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Update on Japan's Biotechnology Safety Approval and Labeling Policies

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Report Highlights: Japan has approved 44 biotech varieties as food through its ongoing safety assessment process. It is illegal to import biotech varieties which have not been approved in Japan for food use. Food products containing approved biotech varieties must be so labeled, if the biotech ingredients are scientifically detectable.

Includes PSD changes: No
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Executive Summary

As of December 2002, Japan's Ministry of Health, Labor and Welfare (MHLW), which is responsible for granting food safety approvals for biotech products, had approved 44 biotech varieties for food use. Legislation was introduced in 2000 to prevent the import of products for food use which contain biotech varieties which are not yet approved in Japan. To enforce this legislation, MHLW routinely samples and tests imported foodstuffs at ports of entry. Their testing has focused on biotech products which are in commercial production abroad, but not yet approved in Japan. Foods found to contain unapproved biotech varieties must be re-exported, destroyed or diverted to non-food use. As a result of this testing and tests of retail food products by local government authorities, one unapproved biotech variety of potatoes, two instances of unapproved biotech papayas, and one incident of StarLink corn commingled with food-use corn have been discovered.

The Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for environmental safety approvals, feed safety approvals and biotech labeling for foods. On April 1, 2001, MAFF established a labeling scheme under the Japan Agricultural Standards (JAS) which requires labeling for biotech food products if the biotech DNA or protein can be scientifically detected in the finished foods. Biotech advisory labels for the 30 products covered under this program are mandatory if the biotech content exceeds 5%. MHLW also plays a role in enforcing labeling standards under the Food Sanitation Law, but their standards are practically the same as MAFF's Japan Agricultural Standards. In order for a product to be labeled "Non-GM", certification must be provided to show that the ingredients were handled on an "identity-preserved" (IP) basis at each step of the production and distribution process.

Additional information on the market impact of Japan's labeling and monitoring policies can be found in FAS/Japan's reports on-line at <http://www.fas.usda.gov>.

Safety Assessment Procedures for Products of Biotechnology

The Ministry of Health, Labor and Welfare is responsible for conducting scientific reviews to assess the safety of new biotech varieties. Companies developing new biotech products must first submit their application to MHLW's Inspection and Safety Division which checks to make sure that the application is properly prepared. MHLW then submits the application to the Expert Panel of the Biotechnology Subcommittee within the Food Sanitation Committee. The Expert Panel reviews the application and then makes a recommendation with regard to approval to the Biotechnology Subcommittee. This committee then provides its judgement to the Food Sanitation Committee which reviews the application and then makes a recommendation on approval to MHLW's Minister. Approved applications are published in the Japanese Government's "Gazette", which is similar to the Federal Register. MHLW's most recent list of approved biotechnology events may be found on the internet at the following address: <http://www.mhlw.go.jp/english/topics/food/sec01.html>.

The Ministry of Agriculture Forestry and Fisheries administers environmental safety assessments and feed safety assessments for biotech products. MAFF's environmental safety assessment is voluntary,

but virtually all biotech developers submit applications for new events either for importation or for cultivation in Japan. All varieties which will be either imported or cultivated in Japan, must receive approval for field testing that is required to be carried out in Japan by the Japanese government.

MAFF is also responsible for approving new biotech varieties for feed use and for a marketing program which includes a feed safety assessment. In April 1, 2003, MAFF will make the feed safety assessment mandatory. Under MAFF's approval process, the application is reviewed by MAFF's Feed Division to make sure that has been properly prepared. It is then reviewed by the Experts Committee of the Agricultural Materials Council. The Council then reviews the application and makes its recommendation to MAFF's Minister on whether or not to approve the variety for feed use.

The following list of biotech traits have been approved in Japan for the specific purposes listed below.

List of Currently Approved Biotechnology Crops and Plant Products in Japan

As of December 2002

| Plant species | Trait/ Variety | Developer | Characteristics | Year of Approval | | | |
|---------------|-------------------|-----------------------------|--|------------------|----------|------|------|
| | | | | Import | Planting | Feed | Food |
| Azuki bean | AR-9 | Nat'l Agr. Res. Ctr. | Insect resistant | 1999 | 1999 | - | - |
| Broccoli | BR891 | Takii Shubyo | Male sterile and herbicide tolerant | - | 2001 | - | - |
| Canola | RT73 | Monsanto | Herbicide tolerant | 1996 | 1996 | 1996 | 2001 |
| | HCN92 | AgrEvo | Herbicide tolerant | 1996 | - | 1996 | 2001 |
| | HCN10 | AgrEvo | Herbicide tolerant | 1997 | - | 1998 | 2001 |
| | PGS1 | Plant Genetic Systems (PGS) | Herbicide tolerant | 1996 | - | 1996 | 2001 |
| | PHY14 | PGS | Herbicide tolerant | 1997 | - | 1998 | 2001 |
| | PHY35 | PGS | Herbicide tolerant | 1997 | - | 1998 | 2001 |
| | T45 | AgrEvo | Herbicide tolerant | 1997 | - | 1997 | 2001 |
| | PGS2 | PGS | Herbicide tolerant, male sterile, sterility recovery | 1997 | - | 1997 | 2001 |
| | PHY36 | PGS | Herbicide tolerant, male sterile, sterility recovery | 1997 | - | 1997 | 2001 |
| | PHY23 | PGS | Herbicide tolerant, male sterile, sterility recovery | 1997 | - | 1999 | 2001 |

| | | | | | | | |
|-------------|----------------|-------------------------|--|------|------|------|------|
| | Westar-Oxy-235 | Rhone Poulanc | Herbicide tolerant | 1998 | - | 1999 | 2001 |
| | MS8RF3 | PGS | Herbicide tolerant, male sterile, sterility recovery | 1998 | - | 1998 | 2001 |
| | MS8 | PGS | Herbicide tolerant, male sterile | 2002 | - | 1999 | 2001 |
| | RF3 | PGS | Herbicide tolerant, sterility recovery | 2002 | - | 1999 | 2001 |
| | RT200 | Monsanto | Herbicide tolerant | - | - | 2001 | 2001 |
| Carnation | A-127 | DNAP/Suntory | Long life | 1996 | 1996 | N/A | N/A |
| | 2 | Florigene/Suntory | Color change | 1997 | 1997 | N/A | N/A |
| | 11 | Florigene/Suntory | Color change | 1997 | 1997 | N/A | N/A |
| | 1351 | Florigene/Suntory | Color change | 1998 | 1998 | N/A | N/A |
| | 1363 | Florigene/Suntory | Color change | 1998 | 1998 | N/A | N/A |
| | 121.2.7 | Florigene/Suntory | Color change | 1999 | 1999 | N/A | N/A |
| | 121.3.12 | Florigene/Suntory | Color change | 1999 | 1999 | N/A | N/A |
| | 123.1.36 | Florigene/Suntory | Color change | 1999 | 1999 | N/A | N/A |
| | 123.2.38 | Florigene/Suntory | Color change | 1999 | 1999 | N/A | N/A |
| | 8.6.25 | Florigene/Suntory | Long life | 1999 | 1999 | N/A | N/A |
| | 12.1.8 | Florigene/Suntory | Long life | 1999 | 1999 | N/A | N/A |
| | 17.3.67 | Florigene/Suntory | Long life | 1999 | 1999 | N/A | N/A |
| | 18.3.33 | Florigene/Suntory | Long life | 1999 | 1999 | N/A | N/A |
| | 20.9.53 | Florigene/Suntory | Long life | 1999 | 1999 | N/A | N/A |
| | 123.8.8 | Suntory | Color change | 2000 | 2000 | N/A | N/A |
| 1.8.124 | Suntory | Low ethylene production | 2000 | 2000 | N/A | N/A | |
| 16.0.66 | Suntory | Low ethylene production | 2000 | 2000 | N/A | N/A | |
| Cauliflower | CF156 | Takii Shubyo | Male sterile and herbicide tolerant | 2001 | 2001 | - | - |
| Corn | T-14 | AgrEvo | Herbicide tolerant | 1997 | - | 1997 | 2001 |
| | T-25 | AgrEvo | Herbicide tolerant | 1997 | - | 1997 | 2001 |
| | MON810 | Monsanto | Insect resistant | 1996 | - | 1997 | 2001 |

| | | | | | | | |
|--------|---------------------|---------------|--|------|------|------|------|
| | MON802 | Monsanto | Insect resistant, herbicide tolerant | 1997 | - | - | - |
| | Bt11 | Northlap King | Insect resistant | 1996 | 2002 | 1996 | 2001 |
| | Event176 | Ciba Seed | Insect resistant | 1996 | - | 1996 | 2001 |
| | DLL25- DK566 | Dekalb | Herbicide tolerant | 1997 | 1997 | - | - |
| | DBT418- DK566 | Dekalb | Insect resistant, herbicide tolerant | 1997 | 1997 | - | - |
| | MON809 | Monsanto | Herbicide tolerant | 1997 | - | 1998 | - |
| | CBH351 | PGS | Insect resistant, herbicide tolerant | 1999 | - | - | - |
| | GA21 | Monsanto | Herbicide tolerant | 1998 | 1998 | 1999 | 2001 |
| | DLL25 | Dekalb | Herbicide tolerant | 1999 | - | 2000 | 2001 |
| | DBT418 | Dekalb | Insect resistant, herbicide tolerant | 1999 | - | 2000 | 2001 |
| | NK603 | Monsanto | Herbicide tolerant | 2001 | 2001 | 2001 | 2001 |
| | Sweet corn, Bt11 | Novartis | | 2002 | 2002 | - | 2001 |
| | MON863 | Monsanto | Insect resistant | 2001 | - | 2002 | 2002 |
| | 1507 | Dow Chemicals | Insect resistant and herbicide tolerant | 2002 | - | 2002 | 2002 |
| Cotton | 531 | Monsanto | Insect resistant | 1999 | - | 1997 | 2001 |
| | 757 | Monsanto | Insect resistant | 1999 | - | 1997 | 2001 |
| | 1445 | Monsanto | Herbicide tolerant | 1997 | - | 1998 | 2001 |
| | 10211 | Monsanto | Herbicide tolerant | 1997 | - | - | 2001 |
| | 10215 | Monsanto | Herbicide tolerant | 1997 | - | 1998 | 2001 |
| | 10222 | Monsanto | Herbicide tolerant | 1997 | - | 1998 | 2001 |
| | 10224 | Monsanto | Herbicide tolerant | 1997 | - | 1998 | - |
| | 31807 | Monsanto | Insect resistant, herbicide tolerant | 1998 | - | 1999 | - |
| | BG4740 | Monsanto | Insect resistant, herbicide tolerant | 1998 | - | - | - |
| | 15985 | Monsanto | Insect resistant | 2001 | - | - | 2002 |

| | | | | | | | |
|--|------------------|----------------------|--------------------------------------|------------|------------|-----|------|
| Crysanthemum (limited to breeding purpose) | pac1,2 | Kirin Beer | Disease resistant | - | 2002 | N/A | N/A |
| | pac1, 14-2 | Kirin Beer | Disease resistant | - | 2002 | N/A | N/A |
| | pac1, 29 | Kirin Beer | Disease resistant | - | 2002 | N/A | N/A |
| Cucumber | CR-29 | Nat'l Agr. Res. Ctr. | Disease resistant | 1999 | 1999 | - | - |
| | CR32 | Nat'l Agr. Res. Ctr. | Disease resistant | 1999 | 1999 | - | - |
| | CR33 | Nat'l Agr. Res. Ctr. | Disease resistant | 1999 | 1999 | - | - |
| Melon | Prince melon | Nat'l Agr. Ctr. | Virus resistant | 1996 | 1996 | - | - |
| Papaya | 55-1 | Univ. Hawaii | Ringspot Virus resistant | 2000 | - | - | - |
| Petunia | | Suntory | Virus resistant | 1994 | 1994 | N/A | N/A |
| Potato | BT6 | Monsanto | Insect resistant | Not needed | Not needed | N/A | 2001 |
| | SPBT02-05 | Monsanto | Insect resistant | Not needed | Not needed | N/A | 2001 |
| | RBMT21-129 (NLP) | Monsanto | Insect resistant and virus resistant | Not needed | Not needed | N/A | 2001 |
| | RBMT21-350 (NLP) | Monsanto | Insect resistant and virus resistant | Not needed | Not needed | N/A | 2001 |
| | RBMT22-82 (NLP) | Monsanto | Insect resistant and virus resistant | Not needed | Not needed | N/A | 2001 |
| Rice | Nipponbare 16-2 | Nat'l Agr. Ctr. | Virus resistant | 1994 | 1994 | - | - |
| | Kinuhikari | Plant Tech. Ctr | Virus resistant | 1994 | 1994 | - | - |
| | Kinuhikari | Mitsui Chemicals | Low allergenicity | 1995 | 1995 | - | - |
| | Nipponbare: 20-2 | Nat'l Agr. Res. Ctr. | Virus resistant | 1997 | 1997 | - | - |
| | Nipponbare: 21-3 | Nat'l Agr. Res. Ctr. | Virus resistant | 1997 | 1997 | - | - |
| | H39 | Japan Tobacco | Low protein | 1998 | 1998 | - | - |
| | H75 | Japan Tobacco | Low protein | 1998 | 1998 | - | - |

| | | | | | | | |
|------------|-----------|---|----------------------------|-------------------|---------------|------|------|
| | KA130 | Orynova | Low glutenin | 2000 | 2000 | - | - |
| | LLRICE62 | AgrEvo | Herbicide tolerant | 2000 | - | - | - |
| | 730 | Monsanto | Herbicide tolerant | 2000 | 2000 | - | - |
| | 1107 | Monsanto | Herbicide tolerant | 2000 | 2000 | - | - |
| | 1316 | Monsanto | Herbicide tolerant | 2000 | 2000 | - | - |
| | 1702 | Monsanto | Herbicide tolerant | 2000 | 2000 | - | - |
| | 1708 | Monsanto | Herbicide tolerant | 2000 | 2000 | - | - |
| | 1763 | Monsanto | Herbicide tolerant | 2000 | 2000 | - | - |
| | G2-59 | Aichi Prefecture Ag Station, Monsanto | Herbicide tolerant | 2001 | 2001 | - | - |
| | G2-70 | Aichi Prefecture Ag Station, Monsanto | Herbicide tolerant | 2001 | 2001 | - | - |
| | G2-138 | Aichi Prefecture Ag Station, Monsanto | Herbicide tolerant | 2001 | 2001 | - | - |
| Soybean | 40-3-2 | Monsanto | Herbicide tolerant | 1996 | 1996 | 1996 | 2001 |
| | 260-05 | DuPont | High oleic acid | 1999 | - | 2000 | 2001 |
| | A2704-12 | AgrEvo | Herbicide tolerant | 1999 | - | - | 2002 |
| | A5547-127 | Aventis | Herbicide tolerant | 2001 | - | - | 2002 |
| Sugar beet | T120-7 | AgrEvo | Herbicide tolerant | Not neede d | Not needed | 1999 | 2001 |
| Tomato | | Nat'l Agr. Ctr. | Virus resistant | 1992 | 1992 | - | - |
| | 405 | Nat'l Veg. Res. | Virus resistant | 1996 | 1996 | - | - |
| | 707 | Nat'l Veg. Res. | Virus resistant | 1996 | 1996 | - | - |
| | ICI9 | Zeneca/Kagome | High pectin | 1996 | 1996 | - | - |
| | ICI13 | Zeneca/Kagome | High pectin | 1996 | 1996 | - | - |
| | | Calgene | High pectin (long life) | 1996 | 1996 | - | - |
| | 117 | Nat'l Veg. Res. | Virus resistant | 1997 | 1997 | - | - |
| | 1046 | Nat'l Veg. Res. | Virus resistant | 1997 | 1997 | - | - |
| | 1204 | Nat'l Veg. Res. | Virus resistant | 1997 | 1997 | - | - |
| | 1208 | Nat'l Veg. Res. | Virus resistant | 1997 | 1997 | - | - |

| | | | | | | | |
|------------------------|------|-----------------------|-----------------|--------|----------|------|------|
| | 4-7 | Hokkaido Agr. Station | Virus resistant | 2000 | 2000 | - | - |
| Trenia | 1165 | Florigene/Suntory | Color change | 1998 | 1998 | N/A | N/A |
| | 1382 | Florigene/Suntory | Color change | 1998 | 1998 | N/A | N/A |
| Total approval numbers | | | | Import | Planting | Feed | Food |
| | | | | 98 | 66 | 37 | 44 |

For each biotechnology variety, the years in which safety approvals were granted are shown for environmental (import and planting), feed and food safety. ‘-’ indicates that the safety of the event has not been confirmed by the Government of Japan. Potatoes and sugar beets are imported to Japan only as processed foods, thus indicated as ‘Not needed’ for import and planting. ‘N/A’ means not applicable.

Labeling Policy for Biotech Products

MAFF and MHLW have implemented labeling requirements under the Food Sanitation Law and the Japan Agricultural Standards (JAS) Law, respectively for biotech products which have been approved in Japan. Although the labeling requirements for the Ministries are listed separately, both sets of requirements are identical. MAFF’s labeling policy on biotechnology traits may be found at the Internet site: http://www.maff.go.jp/soshiki/syokuhin/hinshitu/organic/eng_yuki_gmo.pdf

The 30 foods currently subject to JAS labeling requirements were selected because they are made from ingredients which could include biotech products and because genetically-introduced DNA or protein can be identified in the foods. If the biotech content of these 30 foods exceeds 5 percent, they must be labeled with either the phrase "GM Ingredients Used" or "GM Ingredient Not Segregated." In order to be labeled "Non-GM", the biotech content of foods must be less than 5%, and the processor must be able to show that all biotech ingredients were "identity-preserved" (IP) from production through processing. The initial suppliers of the products are responsible for supplying this certification not with Japan’s food importers or manufacturers. The English version of the manual for the IP handling of corn and soybeans is available at the Japan Food Industry Center’s website (http://www.shokusan.or.jp/business/pdf/ip_manul.pdf). The manual for potatoes is not on the website but may be obtained from the Center (see GAIN report JA2010 for more information)

MAFF and MHLW periodically revise the list of foods subject to monitoring and labeling as new biotech varieties go into production and new detection methodologies are developed.

Monitoring of GM or Non-GM Labeled Foods

MAFF and MHLW both randomly monitor samples of the 30 foods which are currently under the labeling program for biotech ingredients. The Japanese Government’s recognizes that even though proper IP handling and distribution methods are used, a possibility exists for adventitious commingling of biotech products in non-GM products. They have therefore set an informal tolerance of 5% for biotech ingredients in products which are labeled "Non-GM." This tolerance only applies to varieties

which have been approved in Japan. If officials find products labeled "Non-GM" which have a biotech content of over 5 %, the ministry which identified the problem issues guidance directing the food manufacturer or importer to correct the product's label to show that it was made with "Genetically Modified Ingredients."

Monitoring for Unapproved Biotech Varieties in Foods

Like the United States, Japan has a zero tolerance for unapproved biotech varieties in foods. To assure compliance, a sampling program is in place to test both import shipments and processed food products at the retail level. Any detection of an unapproved biotech variety in a food is deemed a violation of Japan's Food Sanitation Law. 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, destroyed or diverted for non-food use. If the detection is at the retail level, the manufacturer of the product must issue an immediate recall. The main products currently being tested are soybeans, corn, papayas, and potatoes. MHLW has so far found one unapproved biotech variety of potatoes, two unapproved biotech papaya cases and one unapproved StarLink corn as a result of this testing, and ongoing testing of finished food products by local governments.

The positive test for StarLink was found during a monitoring test performed on 19,324 tons of U.S. corn for corn starch, whose import notification was submitted to the Nagoya Quarantine Station on December 20, 2002. MHLW found StarLink to be commingled in a 1,200 ton lot within the corn shipment. This was the first confirmation of commingling since MHLW began inspecting for StarLink since April 1, 2001 when safety assessments of genetically modified foods were mandated. As a result of the finding, the monitoring testing on imported U.S. corn was raised the rate of sampling from 5 % to 50 % of all the corn shipments from the U.S.

Monitoring for Unapproved Biotech Varieties in Feed

Since MAFF's feed safety assessment currently voluntary, MAFF may not legally ban the import of feed corn containing StarLink. However, MAFF and USDA established a testing protocol to ensure that any commingling of StarLink in U.S. corn be kept to a minimum. MAFF continues to perform random monitoring tests for StarLink with the results summarized below. StarLink is still being found in feed corn but MAFF recognizes that the StarLink positive ratio and the commingling ratio are declining.

| Period | Positive Ratio | Commingling Concentration |
|----------------------------|----------------|---------------------------|
| April to September 2000 | 20/30 (66.7 %) | 0.51 % |
| October 2000 to March 2001 | 34/72 (47.2 %) | 0.17 % |
| April to September 2001 | 8/53 (15.0 %) | 0.05 % |

| | | |
|----------------------------|---------------|--------|
| October 2001 to March 2002 | 5/45 (11.1 %) | 0.09 % |
| April to September 2002 | 4/42 (9.5 %) | 0.10 % |

On April 1, 2003, new legislation will go into effect making a feed safety assessment mandatory. As part of this law, MAFF has set a 1% tolerance for the unintentional commingling of biotech varieties in feed which are approved in other countries but not yet approved in Japan. In addition, the exporting country must be recognized by the MAFF Minister as having a safety assessment program that is at equivalent to or stricter than that of Japan. In regards to the presence of StarLink in U.S. feed corn, MAFF is currently evaluating the equivalency of the U.S. feed safety assessment program.