Required Report: Required - Public Distribution **Date:** November 14, 2022

Report Number: KS2022-0024

Report Name: Agricultural Biotechnology Annual

Country: Korea - Republic of

Post: Seoul

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Korea is in the process of revising its Living Modified Organism (LMO) Act. Once completed, these revisions will define Korea's regulatory policies for products that utilize innovative technologies, including genome editing. Finalized changes to the LMO Act are expected by the end of 2022 with implementation planned for the end of 2023. Additionally, Korea has announced mandatory biotech labeling will be required for all products containing biotech ingredients beginning in 2026.

Executive Summary

Korea depends on agricultural imports to satisfy its food and feed demand. However, Korea's generally pessimistic attitude towards the use of biotechnology in food has limited availability of these products for direct human consumption and, discouraged Korea's domestic agricultural producers from adopting this technology. Conversely, the bulk of livestock feed imported into Korea is biotech corn and soybeans. The United States is a leading exporter of genetically engineered (GE) grain and oilseeds to Korea, along with Argentina and Brazil. Total U.S. GE grain and oilseed exports to Korea from January to August 2022 reached 1.6 million metric tons (MMT). This volume accounts for a quarter of Korea's total GE grain and oilseed imports during the eight-month period.

Korea's draft revision of the LMO Act, announced in May 2021, was submitted to the National Assembly for approval in July 2022. This proposal includes regulations for products of innovative biotechnologies (e.g., genome editing) and sets the legal basis for determining exemptions of certain genome edited products. Korea intends to finalize the LMO Act revision by the end of 2022 with enforcement one year following its official publication. During this period, Korea will develop its policies and procedures for implementing the LMO Act revision.

Korea requires mandatory GE labeling for any food containing detectable GE ingredients. Due to strong pressure from local NGOs and consumer groups, the Ministry of Food & Drug Safety (MFDS) will expand mandatory GE labeling to any products made with GE ingredients beginning in 2026. To do so, MFDS will revise its current labeling regulations in 2024.

Although commercial acceptance of biotech food in Korea is lacking, public and private research institutions within the country are actively exploring and developing products using innovative technologies. Some research groups strongly advocate in favor of agricultural biotechnology and urge Korean authorities to create a regulatory environment that is less burdensome and supports innovative development.

Useful Acronyms

APQA: Animal and Plant Quarantine Inspection Agency
ERA: Environmental Risk Assessment
GE: Genetically Engineered
GMO: Genetically Modified Organism
KBCH: Korea Biosafety Clearing House
LMO: Living Modified Organisms
MAFRA: Ministry of Agriculture, Food, and Rural Affairs
MOE: Ministry of Environment
MFDS: Ministry of Food and Drug Safety
MHW: Ministry of Health and Welfare
MOTIE: Ministry of Trade, Industry and Energy
NAQS: National Agricultural Products Quality Management Service
NFRDI: National Fisheries Research & Development Institute
NIAS: National Institute of Animal Science
NIE: National Institute of Ecology
NSMA: National Seed Management Agency
RDA: Rural Development Administration
KDCA: Korea Disease Control and Prevention Agency

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CHAPTER 1: PLANT BIOTECHNOLOGY

Part A. Production and Trade

A) Research and Product Development
In Korea, the development of modern biotechnology (biotech) products that can be genetically engineered is led by various government agencies, universities, and private entities. Research is principally focused on second and third generation traits such as environmental tolerance, disease resistance, and nutrient enrichment. From January to August 2022, the Rural Development Agency (RDA) has approved 90 field trial research projects conducted by RDA's designated evaluation entities and private organizations.

Korea has various products under development using modern biotechnology. These products include but are not limited to:

- rice containing new materials and functional ingredients
- insect-resistant rice
- environmental stress-tolerant rice
- virus-resistant pepper
- beans with functional trait (Vitamin E);
- insect-resistant bean
- herbicide-tolerant bentgrass
- Korean cabbage producing antigen protein
- herbicide-tolerant canola
- calcium-fortified apple

Safety assessment data is currently being generated for bentgrass. Jeju National 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 which remains under review. Commercialization is expected to be delayed due to continued opposition from anti-biotech NGOs and local farmer groups.

Private entities in Korea have also been involved in programs using innovative technologies due to faster development capability and reduced costs when compared to modern biotechnology. Research development announced in 2022 by private entities includes 1) development of "golden sweet potato" with high antioxidant substances developed through CRISPR Cas9, 2) development of high oleic soybean and seed potato that inhibits a browning effect using CRISPR Cas9, and 3) development of gene edited flaxseeds for use in medical and food products. Also, RDA has announced plans to develop gene-edited cabbage.

In March 2022, the Ministry of Agriculture, Food and Rural Affairs (MAFRA) publicized the opening of the "Green Vaccine Demonstration Support Center." This center consists of vaccine production lines, a plant growing facility, and laboratories to evaluate the efficacy of plant or plant cell-based vaccines for animal use. This center aims to assist Korea in quickly responding to emerging epidemic diseases.

In 2016, resveratrol-enriched rice received approval for health and medical use from the Ministry of Health & Welfare (MHW). Resveratrol is known to be an antioxidizing polyphenol. This product was initially developed for food use, but due to push back from anti-biotech NGOs and local rice farmers, RDA did not approve the intended use.

Without stronger support and advocacy from Korean farmers and consumers, commercialization of GE crops in Korea is unlikely. For example, in September 2017, RDA acquiesced to local NGOs requests to stop commercialization of GE products in Korea and downsize its leading GE product development team within the National Center for Genetically Modified (GM) Crops (renamed the Agricultural Biotechnology Research Center).

While RDA continues to develop GE products, it does so under increased scrutiny and opposition from some consumer groups. In addition to their own research, RDA funds GE research teams through the Next Generation Bio-Green 21 Project, which received 300 billion won (approximately $260 million USD) in 2020 to develop additional projects.

In April 2019, the Rural Development Administration (RDA) announced a new Center to Commercialize New Breeding Technologies. This Center supports improvement of Korea's competitiveness in the field of breeding, which it sees as an engine for future growth. The Center leads development and commercialization of innovative biotechnologies products, investing a total of 76 billion Korean won (approximately $63 million USD) over seven years.

In 2017, Korea published its 3rd LMO Safety Management Plan, which aimed to:

- Establish an emergency response team for unintentional release incidents of GE events,
- Further develop an effective biotech management system,
- Prepare a safety management plan for innovative biotechnologies,
- Improve the LMO Act, and
- Other related tasks.

In 2018, the plan went into effect, and Korea projected to spend 82 billion Korean won (approximately $75 million USD) over five years to implement the LMO Safety Management Plan.

In September 2020, 10 Ministries led by the Ministry of Agriculture, Food and Rural Affairs (MAFRA) finalized a "Plan to Promote Green-Bio Convergence Emerging Industry" to address agricultural, environmental, and health issues and create more jobs. The goal of this plan is to double the industry scale of Korea's five green-bio sectors by 2030. The five green-bio sectors include: 1) microbiome, 2) meal replacement/medical food, 3) seeds, 4) veterinary medicine, and 5) other biomaterials (insects, marine, and forestry). For seed production, "gene scissors" (genome editing) and digital breeding were chosen as core technologies to invest and develop. In veterinary medicine, the government will support development of animal vaccines using protein recombinant technologies and stem cell research. As a follow up, MAFRA selected 10 companies in April 2021 and will dedicate 2.8 billion Korean won (approximately $2.3 million dollars) to the selected companies.

B) Commercial Production

Despite substantial investment in biotech research, Korea has yet to commercially produce any biotech products. In 2017, RDA announced it would not allow domestic commercial production of biotech crops in response to domestic NGOs' anti-biotech petitions.

C) Exports

Korea does not export any biotech crops.

D) Imports

Korea imports biotech products for food, feed, and processing; but not for cultivation. The United States and Argentina are the two largest suppliers of biotech grains and oilseeds to the Korean market.

In calendar year 2021, Korea imported a total of 11.6 MMT of corn, which consisted of 9.3 MMT for feed and 2.3 MMT for processing. Imports from the United States reached 3.2 MMT or 28 percent of the total. Nearly all of the corn imported from the United States was GE.

In processing, imported GE corn is generally used to make high fructose corn syrup or corn oil. Both uses are exempt from GE labeling requirements due to the absence of detectable GE proteins in the final product. Despite pressure from anti-biotech NGOs, some Korean processors continue to use biotech corn as it is readily available and affordable.

In 2021, Korea imported a total of 1.27 MMT of soybeans, primarily for crushing. The United States was the largest soybean supplier, exporting nearly the entire volume.

Soybean oil is also exempt from GE labeling requirements because the GE protein is undetectable. Soybeans for food processing, used to make tofu, bean paste, and bean sprouts, are primarily derived from conventional varieties.

Table 1: Imports Statistics for GE Soybeans and Corn (Calendar year basis / Unit: 1,000 MT)

Classification			2018	2019	2020	2021	2022 Jan-Aug
				Volume	Volume	Volume	Volume
Soybean	Food (Crushing)	US	576	885	374	400	178
		Non-US	473	118	612	656	538
		Total	1,049	1,003	986	1,056	716
Corn	Food	US	989	553	354	344	127
		Non-US	169	599	644	356	184
		Total	1,158	1,152	998	700	311
	Feed	US	6,137	2,046	2,603	2,885	1,272
		Non-US	1,714	7,284	7,184	6,349	4,556
		Total	7,851	9,330	9,787	9,234	5,828
Oilseeds	Feed	US	131	112	181	81	76
		Non-US	21	46	20	75	33
		Total	152	158	201	156	109

Source: Korea Biosafety Clearing House
Note: *Table 1 contains import statistics for biotech grains and oilseeds. This data differs slightly from numbers reflected in the preceding paragraphs as it is based on Korea's reported import approval volumes and not customs data. For more information on Korea's feed grain and oilseeds production, supply, and demand, please see the latest reporting in the GAIN system.*

E) Food Aid

Korea is not a food aid recipient. Korea provides intermittent food aid to North Korea depending on political conditions, as well as some other countries for humanitarian purposes. Korea participates in the Association of Southeast Asian Nations (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 metric tons (MT) of rice to date out of their 150,000 MT commitment. In January 2018, Korea joined the Food Assistance Convention, which allows Korea to draw down its rice stocks that are currently held in storage.

In 2019, 2020, 2021, and 2022, Korea shipped 50,000 MT of domestic rice annually through the WFP. In 2022, Korea shipped 18,686 MT to Yemen, 13,000 MT to Ethiopia, 11.000 MT to Kenya, 6,000 MT to Uganda, and 1,314 MT to Laos. In 2019, Korea shipped 500 MT of domestic rice to Myanmar and Laos each through APTEER, and in 2020 it shipped 950 MT of domestic rice to the Philippines through the same organization.

F) Trade Barriers

Concerns linger over Korea's risk assessment and approval process for imported biotech products intended for food, feed and processing (FFP). Specifically, industry considers some of Korea's five reviewing agencies to be redundant. As previously stated, Korea does not cultivate GE crops domestically, and its risk assessment requirements, particularly for FFP, have drawn international scrutiny. There are concerns that some data requirements lack scientific justification or relevance to the products' intended use. Korea's approval process is often slow and contributing to delays agricultural producers access and availability to utilize biotech tools for products intended for the Korean market. See further details on this issue under the Policy/ Approvals subsection.

Additionally, in accordance with the MFDS requirements for food labeling, Korea maintains a zero-tolerance policy for the inadvertent presence of biotech ingredients in processed organic-labeled products. Any supplier of organic products that test positive for GE material, at any level, must remove an organic claim from the product label. In the event of a violation, Korea's National Agriculture Product Quality Service (NAQS) may also investigate the case to determine if the breach was intentional.

Shippers of U.S. processed food products that contain conventional soy, corn, canola, cotton, sugar beet, and alfalfa are required to submit additional documents to receive an exemption from the mandatory biotech labeling requirements. See details on Korea's labeling requirements under the Labeling and Traceability subsection.

Part B: Policy

A) Regulatory Framework
Korea ratified the Cartagena Protocol on Biosafety (CPB) on October 2, 2007 and subsequently implemented their LMO Act as the overarching law governing CPB parties' biotechnology-related rules and regulations.

The LMO Act was implemented in 2008 and revised in 2013. Since the LMO Act's implementation, the U.S. has expressed concerns regarding unresolved redundant regulatory reviews and failure to distinguish between products intended for FFP and cultivation.

i. Definition of terms

Legal Term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
유전자변형생물체	Living Modified Organism (LMO)	LMO Act	Any living modified organism that possesses a novel combination of genetic material obtained through the use of each of the following modern technology; (a) Techniques that artificially recombine genes or directly inject nucleic acids comprising a gene into cells or organelles; (b) Techniques that are the fusion of cells beyond the taxonomy family
후대교배종	Stacked Event	LMO Act	A living modified plant obtained by breeding between living modified plants subject to risk review
유전자변형	Genetic Modification	MFDS Guideline	A gene is modified through the use or utilization of modern biotechnology techniques such as techniques to recombine genes or directly inject nucleic acids comprising a gene into cells or organelles or cell fusion technique beyond the taxonomy family

ii. Responsible Government Ministries

Ministry	Role and Responsibilities
MOTIE	National competent authority for the CPB, responsible for enforcing the LMO Act and managing issues related to the development, production, import, export, sales, transportation, and storage of biotech products intended for industrial use.

Ministry of Foreign Affairs (MOFA)	National point of contact for the CPB.
MAFRA	Possesses authority for matters related to the import or export of agricultural, forestry, or livestock biotech products.
RDA (overseen by MAFRA)	Conducts ERAs and consultations for biotech products and leading developer of biotechnology products in Korea.
Animal and Plant Quarantine Agency (APQA) (overseen by MAFRA)	Conducts import inspection of biotech products for agricultural use at the port of entry.
NAQS (overseen by MAFRA)	Handles import approval of biotech products for feed use.
Ministry of Oceans and Fisheries (MOF)	Possesses authority for matters related to the trade of maritime biotech products, including risk assessments.
MHW	Possesses authority for matters related to the import or export of biotech products used for health and pharmaceutical purposes, including human risk assessments.
Korea Disease Control and Prevention Agency (overseen by MHW)	Oversees human risk consultation for biotech products.
MFDS (under the Prime Minister's Office)	Possesses authority for matters related to the import or export of biotech products for food, pharmaceutical, and medical devices, food safety approvals of biotech products, and the enforcement of labeling requirements for non-processed and processed food products containing biotech ingredients.
Ministry of Environment (MOE)	Possesses authority for issues related to the trade of biotech products that are used for the purpose of environmental remediation or release into the natural environment, including risk assessments, not including biotech products for cultivation.
National Institute of Ecology (NIE) (overseen by MOE)	Handles import approval of biotech products under jurisdiction of MOE and environmental risk consultation
Ministry of Science, Information Communication Technology and Future Planning	Possesses authority for issues related to the trade of biotech products that are used for testing and research, including risk assessments.

iii. Role and Membership of the Biosafety Committee

In accordance with Article 31 of the LMO Act, a Biosafety Committee was formed to review the following items relevant to the import and export of biotech products:

- Factors relevant to the implementation of the Cartagena Protocol,
- Establishment and implementation of the safety management plan for biotech products,
- Re-examination in accordance with the provisions of Article 18 and Article 22 of appeals by an applicant that is denied import approval, etc.,
- Factors relevant to legislation and notification pertinent to the safety management, import, and export, of biotech products,
- Factors relevant to the prevention of damage caused by biotech products, if any, and measures taken to mitigate damage caused by biotech products, if any, and,
- Factors requested for review by the chair of the Biosafety Committee or the head of the competent national authority.

The Biosafety Committee is comprised of 15-20 members, including vice ministers from the seven relevant ministries noted above and the Ministry of Planning and Finance. Non-government specialists, such as professors from Korean universities, can also be members of the Biosafety Committee.

This body is responsible for reconciling differing positions among the relevant ministries. Each relevant ministry holds authority and responsibility in its respective area, and as chair, the MOTIE Minister resolves issues that lack consensus. This group is only believed to have met officially in April 2018 but conducts meetings via document circulation.

Within the Committee, a technical group consisting of experts from relevant ministries also gathers to discuss specific issues; for example, to discuss mitigation measures following the detection of unapproved GE canola. The technical committee meets six times a year and follows the status of risk assessments and consultation reviews.

iv. Political and Social Influence

Regulatory decisions related to agricultural biotechnology are influenced by political pressure, mostly from anti-biotech NGOs, some of which are appointed to the government's food safety and biotechnology risk review committees. These groups use their positions to encourage strict government policies on the use of biotechnology, such as the draft revision to the Food Sanitation Act to require GE labeling and the LMO Act revision and blocking approval of GE potatoes.

v. Regulatory Distinction Regarding Presence of DNA in Finished Products

Korea requires mandatory safety assessments of GE plants to be used as food products. Subsequently, although a finished product may not contain foreign DNA, the GE plant itself (i.e. soy for cooking oil) must be approved for use in food products and undergo a safety assessment. However, for labeling of products made from GE plants, Korea exempts mandatory GE labeling for finished products that do not contain a foreign DNA.

vi. Regulatory Distinction Between Living GE Plants and Non-living GE Plant Products

Non-living plant products, such as meal or cake, are not classified as LMOs and do not require a risk assessment.

vii. Regulatory Distinction Between LMO for food, feed and processing use (FFPs) and Environmental Release

LMO FFPs require approval after risk assessments for food and feed use. As part of the risk assessment for feed use, Korea does not require in-country field trial data since the LMO is not intended for propagation in Korea. If the LMO is intended for propagation in Korea, it must receive approval for environmental release and submit in-country field trial data.

viii. Pending Legislation

Since 2020, five draft revisions of the LMO Act have been submitted to the National Assembly for review and approval. The current draft revision proposes 1) establishment of a policy for a review of products derived through innovative biotechnologies, 2) streamline current approval processes by creating one expert committee to review a new GE event, and 3) suspend imports of LMOs when repeated detections of unapproved GE plants are found. These proposed revisions may be amended while lawmakers review and edit the legislation prior to its final adoption.

In the current proposal, Korea classifies products of innovative biotechnologies as LMOs. The draft revision also includes a pre-review system that will consider risk assessment exemptions for certain genome edited products. Exemptions may be granted under the following two conditions: 1) there is no introduction of a foreign DNA or 2) there is no foreign DNA present in the finished product.

Once the LMO revision is finalized, details regarding pre-review data requirements will be made available within Korea's implementing regulations. MOTIE aims to finalize the LMO revision process before the end of 2022.

ix. Approval Timeline

The statutory review period set by Korea for approval of single events for food and feed use is 270 working days, and 210 days for consultation agencies. Reviews for food and feed approvals and consultations may be conducted simultaneously. These statutory review periods may be extended if additional data is requested. Historically, a significant number of event reviews have exceeded Korea's statutory timeline. The statutory review period for stacked events for food and feed use is 90 working days.

x. Additional Product/Seed Registration

In addition to food and feed approval after risk assessments, a seed registration of GE plants is required if the GE plant for propagation is imported to Korea. To date, no GE plant has been approved for propagation in Korea.

xi. Re-registration

Re-registration is not required.

xii. Approval/authorization limit

Renewal of an approved single event for food use is required every 10 years. Renewal of approval is not required for stacked events and events for feed use.

B) Approvals/Authorizations

Whether grown domestically or import, biotech products must undergo a food safety assessment and an ERA. MFDS conducts the food safety assessment, consulting with RDA, NIE and NFRDI. While the ERA is also referred to as a feed approval, the review is largely focused on environmental impacts and not animal health. RDA conducts the ERA, consulting with NIE, NFRDI, and Korea Disease Control and Prevention Agency.

Overlap between agencies and onerous data requirements often delay Korea's approval process for biotech products. In 2015, in response to continued requests for streamlining their procedures, Korea introduced a pilot project called "Joint Consultation Review Committee", which combined NFRDI and NIE committees. Only one product was reviewed in 2016 under this pilot project.

The results of the pilot project demonstrated few efficiencies were achieved. However, in 2017, Korea proposed another pilot program called the "Committee on Additional Data Requests", which Korea believed would reduce additional information requests by convening a monthly meeting among five reviewing agencies. Like the previous pilot program, there were no significant improvements, as each agency continues to request additional information. Results of the pending legislations may improve the current approval process by streamlining redundant consultation review agencies.

As of October 2022, MFDS has granted food safety approval for 226 events, including 186 plant products, 31 food additives, and nine microorganisms. RDA has approved 172 products for use in feed. See Appendix for a complete list of approved events.

C) Stacked or Pyramided Event Approval/Authorizations

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

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

Similarly, RDA only requires an ERA for stacked events if there is interaction between traits in the inserted nucleic acid of the parental line or other differences are noticed. However, concerns remain over delays and additional information requests by MFDS and RDA to exempt a full safety assessment for stacked events.

D) Field Testing

From January to August 2022, a total of 90 field trials were approved, and in 2021, RDA authorized contained field trials for 105 products. RDA renews the field trial permits every year. According to the Consolidated Notice, field trials are required for imported biotech products used as seed, and RDA will review the data from field trials conducted in the exporting country for those used as FFP. However, RDA may require field trials for FFP use. Products subject to field trials must follow RDA's "Guidelines for Research and Handling of Recombinant Organisms Related to Agricultural Research" and should adhere to voluntary guidelines published by MHW, entitled "Guidelines for Research of Recombinant Organisms."

E) Innovative Biotechnologies

In May 2021, MOTIE proposed a revision of the LMO Act to include a policy on how to regulate products made through innovative biotechnologies (e.g., genome editing). In the proposal, MOTIE classifies products developed through genome editing technologies as LMO. However, the Ministry proposed a pre-review process that will consider risk assessment exemptions for certain products developed through genome editing technologies. Details on the pre-review system such as data requirements will be determined in the implementing regulations once the revision of the Act is complete. MOTIE submitted the proposal to the National Assembly in July 2022 for approval. Korea targets completion of the revision process by the end of 2022 and will draft the implementing regulations in 2023.

F) Coexistence

As biotech crops are not yet grown in Korea, there are no co-existence policies. However, following several reports of GE volunteer corn near Korean feed mills, farmer groups have demanded more government oversight of imports and movement of GE crops in Korea to prevent the inadvertent release of GE crops in domestic production.

G) Labeling and Traceability

In 2017, in accordance with a revision to the Food Sanitation Act, MFDS implemented new mandatory GE labeling requirements that expanded labeling to all detectable products. MFDS is responsible for enforcement of GE labeling guidelines for the purpose of consumers' right to know. Unprocessed and certain processed human food products containing GE ingredients must carry "genetically modified" (GM) food labels. Currently, there are very few products on the market with a "GM" label.

Exempted products include cooking oil, sugar (glucose, fructose, taffy, sugar syrups, etc.), soy sauce, modified starch, and alcoholic beverages (beer, whisky, brandy, liqueur, distilled spirits, etc.). Supporting documents are not required for exemptions from GE labeling requirements for these products. The revised rule also exempts biotech derived processing aids, such as enzymes, carriers, diluents, and stabilizers from GE labeling, but manufacturers are required to provide documentation.

For products that contain or may contain detectable GE ingredients, examples of labels are as indicated in Table 2. For more information, please see the 2017 GAIN report titled "Biotech Labeling Requirements Update."

Table 2: Cases and examples of GE labeling.

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 grains/oilseeds	"May contain GM corn" or "May contain GM soy"	
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 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

Korea allows for up to three percent unintentional presence of approved GE components in unprocessed conventional products that carry an identity preserved or government certificate. For test certificates to get exemptions from GE labeling, only negative test results issued by an MFDS-accredited laboratory are accepted. Intentional mixture of GE ingredients requires GE labeling even if the final presence of biotech ingredients is within the three percent threshold.

Table 3: Unintentional GE Presence and "GM" Labeling

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

Bulk Grains and Processed Products Containing Intentional GE Presence
"GMO" label shall be affixed.
Processed product containing no foreign DNA, such as syrups, oils, alcohols, and processing aids
Exempt from mandatory "GMO" labeling without any further documentation required.

MFDS is conducting a safety assessment for GE potato products that has been ongoing since 2016. Potatoes and any products containing potato-derived ingredients will be subject to mandatory GE labeling as soon as MFDS approves the GE potatoes. Additionally, companies marketing conventional potatoes and processed products containing conventional potato-derived ingredients will be required to submit documents to receive an exemption from mandatory GE labeling.

Anti-biotech NGOs continue to pressure MFDS to expand GE labeling to any products made of GE ingredients. Previously, MFDS attempted to expand GE labeling, but it was not implemented following feedback from the local industry. In 2018, the Korean government recommended the establishment of a consultation body to discuss GE labeling, comprised of NGOs and food industry representatives. There were nine meetings, but parties failed to narrow their differences. In January 2020, MFDS formed a new consultation body consisting of consumer groups, NGOs, and industry to reach an agreement on expanded GE labeling. However, due to the COVID pandemic, very few meetings occurred, and no tangible progress was made. During the National Assembly audit held in October 2022, MFDS announced plans to expand GE labeling through a product-by-product approach. To do so, MFDS will revise relevant regulations in 2024 with implementation expected to begin by 2026.

In January 2021, MFDS proposed a draft revision to GE labeling requirements. The proposal allows 0.9% of unintentional GE presence in products with "Non-GMO" and "GMO-Free" claims. Under the current GE labeling requirements, a zero tolerance applies to products with such claims. This proposal has not been finalized as of October 2022.

In April 2007, MIFAFF (a previous title of MAFRA) revised its Feed Manual to require retail packaged animal feed to carry a "GMO" label when the product contains biotech ingredients. This labeling requirement has been in place for more than a decade with industry conforming to the rule with little to no reported issues.

The 2017 revision to the Food Sanitation Act prohibited a "non-GMO" or "GMO-free" claim on products that do not have GE counterparts. However, it allows for voluntary "non-GMO" or "GMO-free" claims for products that do not contain any trace of a GE component (foreign DNA or protein) and that contain at least 50 percent of raw ingredients or the largest ingredient by volume that are subject to GE labeling rules. Importers must keep relevant documentation to support the voluntary claim, which can include a testing certificate issued by MFDS accredited laboratories. For more information, please see GAIN reports KS1716, KS1004, and KS1046.

H) Monitoring and Testing

Korea actively tests for GE traits in imports and domestic products. MFDS and the Animal and Plant Quarantine Inspection Agency (APQA) test imported agricultural products for GE traits at the port of entry. MFDS and NAQS also test food products and feed grains in the marketplace for GE traits. If an unapproved trait is found, the products will be returned or destroyed.

In 2009, NIE (formerly the National Institute of Environmental Research, NIER), under MOE, began monitoring for imported GE canola, corn, cotton, and soybeans in domestic cultivation. NIE, as the designated ERA agency, collected and tested samples countrywide from 2009 through 2021 and concluded GE FFP imports were inadvertently released during transportation in Korea. Over the past 13 years, NIE checked 8,521 locations and found a total of 797 LMOs (GE corn, GE canola and GE cotton) in 301 locations.

In 2013, the National Seed Management Agency (NSMA) under MAFRA took charge of Korea's monitoring for unapproved GE products in imports and domestic goods. NSMA approves and regulates domestic and imported seeds. In 2017, NSMA detected the first unapproved GE product (canola) in imports and found the unapproved GE canola in 56 locations in Korea.

In 2018, NSMA heightened inspection of imported grain seed by increasing sample size and testing samples of canola and cotton seeds before planting. In 2022, NSMA expanded pre-planting testing to seven seed products: soy, corn, canola, cotton, wheat, alfalfa and flaxseed for monitoring purpose. There has been no report of detection of unapproved GE seeds. MFDS and/or APQA have tested for unapproved GE events in shipments of imported corn, papaya, rice, and wheat. Some testing is random (Liberty Link rice); other testing is mandatory (wheat and papaya).

I) Low Level Presence (LLP) Policy

Korea does not have an LLP policy for unapproved biotech products. Instead, Korea has an "adventitious presence" policy that allows as much as 0.5 percent of the content of a conventional feed shipment to contain unapproved biotech products.

J) Additional Regulatory Requirements

For GE products intended for FFP, no additional registration is required other than an approval. For GE products intended for propagation, the product must complete a seed approval as well as GE approval for cultivation by submitting local field trials data. To date, no GE products have been approved for cultivation in Korea.

K) Intellectual Property Rights (IPR)

Although Korea does not allow for domestic cultivation of GE products, there are intellectual property rights protections under existing domestic regulations.

L) Cartagena Protocol Ratification

Korea ratified the CPB in 2007 and implemented the LMO Act, the legislation implementing the CPB, in 2008. The first revision of the LMO Act was issued in 2012 and was implemented in 2013. MOTIE revised its implementing regulations to harmonize with the LMO Act in 2013 revisions and the Consolidated Notice in 2014. The revision sought to improve the approval process, but MOTIE failed to fully address concerns related to the redundant reviews. After long-term engagement from the United States about concerns from domestic industry and foreign trading partners on language used to implement the CPB, in 2013, Korea began allowing exporters to provide a list of all biotech products approved for use in Korea on the commercial invoice. Importers can use the same list in the import application form, which has reduced trade disruptions.

M) International Treaties and Forums

Korea is actively participating in Codex, International Plant Protection Convention, Asia-Pacific Economic Cooperation, World Trade Organization, Organization for Economic Co-operation and Development, and other meetings on GE plants. Korea notifies the WTO of their proposed changes and gather comments from trading partners. Korea applies substantial equivalence principles of Codex in their safety assessment process.

N) Related Issues

No further issues.

Part C: Marketing

A) Public/Private Opinions

According to local survey results, Korean consumers are generally aware of and hold a pessimistic view of agricultural biotech. In general, they are willing to pay more for non-GE food. The 2013 detection of GE wheat in Oregon alarmed Korean consumers, who perceived it 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" which demanded expanded GM labeling in Korea. This organization is active advocating with the National Assembly and MFDS. Considering these sensitivities, many domestic food manufacturers are somewhat reluctant to use biotech ingredients and carry GM-labeled foods. Repeated detections of GE wheat in Washington in 2016 and 2019 reinforced perceptions that the management of GE production in the United States is inadequate and that future incidents may occur.

There is also support for biotech within the Korean public. Research institutes develop new GE products, and Korea imports substantial biotech ingredients for further processing into products that are exempt from GM labeling. The public seems unaware or indifferent to this fact.

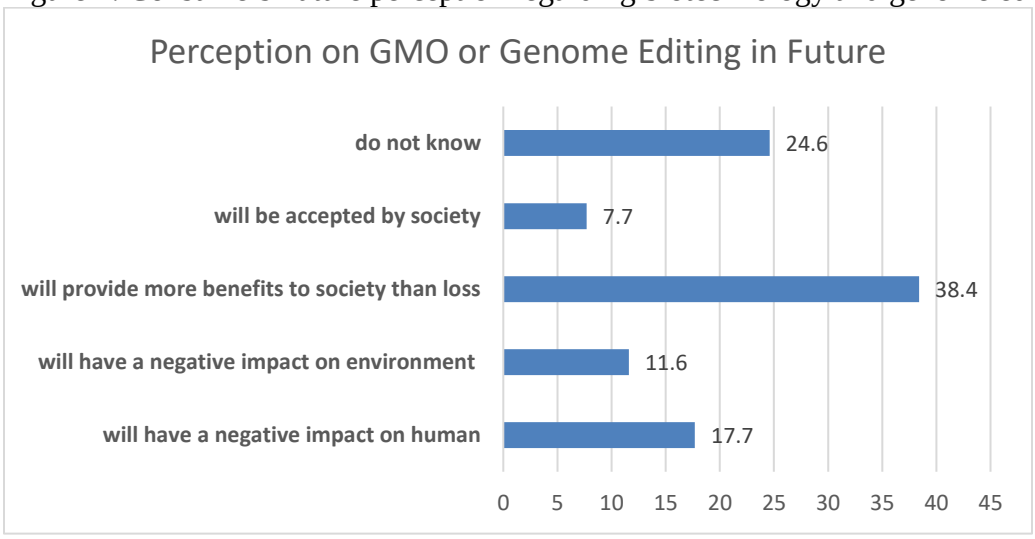
B) Market Acceptance/Studies

The public holds positive views on the use of biotech for animals or medical purposes, but negative views towards its use in in agriculture. This was demonstrated in the 2021 Consumer Union Korea (CUK) survey of 1,000 Korean consumers and the 2020 Korea Biosafety Clearing House (KBCH) annual survey of 800 Korean consumers regarding biotech perceptions.

A 2021 CUK Survey showed that about 80 percent of respondents believed the necessity of R&D of agricultural biotechnology while over 50 percent of the respondents were concerned with safety of GE products. Awareness of terms related to innovative technology is not strong as only 13.2 percent and 23 percent of the respondents were aware of genome editing and gene scissors respectively. Over 67 percent and 53 percent of the respondents answered that products derived through genome editing should be regulated as they might cause unintentional harmful consequences to human health and safety.

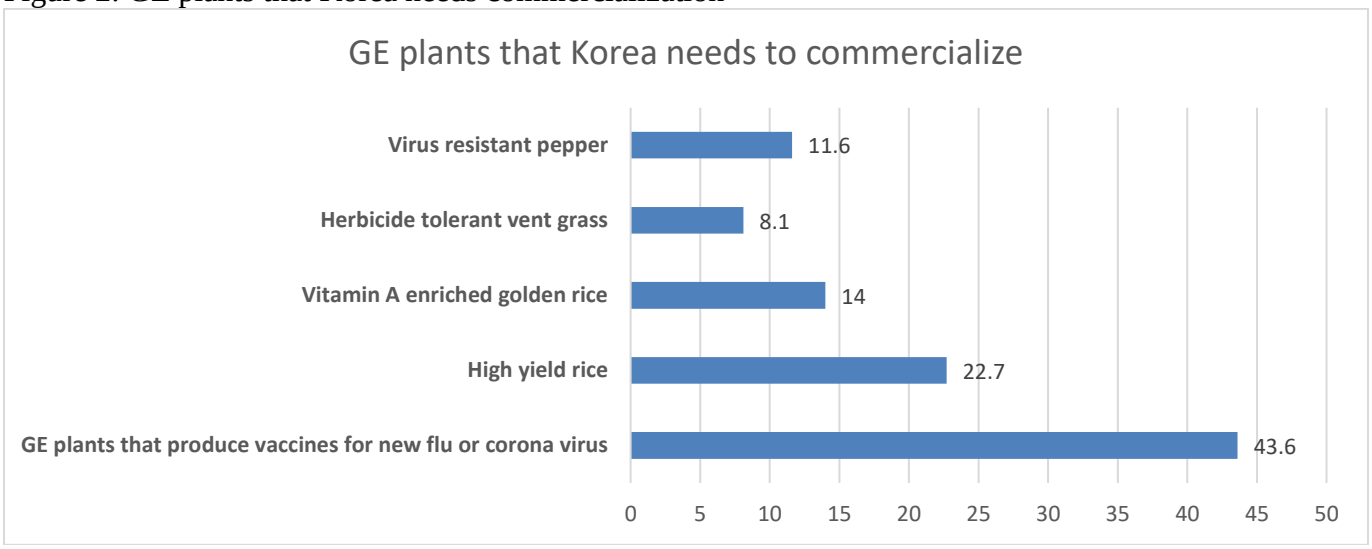
More survey results are as shown in the tables below:

Figure 1: Consumers' future perception regarding biotechnology and genome editing



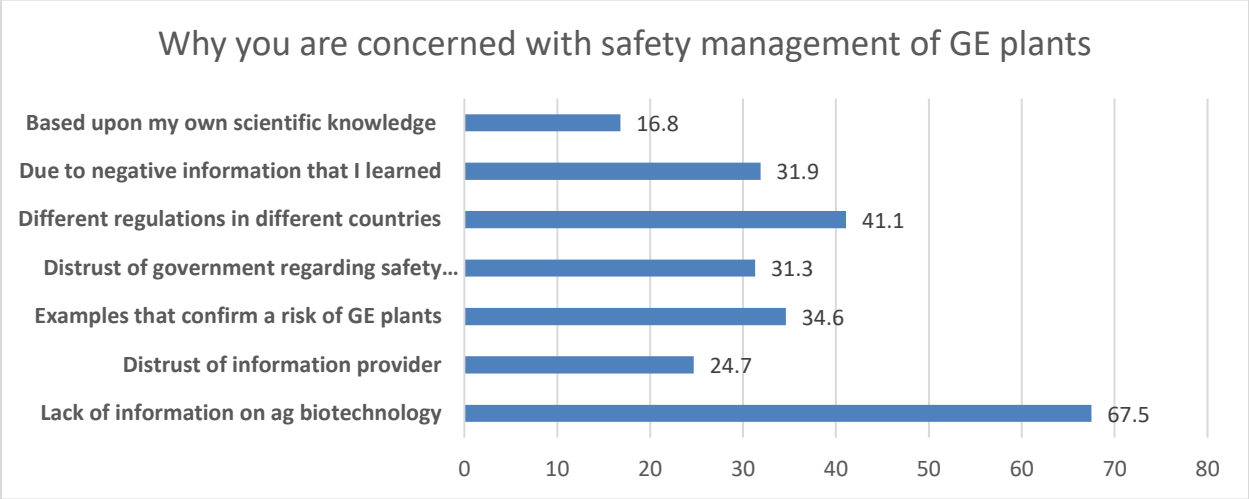
Source: Consumer Union Korea

Figure 2: GE plants that Korea needs commercialization



Source: Consumer Union Korea

Figure 3: Why you are concerned with safety management of GE plants

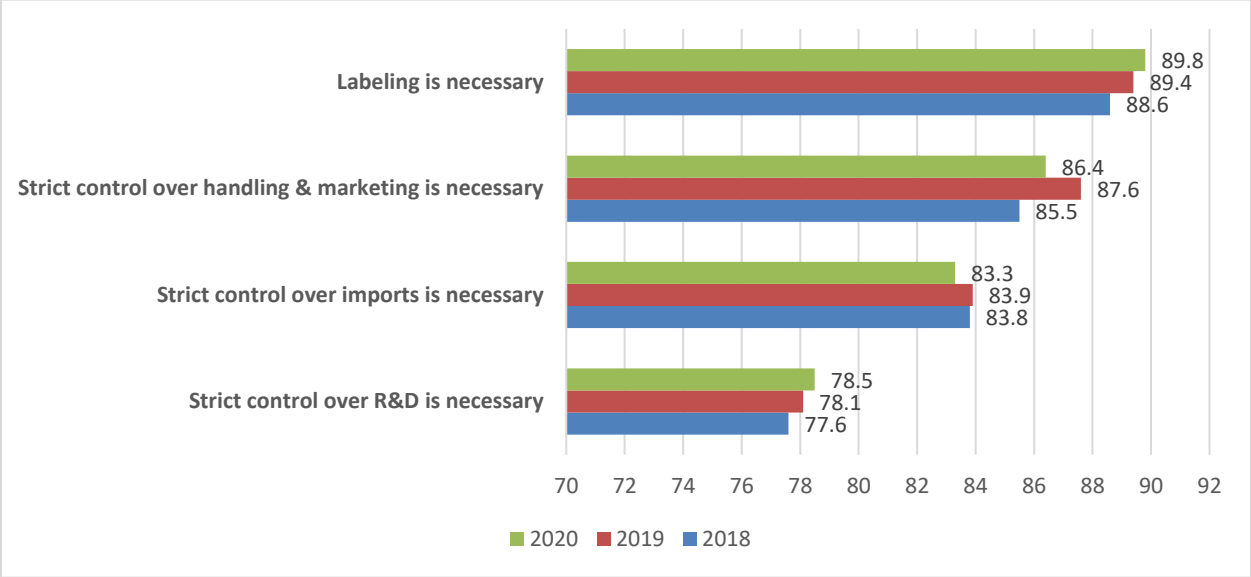


Source: Consumer Union Korea

KBCH survey in 2020 showed consumer awareness remains high, and perceptions have continued to improve gradually from the previous year. Seventy-six percent answered that biotech would be beneficial to humans, which was up from 72 percent in 2019; slightly less than five percent answered to the contrary. Nearly half who answered that biotech is beneficial answered that it was beneficial to curing diseases, such as cancer, and 27 percent answered that it might help solve food shortage issues by producing more food grains. Of those who answered it was not beneficial, 28 percent questioned the safety to humans, which was down from 47 percent in 2019, and 28 percent thought that biotech is unnatural. Thirty-six percent believed biotech would have a harmful effect on the natural eco-system.

For innovative biotechnologies, including gene scissors, 38 percent of the respondents were aware of this new technology. Seventy-six percent and 67 percent of the respondents supported its use in the medical, pharmaceutical, and bio-industry sectors, respectively. Fifty percent and 44 percent support its use in the food/agriculture and livestock sectors. Although many respondents supported its use, 86 percent answered that innovative biotechnologies should be regulated due to safety and unintentional effects, which was up slightly from 84 percent in 2019.

Figure 4: Korea's perspective on biotech regulations



Source: Korea Biosafety Clearing House

Around 77 percent of respondents answered that research and development (R&D) was necessary, and 57 percent answered that it was necessary for Korea to grow biotech crops. Thirty-nine percent of respondents answered that it was necessary for Korea to raise biotech animals domestically. Over 86 percent of respondents supported utilization of GE technologies in the bioenergy and pharmaceutical sectors while only 50 percent signaled support for use by in the food, agriculture, and livestock sectors. About 22 percent responded that it was necessary for Korea to import biotech products from foreign countries. Over 89 and 86 percent were in favor of labeling and strict import controls on biotech products, respectively.

About 25 percent of respondents were interested in biotech products, and 40 percent of these respondents were interested because of safety concerns. Respondents obtained information on biotech products mostly from the internet, followed by television.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Part D. Production and Trade

A) Research and Product Development

Korea is actively using genetic engineering and innovative technologies to research animals that can produce new biomedicines and bio-organs. Korea is also using cloning technology to expand the number of animals with a high capacity to produce biomedical products. The research is being led by various public and private entities, including academia.

In 2022, Korean research entities announced development and research plans for animal biotechnology products through innovative technologies. Plans include: 1) Generation of genome-edited dogs by somatic cell nuclear transfer, 2) Prime editor-mediated correction of a pathogenic mutation in purebred dogs, and 3) Aseptic pig whose retro virus is removed to solve immune-rejection when transplanting bio-organs.

In January 2020, RDA reported that they created a mini-antibody protein producing strain of *Lactobacillus paracasei*. After feeding the mini-antibody protein to virus infected chickens, the level of virus detected in the chickens was decreased. This study confirmed that a transformed *Lactobacillus paracasei* was able to deliver a mini antibody to chicken. In January 2019, RDA announced its annual work plan that included the creation of a future growth engine using agricultural technology for medical purposes, such as research on pig corneal transplants to monkeys. In June 2019, RDA obtained a U.S. patent to produce transgenic pigs as an Alzheimer's disease model to help identify the causes of Alzheimer's and aid in drug screening. RDA has since transferred their technique to a company that specializes in stem cell/cell therapy products.

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

Since 2010, the National Institute of Animal Science (NIAS) of RDA has been focusing on the development of new biomedical materials, such as bio-organs, diversity of animal genetic resources, value-added livestock products, and renewable energy using livestock resources, with the goal of becoming a "world G7 livestock technology country." NIAS is currently conducting research to develop 6 different traits in swine. These traits are designed to produce high-value protein and antivirus materials, swine-producing material that can treat anemia, hemophilia, and thrombus. NIAS is also conducting research using genome editing technologies to prevent certain diseases, but no details have been made publicly available.

In September 2021, RDA announced that they developed a precise breeding technology of silkworms using CRISPR/Cas9. This technology enabled RDA to shorten the breeding time and increase productivity of antimicrobial substances produced by silkworms and change colors of silkworms. RDA plans to apply this technology in insects for industrial use to develop immune enhanced products with

antimicrobial peptides or virus/disease resistant products. RDA is also conducting research to develop 2 different traits using silkworms. Traits under development will enable production of silk in various natural colors and treat a swine disease. In 2018, RDA announced that they developed "Fluorescent silk" using a transgenic silkworm. RDA plans to continue additional research to use fluorescent silk in bio sensors, functional fabric, materials for semi-conductors, and more. NIAS also 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 GE or cloned animals for food use.

In 2018, MAFRA announced details on how to carry out the 2nd Overall Plan for Promotion of Science and Technology for Agriculture, Forestry and Food. MAFRA invested 91 billion Korean won (approximately $90 million USD) in agri-bio resources in 2018, which covered production of pigs for bio-organs, mass production of bio-energy source, and high-value pharmaceutical materials, among others. MAFRA and RDA will continue to develop new biomaterials using animal biotechnology.

Private entities are also developing GE animals that produce high-value protein pharmaceuticals, such as milk producing pigs that express a human growth hormone gene. 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 2015, professors from Korean and Chinese universities announced that they made a pig with higher muscle content using gene editing. 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. In 2022, a professor from Jeju University announced developing a technology to produce cloned pigs with a dementia gene to develop medicine to treat the disease in humans.

B) Commercial Production

As is the case with biotech plants, Korea does not commercially produce any GE animals, and the future of domestic production is uncertain. Korean researchers are relatively unwilling to engage in research on GE animals for commercial food use due to uncertainties over consumer acceptance.

C) Exports

Korea does not export any biotech animals.

D) Imports

Korea imports GE mice for research purposes.

E) Trade barriers

In 2017, MFDS initiated mandatory testing of imported salmon due to reports of GE salmon raised in Panama and marketed in Canada. This testing applied to fresh and frozen salmon originating from the U.S., Canada, and Panama. From October 10, 2017 through December 31, 2017, every import of salmon per manufacturer was tested with no positive detections. Following this period, MFDS conducted random testing on five percent of incoming fresh and frozen salmon from the United States, Canada, and Panama. Currently, MFDS takes one sample of fresh or frozen salmon from any country on a monthly basis and conducts GE testing.

Part E. Policy

A) Regulatory Framework
The LMO Act and its implementing regulations also applies to GE animals, but no specific regulation has been established for the management of GE animals. Pharmaceuticals produced from GE animals are governed by the Pharmaceuticals Affairs Act.

For information on ministries and political factors that may influence regulatory decisions, pending legislations, registration, etc., please refer to Chapter 1, Part B, sub-paragraph A.

B) Approvals/Authorizations
MAFRA is responsible for the approval of GE animals but has not permitted any to date. MFDS is responsible for the safety evaluation of GE animals and fishery products for human consumption under its GE safety evaluation guidelines.

C) Innovative Biotechnologies
In May 2021, MOTIE proposed a revision of the LMO Act to include a policy on how to regulate products developed through innovative biotechnologies (e.g., genome editing). In the proposal, MOTIE classifies products developed through genome editing technologies as LMO. However, they proposed a pre-review process to exempt a full risk assessment of certain products developed through genome editing technologies. Details on the pre-review system such as data requirements, etc. will be determined in the implementing regulations once the revision of the Act is complete.

D) Labeling and Traceability
MAFRA is responsible for the labeling of GE animals but has not yet established any regulations. MFDS is responsible for the labeling of food products containing ingredients originating from GE animals in accordance with MFDS Labeling Requirements for GM Food.

E) Additional Regulatory Requirements
As no policy has been established for animal products derived through innovative technologies, this uncertainty adversely impacts U.S. exporters that wish to export such products to Korea. Predictable and workable regulatory procedures for animal products developed through innovative technologies remain needed in the Korean market.

F) Intellectual Property Rights
Although Korea does not import or domestically produce GE animals, there are intellectual property rights protections under existing domestic regulations.

G) International Treaties and Forums
Korea actively participates in Codex, World Organization for Animal Health (OIE), APEC, and other meetings, but not specifically related to GE animals or fishery products. Korea applies substantial equivalence principles of Codex in their safety assessment process.

H) Related Issues
No related issues have been identified.

Part F: Marketing

A) Public/Private Opinions
Many Koreans believe that biotechnology is an important industry for Korea's economic development. Proponents have had some success in making economic, development, public health, and environmental arguments in favor of biotech. Korea continues to expand investment in R&D for biomaterial, biomedicine, bio-organs, and gene therapy, among others. However, consumers maintain a negative perspective of biotech used to produce animal or fishery products for food.

B) Market Acceptance/Studies
The public holds positive views on the use of biotech for animals or medical purposes but are negative towards its use in in food. This was demonstrated in 2020 though the results of KBCH's 12th annual survey of 800 Korean consumers' perceptions of biotech. In the 2020 KBCH consumer survey, 39 percent of respondents answered that Korea needs domestic production of GE animals, which is slightly higher than the 37 percent that had answered in the 2019 survey.

In the same survey, about 44 percent of respondents supported the application of gene editing technology in a livestock sector while only 17 percent of respondents disagreed with its application.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

Part G: Production and Trade

A) Commercial Production
Korea commercially produces biotech microbes to produce sweeteners, and such microbial biotech-derived sweeteners are available in the domestic market.

B) Exports
Korea does not export biotech microbes or biotech-derived food ingredients yet. However, it is known that some Korean sweetener companies export microbial biotech-derived sweeteners to foreign markets. Korea exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

C) Imports
Korea does not import any biotech microbes. However, Korea imports microbial biotech-derived food ingredients, such as chymosin. Microbial biotech-derived food ingredients likely are in Korean imports of alcoholic beverages, dairy products, and processed products, where microbial biotech-derived ingredients are commonly used in global production.

D) Trade Barriers
No specific trade barrier has been identified.

Part H: Policy

A) Regulatory Framework
The Food Sanitation Act applies to biotech microbes and microbial biotech-derived food ingredients, which requires a safety assessment. The LMO Act also applies to biotech microbes and requires environmental consultation as biotech microbes are considered a living modified organism.

i. Definition of Terms

Legal Term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
셀프클로닝미생물	Self-cloning microorganisms	MFDS Safety Assessment Guideline	Genetically modified microorganisms made by recombining genes of the same species or systematically close species that can exchange genetic materials by means of naturally developed physiological processes among microorganisms that are affiliated with the Biological Risk Group 1 known to be unlikely to cause diseases in healthy adults (including animals or plants) and gene recombination vectors used in self-cloning shall be those that are usually used safely for microorganisms.

ii. Responsible Ministries

MFDS conducts the food safety assessment of biotech microbes for food use and microbial biotech-derived food ingredients.

iii. GE Microbes Used in the Field for Agricultural Production

MAFRA conducts the risk assessment of GE microbes used in the field for agricultural production in the same manner as GE plants for FFP use. GE microbes, intended for use in the environment, require field trial data generated in Korea.

B) Approvals/Authorizations
Biotech microbes, developed domestically or imported, are required to undergo a food safety assessment and environmental risk consultation. MFDS conducts the food safety assessment and consults with RDA, NIE and NFRDI on environmental aspects in accordance with the LMO Act. For microbial biotech-derived food ingredients, MFDS conducts the food safety assessment, and no environmental risk consultation is required. As of October 2022, MFDS has granted food safety approval for nine GE microbes. See the Appendix for a complete list of approved microbes and food ingredients.

C) Labeling and Traceability

Korea does not require biotech labeling for processing aids. Food ingredients derived from biotech microbes do not require biotech labeling. Thus, microbial biotech-derived sweeteners do not carry biotech labels. The same rule applies to food products containing microbial biotech-derived ingredients (e.g., cheese made with chymosin produced with GE microbes). No biotech labeling is required for food products made from biotech food ingredients.

D) Monitoring and Testing

No specific information is available.

E) Additional Regulatory Requirements

Korea requires a safety assessment for food ingredients that are made with biotech microbes despite these microbes having undergone a biotech safety assessment. Korea authorities attempted to simplify this redundant safety assessment requirement in July 2020 but failed to implement due to concerns raised by NGOs.

F) Intellectual Property Rights

Intellectual Property Rights (IPR) are protected under existing domestic IPR regulations.

G) Related Issues

No related issues have been identified.

Part I: Marketing

A) Public/Private Opinions

Generally, Koreans have a positive view of technological innovation and its use in everyday life. However, this view does not carry into advances in food for human consumption. Since biotech microbes and derived food ingredients are not free-standing items thought to be directly consumed, there is little public awareness that this technology is widely used in food production. As result, there are minimal public or private opinions surrounding these topics.

B) Market Acceptances/Studies

Sweetener companies advertise that microbial biotech-derived sweeteners are a healthy low-calorie substitute for sugar. As consumer-ready products do not carry biotech labeling, consumers are generally unaware they are made from biotech microbes. Various meal substitutes and special food products for individuals with health conditions are commercially available in the Korean market.

Market acceptance studies are not readily available in Korea.

APPENDIX: APPROVED EVENT LIST

TABLE OF APPROVED PLANT BIOTECHNOLOGY PRODUCTS AS OF OCTOBER 2022

Note: Biotechnology products are required to undergo a food safety assessment and ERA.

Crop	Event	Applicant	Trait	Approval	Approval Date
Soybean	GTS40-3-2	Monsanto	Herbicide Tolerance (HT)	Food & Feed	2020* & 2004
Soybean	MON89788	Monsanto	HT	Food & Feed	2019* & 2009
Soybean	A2704-12	Bayer	HT	Food & Feed	2019* & 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-44406-6	Dow	IR, HT	Food & Feed	2017 & 2018
Soybean	MON87708 X MON89788 X A5547-127	Monsanto	HT	Food & Feed	2017 & 2018
Soybean	DP-305423-1 X MON87708 X MON89788	Dupont	HT, High oleic	Food & Feed	2018
Corn	MON810	Monsanto	IR	Food & Feed	2012* & 2004
Corn	TC1507	DuPont	HT, IR	Food & Feed	2012* & 2004
Corn	GA21	Monsanto	HT	Food & Feed	2020* & 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	Monsanto	HT, IR	Food & Feed	2006 & 2008

	MON810				
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	2019* & 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 & 2021
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 & 2022
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	Syngenta	HT, IR	Feed & Food	2012

	TC1507 X GA21				
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 & Feed	2014
Corn	MON87427 X MON89034 X MON88017	Monsanto	HT, IR	Food & Feed	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	Dow	IR, HT	Food & Feed	2014 & 2015

	DAS-40278-9				
Corn	TC1507 X MON810 X MIR162	DuPont	IR, HT	Food & Feed	2015
Corn	NK603 X DAS-40278-9	Dow	HT	Food & Feed	2015
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 & Feed	2016 & 2017
Corn	MON87403	Monsanto	Increased corn ear	Food & Feed	2017 & 2016
Corn	MON87419	Monsanto		Food & Feed	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 & Feed	2017
Corn	MON89034 X TC1507 X MIR162 X NK603	Dow	HT, IR	Food & Feed	2017 & 2018
Corn	MON89034 X	Monsanto	IR	Food & Feed	2017

	MIR162				
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-59122-7	Monsanto	HT,IR	Food & Feed	2018 & 2017
Corn	MON89034 X TC1507 X MIR162 X NK603 X DAS-40278-9	Dow	HT, IR	Food & Feed	2018
Corn	MON87427 X MON89034 X MIR162 X MON87419 X NK603	Monsanto	HT, IR	Food & Feed	2018
Corn	MON87427 X MON89034 X MON810 X MIR162 X MON87411 X MON87419	Monsanto	HT, IR	Food and Feed	2019
Corn	MZIR098	Syngenta	HT, IR	Food & Feed	2019
Corn	MON87427 X MON89034 X MON87419 X NK603	Monsanto	HT, IR	Food & Feed	2020
Corn	NK603 X T25 X DAS-40278-9	Dow	HT	Food & Feed	2020
Corn	MON87427 X MON87419 X NK603	Monsanto	HT	Food & Feed	2020 & 2021
Corn	DP-004114-3 X MON89034 X MON87411 X DAS-40278-9	Corteva	HT, IR	Food & Feed	2021
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 & Feed	2014 & 2013
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	Monsanto	IR, HT	Food & Feed	2016

	MON88913 X MON88701				
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
Cotton	T304-40 X GHB119 X COT102	BASF	IR, HT	Feed	2018
Cotton	GHB811	BASF	HT	Food & Feed	2019
Cotton	MON88702	Monsanto	IR	Food & Feed	2021
Cotton	GHB811 X T304-40 X GHB119 X COT102	BASF	IR, HT	Food	2021
Cotton	281/3006 X COT102 X DAS-81910-7	Corteva	IR, HT	Food	2022
Cotton	GHB811 X T304-40 X GHB119 X COT102 X MON88701	BASF	IR, HT	Food	2022
Cotton	T304-40 X GHB119 X COT102	BASF	IR, HT	Food	2022
Cotton	GHB811 X LLCotton25 X MON88701	BASF	HT	Food	2022
Cotton	MON88702 X MON15985 X COT102 X MON88701 X MON88913	Monsanto	IR, HT	Food	2022
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, Male sterility	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, Fertile	Food & Feed	2014 & 2015

			restore		
Canola	MON88301 X MS8 X RF3	Monsanto	HT, Fertile restore	Food & Feed	2014 & 2015
Canola	MS8 X RF3 X RT73	Bayer	HT, Fertile restore	Food & Feed	2015
Canola	DP-073496-4	DuPont	HT	Food & Feed	2015
Canola	DP-073496-4 X RF3	DuPont	HT, Fertile restore	Food & Feed	2017
Canola	MS11	BASF	HT, Male sterility	Food & Feed	2019
Canola	MS11 X RF3 X MON88302	BASF	HT, Male sterility, Fertile restore	Food & Feed	2020
Canola	MS11 X RF3	BASF	HT, Male sterility, Fertile restore	Food & Feed	2020
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
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: 186
Total Feed Approval: 172
* Food approvals must be renewed every 10 years after the initial approval
1) MFDS conditional approval for discontinued items
2) MFDS conditional approval for items that are not intended for commercialization
3) MFDS conditional approval as other category and adventitious presence is accepted

TABLE OF APPROVED BIOTECH MICROBES AS OF OCTOBER 2022

Note: Biotech microbes are required to undergo a food safety assessment and environmental consultation.

No	Name	Developer	Character (Microbe)	Approval
1	FIS001	CJ	To produce L-arabinose isomerase Host: Corynebacterium glutamicum Donor:Thermotoga neapolitana and E.coli	June 2011
2	FIS00	CJ	To produce D-cycos-3-isomerase Host: Corynebacterium glutamicum Donor: A. tumefaciens and E.coli	Feb 2015
3	DS00001	Daesang	To produce D-cycos-3-isomerase Host: Corynebacterium glutamicum Donor: F. plautii and E.coli	Nov 2016
4	SYG321-C	Samyangsa	To produce D-cycos-3-isomerase Host: Corynebacterium glutamicum Donor: C. scindens and E.coli	Jan 2017
5	DS00001-1	Daesang	To produce D-cycos-3-isomerase Host: Corynebacterium glutamicum Donor: F. plautii and E.coli	Mar 2018
6	FIS003	CJ	To produce D-fructose-4-isomerase Host: Corynebacterium glutamicum	Aug 2018
7	APC199	AP Technology	To produce 2'-fucosylactose Host: Corynebacterium glutamicum Donor: E.coli K12	Aug 2020
8	BD001	Intelligent Bio Designeering	To produce β-glucosidase Host: Corynebacterium glutamicum Doner: Microbacterium testaceum and E.coli	Dec 2021
9	BD002	Intelligent Bio Designeering	To produce β-glucosidase Host: Corynebacterium glutamicum Doner: Paenibacillus mucilaginosus and E.coli	Dec 2021

Total Biotech Microbe Approvals: 9

TABLE OF APPROVED MICROBIAL BIOTECH-DERIVED FOOD INGREDIENTS AS OF OCTOBER 2022

Note: Microbial biotech-derived food ingredients are required to undergo a food safety assessment.

No	Name	Applicant	Characteristics	Approval
1	Maltogenic amylase (Novamyl 1500MG, Novamyl 10000BG, Maltogenase 4000L)	Novozymes	Activate maltogenic amylase	2000 / 2010 / 2020
2	α – amylase (Termamyl SC)	Novozymes	Activate α-amylase	2001 / 2011

3	Pulluranase (Promozyme)	Novozymes	Activate pulluranase	2002 / 2012
4	Lipase (Lipozyme RM IM)	Novozymes	Activate lipase	2002 / 2012
5	Riboflavin	DSM Nutrition	Vitamin B2	2003 / 2013 Discontinued in 2016
6	Pectinase (Novoshape)	Novozymes	Activate pectin esterase	2003 / 2013
7	Pullaranase (Optimax L-1000)	Danisco	Activate pulluranase	2004 / 2014
8	Maturex L	Novozymes	Activate α – acetolactate dicarboxylase	2004 / 2014
9	Lipase (Lipopan H BG/ Lecitase Ultra)	Novozymes	Activate lipase	2004 / 2014
10	Lipase (Lipopan F BG/ Lecitase Novo)	Novozymes	Activate lipase	2004 / 2014
11	Lipase (Lipopan 50 BG/ Lipozyme TL IM)	Novozymes	Activate lipase	2004 /2014
12	Xylanase (Pentopan Mono BG)	Novozymes	Activate xylanase	2008 / 2018
13	Xylanase (Shearzyme 2X/500L)	Novozymes	Activate xylanase	2008 / 2018
14	Gluco-amylase (Saczyme go 2X)	Novozymes	Activate glucoamylase	2010 / 2020
15	Lipase (Lipozyme 435, Lipozyme CALBL)	Novozymes	Activate lipase	2012
16	Trans-glucosidase	Danisco	Activate trans glucosidase	2013
17	Pulluranase (Novozym26062)	Novozymes	Activate pulluranase	2015
18	Branching Glycosyltransferase (Branchzyme)	Novozymes	Activate brancing glycosyltransferase	2015
19	Chymosin (ChyMax)	Christian Jansen	Activate chymosin	2016
20	Lactase (Saphera 2600L)	Novozymes	Activate lactase	2018
21	β-amylase (Secura)	Novozymes	Activate β-amylase	2018
22	A-amylase (Extenda Go 2 Extra)	Novozymes	Activate α-amylase	2018
23	Pulluranase (Extenda Go 2 Extra)	Novozymes	Activate pulluranase	2018
24	Chymosin (ChyMax M1000)	Christian Jansen	Activate chymosin	2018

25	Glucoamylase (Extenda Go 2 Extra)	Novozymes	Activate glucoamylase	2019
26	1.4-α-glycosyltransferase (CCD)	Daesang	Activate glycosyltransferase	2020
27	Pulluranase (Optimax L-2500)	Ojeon Biotech	Hydrolysis of α-1.6 bond of starch	2021
28	Frontia Fiberwash	Novozymes	Activate xylanase	2021
29	Frontia Fiberwash	Novozymes	Activate arabinofuranosidase	2021
30	Quara LowP	Novozymes	Activate phospolipase	2021
31	Spezyme Powerliq, Amylex 5T	Danisco	Activate α-amylase	2022

Total Microbial Biotech-Derived Food Ingredient Approvals: 31

Attachments:

No Attachments