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Biotechnology

Annual Report

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Approved by:
Paul Spencer
Senior Agricultural Attaché, Tokyo

Prepared by:
Dr. Suguru Sato

Report Highlights:
Japan is the world's largest per capita importer of foods and feeds that have been produced using modern biotechnology. In spite of this, Japanese consumers remain wary about having biotech foods at 'the end of their chopsticks.' Mandatory labeling discourages the retail sale of products made using biotech ingredients, although there are broad exceptions to this policy. This year, Japanese processors are using biotech corn for the first time in high fructose corn syrup and other unlabeled food products, apparently without a consumer backlash. To date, Japan has approved 88 biotech events for food, 75 for feed, 75 for planting and 14 for food additives. New biotech applications continue to surge and this will pose challenges to Japan's complex regulatory system. Major U.S. technology and producer groups have pledged to gain Japanese approval before making new biotech traits available to American farmers. The low level presence of unapproved biotech varieties remains a trade issue. Japan does not produce any biotech products commercially but does have several under development. This report provides current information on approved biotech events, updates on Japan's regulatory system, biotech research initiatives, and information related to the sale and marketing of biotech crops. General information on other new production technologies, such as animal cloning and nanotechnology, is also included.

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SECTION I – EXECUTIVE SUMMARY

Japan is the world's largest per capita importer of foods and feeds that have been produced using modern biotechnology. Japan annually imports 16 million metric tons corn and 4.2 million metric ton soybeans valued at over $3 billion. Approximately two-third of the imported corn and three-quarters of the imported soybeans 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 mandatory safety food and feed reviews, and domestic regulations that implement a Biosafety Protocol-based environmental review.

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 established in July 2003, performs food and feed safety risk assessment for MHLW and MAFF. 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 does not commercially produce plants that have been enhanced using modern biotechnology. A number of public research institutes are carrying out plant biotechnology research but most have not progressed to the field trial stage because of strong consumer concerns and because the crops chosen do not have the economic potential to justify the costs associated with surmounting Japan's regulatory system. Because there is no market for biotech seeds in Japan, the private sector has little incentive to develop Japan-specific varieties of biotech crops. Major agricultural biotechnology companies do maintain offices in Japan but their primary function is to navigate Japan's complex regulatory approval process for crops produced in other countries rather than to advance technology for use by Japanese farmers.

SECTION II. BIOTECHNOLOGY USE, PRODUCTION, AND RESEARCH

Use

Japan is the largest export market for U.S. corn and is forecast to import 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 now comprised of biotech varieties. Feed use accounts for about 70% of corn consumption and, on average, half of the calories consumed by Japanese livestock come from the United States.

There is a separate market for food-use corn, accounting for about 30% of consumption. Food use corn has for many years been 'non-GMO' and commands a premium over feed corn because it is collected outside of the main U.S. corn marketing channel and because it is physically segregated before and during transport. Recent high premiums for non-biotech/segregated corn are causing the industry to reevaluate its decade old practice of only using biotech corn for feed. In April, Japan's largest corn starch processors announced that they would use biotech corn as a raw material both in industrial products and in some foods, such as high fructose corn sweetener and beer. The food products being manufactured do not contain protein and are thus exempt from Japan's biotech food labeling laws.

Total Imports	**CY 2007**
Corn	Million Metric Tons
Feed	10.75
Tariff Quota for Starch	3.41
Others	2.47
Total:	16.63

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 existing lines of biotech soy, canola, cottonseed and corn 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. Soy sauce is exempted from the labeling rules and it is estimated that 10% of manufacturers use biotech soy meal as an ingredient. As with corn, non-biotech soybean users are concerned about increasing premiums for segregated 'non-GMO' soybeans. Some specialized soybean varieties used in Japanese cuisine, such as those used for tofu, do not usually incorporate biotech traits. However, care steps must be taken in production and distribution so they are not inadvertently mixed with normal soybeans that do contain biotech traits.

Production

There is no commercial production of biotech crops in Japan. A few pioneering farmers have in the past "experimentally" grown biotech soybeans in Japan in order to confirm their benefits. The 'experiment' was terminated before the crop flowered due to concerns from surrounding farmers about cross pollination and concerns from agricultural cooperative opposing biotech crops. There are also numerous local restrictions on growing biotech crops in Japan that further discourage farmers from using the technology, although in theory many biotech traits would be legal to grow.

Research

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. Only large and experienced multinationals are equipped to spend the millions of dollars and, on average, three years to gain full approval for a food crop. For many of the crops commonly grown by Japanese agriculture (e.g., horticultural crops), the size of the seed market would not justify Japan-specific biotech product development. In addition, as the regulatory system has become more complex, only large multinational companies have the experience and expertise to gain full approval. Much of Japan's research is being conducted by universities that are ill equipped to take on the regulatory burden. Finally, since final products would have to be labeled, there would remain the real possibility of consumer rejection.

A number of public research institutes are active in plant and industrial biotech research and development. One popular crop for transformation is rice and Japan has invested over $400 million dollars on a rice genomic project which completed a full sequencing of the rice genome. Consequently, there are a number of experimental field trials including rice containing cedar pollen peptide to suppress allergies and rice tolerant to low iron availability. Following is the list of on-going research from presentations in local academic conferences and seminars.

- Development of male sterile Brassica crops using endogenous promoters and genes
- Transgenic protein production by silk grand.
- Production of transgenic wheat transformed with low-molecular-weight glutenin genes to better understand dough strength.
- Production of transgenic cabbage with a Bt-gene.

Much of this research is in the early experimental stage and has not progressed to field trials. Taking into consideration the time required to obtain necessary regulatory approvals, it will be years before these products are commercially available. One of the earliest candidates might be a biotech rice which mitigates cedar pollen allergies and was developed by the National Institute of Agrobiological Science in Tsukuba. Approval for this product is being sought but as a pharmaceutical rather than a standard food item. Private industry is generally limiting itself to basic research. A uniquely colored (blue) carnation was developed by Suntory Co. but it is grown abroad and imported into Japan.

On June 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.' In July, 2007, MAFF announced a Biodiversity Strategy that emphasizes the importance of biodiversity in local ecosystems as well as the sustainable application and preservation of beneficial genetic resource and the importance biotechnology regulation under the Cartagena Protocol. Also in July 2007, a MAFF-established panel published and interim report identifying seven biotech research priorities, including functional foods (e.g., rice with high GABA accumulation), crops resistant to complex pests (e.g., rice resistant to both filamentous fungi and bacteria), crops adapted to climate change, and biofuels.

SECTION III. BIOTECHNOLOGY POLICY

Regulatory Process

In Japan, commercialization of biotech plants products requires food, feed and environmental approvals. Four ministries are involved in the regulatory framework; the Ministry of Agriculture, Forestry and Fisheries (MAFF), the Ministry of Health, Labor and Welfare (MHLW), Ministry of Environment (MOE), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The Food Safety Commission (FSC), an independent risk assessment body established in 2003, 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.

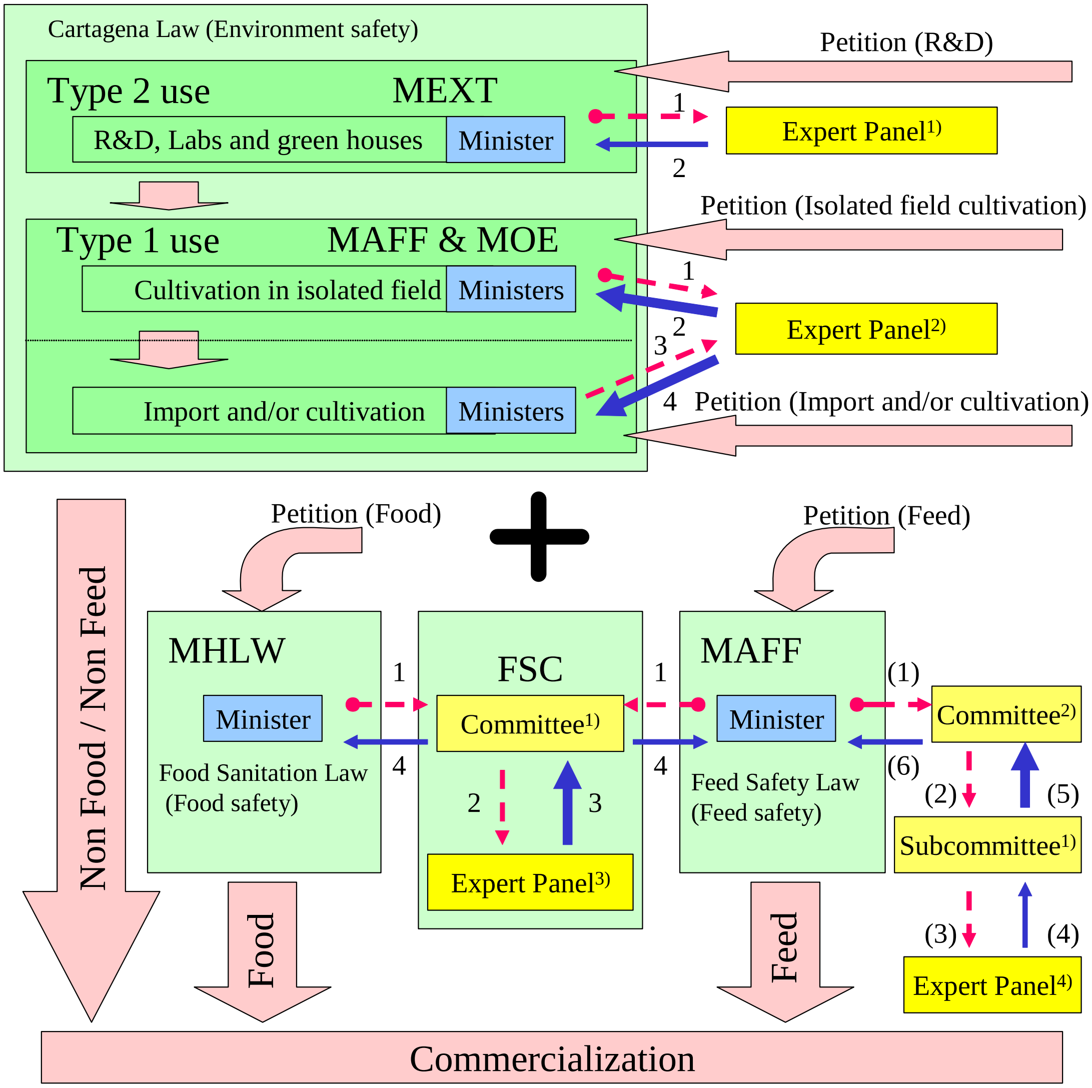
Biotech plants that are used for food must obtain food safety approvals from the MHLW Minister. Based on the Food Sanitation Law, and upon receiving a petition for review from an interested party (usually a biotech company), the MHLW minister will request the FSC to conduct a food safety review. The 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 also used as feed must obtain approvals from the MAFF Minister based on the Feed Safety Law. Upon requests from petitioners, the MAFF Minister asks the Experts Panel on Recombinant DNA Organisms, which is part of the MAFF affiliated Agricultural Materials Committee (AMC), to review the event. The Expert Panel evaluates feed safety on livestock animals, which 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 need to be discussed 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.

Approved Biotech Products

As of June, 2008, 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 in CY2007 and 2008(as of June 2008).

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.

Regulatory Policy Issues and Trade

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 unapproved low level presence of a biotech crop grown in the United States can lead to costly export testing requirements and trade disruptions. To address this issue, the Biotechnology Industry Organization's (BIO) Product Launch Stewardship Policy generally calls for new biotech crops to be approved in Japan before they are introduced in the United States. Similarly, the National Corn Growers Association's Position on Biotechnology states, 'Full Japanese approval must be expected by May 1, of the year seed is released.'

Growing Number of New Traits Entering Regulatory System

For Japanese fiscal years (running April-March) 2008 and 2009, it is estimated that there will be 51 new entrants into the Japanese approval system. Seven of these are traits are new to the Japanese regulatory system (e.g., nutritional enhancement or environmental response). This may challenge the Japanese regulatory system and may require additional resources and expertise to ensure timely approvals. Currently, it can take up to three years to complete fully Japan's biotechnology regulatory process.

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.

Japan has a zero tolerance for unapproved biotech events in foods. To assure compliance, a 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. MAFF also has a testing program in place for unapproved biotech events in feed.

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 Bt10 in all corn, 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). More positively, the 2001 StarLink testing protocol between Japan and the United States was terminated earlier this year.

Ministry of Agriculture (MAFF) Polocies 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 from the regulation, MAFF has 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.

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 for food and feed-use biotech crops but, to date, this has not posed challenges to trade.

Codex LLP Supported but Not Implemented

In 2006, the Codex Task Force agreed to draft international guidance on food safety assessment of low-level presence of genetically modified (GM) products authorized as safe for use in food, feed, etc. The draft was approved late last year and was officially adopted by the commission in July 2008, as the 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 this process 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 the area of food, where the Codex Annex could allow for more than a 'zero' tolerance.

Labeling

MAFF and MHLW have implemented labeling requirements under the Food Sanitation Law and the Japan Agricultural Standards (JAS) Law, respectively for biotech products that have been approved in Japan. MAFF introduced the biotech labeling in response to a demand of "the consumers' right to know" while MHLW introduced its labeling from a more scientific standpoint to clarify that the biotech ingredients used are those whose safety is confirmed. 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.

Both MAFF and MHLW biotech labeling schemes for non-biotech products are based on and rely on IP handling of non-biotech ingredients from production to final processing. The initial suppliers and operators of distribution of the products are responsible for supplying this certification to the exporter to Japan, who in turn supply its certification of IP handling in the U.S. 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. 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	Soybean
14. Item containing edamame (green soybean) as a main ingredient	Edamame
15. Item containing soybean sprouts as a main ingredient	Soybean sprouts
16. Corn snacks	Corn
17. Corn starch	Corn
18. Popcorn	Corn
19. Frozen corn	Corn
20. Canned or bottled corn	Corn
21. Item containing corn flour as a main ingredient	Corn
22. Item containing corn grits as a main ingredient	Corn
23. Item containing corn (for processing) as a main ingredient	Corn
24. Item containing food of items 16 to 20 as a main ingredient	Corn
25. Frozen potato	Potato
26. Dried potato	Potato
27. Potato starch	Potato
28. Potato snacks	Potato
29. Item containing food of items 25 to 28 as a main ingredient	Potato
30. Item containing potato (for processing) as a main ingredient	Potato
31. Item containing alfalfa as a main ingredient	Alfalfa

In addition to the 31 food items in the table, Japan applies the biotech labeling on the 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. 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)

Monitoring of "Biotech" or "Non-Biotech" Labels

Japan recognizes that even though proper IP handling and distribution methods are used, the possibility exists for adventitious commingling of biotech products in non-biotech products. Therefore, for corn and soybeans, Japan set an informal tolerance of 5% for biotech ingredients in products that are labeled "non-biotech." This tolerance only applies to events that have been approved in Japan. If MAFF or MHLW finds a product labeled "non-biotech" that has a biotech (corn and soybeans) content of over 5 %, it is determined that the IP handling had not been carried out adequately. The ministry orders the manufacturer or importer to present the IP handling certificates to verify them and issues guidance directing it to correct the product's label to show that it was made with "Biotech Ingredients."

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 perhaps 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. These are listed below by prefecture along with the prefecture's relative agricultural production. Most, if not all, of these rules are political responses to popular concerns and are not based in science.

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 a series of public forums from November 2006 to February 2007, to seek input on whether the biotech regulations should be revised. Attendees did not reach a consensus, but it was clear at the meetings that local anxiety about biotech crops remains high.

Household surveys taken in 2004 and 2005 by the Hokkaido government before the implementation of the biotech regulations showed that while 80% of respondents are concerned about consuming biotech crops, nearly 70% of respondents also support further research testing on biotech crops.

The Hokkaido Prefectural Government plans to hold several additional meetings in 2008 to discuss possible revisions of the ordinance for 2009.

2. Iwate (Guidelines)

The 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. However, this never happened. Iwate officials now say they still plan 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.

3. Miyagi

Miyagi Prefectural Government expects to announce prefectural rules in 2009. 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.

4. 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).

5. 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.

6. 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.

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)

Although biotech crop production and consumption is allowed by law, consumer safety concerns and farmers' uneasiness with genetic interaction between biotech and conventional crops led to the government to establish guidelines, which 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 Ma 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.

In the case of Tokushima, biotech crop guidelines are stressed as a part of its "farm brand strategy" to compete with other production centers.

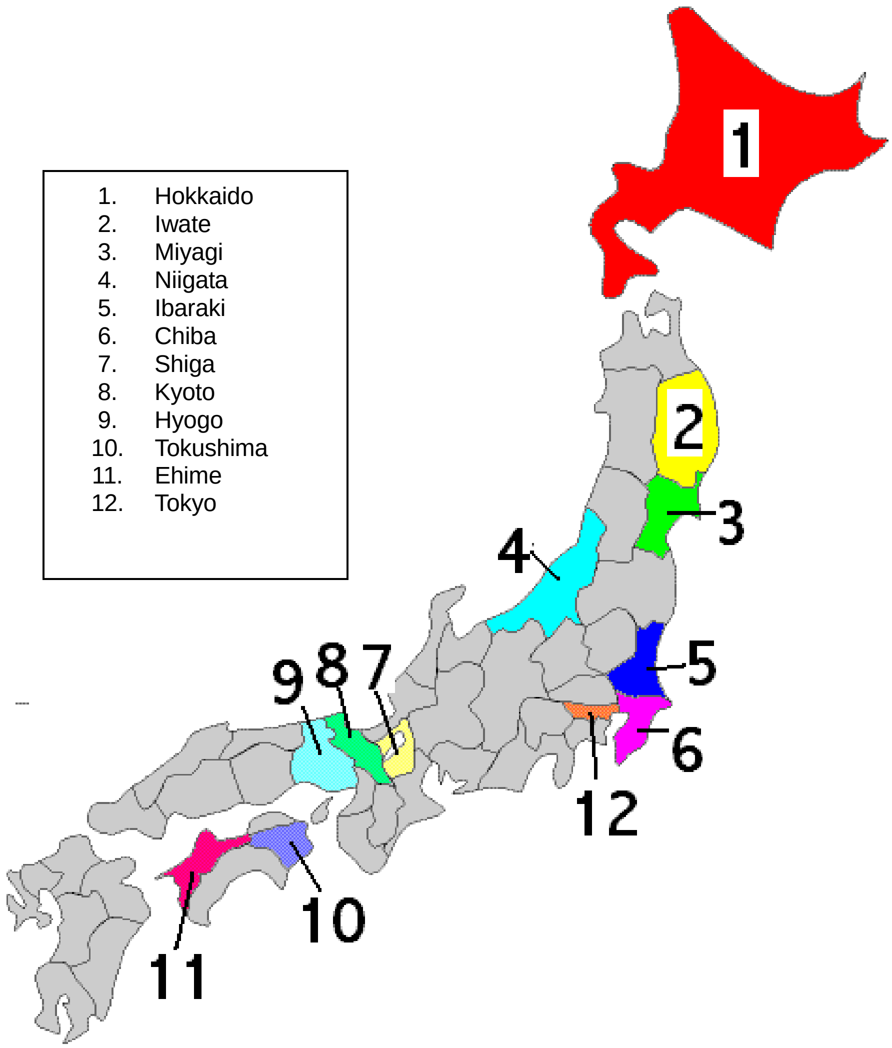
11. Imabari City in Ehime Prefecture (Guidelines)

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.)

Figure 1: Prefectures With Ordinances Or Guidelines On Growing Biotech Crops



Agricultural Output by Prefecture

Rank	Prefecture	Agricultural Output (Billion US$)	% of Total Agricultural Output
1	Hokkaido	9.93	12
2	Chiba	3.83	5
3	Ibaragi	3.81	5
9	Niigata	2.65	3
11	Iwate	2.38	3
22	Hyogo	1.23	2
25	Ehime	1.18	1
31	Tokushima	0.95	1
39	Kyoto	0.65	1
42	Shiga	0.59	1

Source: Ministry of Agriculture, Forestry and Fisheries based on 2005 data.

SECTION IV. OTHER FOOD PRODUCTION TECHNOLOGIES

Somatic Cell Nuclear Transfer (SCNT) Cloning (a reproduction technology)

On April 1, Japan's Ministry of Health asked the independent Food Safety Commission to conduct a risk assessment on products from clones and the offspring of clones. The review is likely to take about a year. Almost concurrently, a research section from the Ministry of Agriculture made public its findings on the safety of clones.

Japanese research into somatic cell clones is advanced and is conducted at government-run facilities. One purpose of the trip was to understand the potential for Japanese cloned animals to be used in commercial milk, for beef, and for breeding programs. Measures are taken to ensure that the somatic clones are not used for breeding programs and their products are tightly controlled and not consumed.

Cloned SCNT 'wagyu' cattle in Obihiro Japan(USDA/Tokyo Photo)

Meat from embryonic clones was briefly sold in 2000-2001 as part of a pilot program that included labeling. The program was discontinued due to negative media coverage.

Nanotechnology

Food nanotechnology research is being conducted in Japan and is listed as one of the priority research targets in the government's, 'Third Science and Technology Basic Plan,' which was announced in March, 2006. (A good history of food nanotechnology in Japan may also be found on the institute of World Food Science website). To date, there are no commercial food products that are openly 'nano-tech.' additionally, the Japanese Government has not established special regulatory guidelines unique to food products meeting a certain 'nano-tech' definition.

SECTION V. MARKETING ISSUES

Although the food industry and the Japanese government can be quite open minded about agricultural biotechnology, they are very cautious about publicly. Consumer concerns, particularly among some small but vocal consumer associations, have been strong since biotech products were first put on the market in late 1990's. As a result, the food industry is hesitant to even attempt to provide a biotech product directly to consumers. In fact, out of a fear of a consumer backlash, retailers, particularly large supermarket chains, demanded the food industry to supply non-biotech foods - even for products that do not have to be labeled, which in turn resulted in procurement of non-biotech raw ingredients by importers. In fact, in the past, many retailers use consumer concerns to their advantage by marketing store brand products as "safer" and "more natural" than those provided by their competitors.

In the context of the global run up in commodity prices, premiums for non-biotech corn and soy have increased significantly. As a result, the current model of 'buy non biotech only when you have to label' is being tested.

Some food products where labeling has not been required have traditionally only used non-biotech ingredients. These include soy sauce, beer, and foods with high fructose corn sweetener. However, the switch to standard biotech commodities is beginning to become more widespread as food manufacturing margins have come under pressure. In July, one manufacturer of soy sauce was quoted as saying, "I hope [a major manufacturer] will take the initiative in leading the entire soy sauce industry toward the use of genetically modified soybeans." Similarly, in April, Japan's largest corn starch processors announced that they would use biotech corn as a raw material both in industrial products and in some foods, such as high fructose corn sweetener and beer. Major beer brewers have privately said they are looking into standard biotech ingredients and one whisky distiller is known to have switched to biotech corn. Although quite widely distributed, none of these foods contain protein and are thus exempt from Japan's biotech food labeling laws.

At the same time, resistance against biotech persists in some food sectors, such as miso and tofu. Hanamaruki, one of major miso manufactures, and the Japan Federation of Miso Manufacturers Cooperatives are seeking alternate, non-biotech soybean suppliers in South America and Australia. In another example, an Aomori Prefecture farmer started producing non-biotech soybeans in Ukraine for export to a Japanese tofu maker.

SECTION VI. CAPACITY BUILDING AND OUTREACH

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:

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.

In the fall of 2007, Ms. Eiko Nakano, a Japanese journalist, traveled widely in the United States as part of the U.S. Department of State's International Visitor Leadership Program (ILVP). The U.S. Embassy in Tokyo worked with contractors and volunteers in the United States to set up a program of visits titled, Current Trends in Agribusiness. The goals of the visit were to:

- Examine U.S. food safety risk management and risk communication;
- Explore the role biotechnology plays in meeting domestic and foreign demand for commodities;

- Learn about bio fuels and their impact on rural America;
- Examine U.S. agricultural trade policies;
- Study U.S. agricultural policies, including budget allocation for subsidies; and
- Determine trends in America's food culture.

Ms. Nakano is Deputy Editor for Biotechnology Japan (BTJ), a portal site of biotechnology-related information with 1.5 million hits per month. She is also the Chief Editor for the wed-based journal Food Science.

On June 20, 2007, USDA and the U.S. Consulate in Sapporo supported the Hokkaido visit of U.S. Grains Council Chairman, Vic Miller. He spoke about the safety of biotech traits used in U.S. corn production and reassured Japanese corn users that the Untied States, is and will continue to be, a reliable supplier. The day included an interview with the Hokkaido Shimbun (Hokkaido's largest newspaper) and Mr. Miller fielded questions on the safety of biotechnology and on the U.S. ability to continue to supply feed to Hokkaido dairy farms. There was a high level of interest in the growing expansion and demand for corn for fuel ethanol in the United States. Mr. Miller then met with a local pro-biotech farmer who is a member of the Japan's Biotech Crop Discussion Group. During a press event at a local dairy farm that uses U.S. corn the questions centered on U.S. corn supply and prices, biotech corn production and the safety of biotech corn. This activity generated three articles.

In April 2007, the USDA Office of Agricultural Affairs at the U.S. Embassy in Tokyo translated and distributed an essay on regulatory history of agricultural biotechnology by Dr. Fred Genthner, a Microbiologist with the U.S. Environmental Protection Agency.

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

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 (5)	11	Suntory	Color change	2004 (FLO-07442-4)	N/A	N/A

	123.2.38	Suntory	Color change	2004 (FLO-40644-4)	N/A	N/A
	123.8.8	Suntory	Color change	2004 (FLO-40685-1)	N/A	N/A
	123.2.2	Suntory	Color change	2004 (FLO-40619-7)	N/A	N/A
	11363	Suntory	Color change	2004 (FLO-11363-1)	N/A	N/A
Corn (36)	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	2004 (MON-00603-6xMON-00810-6)	2002	2003

		resistant			
T25 x MON810	DuPont	Herbicide tolerant, Insect resistant	2005 (ACS-ZM003-2xMON-00810-6)	2001	2003
1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2005 (DAS-01507-1xMON-00603-6)	2003	2004
Mon810 x Mon863	Monsanto Japan	Insect resistant	2004 (MON-00810-6xMON-00863-5)	2004	2004
Mon863 x MON810 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00863-5xMON-00810-6xMON-00603-6)	2004	2004
59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7)	2006	2005
MON88017 x MON810	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88017-3 x MON-00810-6)	2006	2005
1507 x 59122	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-01507-1 x DAS-59122-7)	2006	2005
59122 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x MON-00603-6)	2006	2005
59122 x 1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x DAS-01507-1 x MON-00603-6)	2006	2005
LY038	Monsanto Japan	High lysine content	2007 (REN-00038-3)	2007	2007
TC6275	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2008 (DAS-06275-8)	2007	2007
MIR604	Syngenta Seeds	Insect resistant	2007 (SYN-IR604-5)	2007	2007
MON89034	Monsanto Japan	Insect resistant	2008 (MON-89034-3)	2007	2007
Bt11 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-BT011-1 x MON-00021-9)	2007	2007
Bt11 x MIR604	Syngenta Seeds	Herbicide tolerant,		2007	2007

			Insect resistant			
	MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant	2007 (SYN-IR604-5 x MON-00021-9)	2007	2007
	Bt11 x MIR604 x GA21	Syngenta Seeds	Herbicide tolerant, Insect resistant			2007
	LY038 x MON810	Monsanto Japan	High lysine content, Insect resistant	2007 (REN-00038-3 x MON-00810-6)	2007	2007
	MON89034 x MON88017	Monsanto Japan	Herbicide tolerant, Insect resistant			2008
	MON89034 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant			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,	2006 (MON-88913-8	2006	2005

			Insect resistant	× MON-15985-7)		
	281	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	-	2005	2005
	3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	-	2005	2005
	281 x 3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 (DAS-24236-5×DAS-21023-5)	2006	2005
	281 x 3006 x 1445	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 DAS-24236-5×DAS-21023-5×MON-01445-2)	2006	2006
	281 x 3006 x MON88913	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006(DAS-24236-5×DAS-21023-5×MON-88913-8))	2006	2006
	LLCotton 25 x 15985	Bayer Crop Science	Herbicide tolerant, Insect resistant	2007 (ACS-GH001-3×MON-15985-7)	2006	2006
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
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
				75 (1*)	75 (52**)	88

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.
* in BSP approvals indicates temporary approvals until full risk assessment completes.
** in Feed approvals indicates the number of events excluding stacks, which 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.

Products	Name	Characteristics	Developer	Public announcement
-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	Genencor	2007

		tolerance	International, Inc.	
Chymosin	Maxiren	Improved productivity	DMS	2001
	CHY-MAX	Improved productivity	CHR HANSEN A/S	2003
Pullulanase	Optimax	Improved productivity	Genencor International, Inc.	2001
	SP962	Improved productivity	Novozymes A/S	2002
Lipase	SP388	Improved productivity	Novozymes A/S	2001
	NOVOZYM677	Improved productivity	Novozymes A/S	2003
Riboflavin	Riboflavin (Vitamin B2)	Improved productivity	F. Hoffmann-La Roche	2001
Glucoamylase	AMG-E	Improved productivity	Novozymes A/S	2002

Attachment C – Biotech crops under food safety assessment process

Plant species	**Trait or Variety**	**Applicant/Developer**	**Characteristics**
Papaya	55-1	Hawaii Papaya Industry Association	Virus resistant
Soybean	DP-356043-5	DuPont	Herbicide-tolerant
Corn	3272	Syngenta Seeds	heat stable amylase

Attachment D – Biotech additives under food safety assessment process

Products	**Name**	**Applicant/Developer**	**Characteristics**
Kinase	Kinase (pNAG)	Nagase & Co., Ltd.	Improved productivity
L-Serine	L-Serine (WSH)	Kyowa Hakko Kogyo Co., Ltd.	Improved productivity

Attachment E - LMO's Type 1 Use

Approval Date	Name of the type of Living Modified Organism	Applicant
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 (	University of Tsukuba

	codA, Eucalyptus globulus Labill.)(2-1-1)	
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* L.) (7Crp#242-95-7)	National Institute of Agrobiological Sciences(NIAS)
2007-7-19	Maize resistant to Lepidoptera(*Modified vip3A, Zea mays* subsp. *mays* (L.) Iltis) (MIR162, OECD UI:SYN-IR162-4)	Syngenta Seeds K.K.
2007-6-26	Rice containing cedar pollen peptide(*7Crp, Oryza sativa* L.) (7Crp#10)	National Institute of Agrobiological Sciences(NIAS)
2007-5-30	Maize tolerant to glyphosate herbicide and tolerant to acetolactate synthase inhibitor (*gat4621, zm-hra, Zea mays* subsp. *mays* (L). Iltis.) (DP-098140-6, OECD UI:DP-098140-6)	Du Pont Kabushiki Kaisha
2007-5-30	Soybean high oleic acid and tolerant to acetolactate synthase inhibitor (*gm-fad2-1, gm-hra, Glycine max* (L). Merr.) (DP-305423-1, OECD UI:DP-305423-1)	Du Pont Kabushiki Kaisha
2007-5-30	Cotton resistant to Lepidoptera (*Modified cry1Ab, Gossypium hirsutum* L.) (COT67B, OECD UI:SYN-IR67B-1)	Syngenta Seeds K. K.
2007-5-30	Cotton resistant to Lepidoptera (*Modified vip3A, Gossypium hirsutum* L.) (COT102, OECD UI:SYN-IR102-7)	Syngenta Seeds K. K.
2007-5-17	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide (Modified *cry1Ab, bar, Zea mays* subsp. *mays* (L.) Iltis) (Event176, OECD UI : SYN-EV176-9)	Syngenta Seeds K.K.

2007-5-17	Oilseed rape tolerant to glufosinate herbicide (*pat, Brassica napus* L.) (Topas 19/2, OECD UI :ACS-BN007-1)	Bayer Crop Science K.K.
2007-4-24	Sugar beet tolerant to glyphosate herbicide(modified *cp4 epsps, Beta vulgaris* L. ssp. *vulgaris var. altissima*)(H7-1,OECD UI: KM-000H71-4)	Monsanto Japan Limited
2007-4-24	High oleic acid soybean (*GmFad2-1, Glycine max* (L.) Merr.) (260-05, OECD UI : DD-026005-3)	Du Pont 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.