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Food Use of Biotech Grains Continues to Increase

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Report Highlights:
This report provides current information on the sale, marketing, and regulation of biotech foods and feeds 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 corn and 4.2 million metric ton soybeans, most 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.

In spite of this, Japanese consumers remain wary about having biotech foods at 'the end of their chopsticks.' In response, the Japanese government has over the years taken extensive regulatory measures to address public concerns. These include mandatory biotech labeling, complex and

lengthy safety food and feed reviews, and Biosafety Protocol-based environmental rules.

Major U.S. technology and producer groups have pledged to gain Japanese government approval before making new biotech traits available to American farmers and, in this sense, Japanese regulators influence the production technology choices available to U.S. farmers. While Japan's regulatory system is complex and costly, it does function and to date 88 biotech products have been approved for food use.

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, no explicitly labeled 'GMO' foods are yet on the market in Japan.

Japanese farmers do not commercially grow any biotech food crops and are unlikely to do so 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 the crops chosen do not have the economic potential to justify the costs associated with surmounting Japan's regulatory system.

The Japanese government, through education and outreach programs, is making an effort to reconcile the reality of widespread biotech use with consumer concerns.

Section II. Biotechnology Trade and Production:
Processed Products

In Japan, three types of biotech claims may be made with regard to food: Non-GMO, GMO and non-segregated. To make labeling claims about foods or ingredients in the first category, the commodities must be handled under identity preservation (IP) system and segregated. 'GMO' products must be labeled. Finally, 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.

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	potato chips

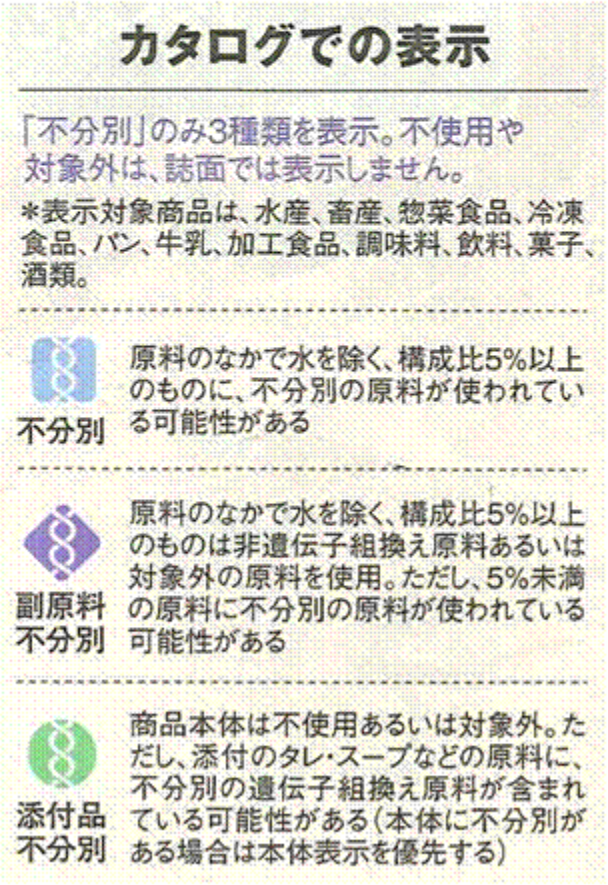
	protein	
Soybean	Soy sauce	dressing, rice crackers
	Soybean sprout	Supplements
	Margarine	snacks, supplements
	Hydrolyzed protein	pre-cooked eggs, past, beef jerky, potato chips
Canola	Canola oil	fried snacks, chocolate, mayonnaise

Source: Modified from the Nikkei Biotechnology Annual, 2009

Despite the widespread use of biotech ingredients, manufacturers and retailers still show a bias against their use. A good example is the Japanese Consumers' Co-operative Union (JCCU), 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 recent catalog, JCCU provided an explanation of why they use biotech ingredients focusing on the difficulties 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 on the environment, and economic concentration in the commercial seed industry.

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 be used (excluding water). The purple diamond in the middle indicates that ingredients consisting of up to 5% 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)

Grains

Japan is the largest export market for U.S. corn and is forecast to buy over 16 million metric tons in the coming crop year. Japan is heavily dependent on the United States for its supply and it is estimated that 80% of the U.S. corn crop is comprised of biotech varieties. Feed use accounts for about 75% of Japan's corn consumption and it is assumed that all feed-use corn contains biotech varieties. 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. For 2009, industry sources estimate that up to 2 million metric tons of 'non-segregated' (i.e., biotech) corn will be used for food uses that do not require labeling under Japanese law (e.g. starch, sweeteners, etc.).

Japanese Corn Imports *(1,000 MT – CY 2008)*	
Corn for feed	
United States	10,728
Argentina	54
China	2

Brazil	1
Others	56
Total Feed	10,841
Corn for food, starch, manufacturing	
United States	5,549
Argentina	33
Australia	0
China	0
South Africa	0
Brazil	5
Others	30
Total Food & Other	5,617
Total	16,459
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 processing 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 do not face consumer resistance. However, Japan's biotech labeling rules would 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).

At What Point Has 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. However, 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 apprehensions biotech foods and, perhaps more importantly, the implications for actual purchasing behavior. Still, consumer-ready food products explicitly labeled as 'GMO' are not yet carried by retailers in Japan and, in this sense, the market remains untested.

Production

There is no commercial production of biotech food crops in Japan. A few pioneering farmers have in the past 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.

Section III. New Technologies:

MAFF is devoting a significant human and financial resources to basic research into genomics and biotech crop development. Example of this effort can be seen in Japan's contribution in rice genome sequencing as well as genome analysis of other plants such as soybean and *Solanaceae* plants. To build public support for research, MAFF's Agriculture, Forestry and Fisheries Research Council (AFFRC) published a report titled, '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. In JFY2009, AFFRC-MAFF will hold 50 risk communication events in various locations in Japan. Also, the report lays out a goal that biotech events researched and developed in Japan also be grown, distributed and consumed in Japan. The report sets out a five year time line 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 but only multinational companies have the needed regulatory experience and resources to gain full approval for a food crop. Industry sources estimate that a single food approval in Japan costs millions of dollars and can take up to three years. Futhermore, for most of the crops common to Japanese agriculture (e.g., horticultural crops), the size of the seed market would not justify Japan-specific biotech product development. Finally, since most of the likely products to would have to be labeled, there would remain the possibility of consumer rejection.

Section IV. 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 in charge of feed and environmental safety. The Food Safety Commission (FSC), an independent risk assessment body, performs food and feed safety risk assessment for MHLW and MAFF.

Type of Approval	Examining body	Jurisdiction	Legal Basis	Main Points Considered
Safety as food	Food Safety Commission	Cabinet Office	Basic Law on Food Safety	• Safety of host plants, genes used in the modification, and the vectors • Safety of proteins produced as a result of genetic modification, particularly their allergenicity. • Potential for unexpected transformations as the result of genetic modification • Potential for significant changes in the nutrient content of food
Safety as animal feed	Agricultural Materials Council	Ministry of Agriculture, Forestry, and Fisheries	Law Concerning the Safety and Quality Improvement of Feed (the Feed Safety Law)	• Any significant changes in feed use compared with existing traditional crops • Potential for the production of toxic substances (especially with regard to interactions between the transformation and the metabolic system of the animal)
Impact on biodiversity	Biodiversity Impact Assessment Group	Ministry of Agriculture, Forestry, and Fisheries Ministry of the Environment	Law Concerning Securing of Biological Diversity (Regulation of the Use of Genetically Modified Organisms)	• Competitive superiority • Potential production of toxic substances • Cross-pollination

Regulatory Process

In Japan, commercialization of biotech plants 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) also 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 are mainly made up of researchers, academics, and 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 back the decision to the responsible ministries. The minister of each ministry then the typically approves the product.

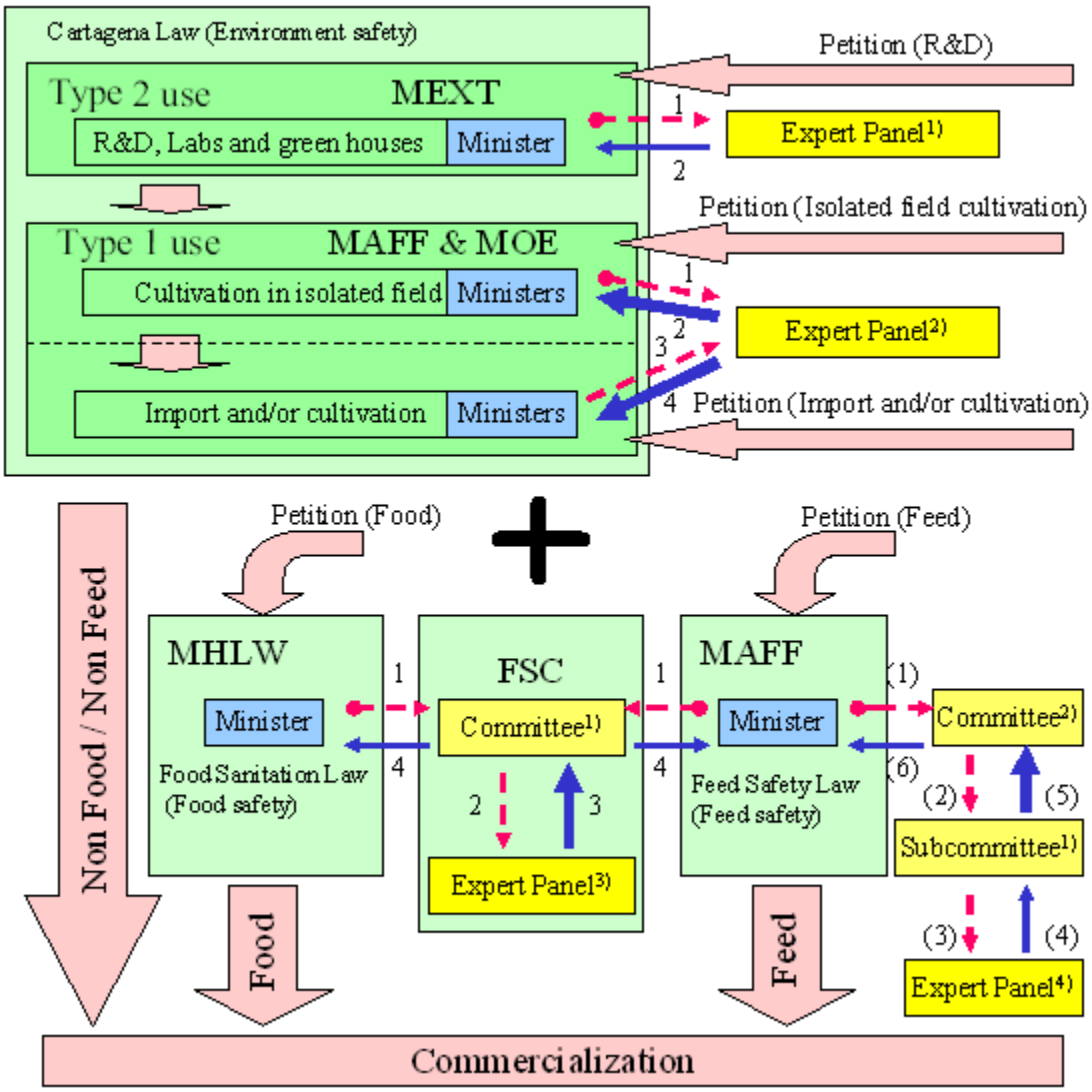
Biotech plants that are used for food must obtain food safety approvals from the MHLW Minister. Based on the Food Sanitation Law, and upon receiving a petition for review from an interested party (usually a biotech company), the MHLW minister will request the FSC to conduct a food safety review. The FSC is an independent government organization under the Cabinet Office that was established 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 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, the MAFF asks the Experts 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 evualation 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 approvals the feed safety of the biotech event.

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' 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) may be addressed by the Pharmaceutical Affairs and Food Sanitation Council of MHLW, and/or Japan Agricultural Standards Council of MAFF.

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 it ratified 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 Japan Biosafety Clearing House (J-BCH) website.

With regard to the Protocol's potential impact on the international trade in grains, Japan's implementation of the Biosafety Protocol articles 18.2.a (documentation and compliance enforcement) and 27 (Liability and Redress) have 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.

The tenth Conference of the Parties (COP-10) to the CBD will take place in Japan in October 2010.

Approved Biotech Products

As of June, 2009, Japan has approved 88 biotech events for food, 75 for feed, 55 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 except for those developers who requested to maintain the approvals temporarily. All products approved prior to the ratification of the Biosafety Protocol had to be reviewed again before being re-approved.

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.
Attachment E – LMO's for Type 1 Use

Events in Field Trials

The Japanese government requires all entities to obtain approval before performing field trials of biotech crops. Attachment E is a list of those biotech crops approved for field trial (as of June 2009).

TRADE AND APPROVAL POLICY 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. 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) 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 Position on Biotechnology states biotech events

must receive full approval by, 'Japanese regulatory agencies.'

Low Level Presence (LLP) of Unapproved Biotech Events

The Low Level Presence (LLP) of unapproved biotech crops has the potential to disrupt trade 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.

It is illegal to import biotech-derived foods that have not been approved, regardless of the amount, form, or their known safety outside of Japan. Japanese regulatory agencies extensively test and use other enforcement tools, even when there is no apparent health or environmental concern.

Japan has a zero tolerance for unapproved biotech events in foods. To assure compliance, monitoring is in place for both import shipments and processed food products at the retail level. As a part of the monitoring program for imported foods, 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 Policies on LLP

In 2001, Japan began legally requiring safety assessment of biotech foods. This was done under the broad authority contained in Article 11 of the 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 No. 232 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 E32 in non-segregated food use (biotech) corn, and 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 and Bt10, has been phased out by MHLW.

Ministry of Agriculture (MAFF) Policies on LLP

Under the Feed Safety Law, MAFF monitors 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 in the first place, establishes procedures for when an LLP incident happens in the future, and provides a mechanism for ending testing requirements when they are no longer needed (e.g., StarLink).

Ministry of Environment (MOE) Policies on LLP

Japan's environmental rules also have a zero tolerance for living modified organisms (LMOs) that are unapproved. A strict enforcement of this aspect of Japan's environmental rules by either MAFF or the Ministry of Environment is theoretically possible but, to date, this has not hindered trade.

CODEX LLP Supported but Not Implemented

International gudelines on food safety assessments for 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). Japan played a very constructive role in setting the guidelines by hosting meetings and facilitating discussion among Codex members. However, Japan does not fully apply this internationally-recognized approach in the implementation of its own LLP policies. This is especially evident in MHLW's policies, where the Codex Annex could allow for more than a 'zero' tolerance.

Labeling

MAFF and MHLW enforce biotech labeling requirements 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. MAFF's labeling policy on biotech traits is available in English on the internet.

In Japan, three types of biotech claims may be made with regard to food: 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. 'GMO' products must be labeled. Finally, 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 distribution 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 31 foods currently subject to JAS labeling requirements (and MHLW 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 31 foods exceeds 5 percent of total weight of the foods, 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 the 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 according to the above manuals.

Items subject to labeling	Ingredient to be labeled
1. Tofu (soybean curd) and fried tofu	Soybean
2. Dried soybean curd, soybean refuse, yuba	Soybean
3. Natto (fermented soybean)	Soybean
4. To-nyu (soy milk)	Soybean
5. Miso (soybean paste)	Soybean
6. Cooked soybean	Soybean
7. Canned soybean, bottled soybean	Soybean
8. Kinako (roasted soybean flour)	Soybean
9. Roasted soybean	Soybean
10. Item containing food of items 1 to 9 as a main ingredient	Soybean
11. Item containing soybean (for cooking) as a main ingredient	Soybean
12. Item containing soybean flour as a main ingredient	Soybean
13. Item containing soybean protein as a main ingredient	
14. Item containing edamame (green soybean) as a main ingredient	Soybean
15. Item containing soybean sprouts as a main ingredient	Edamame
16. Corn snacks	
17. Corn starch	Soybean sprouts
18. Popcorn	Corn
19. Frozen corn	Corn
20. Canned or bottled corn	Corn
21. Item containing corn flour as a main ingredient	Corn
22. Item containing corn grits as a main ingredient	Corn
23. Item containing corn (for processing) as a main ingredient	Corn Corn
24. Item containing food of items 16 to 20 as a main ingredient	Corn
25. Frozen potato	Corn
26. Dried potato	
27. Potato starch	Potato
28. Potato snacks	Potato
29. Item containing food of items 25 to 28 as a main ingredient	Potato Potato
30. Item containing potato (for processing) as a main ingredient	Potato
31. Item containing alfalfa as a main ingredient	Potato

	Alfalfa

In addition to the 31 food items in the table, Japan applies the biotech labeling on 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 issue of inappropriate, inaccurate, or misleading food labels is a major political concern in Japan. For 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 was a violation of the Japan Agricultural Standards Law because there is currently no commercial production of biotech adzuki and red kidney beans

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 actually quality. As a result, JFTC issued recommendations to suppliers about the use appropriate and objective labeling.

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

Stage 3 Trials Burdensome

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 have the burden of conducting stage III field testing for biotech crops that 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 already approved traits, such as herbicide tolerance and insect resistance. For most stacked products, this is an unwarranted regulatory burden.

MAFF and MOE require environment safety reviews or stacked events but existing data and information on the parent lines may be used. It is generally unnecessary to carry out field trials.

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 the crossed event if the crossing occurs above the subspecies level between a biotech event and a non-biotech event, and if the crossing occurs 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 parents. The FSC requires safety approvals on stacked events between biotech events in 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 feed safety full approvals, the approvals by the Expert Panel are neither subject to MAFF Minister notification nor public comments.

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 need to be held.

Buffer zones must also be established to prevent related plant species in the surrounding environment from 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 in 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 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 MAFF for its research entities.

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). First, farmers must 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.

Next, 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 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 want 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 the knowledge of food safety. Within HFSCC, there is also a separate subcommittee made up of six professional researchers who study the application from 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, however, 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 strict the committee would be in evaluating individual applications.

The Hokkaido prefectural government hosted several additional public meetings from August 2008 to March 2009, to continue to seek input on whether the biotech regulations should be revised. As during the November 2006-February 2007 public forums, attendees once again failed to reach a consensus. It was clear at the most recent meetings, however, 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 previous 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 1) hold additional meetings with a wider variety of participants to increase public understanding about biotech foods and crops; 2) urge the Government of Japan to improve labeling for biotech food products and secure a stable supply of non-biotech seeds; and 3) re-examine the biotech crops ordinance as well as current cross-pollen prevention methods after three years to take into account new approaches to biotech crop management.

2. Ibaragi (Guidelines) - The biotech crop guidelines were set up 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 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 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 ordinance on food safety, 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 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 one of its municipalities that has drawn up ordinances on biotech crops. These 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 would reportedly take 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 regulating biotech crop production. There is an R&D laboratory studying agricultural biotechnology and biotech traits.

Section VI. Capacity Building and Outreach: Japanese Government Activities

In 2008, Japan's Cabinet Office released the results of a biotech awareness survey. The survey 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 biotechnology in agricultural themselves had a negative image of the technology.

In 2002 a committee on Biotechnology Strategy, headed by the Prime Minister, was created to work on biotechnology strategy. In December 2008, this committee issued a report titled, 'Drastic Reform with Effective and Agile Movements for BT (DREAM BT) initiative. One of the 11 prioritie addressed is the public acceptance of biotechnology. Public acceptance of biotechnology is to be promoted in the classroom through risk communication and through governmental leadership. It is hoped by some within the government, notably MAFF, that DREAM BT, will support the eventual cultivation, distribution and consumption of biotech crops developed in Japan.

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 the future, MAFF plans to focus on students and teachers working closely with Ministry of Education. MAFF also plans to work with METI which has been conducting public outreach activities for biotechnology as a new technology.

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:

April 17, 2009 - Lecture on Food Security – A U.S. Embassy Agricultural Attaché gave a lecture titled, 'Managing Risks to Japan's Food Security: The Role of Trade and Technology,' at Yokohama City University. The lecture is the first of 16 lectures on various topics being given by U.S. diplomats living in Japan and provided information on agricultural biotechnology. The presentation may be downloaded in English and Japanese.

February 26 2009 – The U.S. Embassy Discussed the Global Growth of Agricultural Biotechnology

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. The critical role that agricultural biotechnology plays in global food security was discussed. The meeting was featured on the U.S. Embassy Tokyo web page, which receives over one million hits per month.

October 2-3, 2008 - Dr. Nina Fedoroff, the Science and Technology Adviser to the Secretary of State and USAID Administrator, visited Tokyo to build public acceptance for biotech foods. She met with government officials and editors from major media outlets, gave public lectures at the Tokyo American Center and a Japanese government-funded research institute, and did an exclusive TV interview with Japan's largest network

November 7, 2008 – A U.S. Embassy Agricultural staff gave presentations and participated in a round table discussion on risk communication and biotechnology. This event, which was held in Kyoto, was one of a nation-wide series of public outreach events sponsored by MAFF and was the first to include U.S. Embassy representation. About 40 government officials, industry associations, NGOs, and media were present. The Kyoto event was part of larger MAFF communication strategy. In July 2007, the Japanese Cabinet decided on mid and long-term policy goals called 'Innovation 25,' which, among other things, calls for an 'Increase of public awareness on biotechnology, especially agricultural biotechnology.'

June 31-July 1, 2008 – A U.S. Embassy Agricultural Specialist presented at a seminar in Hokkaido titled, 'Agricultural Biotechnology for Improving Environment.' The presentation emphasized the technology's role in addressing world food production under changing environmental conditions and an increasing population, as well as Japan's own food security. The audience included consumers, consumer groups, farmers, regulators, and scientists. The event was organized by Hokkaido Bio-Industry Association, and co-hosted by followings.

On April 21, 2008, U.S. Ambassador J. Thomas Schieffer addressed the 8th annual Life Sciences Summit in Tokyo. About 400 participants from government (including Diet members), industry, academia and the press attended. This annual event is organized by the Life Science Summit Executive Committee, an umbrella organization representing Japan's biotech companies, and is supported the Japan Bioindustry Association (JBA). English and Japanese versions of Ambassador Schieffer's speech were reported in JA8024.

February 29, 2008 – Chargé d'Affaires Joseph Donovan 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. This meeting was featured on the U.S. Embassy Tokyo web page, which receives over one million hits per month.

In February 2008, Japan and the United Sates invited representatives from the 21 APEC economies to a Tokyo workshop to raise awareness in Asia about the risks posed to the international grain trade by proposed liability rules under the Cartagena Protocol on Biosafety.

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
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

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 ACS-BN001-4)	2003	2001
	PHY35	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN004-7 x ACS-BN001-4)	2003	2001
	T45	Bayer Crop Science	Herbicide tolerant	2007 (ACS-BN008-2)	2003	2001
	PGS2	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7xACS-BN002-5)	2003	2001
	PHY36	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7 x ACS-BN002-5)	2003	2001
	PHY23	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2007 (ACS-BN004-7 x ACS-BN002-5)	2003	2001
	Oxy-235	Bayer Crop Science	Herbicide tolerant	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-	N/A	N/A

				40644-4)		
	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 (45)	T-14	Bayer Crop Science	Herbicide tolerant	2006 (ACS-ZM-002-1)	2005	2001
	T-25	Bayer Crop Science	Herbicide tolerant	2004 (ACS-ZM003-2)	2003	2001
	MON810	Monsanto Japan	Insect resistant	2004 (MON-00810-6)	2003	2001
	Bt11	Syngenta Seeds	Insect resistant	2007 (SYN-BT011-1)	2003	2001
	Sweet corn, Bt11	Syngenta Seeds	Insect resistant, herbicide tolerant	2007 (SYN-BT011-1)	-	2001
	Event176	Syngenta Seeds	Insect resistant	2007 (SYN-EV176-9)	2003	2003
	GA21	Monsanto Japan	Herbicide tolerant	2005 (MON-00021-9)	2003	2001
	DLL25	Monsanto Japan	Herbicide tolerant	2006 (DKB-89790-5)	2003	2001
	DBT418	Monsanto Japan	Insect resistant, herbicide tolerant	2007 (DKB-89614-9)	2003	2001
	NK603	Monsanto Japan	Herbicide tolerant	2004 (MON-00603-6)	2003	2001
	MON863	Monsanto Japan	Insect resistant	2004 (MON-00863-5)	2003	2002
	1507	Dow Chemical	Insect resistant and herbicide tolerant	2005 (DAS-01507-1)	2002	2002
	MON88017	Monsanto Japan	Insect resistant, herbicide tolerant	2006 (MON-88017-3)	2006	2005
	Mon863 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00863-5xMON-00603-6)	2003	2003
	GA21 x MON810	Monsanto Japan	Herbicide tolerant, Insect resistant	2005 (MON-00021-9xMON-00810-6)	2001	2003
	NK603 x Mon810	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00603-6xMON-00810-6)	2002	2003
	T25 x MON810	DuPont	Herbicide	2005 (ACS-	2001	2003

		tolerant, Insect resistant	ZM003-2xMON-00810-6)		
1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2005 (DAS-01507-1xMON-00603-6)	2003	2004
Mon810 x Mon863	Monsanto Japan	Insect resistant	2004 (MON-00810-6xMON-00863-5)	2004	2004
Mon863 x MON810 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00863-5xMON-00810-6xMON-00603-6)	2004	2004
59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7)	2006	2005
MON88017 x MON810	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88017-3 x MON-00810-6)	2006	2005
1507 x 59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-01507-1 x DAS-59122-7)	2006	2005
59122 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x MON-00603-6)	2006	2005
59122 x 1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x DAS-01507-1 x MON-00603-6)	2006	2005
LY038	Monsanto Japan	High lysine content	2007 (REN-00038-3)	2007	2007
TC6275	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2008 (DAS-06275-8)	2007	2007
MIR604	Syngenta Seeds	Insect resistant	2007 (SYN-IR604-5)	2007	2007
MON89034	Monsanto Japan	Insect resistant	2008 (MON-89034-3)	2007	2007
Bt11 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-BT011-1 x MON-00021-9)	2007	2007
Bt11 x MIR604	Syngenta Seeds	Herbicide tolerant, Insect resistant	2008 (SYN-BT011-1 x SYN-IR604-5)	2007	2007
MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-IR604-5 x MON-00021-9)	2007	2007
Bt11 x MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect	2008 (SYN-BT011-1 x SYN-	2007	2007

		resistant	IR604-5 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 B.t.Cry34/35Ab1 Event DAS-59122-7 x	Dow Chemical Japan and Monsanto	Herbicide tolerant, Insect resistant	-	2008	2008

	MON88017*	Japan				
	MON89034 x 1507 x B.t.Cry34/35Ab1 Event DAS-59122-7 x MON89017*	Dow Chemical Japan and Monsanto Japan	Herbicide tolerant, Insect resistant	-	2008	2008
Cotton (18)	531	Monsanto Japan	Insect resistant	2004 (MON-00531-6)	1997	2001
	757	Monsanto Japan	Insect resistant	2005 (MON-00757-7)	2003	2001
	1445	Monsanto Japan	Herbicide tolerant	2004 (MON-01445-2)	1998	2001
	10211	Stoneville Pedigreed Seed	Herbicide tolerant	-	-	2001
	10215	Stoneville Pedigreed Seed	Herbicide tolerant	-	1998	2001
	10222	Stoneville Pedigreed Seed	Herbicide tolerant	-	1998	2001
	15985	Monsanto Japan	Insect resistant	2004 (MON-15985-7)	2003	2002
	1445 x 531	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-01445-2xMON-00531-6)	2003	2003
	15985 x 1445	Monsanto Japan	Herbicide tolerant, Insect resistant	2005 (MON-16985-7xMON-01445-2)	2003	2003
	LLCotton25	Bayer Crop Science	Herbicide tolerant	2006 (ACS-GH001-3)	2006	2004
	MON88913	Monsanto Japan	Herbicide tolerant	2006 (MON-88913-8)	2006	2005
	MON88913 x 15985	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88913-8 × MON-15985-7)	2006	2005
	281	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	-	2005	2005
	3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	-	2005	2005
	281 x 3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 (DAS-24236-5×DAS-21023-5)	2006	2005
	281 x 3006 x 1445	Dow Chemicals	Herbicide tolerant, Insect	2006 DAS-24236-5×DAS-	2006	2006

		Japan	resistant	21023-5×MON-01445-2)		
	281 x 3006 x MON88913	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006(DAS-24236-5×DAS-21023-5×MON-88913-8))	2006	2006
	LLCotton 25 x 15985	Bayer Crop Science	Herbicide tolerant, Insect resistant	2007 (ACS-GH001-3×MON-15985-7)	2006	2006
Potato (8)	BT6	Monsanto Japan	Insect resistant	Not needed	N/A	2001
	SPBT02-05	Monsanto Japan	Insect resistant	Not needed	N/A	2001
	RBMT21-129 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	RBMT21-350 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	RBMT22-82 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	SEMT15-15 (NLY)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
	RBMT15-101	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
	New Leaf Y Potato SEMT15-02	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
Rose (2)	WKS82/130-4-1	Suntory	Alteration of flavonoid synthesis pathway	2008 (IFD-52401-4)	N/A	N/A
	WKS82/130-9-1	Suntory	Alteration of flavonoid synthesis pathway	2008 (IFD-52901-9)	N/A	N/A
Soybean (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
				77	85 (53**)	98

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.
* indicate that food review is completed but full approval is not yet granted as of June 10, 2009
** in Feed approvals indicates the number of events excluding stacks, which does not appear on the feed approval table by MAFF.

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 10, 2009).

Products	Name	Characteristics	Developer	Public announcement
alpha-amylase	TS-25	Improved productivity	Novozymes A/S	2001
	BSG-amylase	Improved productivity	Novozymes A/S	2001
	TMG-amylase	Improved productivity	Novozymes A/S	2001
	SP961	Improved productivity	Novozymes A/S	2002
	LE399	Improved productivity	Novozymes A/S	2005
	SPEZYME FRED	Improved heat tolerance	Genencor International, Inc.	2007
Chymosin	Maxiren	Improved productivity	DMS	2001
	CHY-MAX	Improved	CHR HANSEN A/S	2003

		productivity		
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 May 14, 2009)

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	MIR162	Syngenta Seeds	Insect resistant
Cotton	GHB614	Bayer Crop Science	Herbicide tolerant
Corn	DP-098140-6	Dupont	Herbicide tolerant (glyphosate and acetolactate synthase inhibitor)
Soybean	DP-305423-1	Dupont	High oleic acid

Attachment D – Biotech additives under food safety assessment process (as of June 10, 2009)

Products	Name	Applicant/Developer	Characteristics
Hemicellulase	Hemicellulase (XAS)	DSM Nutrition Japan K.K./ DSM Food Specialties B.V.	High productivity
Invertase	Invertase (NIA1718)	Property change	MEIJI SEIKA KAISHA,LTD.
Chitinase	Chitinase (pCHI)	High productivity	NAGASE & CO.,LTD..

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*	Monsanto Japan Limited

	mays subsp. *mays* (L.) Iltis) (MON89034×MON88017, OECD UI: MON-89034-3×MON-88017-3)	
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, Eucalyptus globulus* Labill.)(107-1)	University of Tsukuba
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, Brassica napus* L.)（MS8RF3, OECD UI: ACS-BN005-8×ACS-BN003-6)	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.) (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*	National Institute of

	L.) (7Crp#242-95-7)	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.