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Japan

Biotechnology - GE Plants and Animals

Biotechnology Annual Report 2010

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Report Highlights:
This report provides current information on the production, regulation, and public acceptance of biotech crops in Japan.

Section I. Executive Summary:

Japan is the world's largest per capita importer of foods and feeds that have been produced using modern biotechnology (also known as 'biotech' or 'GMO'). Japan annually imports about 16 million metric tons of corn and four million metric tons of soybeans, approximately three quarters of which are 'biotech'. Japan also imports billions of dollars worth of processed foods that contain biotech-derived oils, sugars, yeasts, enzymes, and other ingredients.

Despite these impressive import figures, it is often stated that Japanese consumers have a negative impression of biotech foods. The Japanese government has responded to this perceived sentiment by implementing onerous regulatory standards. These measures include mandatory biotech labeling, complex and lengthy safety food and feed reviews, and Biosafety Protocol-based environmental rules. On the other hand, some research suggests that there is a disconnect between consumer statements about biotechnology, and consumer food purchasing decisions. This disconnect will be explored in greater detail in this report.

Major U.S. biotechnology and agricultural producer groups have pledged to gain Japanese government regulatory approval of biotech events before making those traits commercially available to American farmers. Because of this concession, Japanese regulators exercise considerable power over the production technology choices available to U.S. farmers. Nonetheless, while Japan's regulatory system is complex and costly, it is predictable and functional. To date 116 biotech products have been approved for food use in Japan. This past year the Government of Japan introduced a new agency, the Consumer Affairs Agency (CAA), whose charge is to act in the best interest of consumers only. To date there is no evidence to suggest that anti-biotech consumer groups have been able to use the CAA to further an anti-biotech, or anti-science, agenda.

Processors are increasingly using biotech ingredients in processed foods that do not require 'GMO' labeling under Japanese regulations. In addition, consumers commonly buy foods with 'non-segregated' ingredient labels that imply biotech ingredients are used. However, there are currently few explicitly labeled 'GMO' foods on the market in Japan.

Although over 88 events are approved for cultivation, until 2008 there has been no commercial production of any biotech crops in Japan. In 2009, the first biotech crop, a rose with modified color, was produced in Japan. There are still no commercial biotech food crops produced in Japan, and it is unlikely that there will be in the near future.

A number of Japanese public research institutes are carrying out plant biotechnology research, but most have not progressed to the field trial stage because of consumer concerns, and because of the limited resource required to comply with Japanese central and local governments' regulatory system.

Section II. Plant Biotechnology Trade and Production:

Processed Products

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 in 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 '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. 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.

Though approximately a third of the corn being imported to Japan is for food use, the proportion of biotech and non-biotech imported corn was not clear until recently. The grain price hike in CY2008 led the industry to start using biotech corn for food in order to reduce costs (see GRAIN section

below). Following that price hike, FAS Tokyo learned from an industry source that approximately 25% of food use corn in CY2008 was biotech, or non-segregated. Following those imports there was no negative media coverage or outrage from consumer groups. Though there is no official/public data on the use of biotech corn in food, Mainichi Shinbun News (November 1, 2009) reported that major soft drink manufacturers in Japan are using High Fructose Corn Syrup (HFCS) made from non-segregated corn. The report was based on a survey of eight major soft drink manufacturers. Five of the eight manufacturers surveyed answered that they are using HFCS made from non-segregated corn for at least some of their products. One manufacturer answered that there was a "possibility" of use of HFSC from biotech corn, one answered they are using HFSC from non-biotech sources, and one refused to reply.

Japanese Co-Op Labeling - Biotech Ingredients

The graphic below provides an example of a JCCU member co-op's labeling scheme for indicating the use of ingredients from non-segregated crops. The top blue square indicates that greater than 5% non-segregated ingredient(s) may have been used (excluding water). The purple diamond in the middle indicates that up to 5% of ingredients may be non-segregated. The green round mark at the bottom indicates that the product is non-biotech but that attached packets of sauce or dressing may include non-segregated ingredients.

An example of a Japanese co-op catalog
(non-segregated ingredients have been highlighted with a red box)

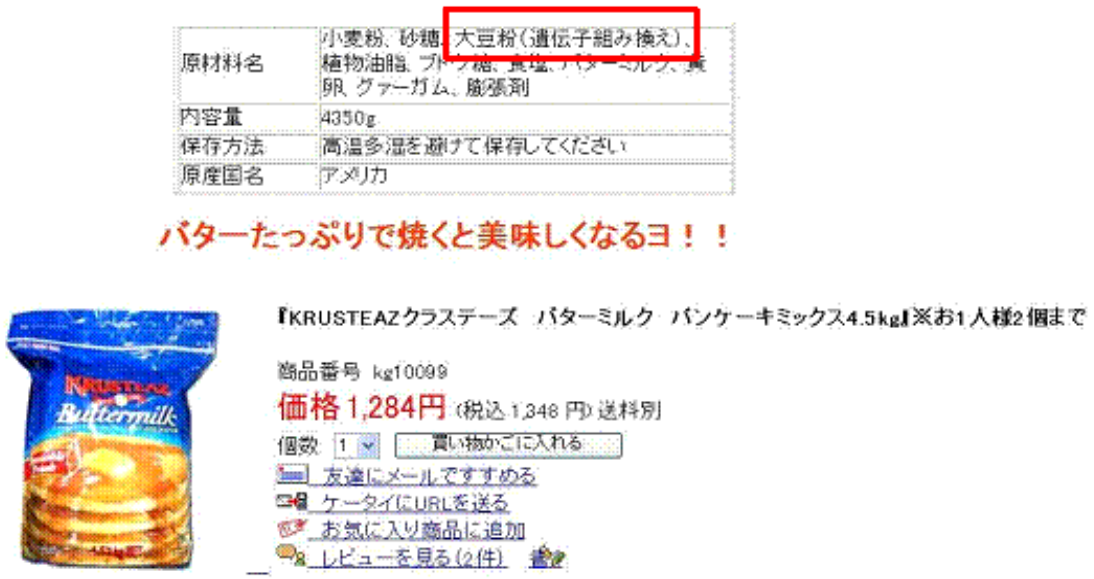
The acceptance biotechnology seems to vary depending on the braches of CO-OP and consumer groups. Some consumer cooperatives retain a strong belief in the safety of non-biotech varieties. Representatives from Seikatsu Kurabu, a section of CO-OP and JA, recently visited Chinese farmers to investigate the possibility of sourcing non-biotech soybeans from China (http://seikatsuclub.coop/activity/20090212.html). The Executive director commented that, "Seikatsu club rengokai has been trying to drive out GM crops, not only from ingredients for processed foods sold to CO-OP member, but also from feed - which we consider as formulation of animals, rather than just a feed."

Ironically, the Chinese government openly embraces modern agricultural biotechnology (GAIN Report CH9138 'China Moves Forward in New Technologies). Furthermore, in November, 2009, the Chinese Government announced the completion of the food-safety approval of biotech rice (Bt), which was developed by researchers at Chinese Agricultural University. China also approved the safety of phytase corn, which will aid phosphorus digestion in swine, therefore enhancing growth and reducing environmental pollution from waste (http://www.reuters.com/article/idUSSP364484). Additionally, China has already approved commercial production of biotech papaya, cotton and tomatoes.

Another example of consumer rejection can be found in Tsukuba City, Ibaraki where GOJ's major research institutes and a university for agricultural biotechnology exist. Tokyo Shinbun News (May 11, 2010) reported that the citizens group in Tsukuba City, Ibaraki 'Tsukuba Citizen's Network' announced that they had requested MAFF and Tsukuba City Education Board to cease distribution of a MAFF-produced informational brochure about agricultural biotechnology in the public school system.

Though large manufacturers and retailers may be too cautious to use biotech crops as food ingredients requiring labeling, food produced by smaller firms, and foreign firms, with biotech labels are lately becoming available in Japan. One example of this recent trend is U.S. made pancake mix which contains soybean powder. Though the label clearly indicates that it contains a biotech-derived crop, the product is quite popular with Japanese consumers.

Pancake mix containing biotech soybean power (text in red box). The product is exported from the U.S.



原材料名	小麦粉、砂糖、大豆粉(遺伝子組み換え)、植物油脂、ブドウ糖、食塩、バターミルク、食卵、グァーガム、膨張剤
内容量	4350g
保存方法	高温多湿を避けて保存してください
原産国名	アメリカ

バターたっぷりで焼くと美味しくなるヨ！！

『KRUSTEAZクラステーズ バターミルク パンケーキミックス4.5kg』※お1人様2個まで

商品番号 kg10099

価格 1,284円 (税込 1,348 円) 送料別

個数 1 買い物かごに入れる

友達にメールですすめる

ケータイにURLを送る

お気に入り商品に追加

レビューを見る(2件)

Grains

Japan is the largest export market for U.S. corn, expected to import over 16 million metric tons in the coming crop year. Feed use accounts for about 75% of Japan's corn consumption, and it is assumed that all feed-use corn contains biotech varieties (roughly 80% of all U.S. corn is biotech). There is a separate market for food-use corn, 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 was

approximately 40 %, based on industry information. Most of food corn in biotech or non-segregated category will be consumed in food uses that does not require labeling under Japanese law (e.g. starch, sweeteners, etc.).

Japanese Corn Imports
(1,000 MT – CY 2009)

Corn for feed	
United States	10,555
Argentina	113
China	11
Brazil	23
Others	258
Total Feed	10,960
Corn for food, starch, manufacturing	
United States	5,170
Argentina	78
Australia	0
China	10
South Africa	0
Brazil	24
Others	54
Total Food & Other	5,336
Total	15,725

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. Typically Japan imports over four million tons of soybeans annually, of which the United States has about an 80% 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).

The acceptance of biotech soybeans is especially low in foods for direct consumption, such as tofu and natto. Kanematsu, a major grain trading house, announced the plan to expand soybean production by seven times more than current level within five years. Based on Bloomberg Japan (December 9, 2009), Kanatsu and Hendricks Seeds (Ontari, Canada), bred a soybean cultivar which can be grown at a high latitude (N50 degrees), and started production on Prince Edwards Island in Spring 2009. CY2009's harvest (for kanematsu contract in the island) is expected to be about 6,000-

7,000 mt. Kanatsu currently imports 120,000 mt of non-biotech soybeans, sourced from Canada and the United States, and plans to increase that amount to 200,000 mt in three years. Industry sources suggested that the limited choices of varieties of biotech soybeans could be a reason for slow consumer acceptance of the product.

What Level of Market Acceptance Of 'GMO's' Been Achieved?
It is common wisdom that Japanese consumers are uneasy about biotech crops and, for over a decade, this understanding of consumer views 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

There is no commercial production of biotech food crops in Japan. In the past a few pioneering farmers have grown biotech soybeans, but the 'experiment' was terminated before the crop flowered due to concerns from surrounding farmers about cross pollination and opposition from a powerful agricultural cooperative. There are also numerous local government restrictions on growing biotech crops in Japan that further discourage farmers from using the technology.

Japanese companies have developed a few ornamental flowers that have been genetically engineered for color. In 2009, Suntory, a major beer brewery and liquor manufacturer, started producing "blue rose", 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.

Figure: Suntory's homepage for biotech blue rose

Research and Technology

MAFF is devoting significant resources towards genomics and biotech crop development research. An example of this effort can be seen in Japan's contribution to rice genome sequencing (http://www.nias.affrc.go.jp/project/inegenome_e/index_e.htm), as well as genome analysis of other plants such as soybeans. To build public support for their research, MAFF's Agriculture, Forestry and Fisheries Research Council (AFFRC) published a report entitled, "Committee for the Research and Development Plan for GMO Crops" in the winter of 2008. Based on the report, AFFRC-MAFF held several risk communication events in JFY2008, and was scheduled to hold 50 risk communication events throughout Japan in FY2009. The report states that biotech events researched and developed in Japan should also be grown, distributed and consumed in Japan. The report sets out a five year timeline, with the earliest product launch coming in 2012. The events for initial release would mostly come from Japanese public sector researchers. Traits could include high yield multi-disease resistant rice (for feed and/or biofuel production), drought tolerant rice and wheat, nutritionally altered rice (value added/function food, or pharmaceutical), and heavy metal accumulating rice (phyto-remediation).

Japan has world-class scientists and is conducting broad research on agricultural biotechnology. However, due in part to regulatory costs, it is becoming increasingly clear that this research will not be commercialized in Japan. Much of Japan's research is being conducted by universities that are ill equipped to take on the regulatory burden. Currently only multinational companies have the needed regulatory expertise and resources required to gain full approval for a biotech food crop. Industry sources estimate that a single food approval in Japan costs millions of dollars and can take up to three years. Furthermore, for most of the crops common to Japanese agriculture (e.g., horticultural crops), the size of the seed market does not justify Japan-specific biotech product development. Finally, since most of the likely products would have to be labeled, there would remain the possibility of consumer rejection.

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	Agricultural	Ministry of	Law Concerning the	• Any significant changes

animal feed	Materials Council	Agriculture, Forestry, and Fisheries	Safety and Quality Improvement of Feed (the Feed Safety Law)	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.

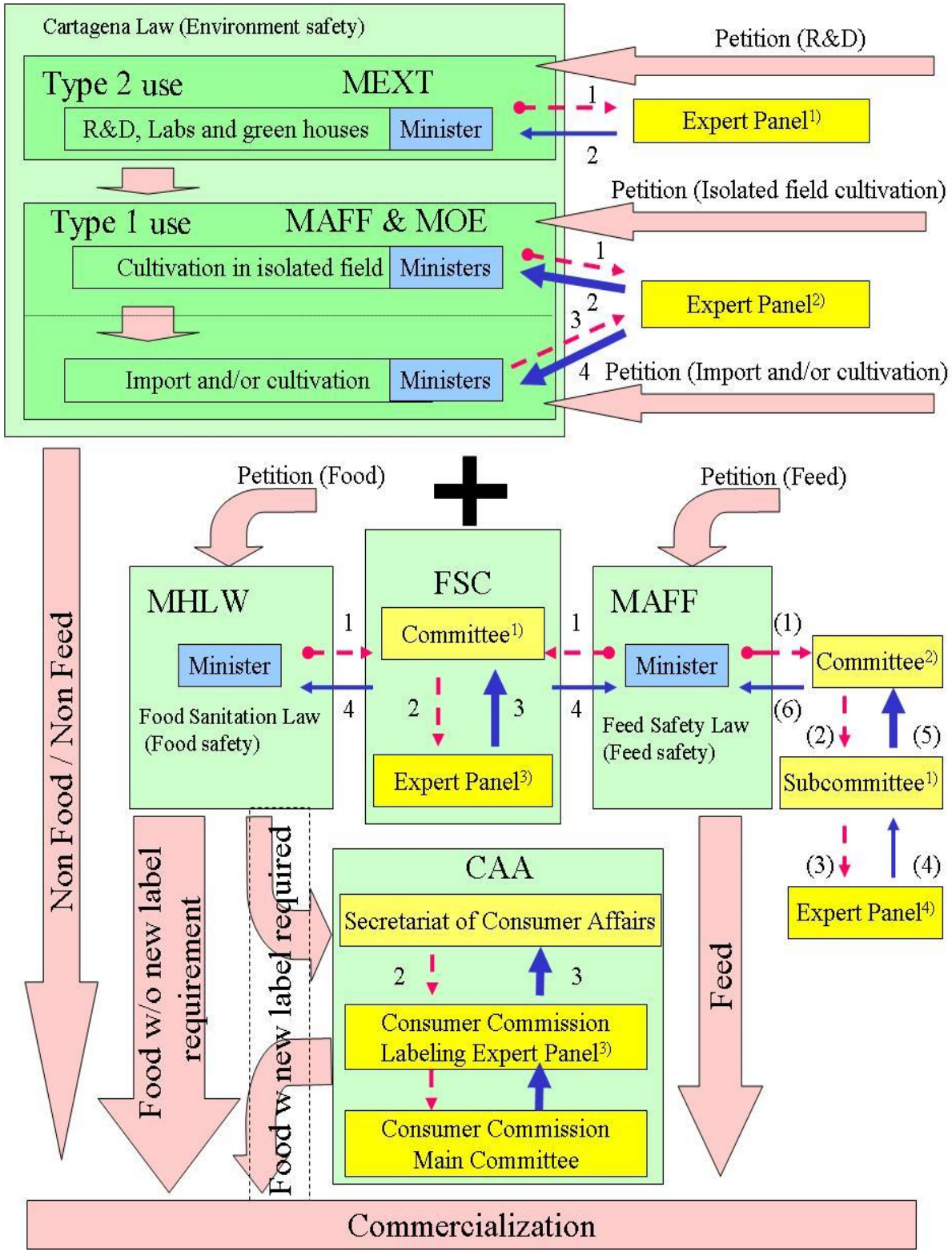
Risk assessments and safety evaluations are performed by advisory committees and scientific expert panels which primarily consist of researchers, academics, and representatives from public research institutions. The decisions by the expert panels are reviewed by the advisory committees whose members 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.

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) will take place in Nagoya, Japan from October 18 to 29, 2010. Prior to COP10, the fifth Member of the Party (MOP5) to the Cartagena Protocol will also take place in Nagoya from October 11 to 15, 2010.

Japan's implementation of Biosafety Protocol article 18.2.a (documentation and compliance enforcement) and article 27 (Liability and Redress) has not been problematic. In fact, Japan's support of a non-binding approach to Liability and Redress in the Biosafety Protocol negotiations demonstrates positive leadership on this issue.

Access and Benefit Sharing (COP10), Liability and Redress (MOP5), and Risk Assessment (MOP5) are some of the more contentious topics to be discussed. The discussion around the broad implications and applications of Article 27 of the Cartagena Protocol, which addresses Liability and Redress, was not concluded at the last meeting. Therefore, the members agreed to finalize the content and text within four years after MOP1, which held on January 2004. Since then, members have discussed 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) Relation of domestic law 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.

Beyond the difficulty in getting agreement from CBD member countries, active participation from non-governmental organizations (NGO) and non-profit organizations (NPO), such as Greenpeace and Friends of Earth, is expected to draw attention to this discussion. NGOs and NPOs were organized under the "CBD Civil Network" on January 2009, and since them have created various campaigns to increase public awareness of the issues. Some of these groups are openly opposed to agricultural biotechnology. The NGO "Food, Agriculture and CBD" published a report entitled "Genetically modified crops will destroy biological diversity and threaten food security". The report contains some discussion of the emergence of herbicide tolerant weeds; however, the majority of the content is based on articles from the internet where the original source of information is not verified.

Approved Biotech Products

As of June, 2010, Japan has approved 116 biotech events for food, 107 for feed, 88 for planting and 14 for food additives. Prior to the ratification of the Biosafety Protocol in November 2003, Japan had approved 106 events for import, and 74 for planting. Those approvals expired when the new legal framework under the Biosafety Protocol was introduced. All products approved prior to the ratification of the Biosafety Protocol were subject to review and re-approval.

Attachment A – Approved commercial biotech traits.
Attachment B – Approved biotech additives.
Attachment C – Biotech crops undergoing food safety assessments.
Attachment D – Biotech additives undergoing safety assessment.

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

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 77% of papaya grown in Hawaii is a biotech variety. (http://www.nass.usda.gov/Statistics_by_State/Hawaii/Publications/Fruits_and_Nuts/papaya.pdf). The dossier for the risk assessment of Rainbow Papaya was turned into GOJ on October 1999. On July 2009, Food Safety Commission (FSC) finalized the risk assessment report and concluded that "unlikely to negatively affect human health". The dossier is now in the hands of Consumer Affairs Agency for a decision on labeling (See Labeling section) and the establishment of a detection method for processed products. The process of regulatory approval for Rainbow papaya is shown below.

Submission to Ministry of Heath and Welfare (former MHLW) and MAFF

Establishment of Food Safety Commission
Re-submission of the environmental safety review under Cartagena Law to MAFF/MOE.
First discussion in Expert Subcommittee group of MAFF/MOE
Re-submission to MHLW. Food safety review by FSC started.
First review by FSC's GM Food Expert Group at 37th meeting.
Second review by the expert group at 60th meeting
Final review by the expert group at 70th meeting and safety approved.
Draft review report from FSC.
Public comment (one comment was sent).
Dossier was returned back to MHLW (risk management body).
Consumer Affairs Agency (CAA) established. The authority of food labeling was transferred from MHLW/MAFF to CAA.
Second discussion in Expert Subcommittee group of MAFF/MOE
Third discussion in Expert Subcommittee group of MAFF/MOE
Fourth discussion in Expert Subcommittee group of MAFF/MOE. Discussion in Expert Subcommittee concluded.
First discussion of the relevance and scope of labeling for Rainbow papaya by Expert Group of Food Labeling Division, CAA at first meeting.
MAFF/MOE General Committee for Cartagena Law agreed for public comment
Public comment period for Type 1 Use permission (import and cultivation) under Cartagena Law by MAFF/MOE*
Second discussion by Expert Group. The members agreed to proceed the labeling process and the establishment of detection method.

(*Full approval from MAFF/MOE will be issued after the completion of food safety review which includes labeling issue)

The case with Rainbow papaya highlighted a few issues that the GOJ will be forced to deal with in the near future. Most other biotech events are submitted for approval by major biotechnology providers. 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's reasonable to expect that with the price of genome sequencing coming down so significantly in recent years that many of 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. .A review under consideration for a significant period of time can create the possibility of low level presence in the food being imported to Japan, or even the disincentive for developers to consider the Japanese regulatory pipeline.

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.'

Low Level Presence (LLP) of Unapproved Biotech Events

Japan has a zero tolerance for unapproved biotech events in foods, 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.

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/monitoring/2009/dl/01g.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.

'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.

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.

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.

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 changed the GOJ"s biotech labeling policies, which are available in English at (http://www.maff.go.jp/soshiki/syokuhin/hinshitu/organic/eng_yuki_gmo.pdf).

In Japan, three types of biotech claims may be made on food lables; 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.

Both MAFF and MHLW 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.

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	
13. Item containing soybean protein as a main ingredient	Soybean
14. Item containing edamame (green soybean) as a main ingredient	
15. Item containing soybean sprouts as a main ingredient	Soybean
16. Corn snacks	
17. Corn starch	Edamame
18. Popcorn	
19. Frozen corn	Soybean sprouts
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	Corn
26. Dried potato	Corn
27. Potato starch	Corn
28. Potato snacks	Corn
29. Item containing food of items 25 to 28 as a main ingredient	
30. Item containing potato (for processing) as a main ingredient	Corn
31. Item containing alfalfa as a main ingredient	
32. Item containing sugar beet (for processing) as a main ingredient	Potato
	Potato
	Potato
	Potato
	Potato
	Potato
	Alfalfa
	Sugar beet

In addition to the 32 food items in the table, Japan applies the biotech labeling requirements to biotech high oleic acid soybean products even though the oil extracted from the soybean does not contain traces of the introduced genes or proteins.

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.

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

Stage 3 Trials

Currently, Japan does not grant separate environment approvals for importation (e.g., for feed use) and for intentional release into the environment (e.g., planting as a commercial crop). As a result, seed companies must conduct stage III field testing for biotech crops, even though they will not be commercially grown in Japan. Within the commercial seed industry, this policy is widely viewed as unnecessary and costly aspect of Japan's regulatory system.

Stacked Events

Japan requires separate environment 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 hosts with insect resistance, herbicide tolerance or virus resistance;
2. Introduced genes which alter host metabolism and endow the hosts 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 on 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. Most stacked events that result from traditional crossbreeding do not require a safety review.

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

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 $4,000). In order to apply, farmers must first host public meetings at their own expense with neighboring farmers, agricultural cooperative members, regional officials, and other stakeholders. At these meetings, they must announce their intention to plant 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 (about $2,600) 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 $1,700).

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 $4,000) 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.

3. Chiba (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.

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. The prefecture is still undecided on whether to use guidelines or ordinances.

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 (approximately $4,300).

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 polinization. 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.

Section V. Plant Biotechnology Capacity Building and Outreach:

Japanese Government Activities

In 2008, Japan's Cabinet Office released the results of a biotech awareness survey which targeted secondary school teachers. On average, 75 % of respondents answered they have covered 'genes', 'gene modification' and/or 'genetically modified food' in their coursework. The results further indicated that mistrust of biotechnology is widespread within the education system. For example, 45 percent of high school home-economics teachers responded that they took rather "careful" or "negative" stance about biotech foods. In all, more than a half of secondary and high school teachers who have chance to teach modern agricultural biotechnology themselves had a negative image of the technology. In an effort to build public acceptance for biotech, MAFF has been particularly active, and in 2008 conducted 54 public outreach events.

FY2008 MAFF Public Outreach for Biotech Crops	
Large-Scale Meeting (about 200 people)	2
Small-Scale Meeting (20~30 people)	30
Activities with students	20
Media Study Session	2
Total	54

In CY2009 to 2010, a number of risk communication events have been programmed by various groups such as government, private sector, industry organization and academia . Some examples are shown below.

October 22, 2009 - Council of Biotechnology Japan organized a biotech site visit tour for mass media with theme of "The latest biotechnology crop research in Japan'. Approximately 20 reporters in mass media joined the tour.

November 6, 2009 - Council of Biotechnology Japan organized 24th media seminar 'Future of health, food, science and technology'.

November 21, 2009 - Japanese Society of Plant Cell and Molecular Biology organized the public seminar 'The potential and advantage of plant biotechnology'.

February 18, 2010 – The Food Safety Commission organized the event 'Risk in food - What is Genetically modified food?' in Okayama Prefecture.

August 6, 2010 - Science Council of Japan organized the symposium 'Step to the commercial use of genetically modified crops'.

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:

June 27-July 4, 2010 - In late July the Office of Agricultural Affairs, in conjunction with the U.S. Grains Council, coordinated a week-long learning tour for Japanese academics that focus on plant physiology, ecology, and breeding. The objective of the tour was to explain U.S. regulatory system for biotech crops, and included meetings with U.S. Government regulatory agencies, such as USDA/APHIS, FDA, and EPA, visits to private sector biotech field trial sites, and a visit to a large scale commercial farm. Most of delegates have never visited U.S. farm before, nor had an opportunity to interact directly with U.S. biotech regulators. As a result of this tour, both the U.S. officials and Japanese participants gained a greater understanding and appreciation for each other’s biotech regulatory systems.

June 9-13, 2010 - Senior Agricultural Attaché, Jeffrey Nawn, attended APEC High Level Policy Dialogue on Agricultural Biotechnology and Low Level Presence meetings in Sapporo.

April 6-9, 2010 - Secretary of Agriculture Tom Vilsack visited Japan to attend various events of ‘Partners in Agriculture’. The events included Global Food Security Symposium, which highlighted the

use of biotechnology as a tool for increasing global food security. Vilsack's message at the symposium was that (1) both the domestic production and the stable supply of safe food from reliable trading partners are equally important for food security, and (2) an approach based on science and technology, including modern agricultural biotechnology, is the key to coping with a growing world population, climate change, malnutrition in developing countries and increasing demand for richer diet. More details can be found in GAIN reports including 'Global Food Security Symposium - Partners in Agriculture _Tokyo ATO_Japan_5-26-2010', and at www.partners-in-agriculture.org.

February 26, 2010 – Minister Counselor Geoffrey Wiggin and Senior Attaché Jeffrey Nawn met with Clive James, Chairman of the International Service for the Acquisition of Agri-biotech Applications, a not-for-profit organization that delivers the benefits of new agricultural biotechnologies to developing countries. They discussed the critical role that agricultural biotechnology plays in global food security.

December 3-4, 2009 - The Steering Committee meeting for High Level Policy Dialogue on Agricultural Biotechnology was held in Tokyo American Center, Tokyo. FAS Tokyo worked actively to facilitate the attendance of GOJ officials.

Summer 2009 - International Visitor Leadership Program (IVLP)
FAS Tokyo nominated three professionals for the delegates to IVLP's Food Safety division. The three delegates work on biotechnology and food safety,, and visited Hawaii to observe rainbow papaya as a part of IVLP program. Rainbow papaya is currently at the final stage of approval system in Japan (see Regulatory section).

June 4, 2009 - Geoffrey Wiggin, Minster Counselor of OAA, visited Hokkaido and held several meetings with wide variety of groups, including consumer group representatives, farmer organizations, media reporters, and local government regulators. Hokkaido is agricultural production center of Japan, and is known for their very strict local regulations for commercial use of agricultural biotechnology. The message focused on two things; 1) the importance of the latest technology and science for agricultural production, and 2) the importance of biotechnology to the country's food security equation.

Section VI. Animal Biotechnology:

Development and use
Currently, there is no known biotech livestock production is Japan, and the research on biotech animals in Japan is very limited. Most of this research is focused on human medical and pharmaceutical purposes. In Japan, this research is mostly operated by university and government/public research institutions, with almost no active involvement of by the private sector.. The non-involvement of private sector seems to be 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. NIAS also conducts research into biotech swine. The purpose of producing biotech swine is to study medical organ transplantation oncology in human beings. Swine are used simply because of the similarity of metabolism and organ size with humans.

Other animal biotech research activity includes goats and chickens. Biotech goats are being developed to produce useful and functional substances in milk. Goat has advantage of short cycle of reproduction and lower input cost for production. The purpose of a biotech chicken is to have mass production of active ingredients in eggs with cheaper input cost. 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 website of information on agricultural biotechnology and biotech foods in English.

Food Safety Commission (biotech food risk assessment standards)
http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf

Ministry of Agriculture, Forestry and Fisheries (Information related to agricultural biotechnology)
http://www.s.affrc.go.jp/docs/sentan/

Ministry of Health, Labor and Welfare (Information related to biotech food regulations)
http://www.mhlw.go.jp/english/topics/food/index.html

(Information on biotech food labeling)
http://www.mhlw.go.jp/english/topics/qa/gm-food/index.html

Biosafety Clearing House (Japan)
http://www.bch.biodic.go.jp/english/e_index.html

Abbreviations Used

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 June 14, 2010)

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 (15)	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	2003	2001

				ACS-BN001-4)		
	PHY35	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN004-7 x ACS-BN001-4)	2003	2001
	T45	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN008-2)	2003	2001
	PGS2	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7xACS-BN002-5)	2003	2001
	PHY36	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7 x ACS-BN002-5)	2003	2001
	PHY23	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7 x ACS-BN002-5)	2003	2001
	Oxy-235	Bayer Crop Science	Herbicide tolerant	2004* (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
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 (61)	T-14	Bayer Crop Science	Herbicide tolerant	2006 (ACS-ZM-002-1)	2005	2001
	T-25	Bayer Crop	Herbicide	2004 (ACS-	2003	2001

	Science	tolerant	ZM003-2)		
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	Monsanto	Herbicide	2004 (MON-	2004	2004

MON810 x NK603	Japan	tolerant, Insect resistant	00863-5xMON-00810-6xMON-00603-6)		
59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7)	2006	2005
MON88017 x MON810	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88017-3 x MON-00810-6)	2006	2005
1507 x 59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-01507-1 x DAS-59122-7)	2006	2005
59122 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x MON-00603-6)	2006	2005
59122 x 1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x DAS-01507-1 x MON-00603-6)	2006	2005
LY038	Monsanto Japan	High lysine content	2007 (REN-00038-3)	2007	2007
TC6275	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2008 (DAS-06275-8)	2007	2007
MIR604	Syngenta Seeds	Insect resistant	2007 (SYN-IR604-5)	2007	2007
MON89034	Monsanto Japan	Insect resistant	2008 (MON-89034-3)	2007	2007
Bt11 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-BT011-1 x MON-00021-9)	2007	2007
Bt11 x MIR604	Syngenta Seeds	Herbicide tolerant, Insect resistant	2008 (SYN-BT011-1 x SYN-IR604-5)	2007	2007
MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-IR604-5 x MON-00021-9)	2007	2007
Bt11 x MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2008 (SYN-BT011-1 x SYN-IR604-5	2007	2007

				x MON-00021-9)		
	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	Dow	Herbicide	-	2008	2008

	B.t.Cry34/35Ab1 Event DAS-59122-7 x MON88017	Chemical Japan and Monsanto Japan	tolerant, Insect resistant			
	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
	Bt11 x MIR162 x 1507 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant		2010	2010
Cotton (20)	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	Herbicide	-	2005	2005

		Chemicals Japan	tolerant, Insect resistant			
	281 x 3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 (DAS-24236-5×DAS-21023-5)	2006	2005
	281 x 3006 x 1445	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 DAS-24236-5×DAS-21023-5×MON-01445-2)	2006	2006
	281 x 3006 x MON88913	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006(DAS-24236-5×DAS-21023-5×MON-88913-8))	2006	2006
	LLCotton 25 x 15985	Bayer Crop Science	Herbicide tolerant, Insect resistant	2007 (ACS-GH001-3×MON-15985-7)	2006	2006
	GHB614	Bayer Crop Science	Herbicide tolerant	2010 (BCS-GH002-5)	2010	2010
	GHB614 x LLCotton25	Bayer Crop Science	Herbicide tolerant	2010 (BCS-GH002-5 x ACS-GH001-3)	2010	2010
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-	Monsanto Japan	Insect resistant and virus	Not needed	N/A	2003

	02		resistant			
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 (6)	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
Sugar beet (3)	T120-7	Bayer Crop Science	Herbicide tolerant	Not needed	1999	2001
	77	Monsanto Japan	Herbicide tolerant	Not needed	2003	2003
	H7-1	Monsanto Japan	Herbicide tolerant	2007 (KM-000H71-4)	2005	2003
Total approval numbers				BSP	Feed	Food
				88	107	116
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.						

The list of approved events for food is also available on line from MHLW (http://www.mhlw.go.jp/english/topics/food/pdf/sec01.pdf).

Attachment B - Approved biotech additives (as of June 14, 2010).

Products	Name	Characteristics	Developer	Public announcement
alpha-	TS-25	Improved	Novozymes A/S	2001

amylase		productivity		
	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

Attachment C – Biotech crops under food safety assessment process (as of June 14, 2010)

Plant species	Trait or Variety	Applicant/Developer	Characteristics
Papaya	55-1	Hawaii Papaya Industry Association	Virus resistant
Corn	3272	Syngenta Seeds	heat stable amylase
Corn	DP-098140-6	Dupont	Herbicide tolerant
Soybean	DP-305423-1	Dupont	High oleic acid
Corn	MON87460	Monsanto Japan	Drought tolerant
Soybean	BPS-CV127-9	BASF Japan	Herbicide (Imazamox-ammonium) tolerant
Cotton	MON88913	Monsanto Japan	Herbicide tolerant
Cotton	15985	Monsanto Japan	Insect resistant
Cotton	COT102	Syngenta Seeds	Insect resistant
Corn	MON89034 x 1507 x NK603	Dow Chemicals Japan Monsanto Japan	Insect resistant and herbicide tolerant
Corn	3272 x Bt11 x MIR604 x GA21	Syngenta Seeds	Heat stable amylase, insect resistant and herbicide tolerant

Cotton	COT67B	Syngenta Seeds	Insect resistant

Attachment D – Biotech additives under food safety assessment process (as of June 14, 2010)

Products	Name	Applicant/Developer	Characteristics
Invertase	Invertase (NIA1718)	MEIJI SEIKA KAISHA,LTD.	Property change
Xylanase	Xylanase (Aspergillus oryzae MT2181)	Novozyme Japan	Improved productivity

Attachment E - LMO's Type 1 Use (as of June 10, 2009)

Approval Date	Name of the type of Living Modified Organism	Applicant
2009-1-29	Purple-violet carnation (*F3'5'H, DFR, sur B, Dianthus caryophyllus* L.)(123.8.12, OECD UI : FLO-40689-6)	Suntory Ltd.
2008-10-14	Maize resistant to Lepidoptera and Coleoptera and tolerant to glyphosate herbicide (*cry1A.105*, modified *cry2Ab2*, *modified cp4 epsps*, modified *cry3Bb1, Zea mays* subsp. *mays* (L.) Iltis) (MON89034×MON88017, OECD UI: MON-89034-3×MON-88017-3)	Monsanto Japan Limited
2008-10-14	Maize resistant to Lepidoptera and tolerant to glyphosate herbicide (*cry1A.105*, *modified cry2Ab2*, modified *cp4 epsps, Zea mays* subsp. *mays* (L.) Iltis) (MON89034×NK603, OECD UI: MON-89034-3×MON-00603-6)	Monsanto Japan Limited
2008-9-18	Oilseed rape tolerant to bromoxynil herbicide (*oxy, Brassica napus* L.) (OXY-235, OECD UI: ACS-BN011-5)	Bayer Crop Science K.K.
2008-9-18	High oil Soybean (*dgat2A, Glycine max* (L.) Merr.) (MON87754, OECD UI: MON-87754-1)	Monsanto Japan Limited
2008-8-18	Maize resistant to Lepidoptera and Coleoptera and tolerant to glufosinate herbicide (modified *cry1Ab*, modified *cry3Aa2, pat, Zea mays* subsp. *mays* (L.) Iltis) (Bt11×MIR604,OECD UI:SYN-BT011-1×SYN-IR604-5)	Syngenta Seeds K.K.
2008-8-18	Maize resistant to Lepidoptera and Coleoptera and tolerant to glufosinate herbicide and glyphosate herbicide (modified *cry1Ab*, modified *cry3Aa2, pat, mEPSPS, Zea mays* subsp. *mays* (L.) Iltis) (Bt11×MIR604×GA21, OECD UI: SYN-BT011-1×SYN-IR604-5×MON-00021-9)	Syngenta Seeds K.K.
2008-7-24	Soybean tolerant to imidazolinone herbicide(Modified *csr1-2, Glycine max* (L.) Merr.)(CV127, OECD UI:BPS-CV127-9)	BASF Agro. Limited
2008-7-24	Stearidonic Acid producing Soybean(Modified *Pj. D6D, Modified Nc. Fad3 Glycine max* (L.) Merr.)(MON87769, OECD UI:MON-87769-7)	Monsanto Japan Limited
2008-5-30	Cotton tolerant to glyphosate (*2mepsps, Gossypium hirsutum* L.) (GHB614, OECD UI:BCS-GH002-5)	Bayer CropScience K.K.
2008-2-8	Eucalyptus tree containing salt tolerance inducing gene *codA* derived from Arthrobacter globformis (*codA,*	University of Tsukuba

	Eucalyptus globulus Labill.)(107-1)	
2008-2-8	Eucalyptus tree containing salt tolerance inducing gene *codA* derived from Arthrobacter globformis (*codA, Eucalyptus globulus* Labill.)(1-9-1)	University of Tsukuba
2008-2-8	Eucalyptus tree containing salt tolerance inducing gene *codA* derived from Arthrobacter globformis (*codA, Eucalyptus globulus* Labill.)(2-1-1)	University of Tsukuba
2008-1-31	Rose Variety with Modified Flavonoid Biosynthesis Pathway (*F3'5'H, 5AT, Rosa hybrida*) (WKS82/130-4-1, OECD UI: IFD-52401-4)	Suntory Limited
2008-1-31	Rose Variety with Modified Flavonoid Biosynthesis Pathway (*F3'5'H, 5AT, Rosa hybrida*) (WKS82/130-9-1, OECD UI: IFD-52901-9)	Suntory Limited
2008-1-31	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide(Modified *cry1F,* modified *bar, Zea mays* subsp. *mays* (L.) Iltis) (TC6275, OECD UI：DAS-06275-8)	Dow Chemical Japan Ltd.
2008-1-31	Maize resistant to Lepidoptera (*cry1A.105,* modified *cry2Ab2, Zea mays* subsp. *mays* (L.) Iltis) (MON89034, OECD UI: MON-89034-3)	Monsanto Japan Limited
2008-1-31	Soybean tolerant to glyphosate herbicide (Modified *cp4 epsps, Glycine max* (L.) Merr.) (MON 89788, OECD UI: MON-89788-1)	Monsanto Japan Limited
2008-1-18	Canarypox virus ALVAC to which a protective antigen protein expression gene derived from feline leukemia virus (vCP97 strain) was transferred (FeLV *-env, gag, pol,* Canarypox virus)	Merial Japan Ltd.
2007-12-26	Nonproliferative and genetically modified Moloney mouse leukemia virus (SFCMM-3) that expresses Herpes simplex type 1 thymidine kinase and human intracellular region-deleted low affinity nerve growth factor receptor, and has env protein of mouse amphotropic virus 4070A in its envelope	Takara Bio Inc.
2007-11-20	High lysine and Lepidoptera resistant maize (*cordapA, cry1Ab, Zea mays* subsp. *mays* (L.) Iltis) (LY038×MON 810, OECD UI:REN- 00038-3×MON-00810-6)	Monsanto Japan Limited
2007-11-06	Oilseed rape tolerant to glufosinate herbicide (*pat, Brassica napus* L.) (T45, OECD UI: ACS-BN008-2)	Bayer Crop Science K.K.
2007-11-06	Purple-violet carnation123.8.12 (*F3'5'H, DFR, sur* B , *Dianthus caryophyllus* L.) (OECD UI: FLO-40689-6)	SUNTORY LIMITED
2007-11-06	Maize resistant to Lepidoptera, and tolerant to glufosinate herbicide and glyphosate herbicide (Modified *cry1Ab, pat, mEPSPS, Zea mays* subsp. *mays* (L.) Iltis) (Bt11×GA21,OECD UI: SYN-BT011-1×MON-00021-9)	Syngenta Seeds K.K.
2007-11-06	Maize resistant to Coleoptera and tolerant to glyphosate herbicide(Modified *cry3Aa2, mEPSPS, Zea mays* subsp. *mays* (L.) Iltis) (MIR604×GA21, OECD UI：SYN-IR604-5×MON-00021-9)	Syngenta Seeds K.K.
2007-8-23	Glufosinate herbicide tolerant, male sterile and fertility restored oilseed rape (Modified *bar, barnase, barstar,*	Bayer Crop Science K.K.

	Brassica napus L.）(MS8RF3, OECD UI: ACS-BN005-8×ACS-BN003-6)	
2007-8-23	Glufosinate herbicide tolerant, male sterile and fertility restored oilseed rape (Modified *bar, barnase, barstar, Brassica napus* L.) (MS1RF1, OECD UI :ACS-BN004-7×ACS-BN001-4)	Bayer Crop Science K.K.
2007-8-23	Glufosinate herbicide tolerant, male sterile and fertility restored oilseed rape (Modified *bar, barnase, barstar, Brassica napus* L.)(MS1RF2, OECD UI :ACS-BN004-7×ACS-BN002-5)	Bayer Crop Science K.K.
2007-8-23	High lysine maize(*cordapA, Zea mays* subsp.mays (L.) Iltis)(LY038, OECD UI : REN-00038-3)	Monsanto Japan Limited
2007-8-23	Maize resistant to Coleoptera (Modified *cry3Aa2, Zea mays* subsp. *mays* (L.) Iltis) (MIR604, OECD UI: SYN-IR604-5)	Syngenta Japan K.K.
2007-7-19	Rice containing cedar pollen peptide(*7Crp,Oryza sativa* L.) (7Crp#242-95-7)	National Institute of Agrobiological Sciences(NIAS)
2007-7-19	Maize resistant to Lepidoptera(*Modified vip3A, Zea mays* subsp. *mays* (L.) Iltis) (MIR162, OECD UI:SYN-IR162-4)	Syngenta Seeds K.K.
2007-6-26	Rice containing cedar pollen peptide(*7Crp, Oryza sativa* L.) (7Crp#10)	National Institute of Agrobiological Sciences(NIAS)
2007-5-30	Maize tolerant to glyphosate herbicide and tolerant to acetolactate synthase inhibitor (*gat4621, zm-hra, Zea mays* subsp. *mays* (L). Iltis.) (DP-098140-6, OECD UI:DP-098140-6)	Du Pont Kabushiki Kaisha
2007-5-30	Soybean high oleic acid and tolerant to acetolactate synthase inhibitor (*gm-fad2-1, gm-hra, Glycine max* (L). Merr.) (DP-305423-1, OECD UI:DP-305423-1)	Du Pont Kabushiki Kaisha
2007-5-30	Cotton resistant to Lepidoptera (*Modified cry1Ab, Gossypium hirsutum* L.) (COT67B, OECD UI:SYN-IR67B-1)	Syngenta Seeds K. K.
2007-5-30	Cotton resistant to Lepidoptera (*Modified vip3A, Gossypium hirsutum* L.) (COT102, OECD UI:SYN-IR102-7)	Syngenta Seeds K. K.
2007-5-17	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide (Modified *cry1Ab, bar, Zea mays* subsp. *mays* (L.) Iltis) (Event176, OECD UI：SYN-EV176-9)	Syngenta Seeds K.K.
2007-5-17	Oilseed rape tolerant to glufosinate herbicide (*pat, Brassica napus* L.) (Topas 19/2, OECD UI :ACS-BN007-1)	Bayer Crop Science K.K.
2007-4-24	Sugar beet tolerant to glyphosate herbicide(modified *cp4 epsps, Beta vulgaris* L. ssp. *vulgaris var. altissima*)(H7-1,OECD UI: KM-000H71-4)	Monsanto Japan Limited
2007-4-24	High oleic acid soybean (*GmFad2-1, Glycine max* (L.) Merr.) (260-05, OECD UI：DD-026005-3)	DuPont Kabushiki Kaisha
2007-4-24	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide (Modified *cry1Ab, pat, Zea mays* subsp. *mays* (L.) Iltis) (Bt11, OECD UI：SYN-BT011-1)	Syngenta Seeds K.K.
2007-4-24	Glufosinate herbicide tolerant and fertility restored oilseed rape(Modified *bar, barstar, Brassica napus* L.)(RF3, OECD UI :ACS-BN003-6)	Bayer Crop Science K.K.

2007-3-22	High cellulose rich white poplar trg300-1(*AaXEG2, Populus alba* L.)	Incorporated Administrative Agency Forest Tree Breeding Center, Japan
2007-3-22	High cellulose rich white poplar trg300-2(*AaXEG2, Populus alba* L.)	Incorporated Administrative Agency Forest Tree Breeding Center, Japan
2007-1-29	Maize resistant to Lepidoptera and torelant to glufosinate herbicide (*cry1Ac, bar, Zea mays subsp. mays* (L.) Iltis) (DBT418, OECD UI: DKB-89614-9)	Monsanto Japan Limited
2007-1-29	Cotton tolerant to glufosinate herbicide and resistant to Lepidoptera (Modified *bar,* Modified *cry1Ac, cry2Ab, Gossypium hirsutum* L.) (LLCotton25×15985, OECD UI:ACS-GH001-3×MON-15985-7)	Bayer Crop Science K.K.