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Biotechnology Annual Report 2011

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Report Highlights:

Korea is in the process of revising its laws and regulations to reflect the current language in the Cartagena Protocol on Biosafety as well as other international practices. These revisions will make the approval of new biotech events and the trade in these products more predictable and transparent. Consumer attitudes toward the use of biotechnology in food are starting to soften, but negative perceptions still persist. Generating local farmers' support to adopt and actively use this technology in locally grown crops is seen as the key to increasing consumer confidence.

Section I. Executive Summary:

Korea is heavily dependent on imported food (except rice) and feed grains, most of which come from the United States. A limited amount of food products are made from biotech ingredients given consumer concerns about biotechnology, whereas the bulk of livestock feed is made from biotech corn and soybean meal.

Imports of biotech grains as well as genetically engineered animals are regulated under the Living Modified Organism (LMO) Act, which became effective January 1, 2008, just a couple of months after the country ratified the Cartagena Protocol on Biosafety (CPB). The intent of the Act is to implement the provisions of the CPB. However, the existing Act has become outdated and no longer reflects the latest CPB provisions, such as the 'may contain' principle. The Act also fails to make the fundamental distinction between seed, and food, feed and processing (FFP), nor does it have a workable adventitious presence definition.

Additionally, some facets of the risk assessment process are considered to be redundant, unprecedented and occasionally lack scientific justification. This cumbersome process is sometimes slow, contributing to delays in the final approval of new events. That being said, though, Korea has already approved one single event and three stacked events in 2011. Moreover, government regulators have shown a fair amount of flexibility in interpreting the Act and its lower level regulations since they want to steer clear of a disruption to grain imports, which would send shockwaves through the local market.

In order to address some of these shortcomings, the Ministry of Knowledge & Economy (MKE) is currently in the process trying to revise the Act and its underlying regulations. On July 15, 2011, MKE notified the WTO (SPS/328) that it had published a draft revision to the LMO Act. Comments are due in mid September. After the international comment period and ensuing revisions, if needed, the Act will go to Korea's National Assembly for approval. Once the Act is finalized, MKE will turn its attention to revising the underlying regulations.

Consumers' negative perceptions towards biotechnology are beginning to slightly soften, but are still very far from embracing the technology with open arms. In fact, according to public surveys, consumers support labeling for food and beverages made from genetically modified crops. The push, though, to expand labeling to products like oil and syrups where the modified protein is undetectable has been put on the back burner because of the enormous trade implications and food price inflation.

While sensitivities remain with biotech food, consumers are much more comfortable with non-agriculture uses, such as pharmaceuticals. Generating local farmers' support to adopt and actively use this technology is considered as the lynchpin for increasing consumer confidence in biotech food and livestock products.

Korea is developing a variety of biotech crops, like herbicide tolerant rice and virus resistant pepper.

This ongoing research will receive a huge boost in the arm under MIFAFF's "Life Industry 2020 Development Strategy", which was announced in December 2010. Under this program, which is viewed as an engine for future economic growth, MIFAFF will invest 7.5 trillion won (\$6.5 billion) over the next 10 years in the country's life sciences infrastructure. With respect to biotechnology, MIFAFF has laid out plans to (1) upgrade its risk assessment system for biotech crops; (2) strengthen bio resource management; (3) develop bio energy crops, like marine algae; (4) increase genomic research and bio-organ production.

As part of the broader 2020 Development Strategy, the Rural Development Administration (RDA) on May 19, 2011, launched the second ten-year phase of the Next Generation Bio-Green 21 Project where RDA plans to invest 1.06 trillion won (approximately \$1 billion U.S. dollars) over the next decade in financing research projects to develop various practical technologies in medicine, engineering, environment, and the food industry.

In particular, RDA plans to focus its support on three areas: (1) national resources technology needed to analyze Korea's bio resources and utilize these to develop around 100 new organisms to respond to climate change and food security challenges; (2) development and commercialization of 20 new biotech crops to introduce in the world seed market; and (3) biomedicine and organs derived from genetically engineered animals and plants. The first phase the Bio-Green 21 Project, which ran from 2001 through 2010, focused on building the foundation for agricultural biotechnology research and development.

Section II. Plant Biotechnology Trade and Production:

A. Commercial Production of Biotechnology Crops

Despite substantial investment, Korea has yet to commercially produce any biotech crops.

B. Biotechnology Crops under Development

The development of biotech crops is being led by various government agencies, universities and private entities. Research is mainly focused on 2nd and 3rd generation traits, such as drought and disease resistance, nutrient enrichment, transformation techniques, and gene expression.

Academic and government experts are busy publishing papers on genetically engineered crops. For example, according to a 2009 survey of local scientific journals, 380 papers on this subject were published between 1990 and 2007. Of those papers, there were 99 about tobacco, 45 about rice, and 29 about potatoes.

RDA has 118 events in 19 different varieties of crops under development. These crops include some of the following: herbicide tolerant rice, pepper, perilla seed, herbicide tolerant rice, virus resistant potatoes and Chinese cabbage, watermelon, sweet potato, apples, and vitamin A enriched rice. The herbicide tolerant rice has completed the internal safety evaluation, while several other crops are still being reviewed. RDA is generating the herbicide tolerant rice dossier for the environmental risk assessment, but this is expected to take longer than originally planned since the rice is intended for propagation and will need seed approval prior to commercialization.

The private sector is also doing research on biotech crops. According to industry estimates, approximately 60 varieties are currently under development, although most of them are still at the laboratory stage. The one noteworthy exception is the virus resistant pepper, which is several steps ahead and has already moved to the internal risk assessment process.

Although significant research has been done, the soonest one of these crops, most likely the virus resistant pepper or disease resistant rice, could finish the regulatory review process in three years. Commercialization, though, is expected to take much longer and will be entirely dependent on the monumental task of getting Korean farmers to first recognize the benefits and adopt this technology. Generating farmers' support to actively use this technology is considered as the lynchpin for increasing consumer confidence in biotech food.

C. Imports of Biotechnology Crops/Products

Korea imports biotech crops and products for food, feed and processing, but not for propagation. The United States is the largest supplier of biotech grains and oilseeds to the Korean market.

Korea imported 8.5 million metric tons of corn in 2010, which was made-up of 6.5 million metric tons for feed and 2.0 million metric tons for processing. The United States was the top supplier with imports reaching 7.3 million MT, or 85 percent of the total. Imports of U.S. corn were made up of 6.0 million MT for animal feed, which was nearly all biotech corn. The remaining 1.3 million metric tons of U.S. corn was used for processing, of which nearly two-thirds was biotech.

Imported biotech processing corn is generally used to make products, like high fructose corn syrup (HFCS) or corn oil, which are exempt from biotech labeling requirements since the biotech protein is undetectable. Despite mounting pressure from local NGOs and consumer groups, some processors continue using biotech corn since it's more affordable and easier to secure on the world market compared to conventional corn. Meanwhile, the processors producing flour, grits and flakes are importing identity preserved (IP) conventional corn from a variety of international suppliers.

In 2010, Korea imported 1.2 million metric tons of soybeans, three-quarters of which are used for crushing. The United States was the top soybean supplier, with imports totaling 730,383 metric tons, which represented about 60 percent of all imports. Of that amount, 501,015 metric tons were used for crushing, 229,174 metric tons for food processing/sprouting, and 194 metric tons for direct feed.

In addition to domestically produced meal, Korea imported 1.8 million metric tons of soybean meal in 2010. The United States was the second largest supplier behind Brazil, with 385,563 metric tons, accounting for 22 percent of total imports.

Soybean oil is exempt from biotech labeling requirements since the modified protein is undetectable. Soybeans for food processing are used in products, such as soybeans for tofu, bean paste, bean sprouts, and are IP-handled, non-biotech beans.

Table 1 contains import statistics for LMO soybeans and corn. This data differs slightly from the numbers reported in the preceding paragraphs since it's based on import approvals instead of customs clearance. Nonetheless, the information contained in the table reinforces the point that Korea imports a significant volume of LMOs for both food and feed purposes. Table 2 highlights the price difference between biotech and conventional grains.

Table 1: Imports Statistics for LMO Soybeans and Corn¹

(Calendar year basis / Unit: 1,000 MT)

Classification			2008	2009	2010	2011 Jan-Mar
			Volume	Volume	Volume	Volume
Soybean	Food (Crushing)	US	336	442	475	216
		Non-US	501	459	447	0
		Total	837	901	922	216
Corn	Food	US	714	471	865	201
		Non-US	2	0	128	0
		Total	716	471	993	201
	Feed	US	6,771	5,008	5,897	1,326
		Non-US	154	802	554	290
		Total	6,925	5,810	6,451	1,616
Oilseeds	Feed	US	76	75	77	30
		Non-US	16	23	41	1
		Total	92	98	118	31

Source: Korea Biosafety Clearing House

¹ Statistics are on an import approval basis; and only cover biotech grains and oilseeds.

**Table 2: Average Price Difference of U.S. Origin Non-LMO
and LMO for Food Use in 2008**

(Unit: Price for One Metric Ton / US dollars)

Crops	LMO	Non-LMO	Difference
Corn	329	386	57 (17.3%)
Soybean	564	768	204 (36.2%)

Source: Korea Biosafety Clearing House (KBCH) Note: This is the latest data available from KBCH.

D. Food Aid

South Korea is not a food aid recipient. South Korea provides intermittent food aid to North Korea depending on the prevailing political conditions and is also considering making donations to third countries.

E. Production of Biotechnology Crops That Were Developed Outside of the United States

At present, Korea does not commercially produce biotechnology crops from any origin.

Section III. Plant Biotechnology Policy:

A. Regulatory Framework for Agricultural Biotechnology

Korea ratified the Cartagena Protocol on Biosafety (CPB) on October 2, 2007. Shortly thereafter, on January 1, 2008, Korea implemented the LMO Act, which is the implementing legislation for the CPB

and the overarching law governing the country's biotechnology related rules and regulations.

The LMO Act has a fairly lengthy history prior to implementation. The Ministry of Knowledge Economy (MKE), which is the competent national authority, spearheaded the drafting of the Act and its underlying regulations back in early 2001. After several years and numerous iterations, MKE published drafts for public comment in September 2005. While the text of the Act and the lower level regulations were finalized just six months later, in March 2006, the regulations were not implemented, as noted above, until January 1, 2008.

Roles & Responsibilities of Government Ministries

Ministry of Knowledge Economy (MKE): National competent authority for the CPB, responsible for the LMO Act and issues related to the development, production, import, export, sales, transportation, and storage of LMOs for industrial use.

Ministry of Foreign Affairs & Trade (MOFAT): National focal point for the CPB.

Ministry for Food, Agriculture, Forestry, and Fisheries (MIFAFF): matters related to the import/export of agricultural/fishery LMOs; labeling requirements for unprocessed biotech crops.

Rural Development Administration (RDA) (overseen by MIFAFF): ERAs for biotech crops and leading developer of biotechnology crops in Korea.

Animal, Plant and Fisheries Quarantine & Inspection Agency (QIA) (overseen by MIFAFF): import inspection of LMOs for agricultural use at the port of entry.

National Agriculture Product Quality Service (NAQS) (overseen by MIFAFF): import approval of LMOs for feed use.

National Fisheries Research & Development Institute (NFRDI), (overseen by MIFAFF): import approval of fisheries and consultations for LMOs for marine environment.

Ministry of Health and Welfare (MHW): monitoring and/or enforcing regulations pertinent to the Food Sanitation Act and issues related to trade of LMOs used for health and pharmaceutical purposes including human risk assessments of such LMOs.

Korea Center for Disease Control and Prevention (KCDC) (overseen by MHW): human risk consultation for LMOs.

Korea Food & Drug Administration (KFDA) (overseen by MHW): food safety approvals of biotechnology crops and the enforcement of labeling requirements for processed food products containing biotech ingredients.

Ministry of Environment (MOE): issues related to the trade of LMOs that are used for the purpose of environmental remediation or release into the natural environment including risk assessments for such LMOs, but does not include agricultural LMOs for planting.

National Institute of Environmental Research (NIER) (overseen by MOE): import approval of LMOs under jurisdiction of MOE and environmental risk consultation for LMOs.

Ministry of Education, Science & Technology (MEST): issues related to the trade of LMOs that are used for testing and research including risk assessments for such LMOs.

Ministry of Land, Transport, and Maritime Affairs (MLTM): issues related to the trade of maritime LMOs including risk assessments for such LMOs.

Role and Membership of the Biosafety Committee and Its Political Implications

In accordance with Article 31 of the LMO Act, a Biosafety Committee was formed in 2008 under the Office of the Prime Minister to review the following factors relevant to the import and export of LMOs:

- Factors relevant to the implementation of the protocol
- Establishment and implementation of the safety management plan for LMOs
- Notification of a list of LMOs that pose no harm in accordance with the provisions of Article 15
- Re-examination in accordance with the provisions of Article 18 of appeals by an applicant who fails to get import approval, etc.
- Factors relevant to legislation and notification pertinent to the safety management, import, and export, etc. of LMOs
- Factors relevant to the prevention of damage caused by LMOs and measures taken to mitigate damage caused by LMOs
- Factors requested for review by the Chair of the Committee or the head of competent national authority.

The Prime Minister is the chair of the 15-20 member committee. Members include Ministers from the seven relevant ministries noted above plus the Ministry of Strategy and Finance (MOSF). Private sector specialists can also be members of the Committee. The Committee may have subcommittees and technical committees.

The most important role of the Committee is to reconcile different positions among the relevant ministries. As each relevant ministry holds authority and responsibility in its respective areas, it may not be easy to reach consensus on some issues. In such cases, the Prime Minister as the Chair of the Committee can be called upon to resolve matters lacking consensus. While the frequency of meetings is not exactly known, it appears as though the committee meets infrequently.

Political Influence

Regulatory decisions related to agricultural biotechnology are influenced by political pressure, mostly from vocal anti-biotech NGOs. Unfortunately, some of these outspoken organizations are appointed as members of the government's food safety and biotechnology risk review committees and use this position as a means to pressure the government to introduce more stringent biotech regulations. One example is KFDA's stalled proposal to expand biotech labeling requirements.

B. Approval of Biotechnology Crops

Biotechnology crops are required to undergo a food safety assessment and environmental risk assessment (ERA). Of note, the ERA is sometimes referred to as a feed approval, though the review is largely focused on the impact to the environment, not animal health.

Several different agencies are involved in the overall assessment process. RDA conducts the ERA's to approve new events in feed grains. As part of the environmental assessment, RDA consults with three different agencies, including the National Institute for Environmental Research (NIER), the National Fisheries Research & Development Institute (NFRDI) and the Korea Centers for Disease Control & Prevention (KCDC). Meanwhile, KFDA conducts a safety assessment for food grains containing biotech events. The KFDA review process includes consultations with RDA, NIER and NFRDI.

The overlaps between the reviewing agencies, particularly between KFDA and KCDC, have led to confusion and unnecessary delays in the approval process. MKE plans to address some of this duplication when it revises the LMO Act and sublevel regulations. This revision process is underway.

KFDA has three categories of approval: full approval and two types of conditional approval. Full approval is given to biotech crops that are commercially produced and imported for human consumption. Conditional approval applies to those crops that have been discontinued or are not grown commercially for human consumption.

As of July 2011, KFDA has granted food safety approval to 73 events out of a total of 95 submissions. Meanwhile, RDA has approved 63 events for use in feed out of a total of 94 submissions. See Appendix for a complete list of approved events.

Although no product has been approved for commercial production in Korea, a local developer approached RDA in 2008 requesting the approval to plant biotech grass used for landscaping purposes. However, the submission was initially turned down due to insufficient data, but was re-submitted with the requested data in October 2010.

C. Field Trials

RDA has authorized contained field trials for 228 events in various crops in 2011. RDA renews the field trial permits every year. The lion share of field trials are for rice with many different traits, such as environmental stress resistance, enhanced nutritional qualities, and insect resistance. Field trials for peppers, beans and grass are also underway.

According to the Consolidated Notice, which is implementing regulations of the LMO Act, in-country field tests are required for imported LMOs used as seed. For LMOs used as food, feed, and processing (FFPs), RDA will review the data from field trials conducted in the exporting country. However, if necessary, RDA may require in-country field tests for LMO FFPs.

The biotech crops being developed by RDA are subject to field trials and must follow the “Guidelines for Research and Handling of Recombinant Organisms Related to Agricultural Research.” Biotech crops developed by private entities, including universities, should adhere to voluntary guidelines published by the Ministry of Health & Welfare, entitled “Guidelines for Research of Recombinant Organisms”. The Consolidated Notice also includes guidelines for local biotech developers and laboratories to comply with during their research and development.

D. Stacked Events

KFDA does not require a full safety assessment for stacked events if they meet the following criteria:

- Traits that are being combined were already approved individually.
- There is no difference in the given traits, intake amount, edible part and processing method in the stacked event and the conventional non-biotech counterpart.
- There is no crossbreeding among subspecies.

The Consolidated Notice announced on December 2007 includes a provision for ERAs for stacked events. The following documents need to be submitted to RDA:

1. Information to verify whether there is interaction of traits in nucleic acid inserted in the parental line
2. Available information pertinent to characteristics of the stacked event
3. Evaluation of 1 and 2 above
4. Confirmation from the developer who received approval for the parental event used in the stacked event and agreement for review of already submitted information for the parental event

RDA reviews the submitted documents. If there is interaction between traits in the inserted nucleic acid of the parental line or other differences are noticed, RDA will then require an ERA. Otherwise, no additional review is required.

Korea is reviewing multi-trait stacked events with crop-based information rather than information for individual intermediate events. This means that intermediate events are not subject to the review unless they become commercialized.

E. Registration Requirement

For biotechnology crops for food or feed or for processing, no additional registration is required other than approval. For LMOs for propagation, however, the crop should complete the process to be

approved as a seed.

F. Coexistence

As noted earlier, biotech crops are not yet grown in Korea. As a result, regulators have not developed co-existence policies, which will undoubtedly be a tricky subject since organic production continues to increase each year.

G. Labeling

Both unprocessed biotech crops for human consumption and certain processed food products containing biotech ingredients must carry GM food labels. The stated purpose behind biotech labeling is to respond to the consumers' right to know. But, since the public sentiment generally tends to be anti-biotech, there are very, very few products on the market with a GM label.

With respect to processed products, including consumer-ready products, KFDA requires biotech labeling for 27 categories of foods if biotech crops are among the top five ingredients in the finished product or if a foreign protein or DNA is present in the finished product. Foods containing refined ingredients derived from these crops, such as soybean oil, high fructose corn syrup and raw sugar are currently exempt from labeling since the biotech protein is undetectable. However, vocal NGOs and consumer groups continue to push KFDA to expand its labeling requirements to include these products.

In 2008, during the candlelight protests against U.S. beef, consumer groups got riled up after learning that some of the country's corn processors would be bringing in biotech corn for the first time because of the short supply of conventional corn and rising international grain prices. These groups threatened to boycott products from food manufacturers using biotech corn ingredients. In response, 21 large-sized companies jointly declared that they would not use ingredients derived from biotech corn in their products.

KFDA was also under mounting pressure from outside groups to expand its labeling requirements. In October 2008, KFDA responded to these pressures with a draft proposal to expand its labeling requirements to include undetectable products like soybean oil and high fructose corn syrup made from GM crops. KFDA had originally planned to finalize this proposal by April 2009, but the PMO intervened because of the concerns of trading partners as well as from the local food manufacturers about upward spiraling inflation. This proposal is on the back burner for the time being.

Some segments of the local food industry are concerned that the proposal to expand GMO labeling would end-up misleading consumers, limit the available selection of products on the market, and increase production costs. For example, if implemented, food manufacturers would be unwilling to develop any food using these ingredients and supermarkets would shy away from carrying any GM-labeled product for fear of losing sales.

In April 2007, MIFAFF revised its Feed Manual requiring retail packaged animal feed products to carry

a GMO label when containing biotech ingredients. This labeling requirement was enforced starting October 11, 2007. There have been no reported problems since almost all animal feed products contain biotech ingredients and are therefore subject to this labeling requirement.

GM Labeling Requirements for Bulk Grains

- Shipments consisting of 100 percent unprocessed biotech crops for human consumption are required to carry labels stating “GM ‘commodity’” (e.g. “GM soybeans”).
- Shipments that contain some biotech-enhanced crops are required to carry labels stating that the product “contains GM ‘commodity’” (e.g. “contains GM soybeans”).
- Shipments that may contain biotech-enhanced crops are required to carry labels stating that the product “may contain GM ‘commodity’” (e.g. “may contain GM soybeans”).

GM Labeling Requirements for Processed Products

- Products that contain biotech corn or soybeans composing less than 100 percent of the product ingredients are required to be labeled as “GM food” or “food containing GM corn or soybeans.”
- Products that may contain biotech corn or soybeans are required to be labeled “May contain GM corn or soybeans.”
- Corn or soybean products that are 100 percent biotech products are required to be labeled “GM” or “GM corn or soybeans.”

Unintentional Presence

MIFAFF allows for up to a three percent unintentional presence of biotech components in unprocessed non-biotech products (i.e. conventional food grade soybeans). MIFAFF’s tolerance is the default threshold for processed food products that are subject to biotech labeling requirements. KFDA also allows for a three percent unintentional presence of biotech components in raw materials, such as soybeans and corn destined for human consumption.

Intentional mixture of biotech ingredients triggers the labeling requirement even if the final level of biotech presence is within the three percent threshold. Grains and processed food products within the three percent threshold are required to submit a full IP documentation or a certificate recognized by the exporting government to be exempted from biotech labeling requirement.

Table 3: Unintentional GM Presence and GM Labeling

	Threshold	Label
Conventional Bulk Grain Shipments Containing Unintentional GM Presence		
with IP or government certificate	3%	GMO label is exempted.
without IP or government certificate	0%	GMO label shall be affixed.
Processed Products Containing Unintentional GM Presence		

with IP or government certificate	3%	GMO label is exempted.
without IP or government certificate	0%	GMO label shall be affixed.
Processed Products Containing Intentional GM Presence (in top five ingredients)		
- with IP or government certificate	3%	GMO label is exempted
- without IP or government certificate	0%	GMO label shall be affixed.
Processed Products Containing Intentional or Unintentional GM Presence (beyond top five ingredients)		
GMO label is exempted without any further documentation requirements.		
Processed Product Containing No Foreign DNA, such as syrups, oils, alcohols and processing aids		
GMO label is exempted without any further documentation requirements.		

Use of Labels Such as Biotech-Free, Non-Biotech, GMO-Free, or Non-GMO

Concerning unprocessed grains for human consumption, MIFAFF allows a voluntary non-GMO label if the product is 100-percent non-biotech. With regard to processed food products, however, KFPA does not encourage non-GMO or GMO-free labeling to prevent the misuse of such labels.

Importers must keep the relevant documents that support their non-GMO claim. Such documents can include a testing certificate stating that there is no presence of GMO components. See [Attaché Reports KS1004](#) and [KS1046](#) for more details on GM labeling.

H. Biosafety Protocol

Korea ratified the Cartagena Protocol on Biosafety (CPB) on October 2, 2007 and implemented the LMO Act, the legislation implementing the CPB on January 1, 2008. The LMO Act has not been revised since its implementation to reflect the most current provisions contained in the CPB.

Korea is in the process of revising the LMO Act. On July 15, 2011, MKE notified the WTO (SPS/328) that it had published a draft revision to the LMO Act. Comments are due in mid September. After the international comment period and ensuing revisions, if needed, the Act will go to Korea's National Assembly for approval. Once the Act is finalized, MKE will turn its attention to revising the underlying regulations.

The most telling example of how outdated the Act has become relates to documentation. The existing Act still refers to the 'does contain' principle, which requires exporters to identify the different biotech events contained in each shipment. However, in the absence of sophisticated testing, which would be very time consuming and expensive, it's nearly impossible to definitively state what events are in the shipment.

As a result, Korea is instead allowing exporters to simply provide a list of all biotech events approved for use in Korea on the commercial invoice. This practice, while not perfect, is more consistent with the CPB 'may contain' documentation policy. Although trade has continued without any disruption,

the LMO Act and its underlying regulations need to be modified to reflect actual practice and to be consistent with the CPB. Furthermore, these and other revisions would make the Act and its sub regulations more transparent and predictable, thereby reducing the likelihood of unfavorable misinterpretations, which could lead to possible trade disruptions in the future.

I. Other International Fora

Korea is actively participating in meetings such as CODEX, IPPC, OIE, APEC and others. Korea tends to loosely follow CODEX regulations in their safety assessment guidelines.

J. Biotechnology-Related Trade Barriers

LLRice: The Korean government requires shipments of U.S. rice to be tested multiple times to confirm the absence of LLRice since the discovery of trace amounts of LLRice 601 in the U.S. rice supply in August 2006. MIFAFF requires two separate tests prior to loading, while the KFDA requires a third test upon arrival. Once rice is released into the market, the National Agricultural Product Quality Service under MIFAFF conducts the fourth test to verify the absence of LLRice in the marketed rice. Please see [KS7068](#) for more details on LLRice test requirements.

Approvals: There have been growing concerns over the risk assessment process for LMO FFP. Specifically, some facets of the risk assessment process are considered to be redundant, unprecedented and occasionally lack scientific justification. This cumbersome consultation process is sometimes slow, contributing to delays in the final approval of new events.

Organics: KFDA maintains a zero-tolerance policy for the inadvertent presence of biotech content in processed organic products. However, this policy might change with MIFAFF becoming the competent authority over processed products and implementation of the new certification program for processed organic products beginning January 1, 2013. In particular, MIFAFF is looking at introducing a processed-based certification program instead of final product verification, which would be a considerable step towards redefining the current zero tolerance policy to something that is more workable.

Expanded Labeling: As noted earlier, the stalled proposal to expand biotech labeling to non-detectable products would be very problematic and as such remains on the watch list.

K. Intellectual Property Rights

As noted in section B above, biotechnology crops are not commercially planted in Korea. However, intellectual property rights are protected under the existing domestic regulations.

Section IV. Plant Biotechnology Marketing Issues:

A. Market Acceptance

There are contradictory views about biotechnology in the Korean marketplace. The public holds positive views about the use of biotechnology in human and animal research, bio-medicine, and in the treatment of disease.

However, consumers are much more sensitive and generally negative towards the use of the technology to produce food and are therefore more willing to pay more for non-GM food. Outspoken NGOs and some in the broadcast media industry tend to reinforce this negative image, vilifying foods made from biotech crops as ‘franken food’. Meanwhile, some local newspapers have recently started to write a few positive stories about biotechnology after recognizing the country’s heavy dependence on imported biotech grains and oilseeds. However, these types of stories have not yet spilled over to broadcast media and the internet.

In light of these sensitivities, many local food manufacturers are very reluctant about using biotech ingredients. In fact, on the heels of the 2008 beef protests, twenty-one large food conglomerates, including several multinational companies, declared themselves GMO-free as a marketing ploy. Local retailers are likewise reluctant to carry GM-labeled foods since they don’t want to put product on their shelves that isn’t going to sell and would inevitably draw public scrutiny.

Nonetheless, Korea imports substantial amounts of biotech food ingredients for further processing into

vegetable oil, corn syrup, and other products that are currently exempt from the GM food labeling requirements. The general public, though, seems unaware of this fact.

B. Korean Market Survey on Biotechnology Products

Consumer Group Survey

In July 2008, the Korea Consumer Union conducted a survey of National Assemblymen to gauge lawmakers' awareness about biotechnology. The survey showed that the ruling conservative Grand National Party (GNP) was more favorable towards the technology compared to the opposition Democratic Party (DP). Overall, though, both the GNP and DP have a rather negative perception on biotechnology.

Over 50 percent of the lawmakers felt uneasy about eating biotech food and more than 75 percent said that biotech labeling should be required for cooking oil. These findings, though, seemed somewhat out of place since over 60 percent of the lawmakers were aware that Korean regulators conduct safety evaluations of each biotech crop used in food and feed before allowing it to come into the country.

While there is apparent reluctance about eating biotech crops, the survey revealed that the Assemblymen were less concerned about the locally developed biotech crops. About 7 percent of the GNP and 24 percent of the DP Assemblymen thought Korea should stop the development of biotech crops. This is a noteworthy finding since it shows that one of the keys to improving consumer confidence in biotech foods lies in the development and commercialization of a Korean biotech crop. As noted earlier, while research is currently underway to develop the country's first biotech crop, commercialization is still several years away under the most favorable circumstances.

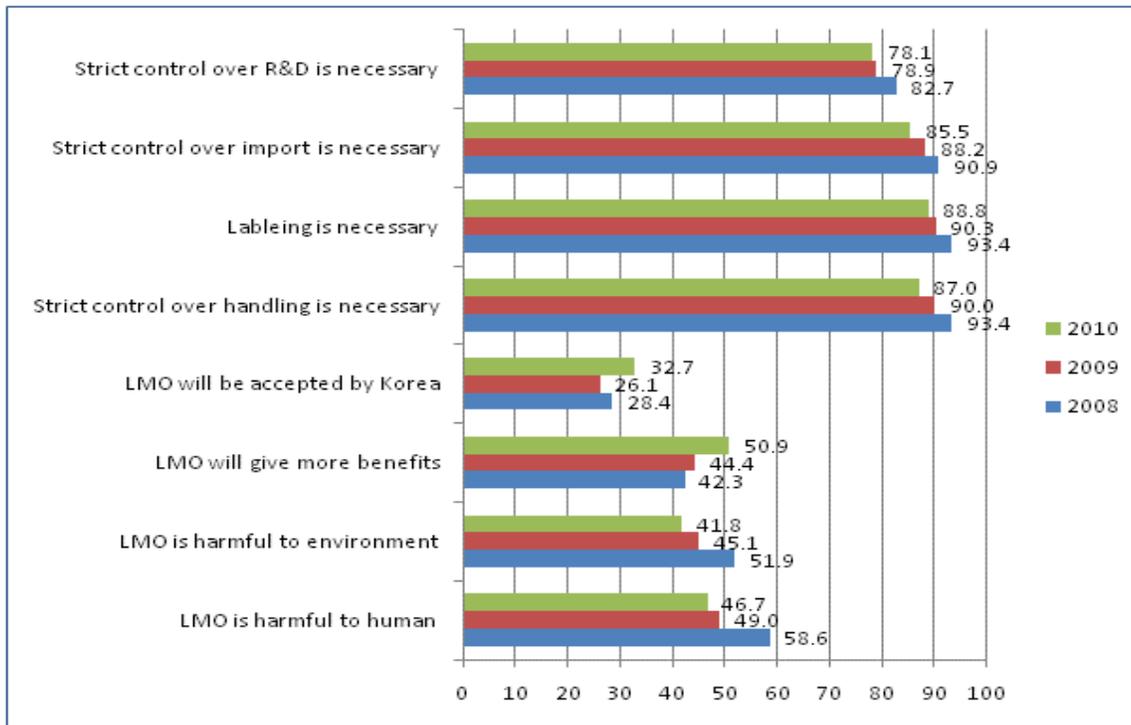
Korea Biosafety Clearing House Surveys

In November and December 2010, the Korea Biosafety Clearing House (KBCH) conducted its fourth annual survey of 1,000 consumers nationwide to gauge public perceptions on biotechnology.

The survey results showed that consumer awareness has remained unchanged from the previous year with negative attitudes toward the technology beginning to soften. In fact, only 47 percent of respondents answered that biotechnology was harmful to humans, down from 70 percent in 2007. Over 50 percent answered that biotechnology would give more benefits than losses. And, 33 percent answered that the Korean public would eventually accept LMOs. While opinions about the technology have shown some improvement, about 90 percent were in favor of labeling and strict import controls on biotech products.

Similar to the survey of the National Assemblymen, the KBCH survey revealed that consumers were more favorable towards the use of the technology outside the agricultural sector. Over 83 percent of the respondents supported its use in the medical and bio-energy sectors, while 36 percent supported its use in livestock and 49 percent in food and agricultural products.

One noteworthy outcome from the 2010 survey is that respondents appeared more favorable to biotech crops with consumer benefit traits, such as rice that would promote fat loss, iron-enriched rice, and grapes to reduce heart disease. In fact, almost 45 percent of those surveyed answered that they would buy rice that promotes fat loss. This finding suggests that one of the keys to consumer acceptance to biotechnology in food is developing a product that has some noticeable health property.



In November 2008, the KCBH conducted a nationwide survey of 1,082 researchers from a various backgrounds to gauge the academic community’s perception of biotechnology. The survey results showed that around 44 percent of the respondents understood LMOs well. Over 69 percent thought that GMO is the most familiar term that refers to LMO. Eighty-five percent of the respondents thought that LMOs would contribute to the development of human life. The survey also revealed that researchers were more positive about LMOs used for pharmaceutical purposes than food use.

Section V. Plant Biotechnology Capacity Building and Outreach:

A. U.S. Government or USDA Funded Outreach Activities

A number of activities have been organized and funded to provide biotechnology outreach in Korea:

1. Biotech briefings for participants in the State Department's International Visitors Program since 1999
2. Biotech press mission to the United States consisting of six reporters in 2000 sponsored by the USDA
3. Cochran Fellowship Program for three Korean biotechnology regulators in 2002
4. Video conference sponsored by the USDA for professors and media in 2002
5. Speakers from the USDA, the State Department, and other agencies/organizations for various local symposiums organized by Korean government agencies including KFDA, RDA, the Korea Research Institute for Bioscience and Biotechnology, etc.
6. U.S. Grains Council's (USGC) annual biotech program for media, NGOs, scientists, and high school science teachers, etc.
7. Dr. Benson's speech and press outreach in June 2006
8. Presentation by an expert from North American Export Grain Association to Korean industry pertinent to the Cartagena Protocol on Biodiversity in December 2007
9. Presentation by U.S. Grain Council's invited speakers for science high school students, graduate students and professors at the university, the Korea Society of Food Science and Korean NGOs in May 2009
10. Presentations to universities by FAS/Seoul staff in 2007-2009
11. USGC-sponsored educator mission to the United States in August 2011
12. USGC-sponsored trip for KFDA and RDA committee members in August 2011

Section VI. Animal Biotechnology:

A. Development and Use

Korea is actively using genetic engineering for the development of animals. The research being led by various government agencies and private entities is mainly related to the development of biomedicines and bio-organs.

In 2010, MIFAFF announced its overall plan for future growth engines for the life industry in Korea. Biomedicine is one of the areas where considerable resources are being invested. RDA's Next Generation Bio-Green 21 Project launched on May 19, 2011 is also focusing on development of biomedicines and bio-organs as one of the three top sectors.

RDA is conducting research to develop 15 different traits in two animals, chickens and swine. These traits are designed to produce high value protein and anti-virus materials, swine producing material that can treat anemia, hemophilia, thrombus and chickens producing eggs with lactoferrin and antioxidant substances. Currently, RDA does not have any plan to develop genetically-engineered animals for food use.

The Ministry of Education announced in July 2010 that they would invest 21 billion won (\$18 million) in research in developing a genetically engineered mouse for new medicine and disease modeling. Colleges are integrating biotechnology into their livestock science programs and have expanded their research capacity in these areas. For example, in 2002, Chungnam National University built the "Transgenic Swine Research Center" to produce swine for the development of new pharmaceuticals.

Private entities are also developing genetically-engineered animals that produce high value protein pharmaceuticals. Others are developing transgenic cattle that can produce lactoferrin and insulin, a

fluorescent dog for human disease research, chickens that purportedly produce substances to cure leukemia and mini-pigs for production of bio organs.

Despite active research by Korean scientists, Korea has yet to commercially produce any genetically-engineered animals. It is too early to estimate how close Korea is to commercial production. As for food use, Korean scientists are unwilling to engage in research as they are concerned with consumer's acceptance of meat from genetically-engineered animals.

B. Regulation

The LMO Act and its implementing regulations apply to the development and import of genetically engineered animals. Pharmaceuticals produced from genetically-engineered animals are governed by the Pharmaceuticals Affairs Act. No specific regulation has been established for the management of genetically engineered animals.

MIFAFF is responsible for the labeling and approval of genetically-engineered animals, but has not yet established any regulations. KFDA is responsible for the safety evaluation of genetically-engineered animals and fishery products for human consumption under its GMO safety evaluation guidelines.

C. Stakeholder/Public Opinions

Many Koreans believe that biotechnology is an important frontier for the economic development of Korea in the 21st century. Proponents have had some success in making the case that biotechnology could be an engine for growth and could solve public health and environmental problems. Korea continues to expand investment on biotechnology research and development for biomaterial, biomedicine and organs, gene therapy, etc.

Despite the Korean government's support for biotechnology research, the Korean public has a negative perception of crops and foods produced through biotechnology. For meat or food from genetically-engineered animals, it is expected that the public will have even more serious concerns. Consequently, the majority of government funding for biotechnology research is directed toward non-agricultural projects such as biomedicine, stem cell research, cloning, and gene therapy. Koreans in general maintain a positive view towards non-agricultural biotechnology and believe biotechnology will play an important role in the country's economic development.

D. International Organizations

Not specifically related to genetically-engineered animals, but Korea is actively participating in meetings such as CODEX, IPPC, OIE, APEC and others. Korea is trying to loosely follow CODEX regulations in their safety assessment guidelines.

E. Outreach, Needs and Strategies

No U.S. government-funded outreach activity related to genetic engineering of agriculturally-relevant animals has been carried out in Korea.

APPENDIX: TABLE OF APPROVED BIOTECHNOLOGY PRODUCTS AS OF JULY 2011

Note: Biotechnology crops are required to undergo a food safety assessment and environmental risk assessment (ERA). Of note, the ERA is sometimes referred to as a feed approval, though the review is largely focused on the impact to the environment, not animal health.

Crop	Event	Applicant	Trait	Approval	Approval Date
Soybean	GTS40-3-2	Monsanto	Herbicide Tolerance (HT)	Food & Feed	2010 & 2004
Soybean	Mon89788	Monsanto	HT	Food & Feed	2009
Soybean	A2704-12	Bayer	HT	Food & Feed	2009
Soybean	DP-356043-5	Dupont	HT	Food & Feed	2010 & 2009
Soybean	DP-305423-1	Dupont	HT & high oleic	Food & Feed	2010
Corn	Mon810	Monsanto	Insect Resistance (IR)	Food & Feed	2002 & 2004
Corn	TC1507	Dupont	HT, IR	Food & Feed	2002 & 2004
Corn	GA21	Monsanto	HT	Food & Feed	2010 & 2007

Corn	NK603	Monsanto	HT	Food & Feed	2002 & 2004
Corn	Bt 11	Syngenta	HT, IR	Food & Feed	2003 & 2006
Corn	T25	Aventis / Bayer	HT	Food & Feed	2003 & 2004
Corn	MON863	Monsanto	IR	Food & Feed	2003 & 2004
Corn	Bt176	Syngenta	HT, IR	Food & Feed	2003 & 2006
Corn ¹⁾	DLL25	Monsanto	HT	Food	2004
Corn ¹⁾	DBT418	Monsanto	HT, IR	Food	2004
Corn	MON863 X NK603	Monsanto	HT, IR	Food & Feed	2004 & 2008
Corn	MON863 X MON810	Monsanto	IR	Food & Feed	2004 & 2008
Corn	MON810 X GA21	Monsanto	HT, IR	Food	2004
Corn	MON810 X NK603	Monsanto	HT, IR	Food & Feed	2004 & 2008
Corn	MON810 X MON863 X NK603	Monsanto	HT, IR	Food & Feed	2004 & 2008
Corn	TC1507 X NK603	Dupont	HT, IR	Food & Feed	2004 & 2008
Corn	Das-59122-7	Dupont	HT, IR	Food & Feed	2005
Corn	Mon88017	Monsanto	HT, IR	Food & Feed	2006
Corn	Das-59122-7 X TC1507 X NK603	Dupont	HT, IR	Food & Feed	2006 & 2008
Corn	TC1507 X Das-59122-7	Dupont	HT, IR	Food & Feed	2006 & 2008
Corn	Das-59122-7 X NK603	Dupont	HT, IR	Food & Feed	2006 & 2008
Corn	Bt11 X GA21	Syngenta	HT, IR	Food & Feed	2006 & 2008
Corn	MON88017 X MON810	Monsanto	HT, IR	Food & Feed	2006 & 2008
Corn ²⁾	Bt10	Syngenta	HT, IR	Food	2007
Corn	MIR604	Syngenta	IR	Food & Feed	2007 & 2008
Corn	MIR604 X GA21	Syngenta	HT, IR	Food & Feed	2008
Corn	Bt11 X MIR604	Syngenta	HT, IR	Food & Feed	2007 & 2008

Corn	Bt11 X MIR604 X GA21	Syngenta	HT, IR	Food & Feed	2008
Corn	Mon89034	Monsanto	IR	Food & Feed	2009
Corn	Mon89034 X Mon88017	Monsanto	HT, IR	Food & Feed	2009
Corn	Smart stack	Monsanto/ Dow	HT, IR	Food & Feed	2009
Corn	Mon89034 X NK603	Monsanto	HT, IR	Food & Feed	2010 & 2009
Corn	NK603 X T25	Monsanto	HT	Food & Feed	2010 & 2011
Corn	Mon89034 X TC1507 X Nk603	Monsanto/ Dow	HT, IR	Food & Feed	2010 & 2011
Corn	MIR162	Syngenta	IR	Food & Feed	2010 & 2008
Corn	DP-098141-6	Dupont	HT	Food & Feed	2010
Corn	TC1507 X Mon810 X NK603	Dupont	HT, IR	Food & Feed	2010
Corn	TC1507 X DAS-591227 X Mon810 X NK603	Dupont	HT, IR	Food & Feed	2010
Corn	Bt11 X MIR162 X MIR604 X GA21	Syngenta	HT, IR	Food & Feed	2010 & 2011
Corn	Event3272	Syngenta	Functional trait	Food & Feed	2011
Cotton	Mon531	Monsanto	IR	Food & Feed	2003 & 2004
Cotton	757	Monsanto	IR	Food & Feed	2003 & 2004
Cotton	Mon1445	Monsanto	HT	Food & Feed	2003 & 2004
Cotton	15985	Monsanto	IR	Food & Feed	2003 & 2004
Cotton	15985 X 1445	Monsanto	HT, IR	Food & Feed	2004 & 2008
Cotton	531 X 1445	Monsanto	HT, IR	Food & Feed	2004 & 2008
Cotton	281/3006	Dow Agro Science	HT, IR	Food & Feed	2005 & 2008
Cotton	Mon88913	Monsanto	HT	Food & Feed	2006
Cotton	LLCotton 25	Bayer	HT	Food & Feed	2005
Cotton	Mon88913 X Mon15985	Monsanto	HT, IR	Food &	2006 &

				Feed	2008
Cotton	Mon15985 X LLCotton 25	Bayer	HT, IR	Food & Feed	2006 & 2008
Cotton	281/3006 X Mon88913	Dow Agro Science	HT, IR	Food & Feed	2006 & 2008
Cotton	281/3006 X Mon1445	Dow Agro Science	HT, IR	Food	2006
Cotton	GHB614	Bayer	HT	Food & Feed	2010
Canola	RT73 (GT73)	Monsanto	HT	Food & Feed	2003 & 2005
Canola	MS8/RF3	Bayer	HT	Food & Feed	2005
Canola	T45	Bayer	HT	Food & Feed	2005
Canola ¹⁾	MS1/RF1	Bayer	HT	Food & Feed	2005 & 2008
Canola ¹⁾	MS1/RF2	Bayer	HT	Food & Feed	2005 & 2008
Canola ¹⁾	Topas19/2	Bayer	HT	Food & Feed	2005 & 2008
Potato ¹⁾	SPBT02-05	Monsanto	IR	Food	2004
Potato ¹⁾	RBBT06	Monsanto	IR	Food	2004
Potato ¹⁾	Newleaf Y (RBMT15-101, SEMT 15-02, SEMT 15-15)	Monsanto	IR, Virus Resistance (VR)	Food	2004
Potato ¹⁾	Newleaf Plus (RBMT21-129, RBMT21-350, RBMT22-82)	Monsanto	IR, VR	Food	2004
Sugar beet	H7-1	Monsanto	HT	Food	2006
Alfalfa	J101	Monsanto	HT	Food & Feed	2007 & 2008
Alfalfa	J163	Monsanto	HT	Food & Feed	2007 & 2008
Alfalfa	J101 X J163 ³⁾	Monsanto	HT	Food & Feed	2007 & 2008

Total Food Approval: 73

Total Feed Approval: 63

¹⁾ Conditional approval for discontinued items

²⁾ Conditional approval for items that are not intended for commercialization

³⁾ Conditional approval as other category and adventitious presence is accepted

