed corn demand for specific non-biotech fed dairy market. 'Concerned' consumer groups and some members of CO-OP are potential customers of such specialized products. The earthquake, however, 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 the demand of customers. However the circumstance after the earthquake forced feed manufacturers to limit inventory. On April 7, 2011, Seikatsu Club, a branch of CO-OP with 350,000 members, announced that they were unable to offer 'non-GMO' feed from contracted feed manufacturers, and instead only sold 'GMO 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).

There is a separate market for food-use corn in Japan, which until 2008 was exclusively, 'Non-GMO.' Due to high premiums for segregated 'Non-GMO' corn and a lack of end-user opposition to biotech ingredients, demand for 'Non-GMO' food use corn has been declining. Industry sources estimate that a quarter of imported food corn (approximately 4 mmt total) was either biotech or non-segregated in CY2008. In CY2009, the proportion of biotech and non-segregated categories in imported food corn rose to approximately 40 %, based on industry information. That proportion has held steady in CY2010. Though most food corn in biotech 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, despite mandatory labeling requirement (see Processed Products).

Japanese Corn Imports *(1,000 MT – CY 2011)*	
Corn for feed	
United States	8,774
Argentina	357
Brazil	750
China	0
Others	140
Total Feed	10,020
Corn for food, starch, manufacturing	
United States	4,994
Argentina	67
Brazil	138
South Africa	45
Others	25
Total Food & Other	5,271
Total	15,290
Source: Ministry of Finance	

The second most heavily traded biotech crop is soybeans, which are used for oil, food, and feed. The meal from soybean crushing is used for both animal feed and further processed into such products as soy protein and soy sauce. Traditionally Japan has imported roughly four million tons of soybeans annually; however demand for soybean has been declining in recent years due to high prices. Japanese soybean imports in FY2011 were 3.0 MMT, of which the United States commanded a 62 percent market share. Oil derived from commodity biotech soy may be sold without a ‘GMO’ label and historically has never encountered any consumer resistance. However, Japan’s biotech labeling rules do require a number of other biotech soy-based foods to be labeled, including natto and tofu. ‘Non-GMO’ soybean users are concerned about increasing premiums for segregated ‘Non-GMO’ soybeans. Excluding soybean oil, food use of ‘non-segregated’ (i.e., biotech) soybeans is only believed to be several hundred thousand tons and is so far limited to products not subject to mandatory labeling (e.g., soy sauce). Last year, however, some food manufacturers started to use non-segregated soybean in a limited number of processed foods (see Processed Products), most likely to reduce the costs. At the same time, the strong Yen to Dollars exchange rate allows Japanese food manufacturers to pay the premium for non-biotech over non-segregated commodities.

The acceptance of biotech soybeans is especially low in foods for direct consumption, such as tofu and natto. As domestic production (all non-biotech) supplies only 5 % of total demand, Japanese grain trading houses are expanding contracts for non-biotech soybean production with overseas growers. In addition to Kanematsu’s contract for non-biotech soybean production in Canada (as reported in JA0025), Marubeni Corporation (http://www.marubeni.com/) cooperates with a Chinese grain trader for the production of non-biotech soybean in Brazil. Mitsui & Co., Ltd (http://www.mitsui.com/jp/en/index.html) also strengthened the contracted production of non-biotech soybeans in Brazil. Hanamaruki (http://www.hanamaruki.co.jp/guide/guide.html), a major miso manufacturer, has been sourcing non-biotech soybeans from Brazil for miso ingredients since the company is having a hard time securing a stable supply of non-biotech soybeans from the United States (Shino-Mainichi, Mary 12, 2010). Furthermore, local food retailers, tofu manufacturers, and consumers in Gifu Prefecture started the corporation GIALINKS (http://www.gialinks.jp/) to import non-biotech soybeans for local tofu production. GIALINKS makes contracts with Japanese immigrant farmers in Argentina, Paraguay, Brazil and Peru.

Industry sources suggest that the limited choices of varieties of biotech soybeans for direct food consumption could be one of the reasons for slow consumer acceptance of the product. Current biotech varieties are bred for higher oil content, which is useful for crushing, but not for food. So, the introduction of biotech soy intended for the food market may result in greater consumer acceptance. However, the reluctance of the

Japanese consumer to embrace modern agricultural technology will discourage technology providers from developing biotech soybean suitable for direct food consumption for Japan for the foreseeable future.

The movement of Japan's food industry to source non-biotech ingredients is observed in corn as well. Zen-Noh (National Federation of Agricultural Co-operative Association, http://www.zennoh.or.jp) has been buying non-biotech corn on a contract basis from U.S. growers. In order to realize some security in the supply situation, Zen-Noh contracted with Pioneer Hi-Bred to make non-biotech corn seed commercially available through CY 2016. Non-biotech corn seed will be used and planted by American corn growers who contract with Zen-Noh. Zen-Noh estimates that 50 MMT of non-biotech corn will be supplied annually for the next five year through the current contract (http://www.jacom.or.jp/news/2011/01/news110112-12187.php).

On May 29, 2012, a Japanese trading house Marubeni announced the purchase of Gavilon, a major U.S. grain trader, with 5.6 billion USD (http://www.reuters.com/article/2012/05/31/gavilon-marubeni-deal-idUSL1E8GUBLZ20120531). The acquisition will give Marubeni plus Gavilon the second largest grain storage capacity in the world next to ADM (http://www.marubeni.co.jp/dbps_data/_material_/maruco_jp/data/ir/briefings_on_business_act/20120530_Gavilon_doc.pdf). As mentioned in their press release, the acquisition of Gavilon will allow for stable access to grains in the face of increasing demand from emerging and expanding economies. At the same time, it will allow Marubeni to ensure a stable supply of non-biotech soybean, much of which are sourced from Brazil through subsidiary trading firm (http://www.marubeni.co.jp/news/2009/090501.html).

GMO market acceptance

Japanese consumers are allegedly uneasy about biotech crops and, for over a decade, this understanding of consumer views has been reflected in government regulations, including labeling rules. Nonetheless, the fact remains that Japan is the world's largest per capita importer of biotech crops. Further upstream from consumers, there has been a shift toward biotech ingredients for processed foods that do not require labeling under Japan's laws. A recent study by the Asian Food Information Centre also shows that only 2% of Japanese consumers spontaneously mentioned 'GM food' as a concern. It is clearly difficult to gauge the true depth of *consumer apprehension towards biotech foods and, perhaps more importantly, the implications for actual purchasing behavior. Still, with the very few exceptions, consumer-ready food products explicitly labeled as 'GMO' are not yet carried by retailers in Japan.*

Production

With a few minor exceptions, there is still no commercial production of biotech food crops in Japan. In the past a handful of pioneering farmers have grown biotech soybeans, but the 'experiments' were terminated before the crop flowered due to concerns from surrounding farmers about cross pollination, and opposition from a powerful agricultural cooperatives. In addition, there are also numerous local government restrictions on growing biotech crops in Japan that further discourage farmers from using the technology (see Regulation).

Though they are not for food use, there are a limited number of cases of biotech plant cultivation for high value products for the pharmaceutical industry. National Institute of Advanced Industrial Science and Technology (AIST, http://www.aist.go.jp/) built 291 square meters (3132 sq feet) of 'Closed-type transgenic plant production system'. The system is a completely closed environment and separated from the outside. Plants are grown in a hydroponic system, and nutrition is 99% recycled. Biotech strawberries are grown in the facility to produce 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% lower than costs associated with conventional production methods.

Figure; Closed-type transgenic plant production system for production of plant-made pharmaceuticals (National Institute of Advanced Industrial Science and Technology, http://www.aist.go.jp/aist_e/aist_laboratories/1lifescience/index.html).

Though it is not plant but animal, two varieties of biotech silkworm developed by National Institute of Agricultural Science (NIAS, http://www.nias.affrc.go.jp/index_e.html) have been grown by six farmers in Gunma Prefecture. The biotech silkworm is modified to produce 'protein A', a protein used for medical diagnostic agents (see Section VI. Animal Biotechnology).

A Japanese company has developed a few ornamental flowers, carnation and roses, that have been genetically engineered for color. Suntory, a major beer brewery and liquor manufacturer, and Florigene, a biotech company in Australia under Suntory's management, developed a color altered carnation in 1995, which they started to sell in Japan in 1997. The biotech carnation was grown in Colombia and exported to Japan and other countries. In 2009, Suntory started producing another biotech ornamental plant, the "blue rose". This flower is grown domestically, making it Japan's first domestically produced biotech crop. Ironically, all four major beer breweries in Japan, including Suntory, pledged that they would only use non-biotech corn for their beer and low-malt beer, or happou-shu, which uses corn starch (see Processed Products).

Figure; Moondust, Suntory's biotech carnation (http://www.moondust.co.jp/)

Figure: Suntory's biotech blue rose, Japanese first domestically produce biotech crop (http://www.suntory.co.jp/company/research/hightech/blue-rose/index.html).

In addition to blue rose and carnation, biotech blue lilies and orhids may follow. Niigata prefecture's Horticultural Research Station and Suntory succeeded in the production of a biotech blue lily and plan to bring it to commercial production by 2018. Similarly, Dr. Masahiro Mii of Chiba University transformed orchid to produce blue pigment. Both lily and orchid do not have a gene to produce blue pigment in their original genome. At the same time, both lily and orchid have a wild species which could cross pollinate. Therefore, both biotech lily and orchid would require a risk assessment as well as management for horizontal gene transfer to wild species for commercial production, if there is an intention of commercial development.

Figure: 'Blue Lily' from Niigata prefecture's Horticultural Research Station and Suntory (R&D stage) (http://www.niigata-nippo.co.jp/news/pref/35218.html)

Blue orchid (R&D stage, no commercial production) (http://www.chiba-u.ac.jp/publicity/press/pdf/2012/20120229_phalaenopsis.pdf)

'New Breeding Techniques' (NBT) have been receiving greater attention by Japanese academia. Though there might be no international definition of NBT, in general, it includes cisgenesis (gene transfer between organisms that could otherwise be conventionally bred), precise control of gene modification (e.g., zinc-finger nuclease), grafting (of biotech stock and non-biotech scion, for instance), RNA viruses for the incorporation of transient gene introduction, and RNA-directed DNA methylation. In addition to the technical advantage of incorporating new genes or traits into plants with greater precision, one of unique aspects of NBT is that plants being produced by the technique may not fall into current definition of biotech plants, or living modified organisms, because the plants as such might not be differentiated from naturally occurring gene modification or detected by current testing methods. Therefore, there are significant questions around how plants produced through new breeding techniques will be regulated. . This past year Japanese academia and regulators attended a workshop 'Comparative regulatory approaches for new plant breeding techniques' which was organized by JRC-European Commission (http://ftp.jrc.es/EURdoc/JRC68986.pdf).

Though it is not a "biotech" crop by current regulatory division, National Institute of Agro-Environmental Science produced the rice cultivar that absorbs very little cadmium, even when cultivated in high cadmium-concentration in soil. The low cadmium-absorption rice was produced by ion beam irradiation. Basically, the method is to screen the plant with the intended effect (low cadmium absorption in this case) from the mass population of seeds after the ion beam irradiation, which causes random genetic mutation. Plants produced from the method are not categorized as biotech or genetically modified under current regulation. The rice cultivar of low cadmium absorption is still early stage of R&D. (http://www.niaes.affrc.go.jp/techdoc/press/120307/press120307.html)

Section III. Plant Biotechnology Policy:

Regulatory Framework

The Ministry of Health, Labor and Welfare (MHLW) is responsible for the food safety of biotech 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	Basic Law on Food Safety	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 biotech 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 the typically approves the product.

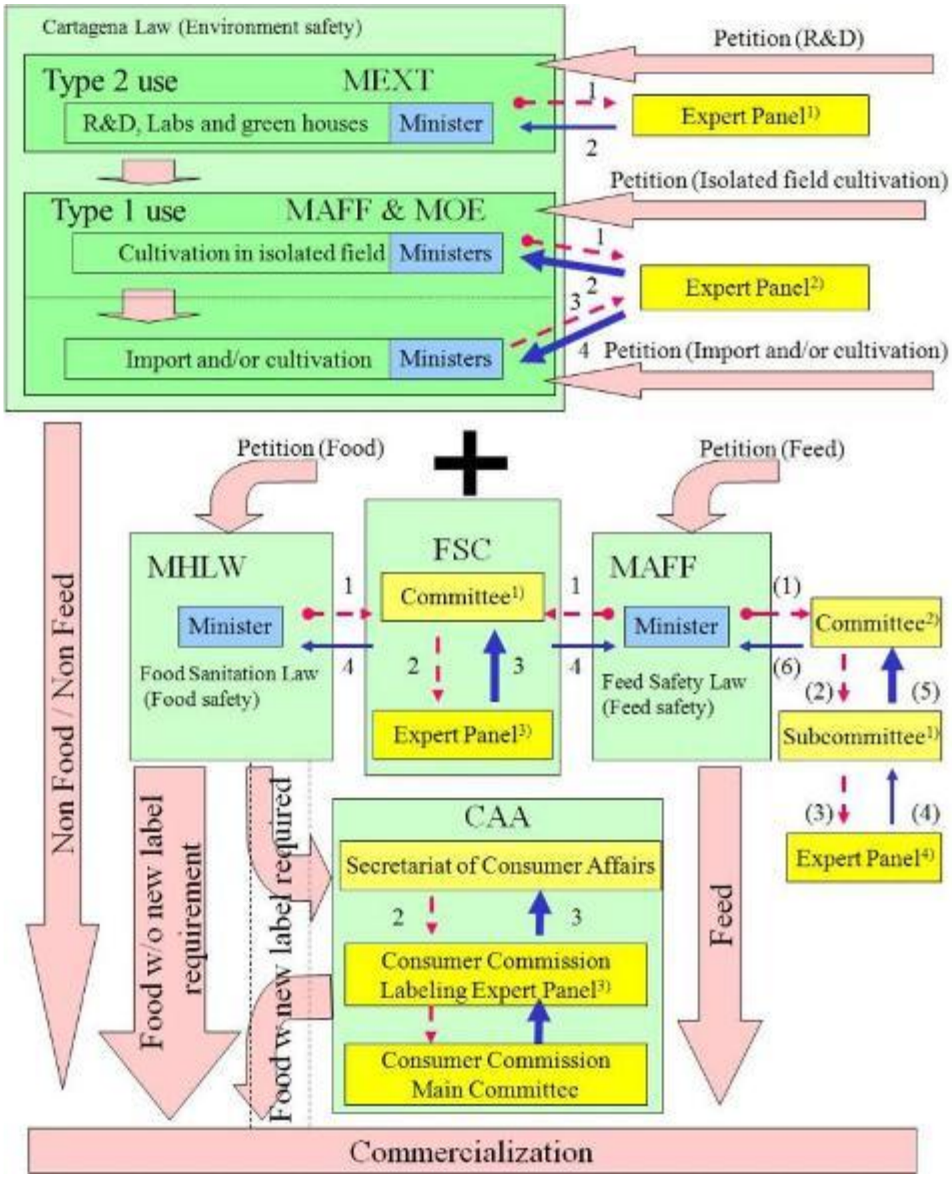
Biotech plants that are used for food must obtain food safety approvals from the MHLW Minister. Based on the Food Sanitation Law, upon receiving a petition for review from an interested party (usually a biotech company), the MHLW minister will request the FSC to conduct a food safety review. The FSC 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 risk assessment conclusions to the MHLW Minister. The FSC has published standards (http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf) in English for its food risk assessments of biotech foods.

Biotech products that are used as feed must, under the Feed Safety Law, 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 biotech feed. The Expert Panel evaluates feed safety for livestock animals and their evaluation is then reviewed by the AMC. The MAFF Minister also asks the FSC Genetically Modified Foods Expert Committee to review any possible human health effects from consuming livestock products from animals that have been fed the biotech product under review. Based on the reviews of AMC and FSC, the MAFF Minister approves the feed safety of the biotech events.

Japan ratified the Biosafety Protocol 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 biotech experiments in laboratories and greenhouses. MAFF and MOE require joint approvals for the use of biotech 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 will be conducted that includes field trials. A joint MAFF and MOE expert panel carries out the environmental safety evaluations. Finally, biotech products that require new standards or regulations not related to food safety, such as labeling or new risk management procedures (including IP handling protocols and detection method) may be addressed by Food Labeling Division of the Consumer Affairs Agency. The Consumer Affairs Agency (CAA) was established on September 1, 2010, with the objective of protecting and enhancing consumer rights. Consequently, food labeling, including biotech labeling, has fallen under the authority of CAA, though the criteria for biotech labeling (JAS Law) in Japan has not changed. Biotech labeling was formally handled by MAFF and 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.

Stage 3 Trials

Currently, Japan does not grant separate approvals for importation (e.g., for food, feed and industrial use) and for intentional release into the environment (e.g., planting as a commercial crop). As a result, seed companies must conduct a field test in an isolated plot on domestic soil – a so-called 'Stage 3 Field Trial' (S3-FT). A S3-FT is required for each biotech event, regardless of the fact that they will not be commercially grown in Japan. Within the commercial industry, this policy is widely viewed as unnecessary to protect Japanese biodiversity. It is also considered to be a costly aspect of Japan's regulatory system for biotech 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, 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. Therefore, only limited technology providers can afford to use such facilities, and this requirement clearly 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 biotech crops intended for import. Ironically the EU, which many in Japan consider to be a model for biotech risk assessment, does not require domestic field trials for import approvals of biotech crops (http://www.fsc.go.jp/sonota/efsa/efsa_211208.pdf).

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 biotech events into three groups:

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 which synthesize new metabolites not common to the original host plant.

The FSC requires a safety approval for a crossed event if the crossing occurs above the subspecies level, or if the crossing involves biotech 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 biotech 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/fsciis/meetingMaterial/show/kai20110721sfc). The new scheme is designed to o review '1 x 1' stacked events without deliberation in the Novel Foods (Genetically Modified Foods) Expert Committee
(http://www.fsc.go.jp/fsciis/attachedFile/download?retrievalId=kai20110721sfc&fileId=310). 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. It is too early to make a judgment about the efficiency gains of the new evaluation system for 1 x 1 stacks.

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.

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

Biosafety Protocol Implementation (dealing with LMOs)

After ratifying the Biosafety Protocol in November 2003, Japan 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 (http://www.bch.biodic.go.jp/) Japan Biosafety Clearing House (J-BCH) website.

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 that meeting was the implementation of Biosafety Protocol 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 Biosafety Protocol negotiations demonstrated positive leadership on this issue. However, the discussions among members regarding provisions on Access and Benefit Sharing (COP10), Liability and Redress (MOP5), and Risk Assessment (MOP5) were some of the more contentious topics discussed. Of greatest concern to technology providers and the grain industry was the discussion around the broad implications and applications of Article 27 of the Cartagena Protocol, which deals with Liability and Redress. That discussion was not concluded in the COP10. Though members agreed to finalize the content and text within four years after MOP1, which held on January 2004, party members are stuck on a discussion of how this article should be interpreted and implemented. The discussion during the last Friends of Chair meeting in Malaysia centered on: (1) Scope of operations; (2) Inclusion of imminent threat of damage; (3) Inclusion of processed products from LMOs; (4) Mandatory financial subsidy for operators and; (5) the relationship between domestic laws with "Civil Liability". These issues are complicated because there are significant differences between developed and developing countries, as well as different viewpoints and interests between biotech product exporting and importing countries. The gap between parties of different interest remained significant until last minutes of the fourth Friends of Co-Chair Meeting, which was held in the days preceding the MOP5. Finally in the predawn hours of October 11, 2011, an agreement on language was reached, just hours before the start of the MOP5.

The agreements in both COP10 (Nagoya Protocol) and COPMOP5 (Nagoya – Kuala Lumpur Supplementary Protocol) was a tremendous achievement, exceeding general expectations. However, a path to the future will not be easy. Though agreement was made in COPMOP5, actual implementation will depend on the domestic law of each member country. The definition of 'risk' from LMOs and related regulations varies widely from state to state. Furthermore, some countries do not have sufficient resource to establish functioning regulatory and governing bodies. Therefore, capacity building in developing countries will be an important factor to decide the effectiveness of the Supplementary Protocol in future.

Japan will not have technical difficulty in this area since the country joined the CBD in November 21, 2003 and enforced CBD based domestic laws on February 19, 2004. Even in the area of Liability and Redress, Japan, as the world's largest LMO importing country per capita, has handled the issue based on Advanced Informed Agreement, which is defined in Article 8 and agreed among the member states. As Japan holds the CBD chairmanship until 2012, Japan is actively involved in capacity building and technology transfer to developing countries (Nikkei, December 15, 2010). This implies that Japan will directly and indirectly affect biotechnology law, regulations, and cultivation practices in African and Asian developing countries.

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. On May 11, 2011, Japan with seven other countries signed Nagoya Protocol on biodiversity at the U.N. headquarters in New York City. Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was opened for signature on 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). .

Approved Biotech Products

As of June, 2011, Japan has approved over 160 biotech events for food, 150 for feed and 100 for environmental release, including commercial planting.

Attachment A – Approved commercial biotech traits.
Attachment B – Approved biotech additives.

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 biotech papaya from Hawaii. This approval was long sought, and is significant, as it is the first direct-to-consumer biotech product, and first biotech horticultural product, available in Japan. Industry analysts are watching Rainbow papaya 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 biotech variety. In 2009 approximately 80% of papaya grown in Hawaii is biotech (http://www.nass.usda.gov/Statistics_by_State/Hawaii/Publications/Fruits_and_Nuts/papaya.pdf). The first step of regulatory approval for Rainbow Papaya was submitted to GOJ was on March 1999, the Stage-3 field trial for environmental risk assessment in Japanese soil. On July 2009, Food Safety Commission (FSC) finalized the risk assessment report and concluded that the product was , "…unlikely to negatively affect human health", a significant step to full approval. On December 1, 2011, Rainbow Papaya was fully de-regulated by GOJ after 12 years since first official submission. The process of regulatory approval for Rainbow papaya is shown below.

October 29, 1999	Submission to Ministry of Health and Welfare (former MHLW) and MAFF
July 1, 2003	Establishment of Food Safety Commission
August 18, 2004	Re-submission of the environmental safety review under Cartagena Law to MAFF/MOE.
October 6, 2005	First discussion in Expert Subcommittee group of MAFF/MOE
January 26, 2006	Re-submission to MHLW. Food safety review by FSC started.
February 27, 2006	First review by FSC's GM Food Expert Group at 37th meeting.
March 17, 2008	Second review by the expert group at 60th meeting
May 19, 2009	Final review by the expert group at 70th meeting and safety approved.
May 28, 2009	Draft review report from FSC.
May 28 – June 26, 2009	Public comment (one comment was sent).
July 9, 2009	Dossier was returned back to MHLW (risk management body)*.
September 1, 2009	Consumer Affairs Agency (CAA) established. The authority of food labeling was transferred from MHLW/MAFF to CAA.
September 3, 2009	Second discussion in Expert Subcommittee group of MAFF/MOE
January 26, 2010	Third discussion in Expert Subcommittee group of MAFF/MOE
February 19, 2010	Fourth discussion in Expert Subcommittee group of MAFF/MOE. Discussion in Expert Subcommittee concluded.
March 23, 2010	Discussion by Expert Group in CAA at First Meeting of Consumer Agency's Food Labeling Committee. The "relevance" and scope of labeling for Rainbow papaya was discussed.
March 24, 2010	MAFF/MOE General Committee for Cartagena Law agreed for public comment
April 19 – May 19, 2010*	Public comment period for Type 1 Use permission (import and cultivation) under Cartagena Law by MAFF/MOE. As three other events (a soybean and two corn events), most comments were not specific to event but general

	about concern on the application of modern biotechnology to agricultural crops, such as possible out-crossing with wild species. No wild plant in Japan can be crossed with papaya as replied to the comment (http://www.bch.biodic.go.jp/download/lmo/public_comment/public42.pdf).
May 24, 2010	Discussion by Expert Group in CAA at Second Meeting of Consumer Agency's Food Labeling Committee. The members agreed on the labeling for papaya and the establishment of detection method for processed products of papaya.
May 28-June 4, 2010	Inter-Ministerial discussion with MHLW based on Food Sanitation Law Article 65, Section 2-2.
May 28-Dec 7, 2010	Inter-Ministerial discussion with MAFF based on JAS Law Article 19, Section 13-5.
October 4, 2010	Discussion by Expert Group in CAA at Fourth Meeting of Consumer Agency's Food Labeling Committee.
March 9, 2011	Discussion by Expert Group in CAA at 8th Meeting of Consumer Agency's Food Labeling Committee. Improvement in detection method was reported.
April 7 – May 6, 2011	Consumer Affairs Agency held domestic public comment regarding the labeling of fresh and processed products of biotech papaya.
April 14 – June 13, 2011	Consumer Affairs Agency notified WTO-SPS for the labeling of fresh and processed products of biotech papaya (G/SPS/N/JPN/276).
April 26 – June 26, 2011	Consumer Affairs Agency notified WTO-TBT for the labeling of fresh and processed products of biotech papaya (G/TBT/N/JPN/355).
July 27, 2011	Discussion by Expert Group in CAA at 12th Meeting of Consumer Agency's Food Labeling Committee. Committee members agreed on the proposal of biotech papaya labeling.
September 1, 2011	CAA issued official notification of biotech papaya labeling on September 1, 2011. As Rainbow is first consumer-ready biotech

	specialty crop to Japan, CAA set 3-month 'get-acquainted period' after the full approval notification.
December 1, 2012	MAFF released the notification that the environmental review of rainbow papaya completed. MHLW also lifted the sanction to rainbow papaya and released the notification of food safety completed which has been used as green sign for the commercial import and distribution of biotech crops for Japanese public.

- MAFF's announcement of the environmental review completed
  http://www.maff.go.jp/j/syouan/nouan/carta/c_list/pdf/list01_20111201.pdf
- MHLW's announcement of the sanction to biotech papaya lifted
  http://www.mhlw.go.jp/topics/yunyu/kensa/2011/dl/111201-2.pdf
- MHLW's notification of the food safety review of biotech papaya completed
  http://www.maff.go.jp/j/syouan/nouan/carta/c_list/pdf/list01_20111201.pdf

**Though technical discussion including public comment in environmental safety aspect has been completed and concluded as the introduction of biotech papaya 55-1 into Japan will not create any significant effects to environment (i.e., biodiversity). Based on their custom, full approval from MAFF/MOE as notification from GOJ was issued after the completion of food safety review which includes labeling issue.*

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 biotech 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 that many applications for novel biotech events in the future will come from the public sector and smaller firms, who have fewer resources for application and regulatory compliance. Biotech papaya 55-1 has already showed that the regulatory approval of GOJ will require not only that the product's development be well documented, but also have significant resources to attain 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 regulatory approval of GOJ 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 biotech rice and corn, with the intention of wide-scale cultivation 2012 or 2013 (Bloomberg, December 1, 2009). Though media reported that the progress of biotech 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 biotech events in the very near future.

It is not only China but other countries in Asia and Even Latin America will start to release commercial biotech events developed by their own institution, most likely public sector. So far, there is no indication that any of these "new players" in agricultural biotechnology are seeking regulatory approval in Japan. The adaption of biotech crops developed by Asian countries may not be primary used for the export market because the crops as such have been developed for own food supply. However, it is very likely that even crop developed for domestic consumption will be comingled and trace-level of every food crop will be involuntarily distributed globally. Many food manufacturers including Japanese have processing plants in Asian countries and will face greater chance that unapproved biotech events commingling into their products in near future.

In December 2010, biotech 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 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 biotech papaya has been found on the farms of local papaya growers in Okinawa. Unknown biotech papaya plants were cut down as it violates Cartagena Biosafety Protocol. For more, note the section, Ministry of Environment (MOE) and MAFF Policies on LLP.

Section IV. Plant Biotechnology Marketing Issues:

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 biotech 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) (http://www.bio.org/foodag/stewardship/20070521.asp) Product Launch Stewardship Policy calls for new biotech crops to be approved in Japan before they are commercialized in the United States. Similarly, the National Corn Growers Association's (http://www.ncga.com/files/POLICYPOSITIONPAPER2-28-09.pdf) position on biotechnology states biotech events must receive full approval by, 'Japanese regulatory agencies.'

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 biotech papaya 55-1, the resources required for regulatory approval are rather significant. JRC reported in 2009 that increasingly biotech 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 resource of regulatory bodies, the approachability and openness for new entries will be equally important for Japan.

<u>Low Level Presence (LLP) of Unapproved Biotech Events</u>
Japan has a zero tolerance for unapproved biotech events in food and environment, and it is explicitly illegal to import biotech-derived foods that have not been approved, regardless of the amount, form, or their known safety outside of Japan. For this reason, the Low Level Presence (LLP) of unapproved biotech crops has the potential to disrupt agricultural trade with Japan. Since the late 1990's potatoes (NewLeaf), papayas (Rainbow), corn (StarLink, Bt10, E32) and rice (LL601) have all been subject to testing or segregation, or have been temporarily banned. As of May 2012, there is no testing of potatoes and corn since the presence of unapproved event was confirmed to be negligible or below 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.

MHLW Policy on LLP in food

In 2001, Japan began legally requiring safety assessments of biotech foods. This was done under the broad authority contained in Article 11 of the (http://www.jetro.go.jp/en/market/regulations/pdf/food-e.pdf) Food Sanitation Law.

1. '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 additive intended for sale, based upon the opinion of Pharmaceutical Affairs and Food Sanitation Council.

2. Where specifications or standards have been established pursuant to provisions of 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.'

The implementation of MHLW's zero tolerance LLP policy is being done through Ministry of Health and Welfare Announcement (http://www.mhlw.go.jp/english/topics/food/3-2.htm) that states: Section A- "Standards Regarding Composition of Foods in General" of Part 1- "Foods":

3. 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 procedure for safety assessment made by the Minister for Health and Welfare and shall be announced to the public in the Official Gazette.

MHLW-mandated testing is currently being enforced for LL601 in bulk rice and some rice-containing processed food products (such as French fries). Testing for other LLP corn events, such as StarLink, Bt10 and Event 32, has been phased out by MHLW.

In the past, testing for LLP in Japan has been focused on bulk products (e.g., corn and rice) and processed product manufactured by non-Japanese companies (e.g., rice noodle). In near future, Japan and other countries could be forced to expand the scope of testing because of increasing number in traits, crops and developers of biotech crops. JRC report, the number of biotech events commercially grown in 2015 will be quadrupled from 2008 (http://ftp.jrc.es/EURdoc/JRC51799.pdf). Fifty percent of biotech crops will be developed and released Asia and Latin America. Crops other than soybean, corn, canola and cotton will take a third of newly developed crops entering market. As the application to regulatory approval requires resource, asynchronous approval and/or lack of regulatory approval in countries other than production countries may occur with growing frequency. . Global food manufacturers, including Japanese firms, are diversifying their production facilities and supply source of ingredients worldwide. When food manufacturers have facilities overseas, it would be increasingly difficult to test all ingredients for manufacturers since the information system to notify of LLP occurrence to stakeholders might not be transparent and systematic enough to prevent unapproved event commingled into commercial distribution.

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

Under the Feed Safety Law, MAFF monitors the quality and safety of imported feed ingredients at the ports. All biotech 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% tolerance for the unintentional commingling of biotech 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% exemption for feed.

On December 25, 2008, MAFF published a new risk management plan addressing the low level presence of unapproved biotech feeds. MAFF believes the new risk management policy will help prevent LLP incidents from happening, but also establishes procedures for when an LLP incident does occur by providing a mechanism for ending testing requirements when they are no longer needed (e.g., StarLink).

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

Japan's environmental rules also have a zero tolerance for living modified organisms (LMOs) that are unapproved. 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.

In December 2010, an unknown biotech papaya with viral resistance was detected from papaya seedlings sold at local DIY in Okinawa Prefecture. This particular papaya was incorporated with Papaya Ringspot Virus resistance, and because of the strain, is known to be a variety developed in Taiwan, not the Rainbow variety developed in Hawaii. Among 29 cultivars being tested, only one cultivar, 'Tainoh #5' shown the positive of unknown biotech trace (http://www.maff.go.jp/j/syouan/nouan/carta/ppykensa.html). Based on MAFF/MOE's report on April 21, 2011, as much as 20% of papaya plants grown in Okinawa could be unapproved papaya (http://www.env.go.jp/press/press.php?serial=13703). Based on the guidance of MAFF/MOE, the agricultural office of local governments have been advising growers in Okinawa and Miyazaki to check papaya plants in field if they fit the characteristics of unapproved papaya (http://www.town.nishihara.okinawa.jp/news/110610_13-news.html). As environmental release of unapproved biotech event is against Biosafety Protocol, the unapproved papaya plants have to be cut down. Papaya production in Japan is relatively small scale. Total production area and volume are 24 ha and 207 MT, respectively (http://www.maff.go.jp/j/syouan/nouan/carta/c_data/ppy/ppy5.html#2). There is no statistics found regarding the number of papaya trees cut down by the incident. Agricultural authorities offered the compensation to cut-down papaya tree by offering free non-biotech papaya seedlings (http://www.city.tomigusuku.okinawa.jp/index.php?oid=4792&dtype=1000&pid=154).

CODEX LLP Supported but Not Implemented

International guidelines on food safety assessments for the low-level presence of genetically modified foods was 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.

Unapproved food additives

On December 5, 2012, GOJ announced that an unapproved food additive produced with biotechnology, Disodium 5'-Inosinate and Disodium 5'-guanylate, had been distributed in Japanese market without regulatory clearance. . Two substances were produced by biotech microorganisms and used as additives to increase 'umami' flavor in various processed foods. However, as the biotech microorganism is used for the production, they require regulatory clearance even though the final products do not contain foreign genetic materials. After the incident was announced, MHLW requested the FSC to 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 resource within the GOJ's food safety review to the detriment of a number of biotech products in the regulatory pipeline.

Labeling

Until August 31, 2009, biotech 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 biotech labeling, were transferred to over to this new agency. However, this transfer did not change the GOJ's biotech labeling policies, which are available in English at (http://www.maff.go.jp/e/jas/labeling/modified.html). The information is available at MAFF's website as JAS is under MAFF's authority even the actual regulation is practiced by CAA.

In Japan, three types of biotech claims may be made on food labels; Non-GMO, GMO, 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 'GMO' products must be labeled. Products in the 'non-segregated' category are assumed to be primarily from biotech 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.

Biotech labeling schemes for non-biotech products are based on IP handling of non-biotech 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 from MAFF's website (http://www.maff.go.jp/e/jas/labeling/pdf/modi03.pdf).

As shown below, the 32 foods currently subject to JAS labeling requirements (and CAA labeling requirements) were selected because they are made from ingredients that could include biotech 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 these 32 foods exceeds 5 percent* of total weight of the foods, or is one of the top three ingredients by weight, they must be labeled with either the phrase "Biotech Ingredients Used" or "Biotech Ingredient Not Segregated" if the raw ingredient does not accompany certificates of IP handling. In order to be labeled "Non-Biotech," the processor must be able to show that the ingredient to be labeled was IP handled from production through processing.

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. To-nyu (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 of items 16 to 20 as a main ingredient	Corn
25. Frozen potato	Potato
26. Dried potato	Potato
27. Potato starch	Potato

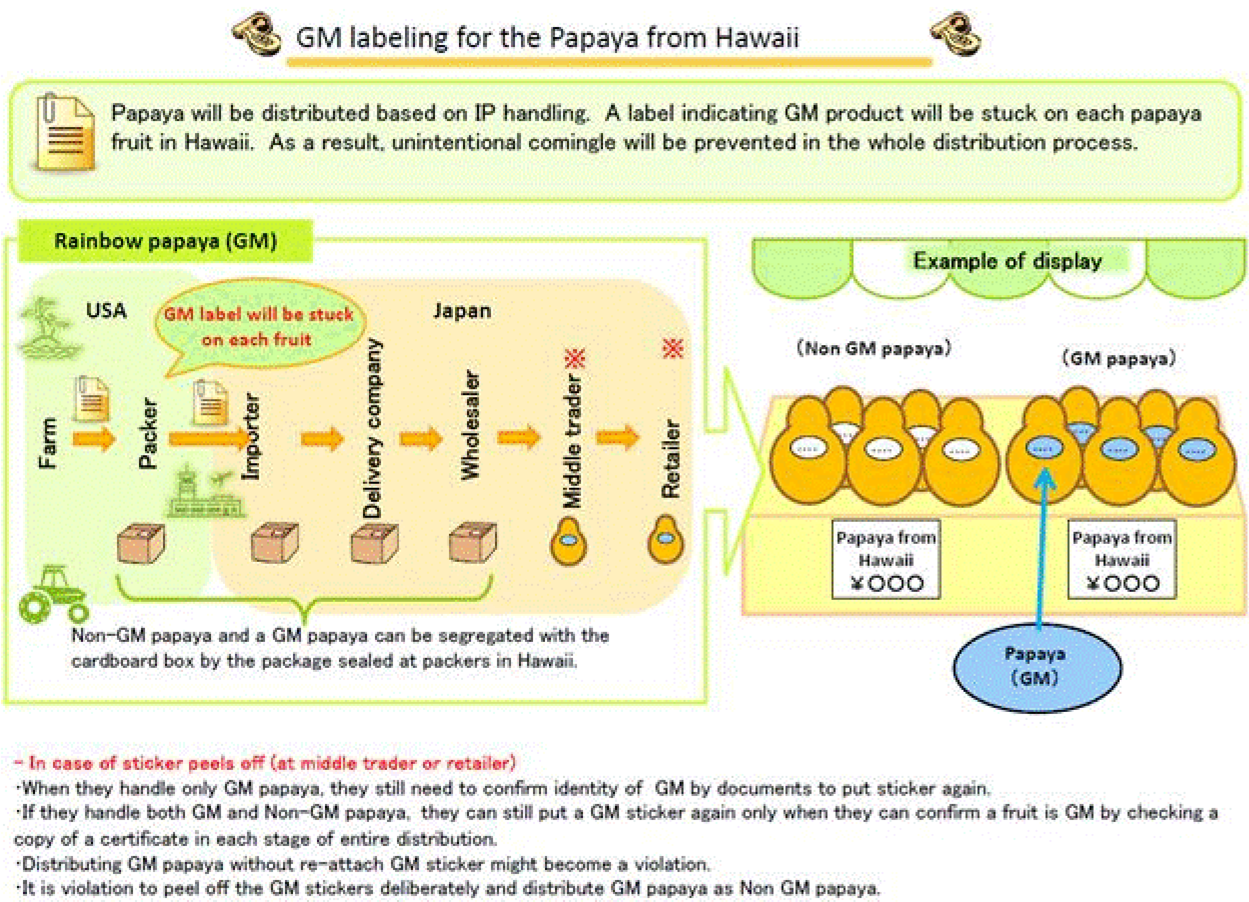
28.	Potato snacks	Potato
29.	Item containing food of items 25 to 28 as a main ingredient	Potato
30.	Item containing potato (for processing) as a main ingredient	Potato
31.	Item containing alfalfa as a main ingredient	Alfalfa
32.	Item containing sugar beet (for processing) as a main ingredient	Sugar beet
33.	Item containing papaya as a main ingredient	Papaya

In addition to the 33 food items in the table, Japan applies biotech 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. Similarly, high lysine corn will be subjected to same labeling requirement.

In case of biotech 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 IPP of non-biotech and biotech papaya based on laborious documentation. As the 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, the product, 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 biotech labeling. Japanese language indicates 'Hawaii Papaya (Genetically Modified).

It is important to note that the labeling of biotech and non-biotech 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 must not be considered as general labeling practice applicable to other biotech specialty crops which may be released in 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 biotech adzuki and red kidney beans.

*”5 percent rule” for non-biotech labeling
For the purpose detecting biotech 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 biotech 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 the 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 'biotech' or 'not-segregated' if the test result indicates more than 5% of biotech grains in the shipment.

On August 3, 2009, MHLW announced a new standard and specification of grain testing for bulk products (http://www.mhlw.go.jp/topics/yunyu/hassyutu/2009/index.html). With the new procedure, imported grains will be initially tested by the conventional method. If the result from the conventional method indicates that the shipment contains more than 5% of biotech grain in a non-biotech shipment, a new test based on single grain will be performed. In this test 90 grains will be used and each grain will be tested individually. This new methodology enables the judgment of biotech or non-biotech for each grain, regardless of whether it is non-biotech, incorporates a single biotech event, or is a stacked biotech event. If the results demonstrate that two or less out of 90 grains are biotech varieties, the shipment will be considered 'non-biotech' because it would contain less than 5% of biotech as bulk. If the test results in three to nine grains being biotech varieties, a second single-grain-based test will be run with a new set of 90 grains. If the sum of biotech grains from first and second run is nine or less out of 180 tested grains (i.e., sum of two tests), the shipment will be considered 'non-biotech'. If the number of biotech positive grains from first single-grain-based test is 10 or more (10 out of 90), the shipment will be judged as non-segregated grains. If the number of biotech positive grain from first and second single-grain-based test is 10 or more (10 out of 180), the shipment will also be considered to be non-segregated grains. This new testing methodology was officially introduced on November 12, 2009 (http://www.mhlw.go.jp/topics/yunyu/monitoring/2009/03.html).

In 2004, Japan Fair Trade Commission (JFTC) conducted a survey for the labeling of eggs. A growing number of egg suppliers have started using labeling 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 consumes 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 biotech feeds were used. (USDA/Tokyo Photo)

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 biotech crops although there would clearly be some commercial applications (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 biotech crops. The Hokkaido rules set minimum distances between biotech crop fields and others. 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 biotech 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 (over $6,400). 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 biotech crops and explain how they will ensure that their crops do not mix with non-biotech crops. Afterwards, the farmers must also 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 biotech 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 biotech ‘contamination,’ and procedures for responding to emergencies. Finally, farmers must pay a processing fee of 314,760 yen (over$4,000) 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 $2,700).

Institutions that wish to conduct research using open-air biotech 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 biotech 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 (over $6,400) for non-compliance, employees of research institutions are not subject to imprisonment if they fail to comply with biotech 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 biotech regulatory regime, no farmers or research institutions have submitted any requests to the Hokkaido governor's office to grow open-air biotech crops. Difficulties in complying with the new Hokkaido biotech regulations, along with continued consumer anxiety about the safety of biotech products and a shift towards conducting biotech crop research inside enclosed environments, all effectively halted attempts at open-air cultivation of biotech 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 biotech regulations should be revised. During the November 2006 - February 2007 public forums, attendees once again failed to reach a consensus. It was clear from the most recent meetings that local anxiety about biotech crops remains high.

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

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

- hold additional meetings with a wider variety of participants to increase public understanding about biotech foods and crops;
- urge the Government of Japan to improve labeling for biotech food products and secure a stable supply of non-biotech seeds; and
- re-examine the biotech crops ordinance as well as current cross-pollen prevention methods after three years in order to take into account new approaches to biotech crop management.

2. Ibaragi (Guidelines) - The Ibaragi biotech crop guidelines were established in March 2004. The guidelines state that a person who plans to grow biotech 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 guideline 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 biotech crops. The last discussion of ‘Provisional Guideline for the Cultivation of Genetically Modified Crops’ was made on March 2008. As of July 2011, the guideline has not yet been finalized.

4. Iwate (Guidelines) - Iwate biotech 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 biotech crops. For research institutes, the prefectural government requests that they strictly follow the experimental guidelines when they grow biotech crops.

When these guidelines were first established, Iwate Prefecture officials agreed to discuss a revision three years later in 2007. As of spring 2009, however, meetings to discuss revision have still not happened. This is in part because no one has approached Iwate Prefecture about growing biotech crops since the establishment of the guidelines. Iwate officials say they still plan to host meetings in FY2009 to seek advice from representatives of various groups including consumers, producers, distributors, local agricultural cooperatives and scientists. It is unlikely, however, that there will be any changes made to the guidelines.

5. Miyagi - Miyagi Prefectural Government expects to announce prefectural rules in FY2009. Following a series of public meetings on biotech crop cultivation in 2007 and 2008, the 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’.

6. Niigata (Ordinance) - Niigata put a stringent ordinance into effect in May 2006. It obliges farmers to get permission to grow biotech 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

requesting farmers to exercise restraint in commercially growing biotech crops. For test plots, the government requests farmers to take measures to prevent cross pollinating and commingling. The guidelines do not apply to research institutions.

8. Kyoto (Guidelines) - Based on a 2006 food safety ordinances, the government has drawn up detailed guidelines for growing biotech crops. The guidelines state that a person who is going to grow biotech crops is obliged to take measures to prevent cross pollinating and commingling. Biotech crops addressed by the guidelines are rice, soybeans, corn and rapeseed. The guidelines were published in January, 2007.

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 biotech crops; the other deals with the labeling of biotech products in order to address consumer concerns.

10. Tokushima (Guidelines) - Tokushima Prefecture published guidelines on biotech crops in 2006. The guidelines state that a person who grows biotech crops in open-air fields must first notify the governor. The fields must then incorporate signage indicating that biotech crops are being grown. The biotech 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 biotech 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 biotech 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 biotech crop production in Aichi. No specific biotech 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 biotech crops.

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

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

16. Kanagawa – On October 29, 2010 Kanagawa Prefecture released the 'Anti cross-pollination ordinance of genetically engineered crops' which was implemented on January 1, 2011.

Section V. Plant Biotechnology Capacity Building and Outreach:

Japanese Government and Risk Reviewer Activities

Public outreach and risk communication on agricultural biotechnology by GOJ seems to have decreased considerably since spring of 2010. The Society for Techno-innovation of Agriculture, Forestry and Fishery or STAFF (http://web.staff.or.jp/) is one of MAFF's affiliated organizations, and was once very active on public outreach on agricultural biotechnology. In JFY2008, MAFF/STAFF organized 54 outreach events throughout Japan. This outreach strategy was a part of the MAFF/GOJ plan to move forward for commercial planting of biotech crops by 2012. However, since spring of 2010, STAFF's homepage has not included information about crop biotechnology, and public outreach has been almost non-existent. .

As resources are required for Japanese regulatory compliance for biotech crop field experiments, Japanese academia (mostly universities with modern biotechnology facilities) organized the 'Liaison Council of the Genetic Research Facilities in Japanese Universities' (http://www1a.biglobe.ne.jp/iden-kyo/index.html, Japanese only). The council is comprised of roughly 50 genetic research institutes and has been conducting outreach activities aimed at increasing the capacity of Japanese institutions to conduct biotech crop experiments.

On May 14, 2012, Science Council of Japan (http://www.scj.go.jp/en/index.html) and Plant Transgenic Design Initiative by Tsukuba University held a Symposium on New Breeding

Technique (NBT). Approximately 400 people, mostly academic researchers, attended the symposium. The symposium included the use of plant RNA virus vector for plant transformation, artificial nucleases such as zinc-finger nuclease (ZFN), and transcription activator-like effector nuclease, RNA directed DNA methylation, and grafting of biotech and non-biotech plants. They also included two sessions about the regulatory aspects of NBT and importance of global harmonization.

U.S. Outreach Activities in Japan

The USDA Office of Agricultural Affairs at the U.S. Embassy in Tokyo frequently organizes activities to increase public awareness about agricultural biotechnology in Japan. Some recent examples include:

September 5-8, 2011 – FAS Tokyo invited Dr. Dennis Gonsalves from USDA Pacific Basin Agricultural Research Center. Dr. Gonsalves, who is a primary researcher of the biotech virus resistant papaya, for presentations in Fukuoka, Tokyo and Osaka. Symposiums in Fukuoka and Osaka were co-sponsored by the Japanese Society for Plant Cell and Molecular Biology. Dr. Ingo Potrykus, the chief researcher for Golden Rice also attended the symposium. Dr. Gonsalves also gave talks at two seminars in Tokyo, which were sponsored by FAS/Japan.
One of the seminars was held at the residence of U.S. Ambassador John Roos to celebrate the approval of biotech papaya for commercial sales in Japan. The event, attended by more than 100 traders, importers, end users, and media representatives, featured a cooking demonstration using Rainbow papaya by Mr. Sam Choy, renowned Hawaiian restaurateur. After the demonstration, dishes incorporating papaya were served to the attendees.

Figure: Dr. Gonsalves at the symposium in Osaka.

December 2, 2011 - FSN Suguru Sato was invited by the National Agriculture and Food Research Organization of GOJ for the presentation of 'The Role of Modern Biotechnology for U.S. Agriculture and Global Food Production'. Audience was approximately 50 people of researchers, regulators and technicians from food industry.

December 6-7, 2011 - FSN Suguru Sato was invited by the Board of Vocational High School Education in Nagano Prefecture for the presentation of 'The Importance of Modern Biotechnology for U.S. Agriculture and Global Food Production'. Two presentations were given during the visit. The first presentation was for educators and representatives for food industry,and the second presentation was for students. Rough 70 attended both events.

December 8, ,2011 – 'Food Communication', a consumer group based on Tokyo organizing science and risk communication events on food issues, invited Jeffrey Nawn, Senior Agricultural Attaché, and FSN Suguru Sato for the presentation of 'Rainbow Papaya, Saving Hawaiian Papaya Industry'. Rickie Deniz, papaya grower in Hawaii also gave speech. Mr. Deniz became first commercial biotech papaya exporter to Japan.

Figure. Jeffrey Nawn (Senior Agricultural Attaché, FAS Tokyo), Rickie Deniz (papaya grower in Hawaii and first commercial exporter of biotech papaya to Japan) and FSN Suguru Sato at food safety and risk communication event on December 8, 2012.

March 9, 2012 - FSN Suguru Sato was invited by Life Plaza 21, a NPO organizing science related risk communication events, for the presentation of 'The implication of Rainbow Papaya approval in Japan to new biotech crops being released in Asia'. The presentation focused on the pressures that regulatory authorities might face in near future due to the locally developed biotech crops which would not seek regulatory approval in the international marketplace.

April 18, 2012, FAS Tokyo presented "Food 2040" to an audience of roughly 250 agribusiness leaders and 30 members of the media. Food 2040 is a study that FAS/Tokyo designed that looks at the future of food and agriculture in East Asia. An entire chapter of the report is dedicated to the growth of bioscience in Asia. The report in its entirety can be found at http://www.usdajapan.org/food2040/index.html .

May 21-25, 2012 – FAS Tokyo and Seoul organized consecutive bilateral meetings on agricultural biotechnology for USG-GOJ and USG-GOK. In past five years, FAS Tokyo, in conjunction with USGC, has been organizing annual agricultural biotechnology study tours for GOJ regulators and reviewers, exposing those officials to the U.S. regulations and their counterparts in the USG, as well as to private sector biotech research and development. However, there is currently no formal mechanism through which the USG and GOJ can communicate on ag-biotech issues on the policy-maker level. With State Department funding, FAS Tokyo organized a visit of regulators from USDA-APHIS, EPA and FDA to Japan . Over the course of two days relevant regulators spoke to each other on topics such as NBT, LLP, AP, regulatory streamlining, and future collaboration. All parties agreed that the discussions were fruitful, and agreed that more frequent communication should be a priority.

May 27, 2012 - Galileo X, a 30 min biweekly science TV program by BS Fuji, broadcasted an episode titled 'The myth of genetically modified food'. The program explained the fact that Japan has been one of top importers of biotech crops in world, and has therefore been the beneficiary of biotechnology for more than a decade. The program also touched up on the growing need for global grain production, and the basic outline of the GOJ's food safety and environmental impact assessments. The program content was based on the interviews with five professionals, including FAS Tokyo's own Suguru Sato. The tone of program was scientifically neutral and supportive of agricultural biotechnology, and explained that despite the negative reaction to biotech crops by general public, agricultural biotechnology has been and will remain important for global food production.

Section VI. Animal Biotechnology:

Development and use

Currently, there is no known biotech livestock production is Japan. Most of 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 private sector seems to be partially related to the negative public reaction to modern biotechnology, especially in genetic transformation of animals.

That being said, the biotech silkworm is relatively close to the commercial application stage in Japan. The National Institute of Agrobiological Science (NIAS, Tsukuba, Japan) has launched The Silkworm Genome Research Program (SGP) in 1994. One of the goals of the biotech silkworm is to produce medical specific materials in silk protein. 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 world's first case of industrial biotech silkworm production. The biotech silkworm is modified to produce 'protein A', a protein used for medical diagnostic agent. Since then, biotech silkworm has been grown by six farmers in Gunma Prefecture at least. Silkworm is domesticated from wild silkworm *Bombyx mandarina* and entirely dependent on humans for its reproduction, 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. Furthermore, modern biotechnology will enable silkworm to produce protein much close to one of animals than microorganisms such as E. coli does. 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 biotech silkworm (http://www.ibl-japan.co.jp/news_img/PR_20110524.pdf). Fibrinogen has been used as hemostat, but the contamination of pathogenic element has been a concerning issue. Biotech 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 biotech silkworm production. Total of 48,000 biotech silkworm were commercially grown at closed culture environment to produce antibodies for medical diagnosis agents (http://www.pref.gunma.jp/houdou/f2300096.html).

NIAS also conducts research into biotech swine (http://www.nias.affrc.go.jp/org/GMO/ Pig/). The purpose of producing biotech 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. Again, there are research in animal biotechnology in Japan, however there is no road map provided for commercial applications.

Regulation

As Japan ratified the Biosafety Protocol in 2003, the handling of animals developed with modern biotechnology also has to be handled based on the same regulation.

Section VII. Author Defined:

Reference Materials

Following is a list of reference information on agricultural biotechnology and biotech foods in English.

Risk assessment standards of biotech food

- Food Safety Commission
  http://www.fsc.go.jp/english/standardsforriskassessment/gm_kijun_english.pdf

Information related to biotech food regulations

- Ministry of Health, Labor and Welfare
  http://www.mhlw.go.jp/english/topics/food/index.html

Information on biotech food labeling

- Ministry of Agriculture, Forestry and Fishery (Japan Agricultural Standard, base regulation of biotech labeling)
  http://www.maff.go.jp/e/jas/labeling/modified.html
- Consumer Affairs Agency (the agency practicing biotech labeling regulation)
  http://www.caa.go.jp/en/index.html

Useful resource for 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/

Abbreviations Used

AP – Adventitious Presence
APEC – Asia-Pacific Economic Cooperation
AFFRC - Agriculture, Forestry and Fisheries Research Council
AFIC - Asian Food Information Centre
AMC Agricultural Material Committee
CAA - Consumer Affairs Agency
CC - Consumer Committee
DREAM BT - Drastic Reform with Effective and Agile Movements for BT
FSC - Food Safety Commission
GMO – Genetically Modified Organism
HFSSC - Hokkaido Food Safety and Security Committee
IP – Identity Preservation
JAS - Japan Agricultural Standards
JBA - Japan Bioindustry Association
JCCU - Japanese Consumers' Co-operative Union
JFTC - Japan Fair Trade Commission
LLP – Low Level Presence
LMO – Living Modified Organism
MAFF - Ministry of Agriculture, Forestry and Fisheries
MEXT - Ministry of Education, Culture, Sports, Science and Technology
MHLW – Ministry of Health, Labor and Welfare
MOE - Ministry of Environment

Attachment A - Approved events for commercial use (as of May 25, 2012)

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	Herbicide tolerant	2007 (ACS-	2003	2001

		Science		BN008-2)		
	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 (6)	11	Suntory	Color change	2004 (FLO-07442-4)	N/A	N/A
	123.2.38	Suntory	Color change	2004 (FLO-40644-4)	N/A	N/A
	123.8.8	Suntory	Color change	2004 (FLO-40685-1)	N/A	N/A
	123.2.2	Suntory	Color change	2004 (FLO-40619-7)	N/A	N/A
	11363	Suntory	Color change	2004 (FLO-11363-1)	N/A	N/A
	123.8.12	Suntory	Color change	2009 (FLO-40689-6)	N/A	N/A
Corn (104)	T-14	Bayer Crop Science	Herbicide tolerant	2006 (ACS-ZM-002-1)	2005	2001
	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

Corn (cont)	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 B.t.Cry34/35Ab1 Event DAS-59122-7 x MON88017	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
	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, herbicide tolerant	-	2010	2010
Corn (cont)	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	-	2011	2009

			tolerant			
	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
Corn (cont)	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 1507	Syngenta Seeds	Insect resistant, herbicide tolerant	-	2010	2011
	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

Corn (cont)	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
	MON97460	Monsanto Japan	Drought tolerant	2012 (MON-87460-4)	2011	2011
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 Japan	Herbicide tolerant, Insect resistant	2005 (MON-16985-7xMON-01445-2)	2003	2003
	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-	2006	2006

				01445-2)		
	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
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
Sugar	T120-7	Bayer Crop	Herbicide tolerant	Not needed	1999	2001

beet (3)		Science				
	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**
				108	156	166
For each biotechnology variety, the years safety approvals were granted are shown for BSP environmental (import and planting), feed and food safety. 'None' indicates the safety has not been confirmed by the Government of Japan. 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 May 25, 2012).

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