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## **Agricultural Biotechnology Annual**

## **2018 Annual Report**

**Approved By:**

Ronald P. Verdonk

**Prepared By:**

Seung Ah Chung / Peter J. Olson

**Report Highlights:**

After 10-years under the Living Modified Organism (LMO) Act, Korea plans to improve and revise the LMO Act to address stakeholders' concerns. Potato and products containing potatoes will be subject to mandatory GE labeling in early 2019 when Korea approves the first commercialized GE potato event.

Korea heightened its monitoring and testing program of seeds after two incidents of unintentional environmental release of unapproved GE canola and cotton seeds.

## **Section I. Executive Summary:**

Korea is heavily dependent on imported food (except rice) and feed grains. A limited number of food products is made from biotech ingredients due to negative consumer sentiment towards biotechnology, whereas the bulk of livestock feed is made from biotech corn and soybean meal. The United States was the top GE grain exporter to Korea in 2017 and 2018, followed by Brazil. Total GE grain exports to Korea from the United States from January through August 2018 reached 4,999,000 MT, out of Korea's total GE grain imports of 6,135,000 MT.

Korea published its 3<sup>rd</sup> LMO Safety Management Plan in December 2017, which will be implemented for five years, starting in 2018. Based on this plan, Korea will set up an emergency response team for unintentional release incidents of GE events, set up an effective LMO management system, prepare a safety management plan for new breeding technology, improve the Living Modified Organism (LMO) Act, etc. Korea will spend 82 billion Korean won (approx. \$75 million dollars) over the five year span.

As it has been over 10 years since it established the LMO Act, Korea plans to evaluate the current LMO Act and prepare improvement plans to address stakeholders' demands and interests. To do so, the Korea Biosafety Clearing House is conducting a survey from September 3 through October 30, 2018. Comments received will be considered in drafting a proposed revision.

Korea requires biotech labeling for any food products that contain detectable biotech ingredients. Cooking oils and syrups continue to be exempt from mandatory biotech labeling. Some lawmakers and NGOs are still demanding European Union-like labeling standards. Korea is likely to require GE labeling for potato and processed products containing potatoes from early 2019 when they plan to approve the first GE potato event for food use in Korea.

After the first unapproved canola (GT73) plant detection incident in the course of the regular monitoring program in May 2017, Korea detected unapproved GE cotton plants, MON531, in November 2017. Both events were imported as conventional seeds. After these two detections, Korea has been tightening monitoring and testing of seeds.

### **Useful Acronyms**

GMO: Genetically Modified Organism  
LMO: Living Modified Organisms  
LMO FFP: LMOs for Food, Feed and Processing  
PMO: Prime Minister's Office  
MFDS: Ministry of Food & Drug Safety  
MHW: Ministry of Health & Welfare  
KCDC: Korea Center for Disease Control and Prevention  
ME: Ministry of Environment  
NIE: National Institute of Ecology  
MAFRA: Ministry of Agriculture, Food, and Rural Affairs  
RDA: Rural Development Administration  
APQA: Animal & Plant Quarantine Inspection Agency

NAQS: National Agricultural Products Quality Management Service  
 NIAS: National Institute of Animal Science  
 MOTIE: Ministry of Trade, Industry and Energy  
 MOFA: Ministry of Foreign Affairs  
 MOF: Ministry of Oceans and Fisheries  
 NFRDI: National Fisheries Research & Development Institute  
 MSIP: Ministry of Science, Information Communication Technology & Future Planning  
 KBCH: Korea Biosafety Clearing House  
 HT: Herbicide Tolerance  
 IR: Insect Resistance  
 VR: Virus Resistance  
 DR: Drought Resistance  
 GE: Genetically Engineered  
 ERA: Environmental Risk Assessment

## Section II

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## CHAPTER 1: PLANT BIOTECHNOLOGY

### *Part A. Production and Trade*

#### **A) Product Development**

The development of biotech, or GE crops, also known as living modified organisms (LMOs) in Korea, is led by various government agencies, universities, and private entities. Research is mainly focused on second and third generation traits, such as drought and disease resistance, nutrient enrichment, transformation techniques, and gene expression. The Rural Development Agency (RDA) has approved a total of 244 research cases for field trials conducted by RDA's designated evaluation entities and private entities from January through October 2018.

In September 2017, RDA agreed with local NGOs that they would stop plans to commercialize GE

crops in Korea and dismantle the National Center for GM Crops, the RDA team leading GE event development, renaming it the Agricultural Biotechnology Research Center. This was in response to the years-long pressure exerted by NGOs to stop GE rice field trials and GE commercialization. Under the agreement, RDA will form a committee with NGOs for consultation on GE research plans. However, RDA will not stop conducting GE research. RDA will continue to develop GE events as it had in the past but they will improve transparency regarding the safety of GE events. RDA said that there are two reasons for RDA to continue GE research. The first reason is that GE technology is a necessary tool for Korea to deal with climate change. The second reason is that Korea imports a great volume of GE crops which they regulate, so Korea should have the requisite technology. RDA will fund research teams under the second phase for the Next Generation Bio-Green 21 Project to continue GE research. Anti-biotech groups welcomed this news while some Korean researchers and politicians who favor GE technology criticized RDA's decision. This group is concerned that RDA made its decision due to the pressure from anti-biotech NGOs and that it will have a negative impact on Korea's GE research.

In May 2015, the RDA released results of the first phase of the Next Generation Bio-Green 21 Project, which aims to develop fundamental technology and commercialize such technology. With a total investment of 271.4 billion won (approximately \$236 million), RDA decoded genomes for 9 organisms including pepper and ginseng and developed anthracnose-resistant pepper and other products between 2011 and 2014. RDA will invest another 300 billion won (approximately \$260 million) by 2020 in order to develop additional technology. Given that these projects and funding have multiyear timelines, RDA intends to continue the efforts, notwithstanding their new commercialization agreement with anti-biotech NGOs.

Korea has 111 events in 13 different varieties of crops under development between 2013 through 2017. These crops include some of the following: resveratrol enriched rice, vitamin A enriched rice, insect resistant rice, environmental stress tolerant rice, virus resistant pepper, vitamin E enriched beans, insect resistant beans, herbicide tolerant bentgrass, virus resistant potatoes, Chinese cabbage, watermelon, sweet potato, and apples. Safety assessment data is currently being generated for four events in two crops: three beans and one bentgrass. A local university developed an herbicide tolerant bentgrass under RDA's Next Generation Bio-Green 21 Project that was submitted to RDA for an environmental risk assessment (ERA) in December 2014 and it is still under review. GE rice enriched with resveratrol, known to be an antioxidant polyphenol, received health and medical use approval from the Ministry of Health & Welfare (MHW). This event was initially developed for food use but due to significant pushback from local NGOs and rice farmers, RDA decided not to use this rice for food use. Instead, they limited production of resveratrol produced by GE rice using cell culture only and received approval from MHW for use in pharmaceuticals or cosmetics in January 2018.

A team from a government research institute developed biotech sweet potatoes that are resistant to drought and tolerate saline soils to surmount the effects of desertification. The institute succeeded in growing the sweet potatoes in China's Kubuchi Desert and Kazakhstan, two of the largest semi-arid areas in northeast Asia. They also started the genome decoding process for sweet potatoes in 2014 in coordination with Chinese and Japanese researchers. With decoded information, the team aims to grow a large amount of biotech sweet potatoes in areas affected by desertification in China, the Middle East, and Africa.

Although significant research has been done, the soonest the regulatory review process for one of these

crops (most likely herbicide-resistant bentgrass) could be completed in five years. Commercialization is expected to take much longer and won't be easy due to opposition from local NGOs and farmer groups. Without stronger support from Korean farmers who recognize the benefits, commercialization of GE crops in Korea will not likely be realized. Generating farmers' support to actively use this technology is considered key to increasing consumer confidence in biotech food.

## **B) Commercial Production**

Despite substantial investment, Korea has yet to commercially produce any biotech crops. The leading government research agency, RDA announced in 2017 that they would not commercially produce biotech crops in Korea in response to continued pressure from domestic anti-biotech NGOs.

## **C) Exports**

Korea does not export any biotech crops as Korea does not commercially produce any biotech crops.

## **D) Imports**

Korea imports biotech crops and products for food, feed and processing but not for propagation. The United States, closely followed by and sometimes surpassed by Brazil, is usually the largest supplier of biotech grains and oilseeds to the Korean market. In the year through August 2018, the United States is the largest supplier followed by Brazil and Argentina.

In calendar year (CY) 2017, Korea imported a total of 9.2 million metric tons of corn, which consisted of 6.9 million metric tons for feed and 2.3 million metric tons for processing. Imports from the United States reached 4.4 million metric tons, or 83 percent of the total. Imports of U.S. corn were comprised of 3.7 million metric tons for animal feed, which was nearly all biotech corn. The remaining 0.7 million metric tons of U.S. corn was used for processing of which nearly 100 percent was biotech.

Imported biotech corn for processing is generally used to make products like high fructose corn syrup (HFCS) or corn oil. Whether for feed or food, both 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 is more affordable and easier to secure on the world market than conventional corn. Meanwhile, processors producing flour, grits and flakes are importing identity preserved (IP) conventional corn from a variety of international suppliers.

In 2017, Korea imported a total of 1.3 million metric tons of soybeans, three quarters of which were for crushing. The United States was the largest soybean supplier, exporting 584,641 metric tons, which represented about 45 percent of all imports. Of that amount, 388,535 metric tons were used for crushing and 195,691 metric tons for food processing/sprouting. Brazil was the second largest soybean supplier to Korea in 2017, exporting 495,925 metric tons.

Supplementing domestically produced meal, Korea imported 1.7 million metric tons of soybean meal in 2017. The United States exported 4,124 metric tons, accounting for 0.2 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 tofu, bean paste, and bean sprouts, and are primarily IP-handled, non-biotech beans.

Table 1 contains import statistics for biotech soybeans and corn. This data differs slightly from the numbers reported in the preceding paragraphs since it is 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. For more detailed information on Korea's feed grain and oil seeds production, supply, and demand situation, please see the latest versions of Post's reporting on these subjects in the [GAIN system](#).

Table 1: Imports Statistics for LMO Soybeans and Corn<sup>1</sup>

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

Classification			2014	2015	2016	2017	2018 Jan-Jul
			Volume	Volume	Volume	Volume	Volume
Soybean	Food (Crushing)	US	445	273	384	397	282
		Non-US	576	756	598	646	357
		Total	1,021	1,029	982	1,043	639
Corn	Food	US	706	354	630	703	621
		Non-US	556	762	392	536	106
		Total	1,262	1,116	1,022	1,239	727
	Feed	US	4,337	2,994	3,715	3,558	4,009
		Non-US	4,020	4,942	3,847	3,610	664
		Total	8,357	7,936	7,562	7,168	4,673
Oilseeds	Feed	US	79	75	16	119	87
		Non-US	102	81	159	32	9
		Total	181	156	175	151	96

Source: Korea Biosafety Clearing House

<sup>1</sup> Statistics are on an import approval basis and only cover biotech grains and oilseeds.

## E) Food Aid

South Korea is not a food aid recipient. South Korea has provided intermittent food aid to North Korea depending on prevailing political conditions. Korea participates in the ASEAN Plus Three Emergency Rice Reserve (APTERR), which was established in 2013 to provide member countries with rice in the event of natural disasters. Korea has provided 90,000 MT of rice to date out of their 150,000 MT commitment. In January 2018, Korea joined the Food Assistance Convention (FAC). This allows Korea to draw down its burdensome rice stocks, currently held in storage. In 2018, Korea allocated and shipped 50,000 MT of domestic rice to four countries in Africa and the Middle East: 17,000 MT to Yemen, 15,000 MT to Ethiopia, 13,000 MT to Kenya and 5,000 MT to Uganda, through the World Food Program (WFP). Korea plans to allocate the same amount of rice for food aid in 2019.

## F) Trade Barriers

Approvals: There has been growing concern over the risk assessment process for LMOs for FFP. Specifically, some facets of the risk assessment process are considered to be redundant, as five agencies are involved in the approval of a single event and data requirements occasionally lack scientific justification. This cumbersome consultation process is sometimes slow, contributing to delays in the final approval of new events. See a further discussion of this issue under Part B: Policy, B) Approvals,

below.

Organics: Korea maintains a zero-tolerance policy for the inadvertent presence of biotech content in processed organic products. Despite hope that Korea would change this policy when making regulations for MAFRA's new certification program for processed organic products in 2014, MAFRA adopted MFDS's zero tolerance policy in their final regulation. Any suppliers of organic products that test positive for GE material at any level will be instructed to remove an organic claim from the product label, and the National Agriculture Product Quality Service (NAQS) may investigate the case to see if there is any intentional violation. Shippers of U.S. processed organic products that are accompanied with NAQS Import Certificate are not required to provide additional documents to be exempt from mandatory biotech labeling in Korea.

## ***Part B: Policy***

### **A) Regulatory Framework**

Korea ratified the Cartagena Protocol on Biosafety (CPB) on October 2, 2007. 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 Trade, Industry and Energy (MOTIE, formerly the Ministry of Knowledge Economy [MKE]), which is the competent national authority, spearheaded the drafting of the Act and its implementing regulations back in early 2001. After several years and numerous iterations, MOTIE published drafts for public comment in September 2005. While the text of the Act and lower level regulations were finalized just six months later in March 2006, the regulations were not implemented until January 1, 2008. After several attempts, the LMO Act was finally revised in December 2012 with a few modifications including a revised definition of stacked events. Overall however, it failed to address U.S. concerns regarding redundant consultation reviews and did not make a distinction between LMOs for FFP and LMOs for propagation. The revised Act went into effect on December 12, 2013.

### **Roles & Responsibilities of Government Ministries**

Ministry of Trade, Industry and Energy (MOTIE): 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 (MOFA): National focal point for the CPB.

Ministry of Agriculture, Food, and Rural Affairs (MAFRA): Authority for matters related to the import/export of agricultural/forestry/livestock LMOs.

Rural Development Administration (RDA) (overseen by MAFRA): ERAs for biotech crops, environmental risk consultation for LMOs and leading developer of biotechnology crops in Korea.

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

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

Ministry of Oceans and Fisheries (MOF): Authority for matters related to the trade of maritime LMOs including risk assessments for such LMOs.

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

Ministry of Health and Welfare (MHW): Authority for matters related to the import/export 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): Oversees human risk consultation for LMOs.

Ministry of Food & Drug Safety (MFDS) (under the Prime Minister's Office): Authority for matters related to the import/export of LMOs for food, pharmaceutical, and medical devices, food safety approvals of biotechnology crops, and the enforcement of labeling requirements for non-processed and processed food products containing biotech ingredients.

Ministry of Environment (MOE): Authority for 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, not including agricultural LMOs for planting.

National Institute of Ecology (NIE) (overseen by MOE): Handles import approval of LMOs under jurisdiction of MOE and environmental risk consultation for LMOs.

Ministry of Science, Information Communication Technology (ICT) & Future Planning (MSIP): Authority for issues related to the trade of LMOs that are used for testing and research 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. In keeping with the LMO Act revision issued on December 11, 2012, the committee was later moved under MOTIE in December 2013. The change of the Committee chair to the MOTIE Minister from the Prime Minister was not intended to downgrade the status of the committee but was meant to achieve more effective and efficient operation of the committee. The committee reviews the following factors relevant to the import and export of LMOs:

- Factors relevant to the implementation of the Cartagena Protocol

- Establishment and implementation of the safety management plan for LMOs
- Re-examination in accordance with the provisions of Article 18 and Article 22 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 the competent national authority.

The MOTIE Minister is the chair of the 15-20 member committee. Members include Vice Ministers from the seven relevant ministries noted above plus the Ministry of Planning and Finance (MOPF). 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 area, it may not be easy to reach consensus on some issues. In such cases, the MOTIE Minister as the Chair of this body can be called upon to resolve matters lacking consensus. The committee is only known to have met formally once. The last meeting was conducted through document circulation rather than face-to-face in December 2014. Instead of the Minister-led committee, a technical committee consisting of technical experts from relevant ministries gather to discuss specific issues. For example, when there was a detection of unapproved LMO canola seed, the technical sub-committee met to discuss mitigation measures. The technical committee meets six times a year. This technical committee also checks the status of risk assessments and consultation reviews of new events.

#### Political Influence

Regulatory decisions related to agricultural biotechnology are influenced by political pressure, mostly from vocal anti-biotech NGOs. 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 way to pressure the government to introduce more stringent biotech regulations. For example, politically influential anti-biotech NGOs have put forth a draft revision to the Food Sanitation Act that would expand biotech labeling requirements to any product made of biotech grain.

#### **B) Approvals**

Biotechnology crops, whether grown domestically or imported, are required to undergo a food safety assessment and an 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 ERAs to approve new events in feed grains. As part of the environmental assessment, RDA consults with three different agencies, including NIE, NFRDI, and KCDC. Meanwhile, MFDS conducts a safety assessment for food containing biotech events. The MFDS review process includes consultations with RDA, NIE and NFRDI.

The overlap between reviewing agencies, particularly between MFDS and KCDC, and redundant data requirements have led to confusion and unnecessary delays in the approval process. In response to continued requests to simplify the current approval process by streamlining the redundant and duplicative approval processes, Korea introduced a pilot project called “joint environmental consultation review.” Korea combined committees of NFRDI and NIE and the joint committee reviewed one event in 2016. However, results of the joint review indicate that few time savings or data collection efficiencies were achieved. After this trial, Korea proposed another pilot program in 2017, dubbed the “Consultation Meeting to Request Additional Documents.” Korea believed that this new pilot program would reduce a number of additional document requests from consultation review agencies by having a monthly meeting among five agencies to filter out additional documents requested by committees of each agency. Once the monthly consultation meeting identifies additional documents to be requested, MFDS and RDA will contact the applicant to provide additional documents. Korea has tried this pilot program for a couple of events and will determine whether they formalize this program or consider other plans to respond to industry request to improve the current approval process. So far, industry believes the new pilot program does not make much difference compared to the current approval process, as each agency continues to have their own committee meeting and each committee will request additional documents. Although the monthly consultation meeting plans to filter out redundant or unnecessary document requests from each committee, it is not clear how effective this consultation committee will be in improving the current approval process.

MFDS 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 October 2018, MFDS has granted food safety approval for 195 events including 166 crops, 23 food additives and six microorganisms. RDA has approved 157 events for use in feed. See Appendix for a complete list of approved events.

Although no product has been approved for commercial production in Korea, a local university funded by RDA approached its donor agency in 2008 to request approval to plant biotech grass used for landscaping purposes. The submission, initially turned down due to insufficient data, was re-submitted with requested data in October 2010. The developer again withdrew the submission in 2012 and submitted a new package with some modifications in late 2014. The package is still under review by RDA.

### **C) Stacked Events Approval**

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

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

The Consolidated Notice released in 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, a full ERA is not required.

Korea reviews 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.

The approval process for stacked events is becoming a cause for concern. Both RDA and MFDS allow the submission of a dossier for stacked events after all parental single events are approved in Korea. Considering the approval time needed for stacked events after submission, which is a minimum of 3 to 6 months and up to one year, developers have to delay commercialization of stacked events approved by USDA until Korea has finished approval. Also, data requirements for stacked events have been increasing in recent years.

#### **D) Field Testing**

RDA authorized contained field trials for 258 events in 2017. From January to October 2018, a total of 244 field trials were approved. Many of the approved field trials are for traits with resistance to environmental stress and functional traits. RDA renews the field trial permits every year. The lion's 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, cabbages, and grass are also underway.

According to the Consolidated Notice, which is the official publication for implementing regulations including those of the LMO Act, in-country field tests are required for imported LMOs used as seed. For LMOs used as FFP, 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.

#### **E) Innovative Biotechnologies**

Korea has not determined the regulatory status of innovative biotechnologies (e.g. genome editing,

among others) although there has been considerable demand from industry. There is growing interest by scientists and regulators in how Korea should approach this issue, particularly CRISPR. Korea is closely watching developments in other countries to determine how they can regulate innovative technologies.

#### **F) Coexistence**

As noted earlier, biotech crops are not yet grown in Korea. As a result, regulators have not developed co-existence policies. Korean farmers including organic farmers are concerned with potential “contamination” by GE crops as there have been several reports of findings of GE corn plants near Korean feed mills. Farmer groups have demanded more oversight by the government over imports and movement of GE crops in Korea to prevent any avoidable release of GE crops into the Korean agricultural environment.

#### **G) Labeling**

MFDS is responsible for establishing biotech labeling guidelines for both unprocessed and processed products and enforcing guidelines in the marketplace. Both unprocessed biotech crops for human consumption and certain processed food products containing biotech ingredients must carry “genetically modified” (GM) food labels. The stated purpose behind biotech labeling is to respond to the consumers’ right to know. Currently, there are very few products on the market with a “GM” label.

MFDS implemented new biotech labeling requirements beginning February 4, 2017, in accordance with a revision to the Food Sanitation Act that expanded mandatory biotech labeling to all detectable products even if it is a minor ingredient. The new rule also prohibits a “non-GMO” or “GMO-free” claim on products that do not have biotech counterparts. However, it allows “non-GMO” or “GMO-free” claims for products containing a non-GM ingredient that is more than 50% of total ingredients if it does not contain any trace of a biotech component (zero tolerance). The revision continues to exempt mandatory biotech labeling for products that do not contain foreign DNA or protein. Exempted products are cooking oil, sugar (glucose, fructose, taffy, sugar syrups, etc.), soy sauce, modified starch, and alcoholic beverages (beer, whisky, brandy, liqueur, distilled spirits, etc.). No supporting document is required to get exempted from biotech labeling requirements for the aforementioned products. It also exempts processing aids such as enzymes, carriers, diluents, and stabilizers from mandatory biotech labeling. In this case, manufacturers are required to provide a document that proves the use of raw ingredients for the aforementioned purpose.

For products that contain or may contain detectable GE raw ingredients, examples of labels are as follows:

Cases	Examples
GE grains or oilseeds	“GM corn” or “GM soy”
Products containing GE grains or oilseeds	“Containing GM corn” or “Containing GM soy”
Vegetables grown from GE grains	“Beansprout grown from GM Soy”
Products containing vegetable from GE grains	“Containing beansprout grown from GM soy”
May contain GE	“May contain GM corn” or “May contain GM soy”

grains/oilseeds		
May contain vegetable from GE grains		“May contain beansprout grown from GM soy”
Food product with detectable GE component (labeled on either principal display panel or ingredient panel)	Principal Display Panel	“GM Food”, “GM Food Additive”, “GM Health Functional Food”, “Food product containing GM soy”, “Food additives containing GM corn”, or “Health functional food containing GM corn”
	Ingredient Panel	“GM” or “GM soy” or “GM corn” in parentheses next to a name of raw ingredient on the ingredient panel
Food products containing GE raw ingredients from multiple sources	Principal Display Panel	“May contain GM corn and soy”
Food products for which detectable GE component is uncertain.	Principal Display Panel	“May contain GM soy” or “May contain GM corn”
	Ingredient Panel	“May contain GM soy” or “May contain GM corn” in parentheses next to a name of raw ingredient on the ingredient panel

Please see Post’s reporting on this issue, included in our GAIN [KS1716](#) for details. As MFDS is expected to complete its safety assessment of a GE potato event in early 2019, potatoes, and any products containing ingredients originating from potatoes, will be subject to mandatory GE labeling as soon as MFDS approves the GE potato event. This means that companies marketing conventional potatoes and processed products containing conventional potatoes will be required to submit documents to get exempted from mandatory GE labeling from early next year. Documents accepted by MFDS include a government-issued certificate (including notarized self-declaration for US origin processed products), IP documents, and testing certificates.

Similar to the situation in other countries, pressure from NGOs to mandate biotech labeling requirements continues to grow. The revision of the Food Sanitation Act published on February 3, 2016 and the revision of biotech labeling requirements published on February 4, 2017 were in response to demands from NGOs and some politicians. NGOs are still pressuring MFDS to expand biotech labeling to any products made of GM ingredients. In the past, MFDS tried to expand biotech labeling similar to the EU scheme but such attempts were not put into place due to feedback from the local food industry.

Two new draft bills to the Food Sanitation Act would expand mandatory biotech labeling to all products made of biotech crops. These bills were submitted to the National Assembly in August and November 2016, respectively and are still pending. Post will provide any updates on progress of those draft bills when they are available.

The local food industry is concerned that expanded biotech labeling would mislead 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 GE-labeled product for fear of losing sales. The industry is also concerned that in the absence of scientifically verifiable measures there could be false

labeling or documentation forgery for imported oil and syrups claiming to be “non-GMO” but actually made of biotech enhanced crops. The domestic industry is demanding to delay expansion of biotech labeling requirements to non-detectable products until there are scientific methods available to detect biotech content or a system put in place that can prevent such falsely labeled products from entering Korea.

In April 2007, MIFAFF (a previous title of MAFRA) revised its Feed Manual requiring retail packaged animal feed products to carry a “GMO” label when the product contains biotech ingredients. This labeling requirement was enforced beginning on October 11, 2007. There have been no reported problems due to the fact that nearly all animal feed products contain biotech ingredients and are therefore subject to this labeling requirement.

### Unintentional Presence

Korea allows for up to three percent unintentional presence of approved biotech components in unprocessed non-biotech products (e.g. conventional food grade soybeans) which carry an IP or government certificate. This three percent tolerance of biotech components in raw materials is the default threshold for processed food products that are subject to biotech labeling requirements.

Intentional mixture of biotech ingredients triggers the labeling requirement even if the final level of biotech presence is within the three percent threshold. Merchandisers of grains and processed food products within the three percent threshold are required to submit full IP documentation or a certificate recognized by the exporting government to be exempted from biotech labeling requirements. As for a testing certificate, only a negative test result issued by an MFDS accredited testing laboratory is acceptable as all recognized testing laboratories are accredited for qualitative testing only.

Table 2: Unintentional GE Presence and “GM” Labeling

	Threshold	Label
<b>Conventional Bulk Grain Shipments Containing Unintentional GE Presence</b>		
with IP or government certificate	3%	“GMO” label is exempted.
without IP or government certificate	0%	“GMO” label shall be affixed.
<b>Processed Products Containing Unintentional GE Presence</b>		
with IP or government certificate	3%	“GMO” label is exempted.
without IP or government certificate	0%	“GMO” label shall be affixed.
<b>Bulk Grains and Processed Products Containing Intentional GE Presence</b>		
“GMO” label shall be affixed.		
<b>Processed product containing no foreign DNA, such as syrups, oils, alcohols and processing aids</b>		
Exempt from mandatory “GMO” labeling without any further documentation required.		

### Use of Labels Such as Biotech-Free, Non-Biotech, “GMO-Free”, or “Non-GMO”:

A voluntary “Non-GMO” or “GMO Free” claim is permitted when the contents of raw ingredients subject to biotech labeling are 50% or higher or when such ingredient is the top ingredient in volume of the product. In this case, MFDS applies a zero tolerance standard so any products testing positive for “GMOs” will be a violation of labeling standards. MFDS does not allow these claims for products that do not have a commercially available biotech counterpart, or for products containing non-GE ingredients as a minor ingredient (i.e. less than 50%).

Importers must keep relevant documentation supporting their “non-GMO” claim. Such documents can include a testing certificate issued by MFDS accredited testing laboratories stating that there are no GE components present. See GAIN Reports [KS 1716](#), [KS1004](#) and [KS1046](#) for more details on GE labeling.

## **H) Monitoring and Testing**

In May 2017, the National Seed Management Agency (NSMA) under MAFRA detected unapproved canola plants at a flower festival site in northeast Korea during their regular monitoring program. Since 2013, NSMA has been carrying out the monitoring program to see if any imported canola, cotton, corn and soybean seed contain unapproved LMOs. The event that NSMA detected was GT73, a GE canola developed by Monsanto and this was the first time they found the unapproved event in imported seed. After the detection, NSMA initiated the investigation to find the cause of this incident and conducted a traceability check to see if this event was also released in other regions in Korea. Finally, NSMA confirmed that 32.4 MT of GE canola seed for planting was imported from China between January 2016 and May 2017. NSMA also confirmed that this unapproved GE canola was found in 56 locations in Korea.

In November 2017, the National Institute of Ecology (NIE) detected another case of unapproved GE cotton plants during their regular monitoring program. All seeds and plants were destroyed. (Note: Cotton is grown as an ornamental in some Korean gardens and not as a commodity crop.)

After these incidents, Korea heightened border inspection of grain seed by increasing sample size and testing canola and cotton seeds prior to planting. NSMA added wheat seed and flaxseed to their regular monitoring program and plans to expand pre-testing before planting soy, corn, wheat, and flaxseed in 2022.

The National Institute of Environmental Research (NIER) under the Ministry of Environment (MOE) started monitoring for the presence of imported LMOs in the Korean environment in 2009. NIER collected and tested samples of corn, soybean, canola and cotton countrywide. Of those samples, 19 samples were identified as LMOs. NIER ascertained that LMO plants were propagated from LMOs imported for FFPs that were inadvertently released during transportation in Korea. NIER continued monitoring and NIE, which replaced NIER as the designated natural environmental risk assessment agency has continued to monitor the fallout of imported LMOs in the Korean environment since 2014. In 2017, they confirmed 135 samples of LMOs in 6 regions in Korea.

Korea has in the past tested for unapproved GE events in shipments of imported rice, wheat, papaya, and corn, as explained below:

**Liberty Link Rice (LLRice):** In 2013, MFDS discontinued mandatory arrival LLRice testing for all incoming US rice shipments, which had been required after LL’s presence was discovered in 2006. MFDS also discontinued quarterly testing for all incoming U.S. rice shipments under its monitoring program. MAFRA also removed requirements for a statement issued by USDA’s Grain Inspection, Packers and Stockyards Administration (GIPSA) on laboratories participating in GIPSA’s proficiency program and a “non-GMO” (genetically modified organism) certificate issued by one of the participating laboratories in 2014. Currently, only one test is performed to check compliance with a

purchase contract by the Korean state trading entity, aT, prior to loading.

**MON71800 & MON71700 Wheat Event:** MFDS discontinued mandatory testing of all US wheat and wheat flour that they had been conducting after the detection of GE wheat (MON71800) in the state of Oregon in May 2013 and the detection of GE wheat (MON71700) in Washington in July 2016. MFDS requires two tests based upon a combination of wheat type/export elevator/terminal. After two clean test results, no additional testing for subsequent shipments of the same combination will be required. For wheat for feed use, MAFRA tested imported wheat for years prior to the finding of the GE wheat in Oregon and Washington. After the finding, MAFRA expanded the number of samples of U.S. origin wheat for feed use to test for the presence of GE wheat. Testing conducted by the Korean government to date has all turned out negative.

**Event 32 Test on U.S. Corn Shipment:** MFDS discontinued mandatory arrival testing of all U.S. origin corn shipments to confirm the absence of Event 32. Instead, MFDS will select one quarter of the year to conduct Event 32 testing for U.S. origin corn. White corn, sweet corn, waxy corn and popcorn are excluded from the testing requirement.

**Papaya:** MFDS requires 100% testing of all incoming papaya and products containing papaya (including health functional food) to check the presence of PRSV-YK, PRSV-SC, Hwanong No. 1, and C16-0-1.

#### **I) Low Level Presence (LLP) Policy**

Korea does not have a low level presence (LLP) policy. Instead, Korea uses the term “adventitious presence” in enforcing mandatory labeling and allows as much as 0.5% of the content of a non-LMO feed shipment to contain unapproved LMOs.

#### **J) Additional Regulatory Requirements**

For biotechnology crops intended for FFP, 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.

#### **K) Intellectual Property Rights (IPR)**

As previously mentioned, biotechnology crops are not commercially planted in Korea. However, intellectual property rights are protected under existing domestic regulations.

#### **L) Cartagena Protocol Ratification**

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 first revision of the LMO Act was issued in December 2012 and the revised LMO Act went into effect on December 12, 2013. MOTIE also revised its implementing regulations to harmonize with the revised Act in December 2013 and the Consolidated Notice in July 2014. Despite the revision, which sought to improve the approval process, MOTIE failed to fully address concerns related to the redundancy of consultation reviews that the U.S. government has recommended for many years.

To address concerns from domestic industry and foreign trading partners on the “does contain” principle in the existing regulation, MOTIE revised the import approval application for LMOs for FFP, which is part of the Enforcement Regulations of the LMO Act, on April 30, 2013. The revised form clearly stipulates “may contain” principles for LMO FFP and therefore it eliminated concerns exporters and

domestic importers had over the gaps between industry practice and principle in the written regulations. Korea allows exporters to simply provide a list of all biotech events approved for use in Korea on the commercial invoice and importers can simply copy and paste the same list in the import application form.

#### **M) International Treaties and Forums**

Korea is actively participating in CODEX, IPPC, OIE, APEC, WTO, OECD, and other meetings. Korea tends to loosely follow CODEX regulations in their safety assessment guidelines.

#### **N) Related Issues**

No further issues.

### ***Part C: Marketing***

#### **A) Public/Private Opinions**

Consumers are much more sensitive and generally negative towards the use of biotechnology to produce food and are therefore willing to pay more for non-GE food. Outspoken NGOs and the broadcast media tend to reinforce this negative image, vilifying foods made from biotech crops as ‘Franken food’.

The detection of GE wheat in Oregon in 2013 alarmed Korean consumers and media and was perceived as inadequate management of GE production in the United States. The detection gave momentum to a civic group called the “Citizens Coalition for Economic Justice (CCCE)” to demand expanded biotech labeling under the pretext of the consumer’s right to know. This organization has put together multiple meetings to debate expanded labeling and keeps pressing the National Assembly and MFDS to expand labeling requirements. To address concerns raised by consumers and end-users, the Korean Flour Millers Association (KOFMIA) temporarily suspended the purchase of U.S. origin wheat for about a month until MFDS released its second test results for GE wheat in wheat and wheat flour imported from the United States. In response to detection of GE wheat in Canada in June 2018, KOFMIA temporarily suspended the purchase of Canadian origin wheat. In light of these sensitivities, many local food manufacturers are very reluctant to use biotech ingredients. In fact, on the heels of the 2008 beef protests, twenty-one large food conglomerates, including several multinational companies, declared themselves GE-free as a marketing ploy. Local retailers are likewise reluctant to carry GE-labeled foods since they do not want to put product on their shelves that will not sell and would inevitably draw public scrutiny. Another detection of GE wheat in Washington State in 2016 reinforced the perception that management of GE research and production in the U.S. is not adequate, creating the perception that the unintentional release of unapproved events may continue to happen.

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) Market Acceptance/Studies**

There are contradictory views about biotechnology in the Korean marketplace. The public holds positive views on the use of biotechnology in human and animal research, bio-medicine, and in the treatment of disease while they tend to be negative towards its use in food production.

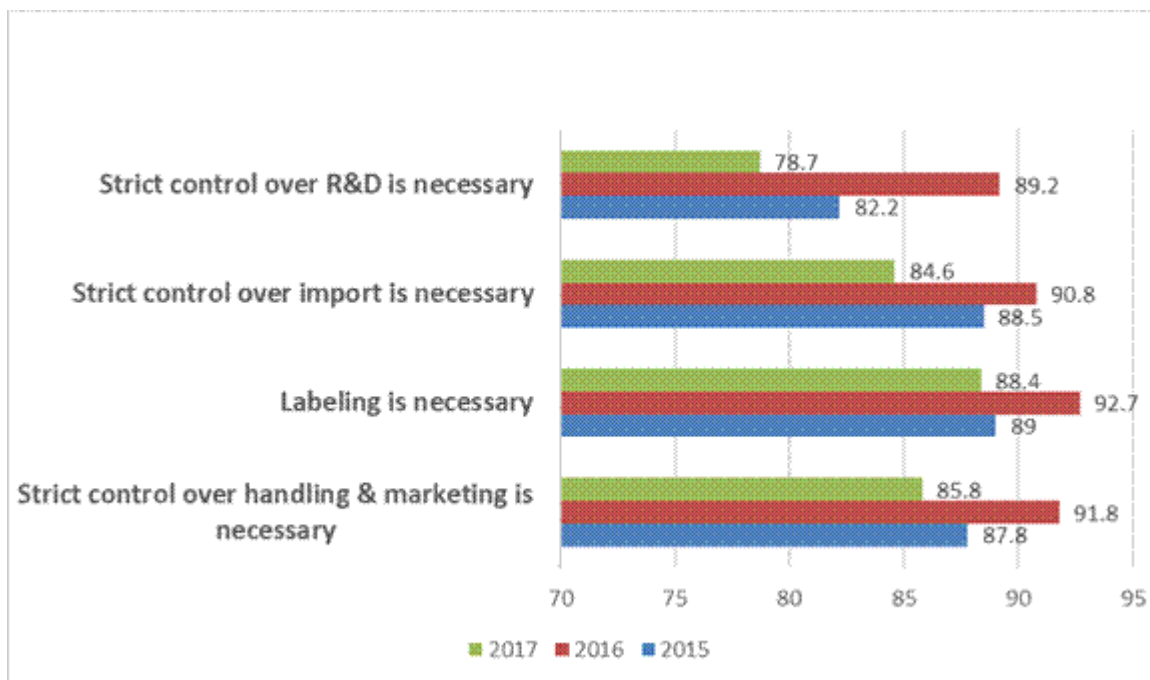
Marketing Studies In July 2008, the Korea Consumer Union conducted a survey of National Assemblymen to gauge lawmakers' awareness of biotechnology. The survey showed that the ruling conservative Grand National Party (GNP) was more favorable towards the technology compared to the opposition Democratic Party (DP). Overall though, both the GNP and DP have a rather negative perception of 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 consumers are apparently reluctant to eat biotech crops, the survey revealed that the assemblymen were less concerned about locally developed biotech crops. About 7 percent of GNP and 24 percent of DP Assemblymen thought Korea should stop 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.

In November 2017, the Korea Biosafety Clearing House (KBCH) conducted its tenth annual survey of 800 consumers nationwide to gauge public perceptions of biotechnology. The survey results showed that consumer awareness has continued to remain high and consumers' perceptions of biotechnology have improved substantially compared to the previous year's survey. Sixty-nine percent answered that biotechnology would be beneficial to humans, which was up from 47 percent in the 2016 survey. Only 6.5 percent of respondents answered that biotechnology was not beneficial. Over half of respondents who think biotechnology is beneficial answered that it was beneficial to curing diseases such as cancer and 25.1 percent answered that it might help solve food shortage issues. Of those who answered it was not beneficial, 50.1 percent of respondents questioned the safety of biotechnology to humans and 20.2 percent of the respondents thought that biotechnology used in making food was against nature.

The KBCH survey confirmed again that consumers were more favorable towards the use of the technology outside the agricultural sector although there were more positive answers for its use in the agricultural sector in the 2017 survey. Over 84.7 percent and 83.5 percent of the respondents supported its use in the medical and bio-energy sectors respectively while over 45.1 percent supported its use in livestock and 54.2 percent in food and agricultural products.



Concerning local development trials, over 74.3 percent of respondents answered that local R&D was necessary and 48.9 percent of respondents answered that it was necessary for Korea to grow biotech crops. Over 33 percent of the respondents answered that it was necessary for Korea to raise biotech animals domestically. About 19 percent responded that it was necessary for Korea to import LMOs produced in foreign countries. Over 88 and 84 percent were in favor of labeling and strict import controls on biotech products, respectively.

About 21 percent of the respondents were interested in LMOs. However, over 69 percent of these respondents were interested because of their concern over the safety of LMOs. The respondents obtained information on LMOs mostly from internet news, followed by TV.

In November 2008, the KCBH conducted a nationwide survey of 1,082 researchers from 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 was the most recognizable term for 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 for food use.

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### *Part A. Production and Trade*

#### **A) Product Development**

Korea is actively using genetic engineering for the development of animals that produce new biomedicines, bio-organs, etc. Korea is also using cloning technology to expand the number of animals with a high capacity to produce such useful materials and bio-organs. The research is being led by

various government agencies and private entities including academia.

In January 2018, RDA announced a three-year cooperation project with the National Swine Resource and Research Center in the United States to introduce a management system to control pathogens, a training program, and some technology to carry out research on transgenic animals. RDA believes that this project will help standardize the management system of transgenic animals, which will lead RDA to produce bio and pharmaceutical materials through transgenic animals.

In 2016, MAFRA announced a plan called “2016 Promotion of Science and Technology for Agriculture, Forestry and Food.” According to the plan, MAFRA will invest in R&D in seven selected areas, which include value-added agri-bio resources. MAFRA plans to invest 111 billion Korean won (approx. 110 million US dollars) for R&D in agri-bio resources. It will cover production of pigs producing bio-organs, production of special purpose dogs using cloning technology (detection dogs), and stem cell production technology, among others.

In 2010, MIFAFF (now MAFRA) announced its overall plan for future growth engines for the life science industry in Korea. Biomedicine is one of the areas where considerable resources are being invested. RDA’s 10 year Next Generation Bio-Green 21 Project launched on May 19, 2011, also focuses on development of biomedicines and bio-organs as one of the three top sectors.

The National Institute of Animal Science (NIAS) of RDA is focusing on the development of new bio materials using biotechnology such as bio-organs, securing diversity of animal genetic resources, developing high value added livestock products, and developing renewable energy using livestock resources, with the goal of becoming a “world G7 livestock technology country.” NIAS is conducting research to develop 24 different traits in two animals: 17 traits in swine and 7 traits in chicken. These traits are designed to produce high value protein and antivirus materials, swine producing material that can treat anemia, hemophilia, thrombus and chickens producing eggs with lactoferrin and antioxidant substances. NIAS produced two transformed mini pigs that can be used to produce bio-organs. In 2012, RDA succeeded in transplanting a heart and a kidney from a transformed mini pig into a monkey. As follow up research in 2014, RDA succeeded in transplanting a heart from a transformed pig called GalT KO+MCP with genes inhibiting hyperacute rejection and acute vascular rejection into a monkey. In 2013, a team of professors from multiple Korean and U.S. universities announced that they succeeded in the production of a cloned mini pig named “GI Blue” whose gene that causes acute immune rejection response was removed. In 2017, RDA produced a  $GT^{MCP/MCP}/iGb3S^{-/-}$  knock out transgenic pig that reduces acute immune rejection response. This is another step toward the development of bio-organs and organ plantation in different species.

RDA is also conducting research to develop four different traits using silk worm. Traits under development will enable production of silk in various natural colors, immune peptides that replace antibiotics in animal feed, and medicine for humans. In August 2018, RDA announced that they developed “Fluorescent silk” using a transgenic silk worm. RDA plans to continue additional research to use fluorescent silk in bio sensors, functional fabric, materials for semi-conductors, etc. As for cloning, NIAS supplied 48 cloned special purpose dogs such as detection or sniffer dogs to other agencies in Korea. Currently, RDA does not have any plan to develop genetically-engineered or cloned animals for food use.

The Ministry of Science, Information Communication Technology (ICT) & Future Planning (MSIP) announced in July 2013 that they would invest 9.2 trillion won (approximately \$8 billion) of R&D funding into science and technology in the five years through 2016. MSIP designated 30 technologies for focused support during the five years, including one related to genetic resource technology for the development and commercialization of value added life science resources. MSIP focused its other investment on the development of new biomedicine and stem cell and genome research. In line with the MSIP investment plan, MAFRA also announced a mid and long-term plan to promote agriculture technology in July 2013. In the plan, the technology to develop bio materials and transformed animals for the production of pharmaceutical products was set as one of the sub-projects under the four major research areas that MAFRA would focus on. The four major areas are: 1) strengthening global competitiveness, 2) creating a new growth engine, 3) ensuring a stable supply of food grain, and 4) improving public happiness. Under the category of creating a new growth engine, MAFRA and RDA will continue to develop new bio materials using animal biotechnology.

Private entities are also developing genetically-engineered animals that produce high value protein pharmaceuticals. In 2014, Choongbuk National University announced that they produced a transformed cloned pig with a trait that can control the expression timing of a particular protein. This technology will allow them to produce a great volume of proteins to treat people. In 2012, one pharmaceutical company announced that they produced 14 transformed pigs inserted with a human growth hormone gene (hGH) and those pigs produced milk in which hGH was expressed. This is one step forward to the development of a pharmaceutical product with hGH. Others are developing transgenic cattle that can produce lactoferrin and insulin, a fluorescent dog for human disease research, chickens that purportedly produce substances to treat leukemia and mini-pigs for production of bio organs.

In July, 2015, a team of professors from Korean and Chinese universities announced that they made a super pig which has higher muscle content than ordinary pigs using a gene editing technology. The team removed a gene called MSTN, which inhibits muscle growth, from a somatic cell and cloned pigs using nuclear transplantation with the edited gene. The team believes that the livestock industry might positively view pork with more muscle and higher protein content.

## **B) Commercial Production**

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 relatively unwilling to engage in research as they are concerned about consumer acceptance of meat from genetically-engineered animals.

## **C) Exports**

Korea does not export any biotech animals as Korea does not commercially produce any biotech animals.

## **D) Imports**

Korea imports genetically engineered mice and e-coli for research.

## **E) Trade barriers**

MFDS initiated mandatory testing of imported salmon in October 2017 due to intelligence indicating GE salmon is raised in Panama and marketed in Canada. This testing applied to fresh/frozen salmon

originating from the United States, Canada, and Panama. MFDS conducted testing to confirm whether it contains GE salmon that is approved for food in the United States and Canada, but not in Korea. From October 10, 2017 through December 31, 2017, every import of frozen and fresh salmon and three samples of smoked salmon per manufacturer were tested. As there were no detections, MFDS now conducts random testing of 5% of incoming fresh/frozen salmon from the United States, Canada, and Panama.

## ***Part B: Policy***

### **A) Regulatory Framework**

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

### **B) Approvals**

Korea has not approved any GE animals.

### **C) Innovative Biotechnologies**

Korea has not determined the regulatory status of innovative biotechnologies. There is growing interest on the part of scientists and regulators related to how Korea should approach this issue. Korea is closely watching developments in other countries.

### **D) Labeling and Traceability**

MAFRA is responsible for the labeling and approval of GE animals, but has not yet established any regulations. MFDS is responsible for the safety evaluation of GE animals and fishery products for human consumption under its GE safety evaluation guidelines.

### **E) Intellectual Property Rights**

As noted above, biotechnology animals are not commercially grown in Korea. However, intellectual property rights are protected under existing domestic regulations.

### **F) International Treaties and Forums**

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

### **F) Related Issues**

No related issues have been identified.

## ***Part C: Marketing***

### **A) Public/Private 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 in biotechnology research and development for biomaterial, biomedicine and organs, and gene therapy, among others.

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.

#### **B) Market Acceptance/Studies**

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 while they tend to be negative towards the use of the technology to produce food. No market studies are available.

#### **APPENDIX: APPROVED EVENT LIST**

##### **TABLE OF APPROVED BIOTECHNOLOGY PRODUCTS AS OF October 2018**

Note: Biotechnology crops are required to undergo a food safety assessment and an 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	High oleic	Food & Feed	2010

Soybean	A5547-127	Bayer	HT	Food & Feed	2011
Soybean	CV127	BASF	HT	Feed & Food	2011 & 2013
Soybean	MON87701	Monsanto	IR	Food & Feed	2011
Soybean	MON87769	Monsanto	SDA	Feed & Food	2012 & 2013
Soybean	MON87705	Monsanto	High oleic	Feed & Food	2012 & 2013
Soybean	MON87708	Monsanto	HT	Feed & Food	2012 & 2013
Soybean	DP-305423-1 X GTS40-3-2	DuPont	High oleic, HT	Food & Feed	2011
Soybean	MON87701 X MON89788	Monsanto	HT, Insect Resistance (IR)	Feed & Food	2012
Soybean	MON87705 X MON89788	Monsanto	High oleic, HT	Food & Feed	2013 & 2014
Soybean	MON87769 X MON89788	Monsanto	HT	Food & Feed	2013 & 2015
Soybean	FG72	Bayer	HT	Feed & Food	2013 & 2014
Soybean	MON87708 X MON89788	Monsanto	HT	Food & Feed	2013 & 2014
Soybean	SYHT0H2	Syngenta	HT	Food & Feed	2014
Soybean	DAS-68416-4	Dow	HT	Food & Feed	2014
Soybean	DAS-44406-6	Dow	HT	Food & Feed	2014
Soybean	DAS-81419-2	Dow	IR, HT	Food & Feed	2016
Soybean	DAS-68416-4 X MON89788	Dow	HT	Food & Feed	2015 & 2016
Soybean	MON87751	Monsanto	IR	Food & Feed	2016
Soybean	FG72 X A5547-127	Bayer	HT	Food & Feed	2016
Soybean	MON87705 X MON87708 X MON89788	Monsanto	High oleic, HT	Food & Feed	2016 & 2017
Soybean	MON87751 X MON87701 X MON87708 X MON89788	Monsanto	IR, HT	Food & Feed	2017
Soybean	DAS-81419-2 X DAS-	Dow	IR, HT	Food &	2017 &

	44406-6			Feed	2018
Soybean	MON87708 X MON89788 X A5547-127	Monsanto	HT	Food & Feed	2017 & 2018
Corn	MON810	Monsanto	IR	Food & Feed	2012* & 2004
Corn	TC1507	DuPont	HT, IR	Food & Feed	2012* & 2004
Corn	GA21	Monsanto	HT	Food & Feed	2010 & 2007
Corn	NK603	Monsanto	HT	Food & Feed	2012* & 2004
Corn	Bt 11	Syngenta	HT, IR	Food & Feed	2013* & 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
Corn1)	DLL25	Monsanto	HT	Food	2004
Corn1)	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 & 2016
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
Corn2)	Bt10	Syngenta	HT, IR	Food	2007
Corn	MIR604	Syngenta	IR	Food & Feed	2017* & 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
Corn	Bt11 X MIR162 X GA21	Syngenta	HT, IR	Feed & Food	2011 & 2012
Corn	TC1507 X MIR604 X NK603	DuPont	HT, IR	Food & Feed	2011
Corn	MON87460	Monsanto	Drought Resistance (DR)	Feed & Food	2011 & 2012
Corn	Bt11 X DAS-591227 X MIR604 X TC1507 X GA21	Syngenta	HT, IR	Feed & Food	2011 & 2013

Corn	TC1507 X DAS-591227 X MON810 X MIR604 X NK603	DuPont	HT, IR	Food & Feed	2012
Corn	Bt11 X MIR162 X TC1507 X GA21	Syngenta	HT, IR	Feed & Food	2012
Corn	3272 X Bt11 X MIR604 X GA21	Syngenta	HT, IR	Feed & Food	2012 & 2013
Corn	MON87460 X MON89034 X NK603	Monsanto	DR, HT, IR	Feed & Food	2012 & 2013
Corn	MON87460 X MON89034 X MON88017	Monsanto	DR, HT, IR	Feed & Food	2012 & 2013
Corn	MON87460 X NK603	Monsanto	DR, HT	Feed & Food	2012 & 2013
Corn	TC1507 X MON810 X MIR162X NK603	DuPont	HT, IR	Feed & Food	2013
Corn	5307	Syngenta	IR	Feed & Food	2013
Corn	Bt11 X MIR604 X TC1507 X 5307 X GA21	Syngenta	IR	Food & Feed	2013 & 2014
Corn	Bt11 X MIR162 X MIR604 X TC1507 X 5307 X GA21	Syngenta	IR	Food & Feed	2013 & 2014
Corn	MON87427	Monsanto	HT	Feed & Food	2013 & 2014
Corn	MON87427 X MON89034 X NK603	Monsanto	HT, IR	Food	2014
Corn	MON87427 X MON89034 X MON88017	Monsanto	HT, IR	Food	2014
Corn	TC1507 X MON810 X MIR604 X NK603	DuPont	HT, IR	Food & Feed	2014
Corn	DAS-40278-9	Dow	HT	Food & Feed	2014
Corn	GA21 X T25	Syngenta	HT	Food & Feed	2014
Corn	TC1507 X MON810	DuPont	IR, HT	Food & Feed	2014
Corn	DP-004114-3	DuPont	IR, HT	Food & Feed	2014
Corn	3272 X Bt11 X MIR604 X TC1507 X 5307 X GA21	Syngenta	IR, HT, α-amylase	Food & Feed	2014 & 2015
Corn	MON89034 X TC1507 X MON88017 X DAS-59122-7 X DAS-40278-9	Dow	IR, HT	Food & Feed	2014 & 2015
Corn	TC1507 X MON810 X MIR162	DuPont	IR, HT	Food & Feed	2015
Corn	NK603 X DAS-40278-9	Dow	HT	Food & Feed	2015

				Feed	
Corn	MON87427 X MON89034 X TC1507 X MON88017 X DAS-59122-7	Monsanto	IR, HT	Food & Feed	2015
Corn	DP-004114-3 X MON810 X MIR604 X NK603	DuPont	IR, HT	Food & Feed	2015
Corn	MON89034 X TC1507 X NK603 X DAS-40278-9	Dow	IR, HT	Food & Feed	2015
Corn	Bt11 X MIR162	Syngenta	IR, HT	Food & Feed	2016 & 2015
Corn	MON87427 X MON89034 X MIR162 X NK603	Monsanto	IR, HT	Food & Feed	2016
Corn	MON87411	Monsanto	IR, HT	Food & Feed	2016
Corn	Bt11 X TC1507 X GA21	Syngenta	IR, HT	Food & Feed	2016
Corn	Bt11 X MIR162 X MON89034 X GA21	Syngenta	IR, HT	Food	2016 & 2017
Corn	MON87403	Monsanto	Increased corn ear	Food & Feed	2017 & 2016
Corn	MON87419	Monsanto		Food	2017
Corn	MON87751 X MON87701 X MON87708 X MON89788	Monsanto		Food	2017
Corn	MON87427 X MON89034 X TC1507 X MON87411 X DAS-59122-7	Monsanto	IR, HT	Food & Feed	2017
Corn	MON87427 X MON89034 X MIR162 X MON87411	Monsanto	IR, HT	Food & Feed	2017
Corn	VCO-01981-5	Genective	HT	Food & Feed	2018 & 2017
Corn	MZHG0JG	Syngenta	HT	Food	2017
Corn	MON89034 X TC1507 X MIR162 X NK603	Dow	HT, IR	Food & Feed	2017 & 2018
Corn	MON89034 X MIR162	Monsanto	IR	Food & Feed	2017
Corn	Bt11 X MIR162 X MON89034	Syngenta	HT, IR	Food & Feed	2017 & 2018
Corn	Bt11 X MIR162 X MIR604 X MON89034 X 5307 X GA21	Syngenta	HT, IR	Food & Feed	2017 & 2018
Corn	MON87427 X MON87460 X MON89034 X TC1507 X MON87411 X DAS-59122-	Monsanto	HT,IR	Food & Feed	2018 & 2017

	7				
Cotton	Mon531	Monsanto	IR	Food & Feed	2013* & 2004
Cotton	757	Monsanto	IR	Food & Feed	2003 & 2004
Cotton	Mon1445	Monsanto	HT	Food & Feed	2013* & 2004
Cotton	15985	Monsanto	IR	Food & Feed	2013* & 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	2014* & 2008
Cotton	Mon88913	Monsanto	HT	Food & Feed	2006 & 2016
Cotton	LLCotton 25	Bayer	HT	Food & Feed	2005
Cotton	Mon88913 X Mon15985	Monsanto	HT, IR	Food & Feed	2006 & 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
Cotton	GHB614 X LLCotton 25	Bayer	HT	Food & Feed	2012 & 2011
Cotton	GHB614 X LLCotton 25 X 15985	Bayer	HT, IR	Feed & Food	2011 & 2013
Cotton	T304-40 X GHB119	Bayer	HT, IR	Feed & Food	2012 & 2013
Cotton	GHB119	Bayer	HT	Feed & Food	2012 & 2013
Cotton	COT67B	Syngenta	IR	Feed	2013
Cotton	GHB614 X T304-40 X GHB119	Bayer	HT, IR	Food & Feed	2013
Cotton	COT102	Syngenta	IR	Food	2014
Cotton	281/3006 X COT102 X MON88913	Dow	IR, HT	Food & Feed	2014 & 2015
Cotton	MON88701	Monsanto	HT	Food & Feed	2015

Cotton	GHB614 X T304-40 X GHB119 X COT102	Bayer	IR, HT	Food & Feed	2015
Cotton	MON88701 X MON88913 X MON15985	Monsanto	IR, HT	Food & Feed	2015
Cotton	COT102 X MON15985 X MON88913	Monsanto	IR, HT	Food & Feed	2015 & 2016
Cotton	DAS-81910-7	Dow	HT	Food & Feed	2016
Cotton	COT102 X MON15985 X MON88913 X MON88701	Monsanto	IR, HT	Food & Feed	2016
Cotton	MON88701 X MON88913	Monsanto	IR, HT	Food & Feed	2016 & 2017
Cotton	281/3006 X COT102 X MON88913 X DAS-81910- 7	Dow	IR, HT	Food & Feed	2017 & 2016
Canola	RT73 (GT73)	Monsanto	HT	Food & Feed	2013* & 2005
Canola	MS8/RF3	Bayer	HT	Food & Feed	2005 & 2014
Canola	T45	Bayer	HT	Food & Feed	2005
Canola1)	MS1/RF1	Bayer	HT	Food & Feed	2005 & 2008
Canola1)	MS1/RF2	Bayer	HT	Food & Feed	2005 & 2008
Canola1)	Topas19/2	Bayer	HT	Food & Feed	2005 & 2008
Canola	MS8	Bayer	HT	Feed & Food	2012 & 2013
Canola	RF3	Bayer	HT	Feed & Food	2012 & 2013
Canola	MON88302	Monsanto	HT	Feed & Food	2014
Canola	MON88302 X RF3	Monsanto	HT	Food & Feed	2014 & 2015
Canola	MON88301 X MS8 X RF3	Monsanto	HT	Food & Feed	2014 & 2015
Canola	MS8 X RF3 X RT73	Bayer	HT	Food & Feed	2015
Canola	DP-073496-4	DuPont	HT	Food & Feed	2015
Canola	DP-073496-4 X RF3	DuPont	HT	Food & Feed	2017
Potato1)	SPBT02-05	Monsanto	IR	Food	2004
Potato1)	RBBT06	Monsanto	IR	Food	2004

Potato1)	Newleaf Y (RBMT15-101, SEMT 15-02, SEMT 15-15)	Monsanto	IR, Virus Resistance (VR)	Food	2004
Potato1)	Newleaf Plus (RBMT21-129, RBMT21-350, RBMT22-82)	Monsanto	IR, VR	Food	2004
Potato	SPS-E12	Simplot	Reduced acrylamide	Feed	2016
Sugar beet	H7-1	Monsanto	HT	Food	2006 & 2016
Alfalfa	J101	Monsanto	HT	Food & Feed	2017 & 2008
Alfalfa	J163	Monsanto	HT	Food & Feed	2017 & 2008
Alfalfa	J101, J163, J101 X J163 3)	Monsanto	HT	Food & Feed	2007 & 2008
Alfalfa	KK179	Monsanto	Reduced lignin	Food & Feed	2015
Alfalfa	KK179 X J101	Monsanto	Reduced lignin, HT	Food & Feed	2018 & 2016

Total Food Approval: 166

Total Feed Approval: 157

\* Food approval has been renewed 10 years after the first approval

- 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