AgBioForum, 16(2): 140-160. ©2013 AgBioForum.

For the Approval Process of GMOs: The Japanese Case

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This article reviews the approval process of genetically modified organisms (GMOs) in Japan. The purpose of this review is to explain the Japanese safety approval procedures for food, feed, and imported GMOs and place it in an international context through a comparison with the United States and the European Union (EU). While the regulatory regime in the United States and EU is often discussed, little is understood about the Japanese regulations. However, Japan plays an important role in terms of biotechnological development as well as international trade through agricultural and food imports. Therefore, this article tries to fill the gap in the existing literature. Within Japanese regulations, GMOs are first tested following the Cartagena Protocol on Biosafety. In a second and final step, compliance with the national laws as well as food and feed safety is assessed. We also summarize the processes used in identity preservation and labeling of approved GMOs. The last section of the article reveals the pragmatic nature of Japanese GMO regulations as compared to the EU and the United States.

Key words: GMOs, policies, regulations, Japan.

Introduction

Today the world faces the challenge of increasing agricultural production to meet the growing demands for food and plant-based fuels in an environmentally sustainable manner. The world's population is currently increasing and is projected to grow even further in the future. Studies suggest that the increasing population will require current food production to double by 2050 (Food and Agricultural Organization of the United Nations [FAO], 2009). In addition, producing fuel from agricultural commodities is becoming more important, and there is an on-going debate of food versus fuel (Edgerton, 2009). Many fear that the production of agricultural commodities cannot keep up with the increasing demand from the food as well as the fuel sectors (Cassman & Liska, 2007). However, some studies suggest that it is possible to supply enough agricultural commodities to meet the needs for both food and fuel if a significant increase in yield is achieved (Slade, 2012).

In the past, yield increases have been driven through increasing inputs such as land and fertilizer (Ruttan, 2002). However, most fertile land is already under cultivation (Ramankutty, Foley, & Olejniczak, 2002). Therefore, the possibility to achieve production increases from using more land for agricultural production is limited. Also, further increases in input use such as fertilizer and pesticides generate concerns over the environmental impacts (Cassman & Liska, 2007).

Since the beginning of the 20th Century, the improvement of agricultural production technology has been the major driving force for increases in productivity. Conventional breeding has increased production quantities by selecting varieties with higher yields and higher resistance towards pests and diseases (Khush, 1995; Rosegrant & Cline, 2003). Currently, the technology of genetic modification (GM) is thought to have a strong potential to achieve further increases in agricultural productivity without increasing negative environmental impacts. Many current GM varieties are tolerant towards agricultural chemicals that are generally used. As a result, producers are able to apply others that are more efficient and therefore reduce the overall production inputs as well as costs (Persley, 2000; Phipps & Park, 2002; Qaim & Zilberman, 2003; Wesseler, Scatasta, & Fall, 2011).

However, despite its potential, the application of biotechnology has always been controversial (FAO, 2001). As a result, public aversion towards genetically modified organisms (GMOs) is reflected in GMO-related policies throughout the world (Lynch & Vogel, 2001). This article summarizes the GMO approval process in Japan. Little is understood about the Japanese regulations related to GMOs compared to the European Union (EU) and the United States. However, Japan plays an important role in development of biotechnology (Organisation for Economic Co-operation and Development [OECD], 2013; Science Council of Japan, 2010). Moreover, imported agricultural goods have a large share in the domestic market (Ministry of Agriculture, Forestry, and Fisheries [MAFF], 2007a). There-

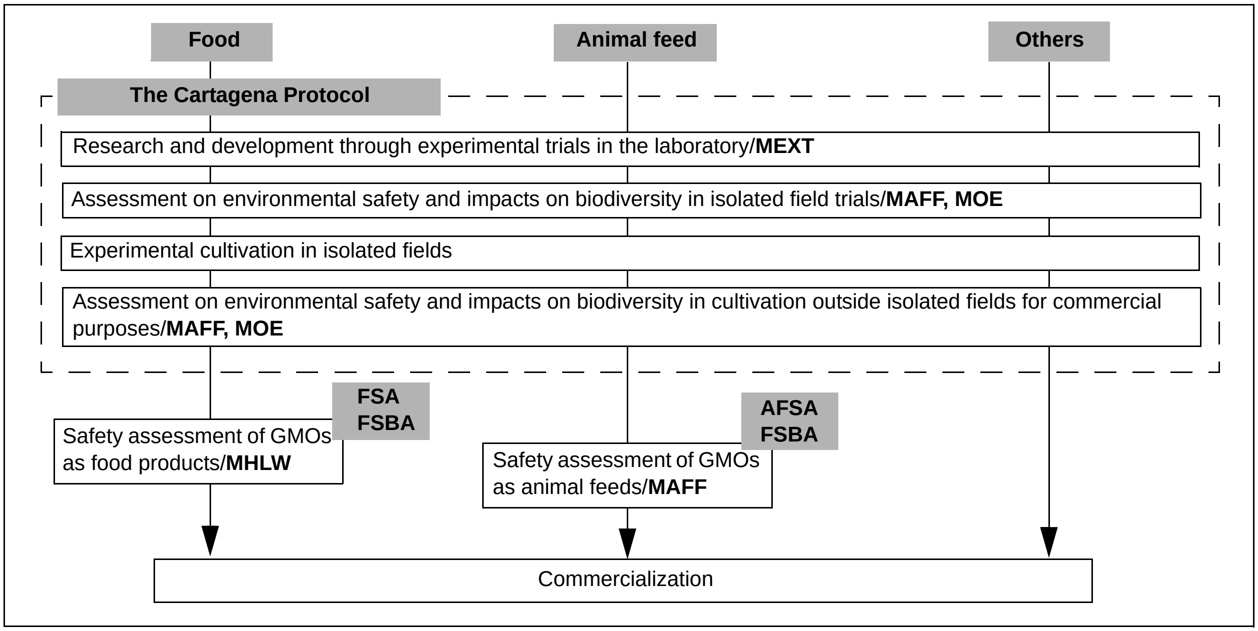

Figure 1. Safety approval process regarding GMOs in Japan.
Source: Council of Biotechnology Information Japan (n.d.), MAFF (2007b).

fore, understanding the GMO regulations in Japan is important. This article begins by providing an overview of GMO approval for food, feed, and imports in Japan, as well as currently approved GMOs. Then, the identity preserved handling (IP handling) process and labeling of GMOs is explained. The article then lays out a comparison between the Japanese GMO approval process and the process in the EU and the United States, followed by a summary and conclusion.

GMO Approval Process in Japan

General Overview

By 2013, Japan has approved eight GM food and feed crops for human consumption and animal feeding purposes (Council of Biotechnology Information Japan, 2013; MAFF, 2013; MHLW, 2013). These are soybeans, sugar beet, corn, canola, cotton, alfalfa, potatoes, and papaya. All GMOs have been tested through approval processes under three national laws and the implementation of an international treaty, namely the Food Safety Basic Act (FSBA); the Food Sanitation Act (FSA); the Animal Feed Sanitation Act (AFSA, officially known as the Act on Safety Assurance and Quality Improvement of Feeds); and the Cartagena Protocol on Biosafety (Council of Biotechnology Information Japan, 2013; MAFF, 2007b). As described in Figure 1, all organisms are first tested at controlled experimental fields in terms of their impacts on biodiversity, following the Cartagena Protocol, under the supervision of the Ministry of Education, Sports, Science, and Technology (MEXT), the MAFF, and the Ministry of the Environment (MOE). Then, products for human consumption are assessed according to the FSA and the FSBA, while animal feed crops are studied following the AFSA as well as the FSBA (Council of Biotechnology Information Japan, n.d.; MAFF, 2007b).

Step 1: The Cartagena Protocol

The goal of the Cartagena Protocol is to ensure safety in terms of biodiversity conservation and human health when transporting and utilizing living modified organisms (LMOs) across borders (Ministry of Foreign Affairs of Japan, 2012). Although the Cartagena Protocol refers to LMOs, we will use the term GMOs for consistency. Based on the Cartagena Protocol, first all GMOs have to be proven safe for the local environment. Under the Japanese approval process, all GM food, processing aids, and food additives are subject to a safety assessment. It generally takes about a year for all organisms to go through the entire approval process. The Ministry of Health, Labour, and Welfare (MHLW) is the main entity in charge of the GMO approval procedure for human consumption, while MAFF is responsible for impacts on the environment, approval of feed crops, and labeling of GMOs (Gruère, 2006).

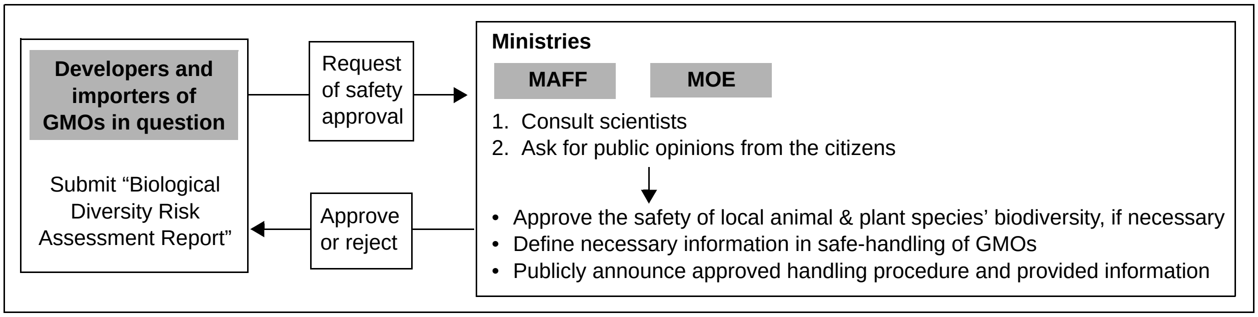

Figure 2. Approval process of GMOs (agricultural plants and tree species) for Type 1 usage under the Cartagena Protocol.
Corresponding ministries: MAFF, MOE. Source: MAFF (n.d.c); University of Tokyo, School of Science (n.d.)

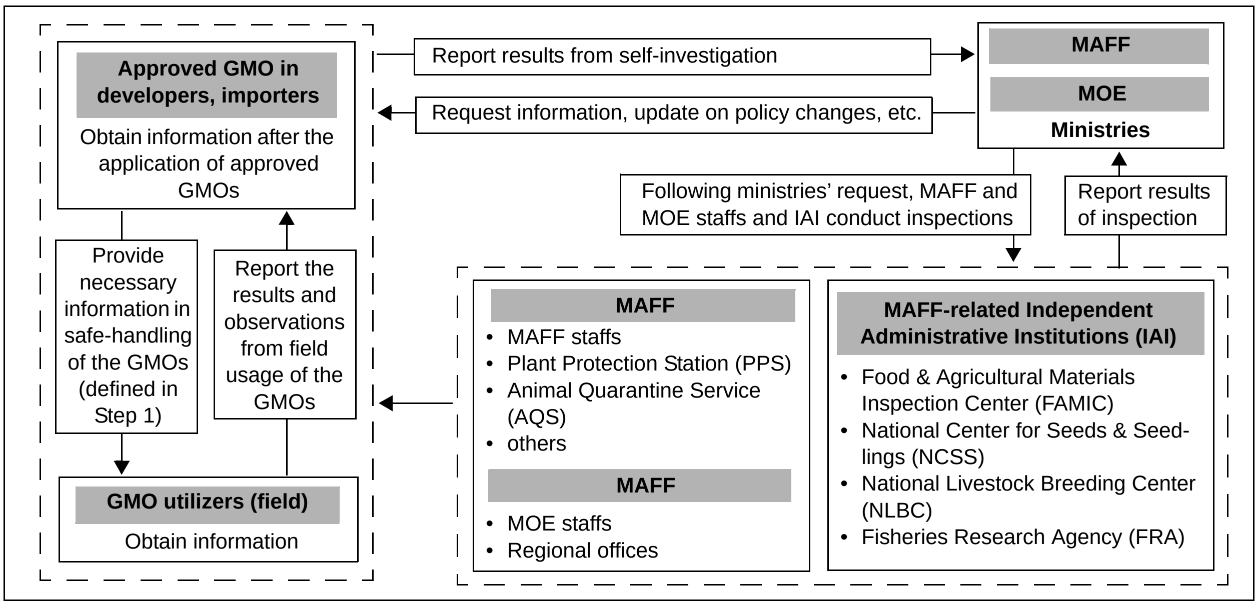

Figure 3. Proper handling of GMOs approved for Type 1 usage.
Corresponding ministries: MAFF, MOE. Source: MAFF (n.d.c)

Under the Cartagena Protocol, all GMOs subjected to an assessment are first categorized into two groups—those for Type 1 use and those for Type 2 use (MAFF, n.d.a). Type 1 use is defined as an open usage of GMOs, i.e., under conditions that may influence the local environment. Type 2 use involves a closed environment where impacts of GMOs are contained. Such applications are relevant in the case of an experimental field or isolated greenhouse (MOE, n.d.).

Type 1 Usage. In order to have GMOs approved by the Cartagena Protocol for Type 1 usage, applicants of GMOs have to submit a “Biological Diversity Risk Assessment Report” to corresponding ministries (MOE, n.d.). The report must be based on research conducted through literature review and laboratory experiments (MOE, n.d.). The ministries will request more information from the applicants if there are possible adverse effects or a lack of information on biological safety. If no adverse effect is observed, they will consult the public and the applications will be further assessed according to the FSA or AFSA, depending on their purposes. Ministries that receive applications include MAFF, MHLW, MOE, and MEXT. In the case of Type 1 usage, MOE is always involved, as the main concern of the assessment is the environmental impacts of the GMOs in question. Figure 2 illustrates the procedure of assessment of GMOs for Type 1 usage.

After GMOs are approved for Type 1 usage, the Cartagena Protocol further requires appropriate monitoring and handling of the GMOs. As shown in Figure 3, importers or developers of approved GMOs are requested to continue obtaining information from field usage, which is to be submitted to the MAFF and the MOE. Independent administrative institutions (IAIs) conduct inspections following requests from both minis-

Table 1. Corresponding ministries in charge for Type 2 approval.

Ministries in charge	Type 2 uses by category
Ministry of Agriculture, Forestry, & Fisheries	Improvements to crops in equipment, development of live vaccines for animals
Ministry of Health, Labour, & Welfare	Viruses for gene therapy
Ministry of Education, Culture, Sports, Science, & Technology	Uses in the experiments of gene recombination in universities
	Use in research and development activities
Ministry of Economy, Trade, & Industry	Uses in the process of production of industrial enzymes
National Tax Agency	Yeast used in the production of alcoholic beverages

Source: Ministry of the Environment (n.d.), Japan Biosafety Clearing House (2004)

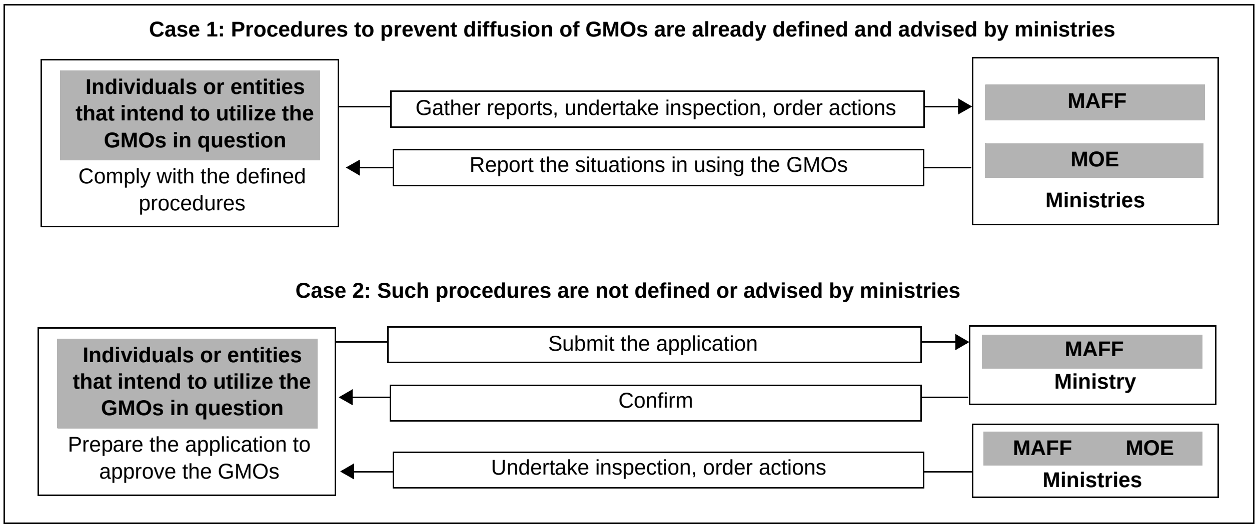

Figure 4. Approval process of GMOs (agricultural plants and tree species) for Type 2 usage under the Cartagena Protocol.
Source: MAFF (n.d.c); University of Tokyo, School of Science (n.d.)

tries. The purpose of such inspections is to ensure that the approved GMOs are produced and handled according to the regulations, to keep records through official documents, and to conduct scientific tests concerning the DNA structure. Different research units are in charge within the ministries depending on the purposes and types of usage of each GMO.

Type 2 Usage. For Type 2 usage, applicants must comply with the procedure to avoid GMOs' diffusion into the local environment. In some cases, corresponding ministries have already defined specific procedures to be undertaken. If this is the case, applicants can follow the already-existent procedures. If the standard has not been set, each application must be submitted to the appropriate ministries for approval. Such institutions include the MAFF, the MHLW, the MEXT, and the National Tax Agency (MAFF, 2007c; MOE, n.d.). Table 1 presents ministries in charge and Figure 4 graphically represents the approval process of GMOs for Type 2 usage.

Summary on the Cartagena Protocol. In summary, the Cartagena Protocol requires assessment of each GMO whose environmental safety has not been tested yet. Individuals or institutions interested in utilizing specific GMOs in Japan must apply to the ministries concerned. They must file either a biological report to investigate the GMO's impact on the local environmental safety or a request to define safety instructions to be followed when handling such organisms. For Type 1 usage, after approving the environmental safety of GMOs, applicants and government entities will discuss the results of field experiments to ensure the safety obtained from actual observations. The GMOs will be assessed finally by the national laws only when proven to be safe in the local environment, complying with the Cartagena Protocol (MAFF, n.d.a). Generally speaking, applicants are developers of GM seeds and predominantly large international corporations. Such corporations include Monsanto Japan Co., DuPont, Bayer Crop Science, and Dow Chemical Japan Ltd. (MAFF, 2013).

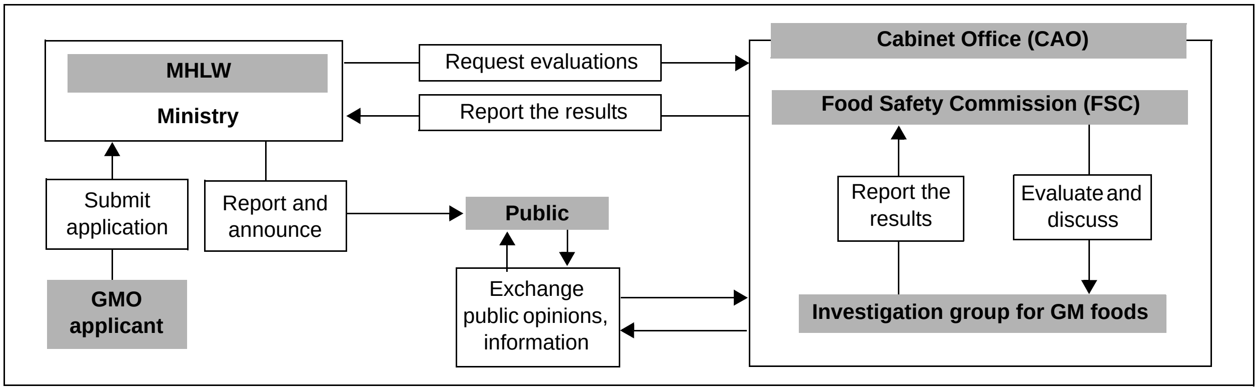

Figure 5. Approval of food item GMOs by the MHLW.
Source: MHLW (2012)

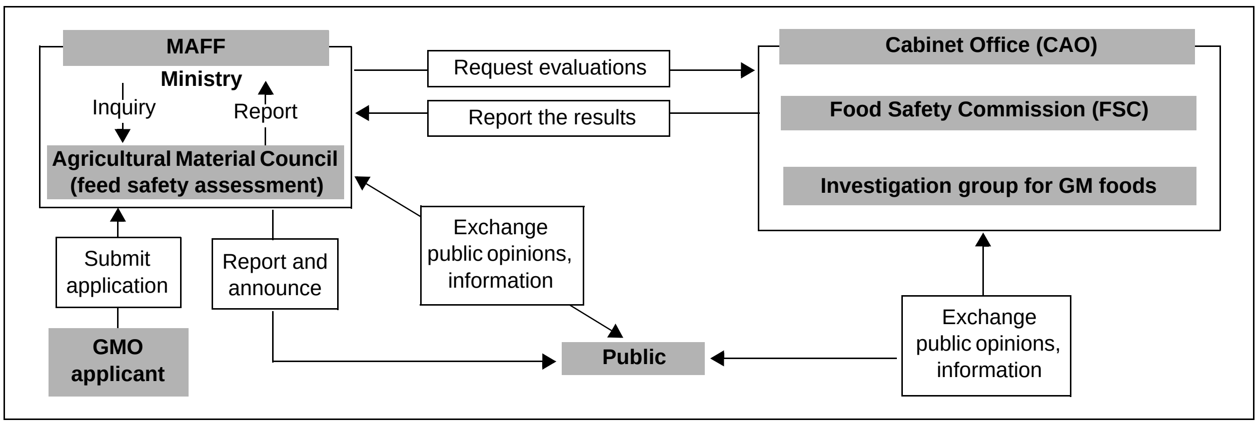

Figure 6. Approval of GM feed items by the MAFF.
Source: MAFF (n.d.c)

Step 2: Food or Feed Safety Assessment

After GMOs are proven to be safe under the Cartagena Protocol, they are further investigated, following the FSBA, the FSA, and the AFSA. Food items are assessed by the FSBA and the FSA, both of which are monitored by the MHLW; feed items are studied based on the FSBA of the MHLW as well as the AFSA of the MAFF.

Food Safety Assessment. The MHLW requires each applicant to request food safety approval by genetic event. Then, the MHLW will submit the request to the Food Safety Commission of Japan (FSC) within the Cabinet Office (CAO) of Japan, which will consult a group of scientists for investigation. The general public will be informed about the newly-considered GMOs and can give feedback to the FSC. If the Minister of the MHLW approves the GMO's safety, it has completed the food-safety approval process. Finally, the public will be notified of the decision (MHLW, 2012). This approval process was made mandatory by the MHLW in 2001 (FSC, 2004). Figure 5 graphically illustrates the approval process of food GMOs by the MHLW.

There are two laws that play a role in food-safety approval, i.e., the FSA and the FSBA. The FSBA emphasizes food safety for consumers (Ministry of Internal Affairs and Communications, 2011), whereas the FSA is concerned with preventing sanitation hazards caused from consuming food (Ministry of Internal Affairs and Communications, 2009). After the safety assessment is done within the CAO, the MHLW Minister will make the final decision, referring to the FSA as well as the FSBA (Honda, 2010).

Feed Safety Assessment. Approval of feed GMOs is done by the MAFF. As described in Figure 6, the MAFF undertakes an assessment of feed safety within the ministry for each application. The assessment is carried out under the AFSA, which ensures feed safety and quality (Ministry of Internal Affairs and Communications, 2007). The act is concerned with feed produced domestically as well as imported. It also aims to promote

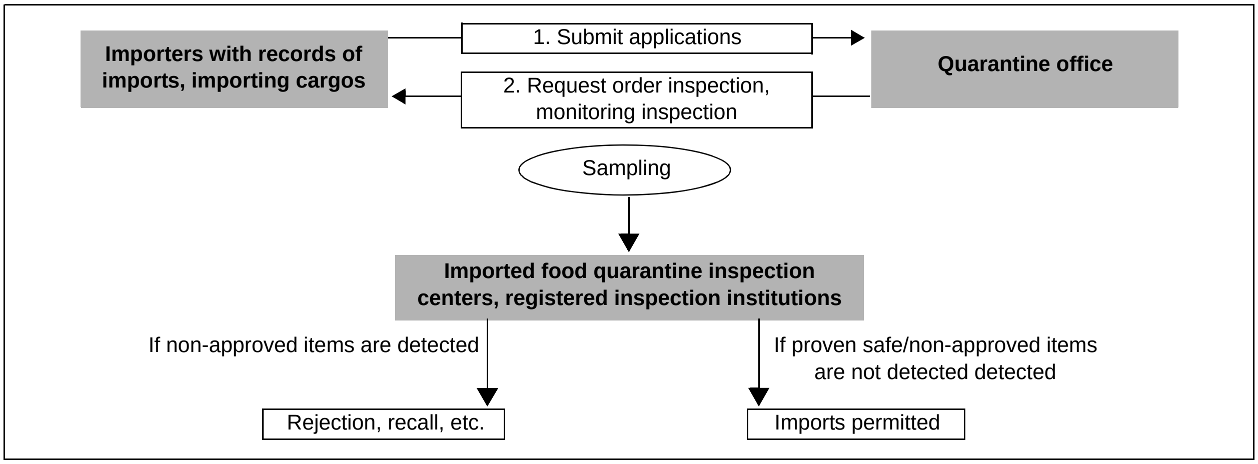

Figure 7. Procedure of quarantine on imported GM food items.
Source: MHLW (2012), Kamada (2011)

improvement of feed quality and to stabilize the supply of high-quality feed (Ministry of Internal Affairs and Communications, 2007). The MAFF also requires all GM feed items to go through the FSC within the CAO as in the case of food GMOs. The purpose is to investigate the impacts from GM feed on human health. Unlike in the case of food GMOs, this food-safety investigation addresses the safety of food products derived from animals fed with GMOs. This assessment is done following the FSBA (Honda, 2010). The public has the opportunity to express its opinions before feed GMOs are officially released (MAFF, n.d.c).

Approval of GMOs for Imports

Before importing GMOs, importers have to obtain approval for Type 1 usage in the Cartagena Protocol (Japan Biosafety Clearing House, n.d.). When importing GMOs, the MHLW conducts random inspections of GMOs at ports of entry. This has been in place since April 2001 to detect non-approved GMOs (MHLW, 2012). The MHLW has a 0% tolerance on GMOs that are not approved abroad. In other words, no import will be made unless exporting countries have certified their GM products' safety through their own regulatory mechanisms (Gruère, 2006). The procedure of inspection is presented in Figure 7.

"Order inspection" in the figure is what importers must comply with when they intend to import GM food items that may not satisfy the safety standards set by the Japanese regulations. In this case, the importers have to evaluate the organisms at registered inspection institutions at their own cost. "Monitoring inspection" occurs when the government proposes a guideline to conduct regular inspections in order to understand the current hygienic situation involving imported food items.

Table 2. Incurred costs by companies from discovery to authorization of a plant biotechnology trait.

Category		Costs ($ millions)
Discovery	Early discovery	17.6
	Late discovery	13.4
	Total cost	31.0
Construct optimization		28.3
Commercial event production & selection		13.6
Introgression breeding & wide-area testing		28.0
Regulatory science		17.9
Registration & regulatory affairs		17.2
Total		136.0

Source: Phillips McDougall (2011)

As of March 2012 (MHLW, 2012), examples of GM items currently subject to inspections are rice (63Bt, NNBt, CpTI, LLRICE601), papaya (PRSV-YK), canola (RT73 B. rapa), and flaxseed (FP967). Since 2001, detected unapproved GMO items include 2 maize, 0 soybeans, 31 rice, 2 flaxseed, and 3 papaya events (MHLW, 2012).

Time and Costs of GMO Approval

A study done by CropLife International summarizes the results of a survey asking major biotechnology companies for the time duration and costs of plant biotechnology research and development (R&D) activities (Phillips McDougall, 2011). Questionnaires were sent to six major companies, namely BASF Corporation, Bayer

Table 3. Duration of each activity stage in the plant biotechnology trait R&D process (months).

Category	Event sold before 2002		Event introduced between 2008-2012		Required to complete each stage in 2011	
	Duration	% share	Duration	% share	Duration	% share
Early discovery	38.0	16.4%	33.9	14.5%	25.8	9.6%
Late discovery	17.3	7.4%	20.0	8.5%	20.9	7.8%
Construct optimization	18.0	7.7%	27.0	11.5%	32.8	12.2%
Commercial event production & selection	24.0	10.3%	30.0	12.8%	34.0	12.7%
Introgression breeding & wide-area testing	40.0	17.2%	37.2	15.9%	42.0	15.7%
Regulatory science	50.5	21.7%	37.2	15.9%	47.0	17.5%
Registration & regulatory affairs	44.5	19.2%	48.8	20.8%	65.5	24.4%
Total	232.3		234.1		268.0	

Source: Phillips McDougall (2011).

CropScience, Dow AgroSciences, DuPont/Pioneer Hi-Bred, Monsanto, and Syngenta AG. Although there are no statistics available specifically for Japan, the aforementioned six corporations are the major players in approving GM traits in Japan. Therefore, the observations described in this section can be considered as an appropriate approximation for the situation in Japan.

The key findings in the article suggest that the average dollar amount that surveyed companies spent on discovery, development, and approval of a new GM trait was a total of $136 million between 2008 and 2012. Out of the total costs, the R&D activities consisted of the highest share: 51% or $69.9 million, followed by approval process (26% or $35.1 million) and gene discovery (23% or $31.0 million). Table 2 summarizes incurred costs organized by categories of different activities.

On average, the time duration for registration and regulatory affairs is 5.5 years as of 2011, while it was approximately 3.7 years prior to 2002. Table 3 shows the average duration of each activity undertaken by companies. The total time taken from discovery to commercialization has increased since 2002. When combining the regulatory science phase and the registration and regulatory affairs phase, the time involving regulatory processes is the longest phase that companies go through in all periods.

The average time length of discovery projects is 13.1 years. It ranges from 11.7 years for canola to 16.3 years for soybeans, with corn (12.0 years) and cotton (12.7 years) in between. This excludes the duration of applying for regulatory approval.

Currently Approved GMOs

By April 2013, of the total of 166 approved events, 11 GM crops have been approved for Type 1 and Type 2 usage, following the Cartagena Protocol (MAFF, 2013). In order to identify the GMOs approved for Type 1 usage, this study uses the records published by both the MAFF and the MHLW. The list of all genetic events approved for food and/or feed can be found in the Appendix. It is organized based on commodities, which are potatoes, soybeans, canola, sugar beet, maize, cotton, alfalfa, and papaya. Besides these eight food and/or feed commodities, several flower species are also approved for Type 1 usage. In addition, rice and a number of other flowers have been approved for Type 2 usage (MAFF, 2013).

Each commodity is further arranged according to the features of the GMOs. The table contains information on the applicants as well as the first date of approval. The date refers to the year that each trait was approved as a food and/or feed item.

Identity Preservation

Identity Preserved Handling

Identity preserved (IP) handling of GMOs is enforced for imported GMOs (MAFF, n.d.b). In 2001, the Japan Food Industry Center (JAFIC) and the MAFF jointly published a logistics manual for IP handling of GM soybeans, maize, and potatoes. With the approval of GM papayas, the JAFIC published guidelines for IP handling of papayas in 2011. IP handling is necessary, as GM products need to be segregated and labeled properly by law. The regulations involving labeling will be revisited more thoroughly in the next section.

IP handling is defined as "the management method where any involved entities ensure careful handling to segregate GM and non-GM agricultural products through providing official statements at each stage involving production, transportation, and processing of

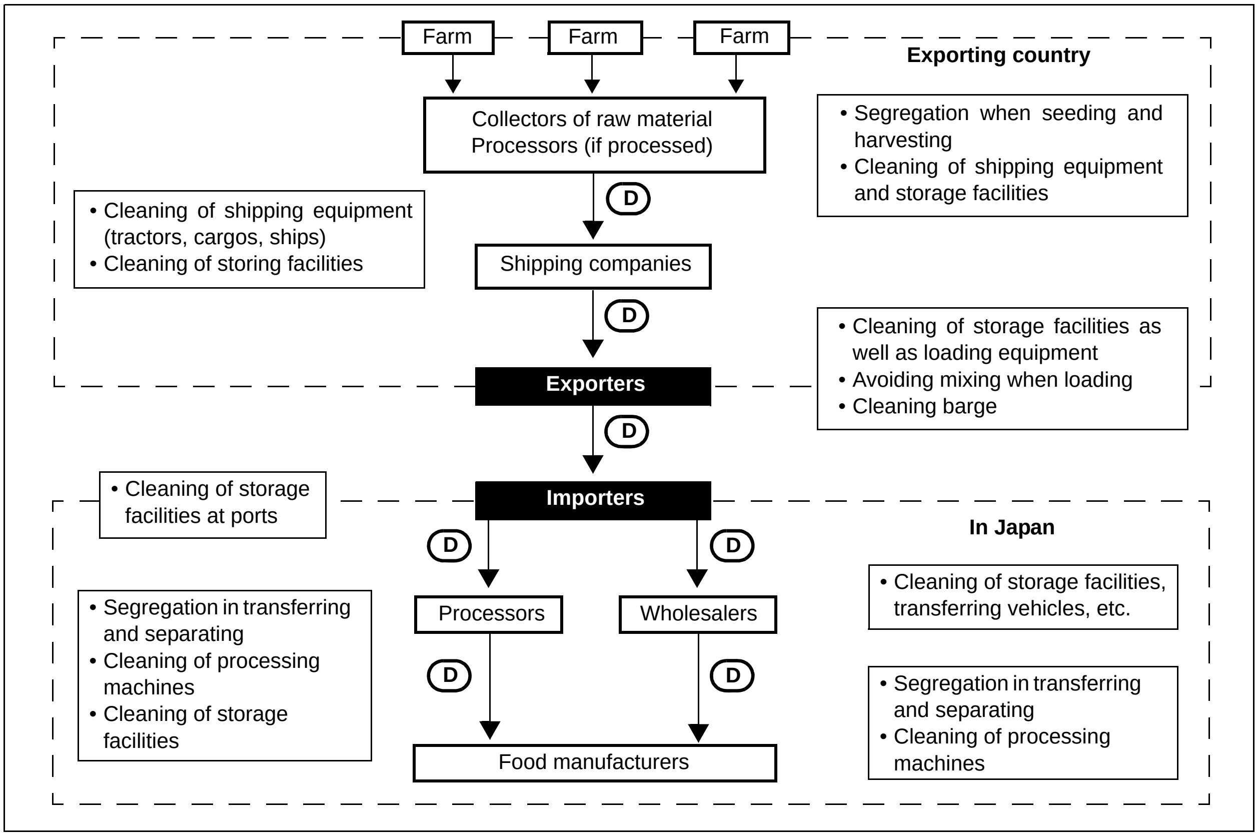

Figure 8. IP handling in segregating GM soybeans, maize, potatoes, and papayas.
(D): *official documents required*
Source: Japan Food Industry Center (2001, 2011), MAFF (n.d.b, 2002)

GM and non-GM agricultural products" (JAFIC, 2001, p. 5). For all four crops, the IP handling process starts from farms in an exporting country until the products reach the final manufacturing entities or consumers in Japan. Although there are slight differences across commodities, the IP handling procedures for all crops in question are rather alike. The standard procedure of IP handling is presented in Figure 8. Since the first exporter of GM soybeans, maize, potatoes, and papaya to Japan was North America, manuals were originally written specifically for imported GM and non-GM goods from the United States and Canada (MAFF, n.d.b). Now, the same IP handling procedure is imposed on other exporting nations if both GM and non-GM products are produced within the same country (JAFIC, 2001).

For all GMOs, raw materials are first collected from individual farms by collectors and/or local processors. Then, products are transferred to exporters through shipping entities. When they reach Japan, importers distribute the products to processors or wholesalers. Finally, the products will be received by food manufacturers to reach consumers. At every step except for the first, it is required to ensure that the IP handling procedure is followed by providing official documents (JAFIC, 2001). In the figure, the "D" indicates the necessity to provide certifying documents. The documents should ensure safe and careful handling of GMOs, such as appropriate maintenance and cleaning of storing, as well as logistic facilities.

Labeling GMOs in Japan

All GM food products as well as their derivatives are subject to mandatory labeling under the Japanese regulations. Table 4 shows all product types subject to mandatory labeling. Labeling regulation has been in place since April 2001 under the Law on Standardization and Proper Labeling of Agricultural and Forestry Products introduced by the Japanese Agricultural Standards (JAS; Consumer Affairs Agency, Government of Japan, 2011). Under the Japanese labeling regulation, there are three

Table 4. Processed food items subject to mandatory labeling (as of August 2011).

Raw materials: soybeans, maize, potato, canola, cotton, alfalfa, sugar beet, papaya; Processed food (33 food items)

No.	Ingredients	Processed food
1	Soybean	Tofu and fried tofu
2		Tofu-derived food items
3		Fermented soybeans
4		Soy milk
5		Miso paste
6		Boiled soybeans
7		Canned and bottled boiled soybeans
8		Soybean powder
9		Fried soybeans
10		Food items derived from 1-9
11		Food items derived from soybeans
12		Food items derived from soybean powder
13		Food items derived from soybean protein
14	Edamame beans	Food items derived from edamame beans
15	Soybean sprouts	Food items derived from soybean sprouts
16	Maize	Corn snacks
17		Corn starch
18		Pop corn
19		Frozen corn
20		Canned and bottled corn
21		Food items derived from corn flower
22		Food items derived from grinded corn (except for cornflakes)
23		Food items derived from corn
24		Food items derived from 16-20
25	Potato	Potato snacks
26		Dried potato
27		Frozen potato
28		Potato starch
29		Food items derived from 25-28
30		Food items derived from potato
31	Alfalfa	Food items derived from alfalfa
32	Sugar beet	Food items derived from sugar beet
33	Papaya	Food items derived from papaya

Source: Consumer Affairs Agency, Government of Japan (2011).

types of GMO labels. Products can be labeled as "genetically modified," "genetically modified organisms not segregated," or "not genetically modified." The first two labeling options are mandatory if GMOs are included in the final products while the last option is voluntary.

The labeling regulations in Japan focus on the final products. Unlike in the case of the EU, traceability is not enforced. Therefore, only when the final products contain the same DNA characteristics as the raw material, they need to be labeled as GM. In contrast, it is not necessary to label products if the end products do not preserve the DNA characteristics of the original crops. Vegetable oils and soy sauce are examples because their DNA characteristics are altered through processing.

Furthermore, the regulations allow a 5% impurity with respect to the total weight of final products when GMOs are accidentally mixed in with non-GM products. Moreover, labeling is only necessary for the top three ingredients. In other words, the products can still be labeled as "non-GM" if the content of GMOs in the top three ingredients is less than 5% of the total weight.

In the case of GM crops whose genetic and nutritional characteristics largely differ from their conventional counterparts, final products need to be labeled to identify how they differs from the conventional products (e.g., "genetically modified to contain higher level of oleic acid in soybeans"; Consumer Affairs Agency, Government of Japan, 2011).

Voluntary labeling of non-GM food items can be found on processed foods. If GMOs are segregated in the supply chain, products can be labeled as "not genetically modified" or sold without labels (Consumer Affairs Agency, Government of Japan, 2011). This applies to the food crops currently approved for human consumption (soybean, maize, potato, canola, cotton, alfalfa, sugar beet, and papaya). Food items for which GM counterparts do not exist cannot be labeled as non-GM. For instance, apples cannot be labeled as non-GM since there is no GM apple available in the market. When labeling as "non-GM," producers need to clearly specify which ingredients the statement refers to (e.g., "potatoes [not genetically modified]").

In general, the nature of GMO labeling regulations has driven GM products out of the market, failing to provide consumer choices (Gruère & Rao, 2007). Due to the fear of losing market share, companies tend to avoid producing GMO-derived products that require labelling. As a result, it is rare to find products at the retail level that are labelled GM. However, because traceability is not enforced and 5% impurity is allowed, consumers do get GMO-derived products without labels. Highly processed food items, such as soy oil and soy sauce, are examples of such products.

GMO-related regulations on labeling in Japan are looser than those in the EU but more stringent than those in the United States, Canada, and many other large exporters of GMOs. While the EU nations require traceability as well as labeling of derived and non-derived products, regulations in the United States, Canada, and Argentina only have voluntary labeling if the GM products do not demonstrate any difference in the final products, i.e., they are substantially equivalent (Gruère, 2006). As mentioned above, Japan imports large amounts of agricultural products from many of the leading producers of GM products. While it is certain that Japan imports GM crops, the final products are not labeled as such because the imported products are largely used for animal feeds as well as processed foods that do not preserve the DNA characteristics of the raw materials.

Regional Comparison

This section presents a regional comparison in the number of GMOs approved and the year of GMO approval between Japan, the EU, and the United States. As seen in the labeling regime, Japan's regulations for GMOs are often described as more stringent than in the United States but looser than in the EU. One way to observe this is to compare the years when the same GM events were approved in each region. Another is to look at the number of approved events over time.

A comparison was made using the GMO Compass from MAFF (2013) for Japan; GMO Compass (2013) for the EU; and US Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) for the United States (2013). In the case of Japan, the approval year is defined as the year the GMO was approved as safe following the food-safety assessment. The reason for this is that both food and feed GMOs have to pass the food-safety assessment to be officially released. Therefore, this date can be considered as the final assessment date of GMOs. For the EU, the date when the European Commission's decision was made is utilized, while the Federal Register (FR) ruling and determination date was used for the United States.

Table 5 summarizes all GMOs accepted in each region. Blanks mean that the GMOs have not been accepted or approval has not been explicitly reported. Generally speaking, GMOs are approved first in the United States, followed by Japan and then the EU. For instance, the canola event T45 was approved in 1998 in the United States, 2001 in Japan, and finally 2009 in the EU. Similarly, the maize event NK603 was approved in

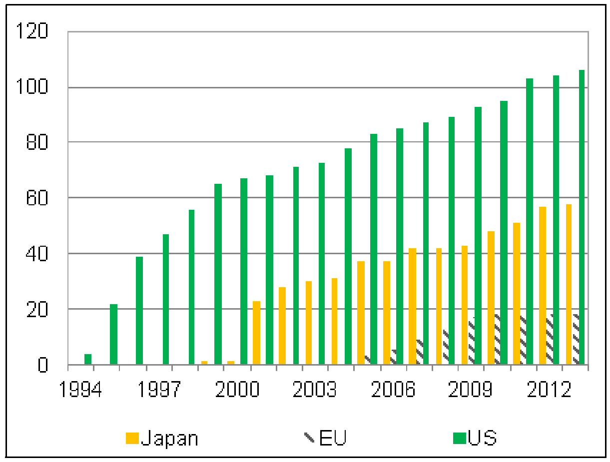

Figure 9. Number of GMO approvals in Japan, the European Union, and the United States.

2000 in the United States, 2001 in Japan, and 2005 in the EU. Assuming applications for approval have been submitted at the same point in time at least for the EU and Japan, this supports the expectation that the Japanese regulatory regime lies between the EU and the United States. Further analysis has to consider the submission date, which is difficult to obtain in the case of Japan.

Figure 9 illustrates the evolution of the number of GMO events accepted in each region over time. Among the three regions under discussion, the United States is the first country that started approving GMOs. Japan followed with its first approval in 1999 and Europe's first approval after the quasi moratorium was in 2004. As of 2013, the United States, Japan, and the EU have approved a total of 106, 58, and 18 events, respectively. The United States has a relatively stable growth of GMO approvals, while Japan observed a significant increase between 1999 and 2001. Note that this comparison was made only on single events or non-stacked traits. This is because Japan and the EU present explicit approval in the sources utilized but the United States does not. Therefore, all the stacked events are excluded from the comparison for this study.

Although explaining the causes of such regional difference in duration of GMO approval is beyond the scope of this study, Table 6 may provide some useful insights. It presents the dates when a GM event was submitted for approval and when it was accepted in each region. For Japan, we use the date when each event was authorized for protected field experiments as the date of application submission since the application date is not provided by the ministries. Generally speaking, Japan takes approximately 2 years between application sub-

Table 5. Comparison of GMO approval processes in Japan, the European Union, and the United States

Crop	Genetic event	Japan	EU	US	Crop	Genetic event	Japan	EU	US
Maize	1507	2002	2006	2001	**Soybeans**	260-05	2001		
	176			1995		40-3-2	2001		1994
	3272	2010		2011		A2704-12	2002	2008	
	1507*DAS-59122-7	2005	2010			A5547-127	2002		
	1507*DAS-59122-7*MON810*NK603	2011				CV127	2012		
	1507*59122*MON810*NK603* MIR604	2012				DP-305423-1	2010		2010
	1507*MIR604*NK603	2011				DP-305423-1*40-3-2	2012		
	1507*MON810*NK603	2011				DP-356043-5	2009		2008
	1507*MON810*MIR162*NK603	2013				G94-1, G94-19, G168			1997
	1507*NK603	2004	2007			MON87701	2011		2011
	3272*Bt11*MIR604*GA21	2010				MON87701*MON89788	2011		
	5307			2013		MON87705	2012		2011
	6275			2004		MON89788	2007	2008	2007
	676, 678, 680			1998		W62, W98, A2704-12, A2704-21, A5547-35			1996
	98140			2009	**Canola**	CDC Triffid			1999
	B16			1995		GT200			2003
	Bt11	2001	2004	1996		GT73		2005	
	Bt11*DAS-59122-7*MIR604*1507*GA21	2011				MS1			2002
	Bt11*GA21	2007	2010			MS1RF1	2001		
	Bt11*MIR162*1507*GA21	2010				MS1RF2	2001		
	Bt11*MIR162*MIR604*GA21	2010				MS8	2001		
	Bt11*MIR604	2007				MS8RF3	2001	2007	1999
	Bt11*MIR604*GA21	2007				MS8*RF3*RT73	2011		1994
	Bt11*MIR162*GA21	2010				pCGN3828-212/86-18 & 23			
	CBH-351			1998		RF3	2001		
	DAS40278	2012		2005		RT73	2001		1999
	DAS-59122-7	2005	2007			RT200	2001		1998
	DAS-59122-7*1507*NK603	2005	2010			T45	2001	2009	
	DAS-59122-7*NK603	2005	2009			Topas19/2	2001		
	DBT418	2001		1997		WESTAR-Oxy-235	2001		
	DLL25	2001			**Sugar beet**	GTSB77			1998
	DP-098140-6			2009		H7-1	2003	2007	2012
	DP-32138-1			2011		T120-7	1999		1998
	Event 176	2003		1995	**Cotton**	531	2001		1995
	GA21	2001	2008	1997		757	2001		1995
	GA21*MON810	2003				1076			1995
	HCEM485			2013		1445	2005		1995
	LY038	2007		2006		15985	2002		2002
	LY038*MON810	2007				1445*531	2003		
	MIR162	2010		2010		15985*1445	2003		
	MIR162*GA21 (sweet corn)	2011				1698			1995
	MIR604	2007	2009	2007		19-51a			1996

Table 5. Comparison of GMO approval processes in Japan, the European Union, and the United States

Crop	Genetic event	Japan	EU	US
Maize cont'd	MIR604*GA21	2007		
	MON80100			1995
	MON87427	2013		
	MON87460	2011		2011
	MON87460*MON89034*MON88017	2011		
	MON87460*MON89034*NK603	2011		
	MON87460*NK603	2011		
	MON802			1997
	MON810	2001		
	MON810*MON863	2004	2010	
	MON863	2002	2006	2002
	MON863*MON810*NK603	2004	2010	
	MON863*NK603	2003	2010	
	MON87460			2011
	MON88017	2005	2009	2005
	MON88017*MON810	2005	2010	
	MON89034	2007	2009	2008
	MON89034*1507*DAS-59122-7*MON88017	2008		
	MON89034*1507*MON88017*DAS-59122-7*DAS40278	2013		
	MON89034*1507*NK603	2010		
	MON89034*1507*NK603*DAS40278	2013		
	MON89034*MON88017	2008		
	MON89034*NK603	2008	2010	
	MS3			1996
	MS6			1999
	NK603	2001	2005	2000
	NK603*DAS40278	2013		
	NK603*MON810	2003	2007	
	NK603*T25	2009		
	T14	2001		1995
	T25	2001		1995
	T25*MON810	2003		
	TC6275	2007		2004
Cotton, cont'd	281*3006	2005		
	281*3006*1445	2006		
	281*3006*MON88913	2006		
	281-24-236			2004
	3006-210-23			2004
	BXN			1994
	COT102	2012		2005
	COT67B	2012		2011
	Events 31807 & 31808			1997
	GHB614	2010		2009
	GHB614*LLCotton25	2010		
	LLCotton25	2004	2008	2003
	LLCotton25*15985	2006		
	MON88913	2005		2004
	MON88913 (Pima cotton)	2010		
	MON88913*15985	2005		
	T304-40XGHB119	2012		2011
Alfalfa	J101	2005		2005
	J101*J163	2005		
	J163	2005		2005
Papaya	55-1	2011		1996
	63-1			1996
	X17-2			2009
Potatoes	BT6, BT10, BT12, BT16, BT17, BT18, BT23			1995
	EH92-527-1		2010	
	EH92-527-1		2010	
	RBMT15-101, SEMT15-02, SEMT15-15			1999
	RBMT21-129 & RBMT21-350			1998
	RBMT22-82			2000
	SBT02-5 & -7, ABBT04-6 & -27, -30, -31, -36			1996
Rice	LLRICE06, LLRICE62			1999
	LLRICE601			2006

Source: MAFF (2013), GMO Compass (2013), USDA APHIS (2013)

mission and approval, while the EU takes 2 to 4 years and the United States goes through the process relatively faster.

Conclusions

This article summarized the GMO approval process in Japan. It gave an overview of the assessment based on

Table 6. Comparison of time length between application approval and acceptance.

	Japan		EU		US	
	Applied*	**Accepted**	**Applied**	**Accepted**	**Applied**	**Accepted**
MON89788	May 2, 2006	January 31, 2008	November 10, 2006	December 4, 2008	June 27, 2006	July 3, 2007
H7-1	May 25, 2005	April 24, 2007	November 26, 2004	October 24, 2007	July 29, 2010	July 20, 2012
MIR604	May 25, 2005	August 23, 2007	February 18, 2005	November 30, 2009	August 2, 2006	March 16, 2007
MON89034	May 2, 2006	January 31, 2008	January 2007	October 30, 2009	October 24, 2006	July 24, 2008

** approved for protected field experiments*
Source: MAFF (2013), GMO Compass (2013), USDA APHIS (2013)

the Cartagena Protocol as well as national regulations that are in place to ensure safe utilization and commercialization of the GMOs. The labeling regime and the IP handling process were also discussed. Finally, an international comparison was made on different GMO approval processes in Japan, the EU, and the United States.

Japan's regulatory regime is often described as less stringent than that in the EU, but is stricter than in North America. However, there was only limited information available about the Japanese regulatory framework to evaluate GMOs. This article contributes to the literature by providing a detailed description of the Japanese regulations as well as evidence for the claims about the strength of its regulation.

Another contribution of this article is the international comparison of GMO approvals. This study revealed that Japan generally approves GMOs after the United States and before the EU. Also, the trend of the number of approved GMOs suggests that the United States and Japan have approved the same number of GMOs since 1994 while the EU approval has been less than half that amount. This study provided empirical observations that the Japanese GMO regulations are, in fact, stricter than in the United States but looser than in the EU.

Japan has responded to the GM technology in a cautious manner and intended to provide both GM and non-GM options in its domestic market. However, this attempt has not been successful, as GMOs are generally used for highly-processed food or feed, thus avoiding the legal responsibility to label the products as GM. The approval process complies with international as well as national laws to ensure safety from utilization of GMOs through consumption, production, and logistics. As the portion of agricultural land devoted to production of GMOs increases throughout the world, Japan may face challenges in securing enough non-GM agricultural products to meet the demand. In summary, Japan's policies involving GMOs are likely to become more and more important in the future.

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Appendix. GMO compass in Japan.

Commodity	Trait	Genetic event	Applicant	First approval
Potatoes	Insect tolerant	BT-6	Monsanto Japan	2011
	Insect tolerant, virus tolerant	RBMT15-101	Monsanto Japan	2003
		RBMT21-129	Monsanto Japan	2001
		RBMT21-350	Monsanto Japan	2001
		RBMT22-82	Monsanto Japan	2001
		SEMT15-02	Monsanto Japan	2003
		SEMT15-15	Monsanto Japan	2003
	Insect tolerant	SPBT02-5	Monsanto Japan	2001
Soybeans	High-oleic acid	260-05	DuPont	2001
	High-oleic acid, acetolactate synthase resistance, herbicide tolerant	305423*40-3-2	DuPont	2010
	Herbicide tolerant	40-3-2	Monsanto Japan	2001
		A2704-12	Bayer CropScience (Germany)	2002
		A5547-127	Bayer CropScience (Germany)	2002
		BPS-CV127-9	BASF Japan	2012
		CV127	BASF Japan	2012
	High-oleic acid, acetolactate synthase resistance	DP-305423-1	DuPont	2010
	Herbicide tolerant, acetolactate synthase resistance	DP-356043-5	DuPont	2009
	Insect tolerant	MON87701	Monsanto Japan	2011
	Insect tolerant, herbicide tolerant	MON87701*MON89788	Monsanto Japan	2011
	Low saturated fat, high-oleic acid, herbicide tolerant	MON87705	Monsanto Japan	2012
	Herbicide tolerant	MON89788	Monsanto Japan	2007
Canola	Herbicide tolerant	HCN10	Bayer CropScience (Germany)	2001
		HCN92	Bayer CropScience (Germany)	2001

Appendix. GMO compass in Japan.

Commodity	Trait	Genetic event	Applicant	First approval
Canola, cont'd	Herbicide tolerant, male sterility, fertility restorer	MS1RF1	Bayer CropScience (Germany)	2001
		MS1RF2	Bayer CropScience (Germany)	2001
		MS8	Bayer CropScience (Germany)	2001
		MS8*RF3*RT73	Bayer CropScience (Germany)	2010
	Herbicide tolerant, male sterility	MS8*RT73	Bayer CropScience (Germany)	2011
	Herbicide tolerant, male sterility, fertility restorer	MS8RF3	Bayer CropScience (Germany)	2001
	Herbicide tolerant	PGS1	Bayer CropScience (Germany)	2001
		PGS2	Bayer CropScience (Germany)	2001
		PHY14	Bayer CropScience (Germany)	2001
		PHY23	Bayer CropScience (Germany)	2001
		PHY35	Bayer CropScience (Germany)	2001
		PHY36	Bayer CropScience (Germany)	2001
	Herbicide tolerant, fertility restorer	RF3	Bayer CropScience (Germany)	2001
		RF3*RT73	Bayer CropScience (Germany)	2011
	Herbicide tolerant	RT200	Monsanto Japan	2001
		RT73	Monsanto Japan	2001
		T45	Bayer CropScience (Germany)	2001
		Topas19/2	Bayer CropScience (Germany)	2001
		WESTAR-Oxy-235	Bayer CropScience (Germany)	2001
Sugar beet	Herbicide tolerant	77	Monsanto Japan	2003
	Herbicide tolerant	H7-1	Monsanto Japan	2003
	Herbicide tolerant	T120-7	Bayer CropScience (Germany)	1999
Maize	Insect tolerant, herbicide tolerant	1507	DuPont	2002
	Heat-tolerant alpha amylase	3272	Syngenta Seeds AG (Switzerland)	2010
	Insect tolerant, herbicide tolerant	1507*DAS-59122-7	DuPont	2005
		1507*DAS-59122-7*MON810	DuPont	2011
		1507*DAS-59122-7*MON88017	Dow Chemical Japan Ltd., Monsanto Japan	2008
		1507*GA21	Syngenta Seeds AG (Switzerland)	2010
		1507*MIR604*NK603	DuPont	2011
		1507*MON810	DuPont	2011
		1507*MON810*NK603	DuPont	2009
		1507*MON88017	Dow Chemical Japan Ltd., Monsanto Japan	2008
	Insect tolerant, herbicide tolerant	1507*NK603	DuPont	2003
		1507*5307	Syngenta Japan Co.	2013
		1507*5307*GA21	Syngenta Japan Co.	2013
		1507*59122*MON810*NK603*MIR604	DuPont	2012
		1507*DAS40278	Dow Chemical Japan Ltd.	2013
		1507*DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
		1507*DAS-59122-7*MON810*MIR604	DuPont	2012
		1507*DAS-59122-7*MON810*NK603	DuPont	2009

Appendix. GMO compass in Japan.

Commodity	Trait	Genetic event	Applicant	First approval
Maize, cont'd	Insect tolerant, herbicide tolerant, cont'd	1507*DAS-59122-7*MON810*NK603*MIR604	DuPont	2012
		1507*DAS-59122-7*NK603*MIR604	DuPont	2012
		1507*MIR162*NK603	DuPont	2013
		1507*MON810*MIR162	DuPont	2013
		1507*MON810*MIR162*NK603	DuPont	2013
		1507*MON810*MIR604	DuPont	2012
		1507*MON810*NK603*MIR604	DuPont	2012
		1507*MON88017*DAS40278	Dow Chemical Japan Ltd.	2013
		1507*MON88017*DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
		1507*NK603*DAS40278	Dow Chemical Japan Ltd.	2013
	Heat-tolerant alpha amylase, insect tolerant, herbicide tolerant	3272*Bt11	Syngenta Seeds AG (Switzerland)	2010
		3272*Bt11*GA21	Syngenta Seeds AG (Switzerland)	2010
		3272*Bt11*MIR604	Syngenta Seeds AG (Switzerland)	2010
		3272*Bt11*MIR604*GA21	Syngenta Seeds AG (Switzerland)	2010
	Heat-tolerant alpha amylase, insect tolerant	3272*GA21	Syngenta Seeds AG (Switzerland)	2010
		3272*MIR604	Syngenta Seeds AG (Switzerland)	2010
	Heat-tolerant alpha amylase, insect tolerant, herbicide tolerant	3272*MIR604*GA21	Syngenta Seeds AG (Switzerland)	2010
	Insect tolerant, herbicide tolerant	5307*GA21	Syngenta Japan Co.	2013
		Bt11	Syngenta Seeds AG (Switzerland)	2001
		Bt11 (sweet corn)	Syngenta Seeds AG (Switzerland)	2001
		Bt11*1507	Syngenta Seeds AG (Switzerland)	2010
		Bt11*1507*GA21	Syngenta Seeds AG (Switzerland)	2010
	Insect tolerant, herbicide tolerant	Bt11*DAS-59122-7*1507	Syngenta Japan Co.	2011
		Bt11*DAS-59122-7*1507*GA21	Syngenta Japan Co.	2011
		Bt11*DAS-59122-7*GA21	Syngenta Japan Co.	2011
		Bt11*DAS-59122-7*MIR604*1507	Syngenta Japan Co.	2011
		Bt11*DAS-59122-7*MIR604*GA21	Syngenta Japan Co.	2011
		Bt11*DAS-59122-7*MIR604	Syngenta Japan Co.	2011
		Bt11*GA21	Syngenta Seeds AG (Switzerland)	2007
		Bt11*MIR162	Syngenta Seeds AG (Switzerland)	2010
		Bt11*MIR162*1507	Syngenta Seeds AG (Switzerland)	2010
		Bt11*MIR162*1507*GA21	Syngenta Seeds AG (Switzerland)	2010
		Bt11*MIR162*MIR604	Syngenta Seeds AG (Switzerland)	2010
		Bt11*MIR162*MIR604*GA21	Syngenta Seeds AG (Switzerland)	2010
		Bt11*MIR604	Syngenta Seeds AG (Switzerland)	2007
		Bt11*MIR604*1507	Syngenta Japan Co.	2011
		Bt11*MIR604*1507*GA21	Syngenta Japan Co.	2011
		Bt11*MIR604*GA21	Syngenta Seeds AG (Switzerland)	2007
		Bt11*1507*5307	Syngenta Japan Co.	2013
		Bt11*1507*5307*GA21	Syngenta Japan Co.	2013
		Bt11*5307	Syngenta Japan Co.	2013
		Bt11*5307*GA21	Syngenta Japan Co.	2013

Appendix. GMO compass in Japan.

Commodity	Trait	Genetic event	Applicant	First approval
Maize, cont'd	Insect tolerant, herbicide tolerant, cont'd	Bt11*DAS-59122-7	Syngenta Japan Co.	2011
		Bt11*DAS-59122-7*MIR604*1507*GA21	Syngenta Japan Co.	2010
		Bt11*GA21 (sweet corn)	Syngenta Japan Co.	2012
		Bt11*MIR162 (sweet corn)	Syngenta Japan Co.	2012
		Bt11*MIR162*1507*5307	Syngenta Japan Co.	2013
		Bt11*MIR162*1507*5307*GA21	Syngenta Japan Co.	2013
		Bt11*MIR162*5307	Syngenta Japan Co.	2013
		Bt11*MIR162*GA21	Syngenta Seeds AG (Switzerland)	2010
		Bt11*MIR162*GA21 (sweet corn)	Syngenta Japan Co.	2012
		Bt11*MIR162*MIR604*1507	Syngenta Japan Co.	2013
	Insect tolerant, herbicide tolerant	Bt11*MIR162*MIR604*1507*5307	Syngenta Japan Co.	2013
		Bt11*MIR162*MIR604*1507*5307*GA21	Syngenta Japan Co.	2013
		Bt11*MIR162*MIR604*1507*GA21	Syngenta Japan Co.	2013
		Bt11*MIR162*MIR604*5307	Syngenta Japan Co.	2013
		Bt11*MIR162*MIR604*5307*GA21	Syngenta Japan Co.	2013
		Bt11*MIR604*1507*5307	Syngenta Japan Co.	2013
		Bt11*MIR604*1507*5307*GA21	Syngenta Japan Co.	2013
		Bt11*MIR604*5307	Syngenta Japan Co.	2013
		Bt11*MIR604*5307*GA21	Syngenta Japan Co.	2013
	Herbicide tolerant	DAS40278	Dow Chemical Japan Ltd.	2012
	Insect tolerant, herbicide tolerant	DAS-59122-7	DuPont	2005
		DAS-59122-7*MON810*NK603	DuPont	2011
		DAS-59122-7*1507*GA21	Syngenta Japan Co.	2011
		DAS-59122-7*1507*NK603	DuPont	2005
		DAS-59122-7*GA21	Syngenta Japan Co.	2011
	Insect tolerant, herbicide tolerant	DAS-59122-7*MIR604*1507	Syngenta Japan Co.	2011
		DAS-59122-7*MIR604*1507*GA21	Syngenta Japan Co.	2011
		DAS-59122-7*MIR604*GA21	Syngenta Japan Co.	2011
		DAS-59122-7*MON810	DuPont	2011
		DAS-59122-7*MON88017	Dow Chemical Japan Ltd., Monsanto Japan	2008
		DAS-59122-7*NK603	DuPont	2005
		DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
		DAS-59122-7*MIR604	Syngenta Japan Co.	2011
		DAS-59122-7*MON810*MIR604	DuPont	2012
		DAS-59122-7*MON810*NK603*MIR604	DuPont	2012
		DAS-59122-7*NK603*MIR604	DuPont	2012
		DBT418	Monsanto Japan	2001
	Herbicide tolerant	DLL25	Monsanto Japan	2001
	Insect tolerant, herbicide tolerant	Event 176	Syngenta Seeds AG (Switzerland)	2001
	Herbicide tolerant	GA21	Monsanto Japan	2001

Appendix. GMO compass in Japan.

Commodity	Trait	Genetic event	Applicant	First approval
Maize, cont'd	Herbicide tolerant	GA21 (sweet corn)	Syngenta Japan Co.	2012
	Insect tolerant, herbicide tolerant	GA21*MON810	Monsanto Japan	2001
	High-lysine	LY038	Monsanto Japan	2007
	High-lysine, herbicide tolerant	LY038*MON810	Monsanto Japan	2007
	Insect tolerant	MIR162	Syngenta Seeds AG (Switzerland)	2010
		MIR162 (sweet corn)	Syngenta Japan Co.	2012
	Insect tolerant, herbicide tolerant	MIR162*1507	Syngenta Seeds AG (Switzerland)	2010
		MIR162*1507*GA21	Syngenta Seeds AG (Switzerland)	2010
		MIR162*GA21	Syngenta Seeds AG (Switzerland)	2010
	Insect tolerant	MIR162*MIR604	Syngenta Seeds AG (Switzerland)	2010
	Insect tolerant, herbicide tolerant	MIR162*MIR604*GA21	Syngenta Seeds AG (Switzerland)	2010
		MIR162*1507*5307	Syngenta Japan Co.	2013
		MIR162*1507*5307*GA21	Syngenta Japan Co.	2013
	Insect tolerant	MIR162*5307	Syngenta Japan Co.	2013
	Insect tolerant, herbicide tolerant	MIR162*5307*GA21	Syngenta Japan Co.	2013
		MIR162*GA21 (sweet corn)	Syngenta Japan Co.	2011
		MIR162*MIR604*1507	Syngenta Japan Co.	2013
		MIR162*MIR604*1507*5307	Syngenta Japan Co.	2013
		MIR162*MIR604*1507*5307*GA21	Syngenta Japan Co.	2013
		MIR162*MIR604*5307*GA21	Syngenta Japan Co.	2013
		MIR162*NK603	DuPont	2013
	Insect tolerant	MIR604	Syngenta Seeds AG (Switzerland)	2007
	Insect tolerant, herbicide tolerant	MIR604*1507	Syngenta Japan Co.	2011
		MIR604*1507*GA21	Syngenta Japan Co.	2011
		MIR604*GA21	Syngenta Seeds AG (Switzerland)	2007
	Drought tolerant, herbicide tolerant	MIR604*NK603	DuPont	2011
	Insect tolerant, herbicide tolerant	MIR604*1507*5307	Syngenta Japan Co.	2013
		MIR604*1507*5307*GA21	Syngenta Japan Co.	2013
	Insect tolerant	MIR604*5307	Syngenta Japan Co.	2013
	Insect tolerant, herbicide tolerant	MIR604*5307*GA21	Syngenta Japan Co.	2013
	Insect tolerant, herbicide tolerant	MIR604*GA21	Syngenta Seeds AG (Switzerland)	2007
	Insect tolerant	MON810	Monsanto Japan	2001
		MON810*MON863	Monsanto Japan	2004
		MON810*MIR162	DuPont	2013
	Insect tolerant, herbicide tolerant	MON810*MIR162*NK603	DuPont	2013
		MON810*MIR604	DuPont	2012
		MON810*NK603*MIR604	DuPont	2012
	Insect tolerant	MON863	Monsanto Japan	2002
	Insect tolerant, herbicide tolerant	MON863*MON810*NK603	Monsanto Japan	2004
		MON863*NK603	Monsanto Japan	2003
	Herbicide tolerant, male sterility	MON87427	Monsanto Japan	2013
	Herbicide tolerant	MON87427	Dow Chemical Japan Ltd.	2013
	Drought tolerant	MON87460	Monsanto Japan	2011

Appendix. GMO compass in Japan.

Commodity	Trait	Genetic event	Applicant	First approval
Maize, cont'd	Drought tolerant, insect tolerant, herbicide tolerant	MON87460*MON88017	Monsanto Japan	2011
	Drought tolerant, insect tolerant	MON87460*MON89034	Monsanto Japan	2011
	Drought tolerant, insect tolerant, herbicide tolerant	MON87460*MON89034*MON88017	Monsanto Japan	2011
		MON87460*MON89034*NK603	Monsanto Japan	2011
	Drought tolerant, herbicide tolerant	MON87460*NK603	Monsanto Japan	2011
	Insect tolerant, herbicide tolerant	MON88017	Monsanto Japan	2005
		MON88017*MON810	Monsanto Japan	2005
		MON88017*DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
	Insect tolerant	MON89034	Monsanto Japan	2007
	Insect tolerant, herbicide tolerant	MON89034*1507	Dow Chemical Japan Ltd., Monsanto Japan	2008
		MON89034*1507*DAS-59122-7*MON88017	Dow Chemical Japan Ltd., Monsanto Japan	2008
		MON89034*1507*MON88017	Dow Chemical Japan Ltd., Monsanto Japan	2008
		MON89034*1507*NK603	Dow Chemical Japan Ltd., Monsanto Japan	2010
		MON89034*DAS-59122-7*MON88017	Dow Chemical Japan Ltd., Monsanto Japan	2008
		MON89034*MON88017	Monsanto Japan	2007
		MON89034*NK603	Monsanto Japan	2007
		MON89034*1507*DAS40278	Dow Chemical Japan Ltd.	2013
	Insect tolerant, herbicide tolerant	MON89034*1507*DAS-59-122-7	Dow Chemical Japan Ltd., Monsanto Japan	2008
		MON89034*1507*DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*1507*MON88017*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*1507*MON88017*DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*1507*NK603	Dow Chemical Japan Ltd.	2010
		MON89034*1507*NK603*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*DAS-59122-7	Dow Chemical Japan Ltd., Monsanto Japan	2008
		MON89034*DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*MON88017*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*MON88017*DAS-59122-7*DAS40278	Dow Chemical Japan Ltd.	2013
		MON89034*NK603*DAS40278	Dow Chemical Japan Ltd.	2013
	Herbicide tolerant	NK603	Monsanto Japan	2001
	Insect tolerant, herbicide tolerant	NK603*MON810	Monsanto Japan	2002
	Herbicide tolerant	NK603*T25	Monsanto Japan	2009

Appendix. GMO compass in Japan.

Commodity	Trait	Genetic event	Applicant	First approval
Maize, cont'd	Herbicide tolerant, cont'd	NK603*DAS40278	Dow Chemical Japan Ltd.	2013
		T14	Bayer CropScience (Germany)	2001
		T25	Bayer CropScience (Germany)	2001
	Insect tolerant, herbicide tolerant	T25*MON810	DuPont	2001
		TC6275	Dow Chemical Japan Ltd.	2007
Cotton	Insect tolerant, herbicide tolerant	281	Dow Chemical Japan Ltd.	2005
	Insect tolerant	531	Monsanto Japan	2001
		757	Monsanto Japan	2001
	Herbicide tolerant	1445	Monsanto Japan	2001
	Insect tolerant, herbicide tolerant	3006	Dow Chemical Japan Ltd.	2005
	Insect tolerant	15985	Monsanto Japan	2002
	Insect tolerant, herbicide tolerant	1445*531	Monsanto Japan	2003
	Insect tolerant	15985 (Pima cotton)	Monsanto Japan	2010
	Insect tolerant, herbicide tolerant	15985*1445	Monsanto Japan	2003
		281*3006	Dow Chemical Japan Ltd.	2005
	Insect tolerant, herbicide tolerant	281*3006*1445	Dow Chemical Japan Ltd.	2006
		281*3006*MON88913	Dow Chemical Japan Ltd.	2006
	Herbicide tolerant	BXN cotton 10211	Stoneville Pedigreed Seed (USA)	2001
		BXN cotton 10215	Stoneville Pedigreed Seed (USA)	2001
		BXN cotton 10222	Stoneville Pedigreed Seed (USA)	2001
	Insect tolerant	COT102	Syngenta Japan Co.	2012
		COT67B	Syngenta Japan Co.	2012
	Insect tolerant, herbicide tolerant	GHB119	Bayer CropScience (Germany)	2012
	Herbicide tolerant	GHB614	Bayer CropScience (Germany)	2010
	Insect tolerant, herbicide tolerant	GHB614*15985	Bayer CropScience (Germany)	2010
	Herbicide tolerant	GHB614*LLCotton25	Bayer CropScience (Germany)	2010
	Insect tolerant, herbicide tolerant	GHB614*LLCotton25*15985	Bayer CropScience (Germany)	2010
	Herbicide tolerant	LLCotton25	Bayer CropScience (Germany)	2004
	Insect tolerant, herbicide tolerant	LLCotton25*15985	Bayer CropScience (Germany)	2006
	Herbicide tolerant	MON88913	Monsanto Japan	2005
		MON88913 (Pima cotton)	Monsanto Japan	2010
	Insect tolerant, herbicide tolerant	MON88913*15985	Monsanto Japan	2005
Alfalfa	Herbicide tolerant	J101	Monsanto Japan	2005
		J163	Monsanto Japan	2005
		J101*J163	Monsanto Japan	2005
Papaya	Virus tolerant	55-1	Hawaii Papaya Industry Assoc.	2011

Source: MAFF (2013), MHLW (2013)