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Report Highlights:

In September 2024, a National Assembly member submitted a draft revision of the Act on Transboundary Movements of Living Modified Organisms, commonly referred to as the LMO Act. This draft bill defines organisms derived from genome editing technology that do not use or contain foreign genes in final products as a new category, distinct from Living Modified Organisms (LMOs) and thus not subject to the same requirements mandated by the current LMO Act, including risk assessments.

Executive Summary

Korea relies on agricultural imports to satisfy its food and feed demand; however, there is mixed acceptance among Korean consumers of food derived from agricultural biotechnology. As a result, there are a limited number of these products available for direct human consumption in Korea. The limited market for food derived from agricultural biotechnology discourages Korean farmers from adopting this technology. Conversely, the bulk of livestock feed imported into Korea is biotech-derived corn and soybeans. The United States is one of leading exporters of genetically engineered (GE) grain and oilseeds to Korea, along with Argentina and Brazil.

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) has been working with stakeholders to expand mandatory GE labeling to all products made with GE ingredients, targeting 2026 implementation.

Announced in early 2023, Korea's "Green Bio Industry Promotion Strategy" aims to grow the country's agricultural industry by fostering competitiveness in the world market. This strategy supports research and development of core technologies such as microbiome, digital breeding, bio-chemical and fertilizers, veterinary drugs and materials produced through fermentation.

On September 20, a National Assembly member submitted Draft Bill #2204098 to the Trade, Industry, Energy, SMEs, and Startups Committee, seeking to revise the Act on Transboundary Movements of Living Modified Organisms, commonly referred to as the LMO Act. This draft bill defines organisms derived from genome editing technology that do not use or contain foreign genes in final products as a new category, distinct from Living Modified Organisms (LMOs) and thus not subject to any requirements mandated by the current LMO Act, including risk assessments. A different National Assembly Member, also in September, submitted a separate draft revision of the LMO Act but has since withdrawn that bill. The withdrawn legislation had closely mirrored the 2022 draft LMO Act revision that Korea's Ministry of Trade, Industry and Energy (MOTIE) submitted to the National Assembly, which would have classified products developed through innovative biotechnologies, such as genome editing, as new LMOs and subject to many of the same requirements mandated by the current LMO Act.

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
GEO: Genome Edited 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, government agencies, universities, and private entities lead the development of modern biotechnology (biotech) products. These entities focus their research on second and third generation traits such as environmental tolerance, disease resistance, and nutrient enrichment. From January to October 2024, the Ministry of Agriculture, Food, and Rural Affairs' (MAFRA) Rural Development Agency (RDA) approved 79 field trial research projects conducted by RDA's designated evaluation entities and private organizations.

Korea has various products under development using modern biotechnology. Examples of these products include:

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

Jeju National University developed an herbicide-tolerant bentgrass under RDA's Next Generation Bio-Green 21 Project and submitted it to RDA for an environmental risk assessment (ERA) in December 2014. The product remained under review until June 2023, when after nearly nine years, RDA denied the application approval citing insufficient supporting data.

Private entities in Korea are also involved in research and development using innovative technologies with faster development capability and reduced costs, notably genome editing. Research and development by private entities includes 1) "golden sweet potato" with high antioxidant substances developed through CRISPR Cas9, 2) high oleic soybean and seed potato that inhibits a browning effect using CRISPR Cas9, 3) gene edited flaxseeds for use in medical and food products, 4) tomato with high provitamin D3 developed through CRISPR Cas9, 5) particular component reduced or flavor enhanced tobacco and 5) genome edited cattle whose major antigens are removed through CRISPR Cas9 to produce artificial blood for human and allergy free meat. Also, RDA has announced plans to develop gene-edited cabbage. With innovative biotechnologies, RDA continues to find genes resistant to disease and to develop products to help producers adapt to climate change.

In March 2022, 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 developed using agricultural biotechnology. This center aims to assist Korea in quickly responding to emerging epidemic diseases.

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 NGO requests to stop the 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).

In April 2019, 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.

While RDA continues to develop GE products in a research capacity, it does so under increased scrutiny from local 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 September 2020, MAFRA led a group of 10 Ministries to finalize 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.

In 2023, Korea published the 4th LMO Safety Management Plan for the next five years, which aimed to:

- Improve the national safety management system of LMOs corresponding to any change,
- Build capacity to conduct safety management of LMOs, and
- Respond to issues related to LMOs and enhance communication.

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 2023, Korea imported a total of 11.26 MMT of corn, which consisted of 9.22 MMT for feed and 2.04 MMT for processing. Imports from the United States reached 0.83 MMT or 7 percent of the total import volume. Nearly all of Korea's corn imports from the United States is GE. Korean food processors largely use imported GE corn to make high fructose corn syrup and corn oil. Korea's Ministry of Food and Drug Safety (MFDS) exempts these products 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 2023, Korea imported a total of 1.3 MMT of soybeans, primarily for crushing. The United States was the largest soybean supplier, providing nearly the half of the entire import volume.

MFDS also exempts soybean oil 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			2020	2021	2022	2023	2024 Jan-Aug
			Volume	Volume	Volume	Volume	Volume
Soybean	Food (Crushing)	US	374	400	450	388	299
		Non-US	612	656	544	540	305
		Total	986	1,056	994	928	604
Corn	Food	US	354	344	127	0	380
		Non-US	644	356	532	289	0
		Total	998	700	659	289	380
	Feed	US	2,603	2,885	1,272	776	1,937
		Non-US	7,184	6,349	7,952	8,154	3,783
		Total	9,787	9,234	9,224	8,930	5,720
Oilseeds	Feed	US	181	81	79	92	
		Non-US	20	75	98	43	8
		Total	201	156	177	135	102

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 19,000 MT of rice to date and Korea plans to support additional 10,000 MT of rice to APTERR in 2024. In January 2018, Korea joined the Food Assistance Convention, which allows Korea to draw down its rice stocks that it holds in storage.

From 2018 through 2023, Korea shipped 50,000 MT of domestic rice to five countries annually through the World Food Program. In 2024, Korea increased the volume of their rice aid to 100,000 MT and expanded recipients to 11 countries from five countries; shipped 18,000 MT to Yemen, 13,600 MT to Ethiopia, 21,000 MT to Kenya, 3,000 MT to Uganda, 4,900 MT to Afghanistan, 15,000 MT to Bangladesh, 2,400 MT to Guinea Bissau, 10,000 MT to Madagascar, 6,700 MT to Mauritania, 3,000 MT to Mozambique, and 2,400 MT to Sierra Leone.

F) Trade Barriers

Industry remains concerned about 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 contributes to delays for agricultural producers seeking to utilize biotech tools for products intended for the Korean market as well as globally. 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 must remove the 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 a breach was intentional.

MFDS requires shippers of U.S. processed food products that contain conventional soy, corn, canola, cotton, sugar beet, and alfalfa to submit additional documents to receive an exemption from the mandatory biotech labeling requirement. 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 implemented the LMO Act as the overarching law governing CPB parties' biotechnology-related rules and regulations.

The Korean Government implemented the LMO Act in 2008 and revised it in 2013. Since the LMO Act's implementation, the United States 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	LMO Act	Any living modified organism that possesses a novel combination of genetic material obtained through

	Organism (LMO)		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. Seven non-government specialists, such as professors from Korean universities are also members of the Biosafety Committee. This body is responsible for reconciling differing positions among the relevant ministries. Each ministry holds authority and responsibility in its respective area, and as chair, the MOTIE Minister resolves issues that lack consensus.

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 2023 detection of unapproved GE zucchini. The technical committee meets six times a year and follows the status of risk assessments and consultation reviews.

iv. Political and Social Influence

Anti-biotech NGOs, some of which the government appoints to its food safety and biotechnology risk review committees, are often successful in applying political pressure to regulatory decisions related to agricultural biotechnology. 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 that food manufacturers and livestock feeders will use as food products and animal feed. 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 animal feed 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 foreign DNA.

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

The LMO Act does not classify non-living plant products, such as meal or cake, as LMOs and does not require a risk assessment. Again, however, the LMO act requires that GE plants used as raw materials for non-living GE plant products must successfully complete the safety 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. Korea requires extensive data to carry out risk assessments and applicants consider some of data requests as not relevant for the intended use of LMO FFPs. 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

On September 20, during the current 22nd session of the National Assembly, a lawmaker submitted Draft Bill #2204098 to the Small and Medium Enterprise Committee, seeking to revise how the LMO Act treats products derived from genome editing technology. This draft bill defines genome edited organisms that do not use or contain any foreign genes in final products as a new category, distinct from LMOs and thus not subject to the full risk assessment required by the current LMO Act. Another National Assembly member, also in September, submitted a separate draft revision of the LMO Act but has since withdrawn that bill. The withdrawn legislation had closely mirrored the 2022 draft LMO revision that MOTIE submitted to the National Assembly and would have classified products developed through innovative biotechnologies, such as genome editing, as new LMOs.

During the previous National Assembly session, MOTIE proposed a revision of the LMO Act to include a policy on how to regulate products made through innovative biotechnologies. In the proposal, MOTIE classified products developed through genome editing technologies as new LMOs. However, the Ministry proposed a pre-review process that would have considered risk assessment exemptions for certain products developed through genome editing technologies. The bill would have granted exemptions 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. MOTIE submitted the proposal to the National Assembly in July 2022 for approval but the legislative body did not vote on the draft bill during the 21st session of the National Assembly and as a result the bill was discarded.

Anti-biotech NGOs are likely to oppose revisions to the LMO Act during the National Assembly review process and demand more stringent oversight over products developed through innovative biotechnologies. Korean researchers have shown support for Draft Bill #2204098 but there are still uncertainties about how responsible ministries would interpret and implement the bill. The GEO Bio-industry Development Consultation Group, consisting of 23 domestic companies that support the use of genome editing technologies, released a statement supporting Bill # 2204098. Click here to view an article about the support from domestic product developers, Korean language only.

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. The relevant ministries may conduct reviews for food and feed approvals and consultations simultaneously. These statutory review periods may be extended if additional data is requested. The statutory review period for stacked events for food and feed use is 90 working days. Historically, a significant number of event reviews have exceeded Korea's statutory timeline.

x. Additional Product/Seed Registration

In addition to food and feed approval for new biotech products, Korea requires registration of GE plant seeds if imported for propagation in Korea. To date, Korea has not approved any GE plants for propagation in Korea.

xi. Re-registration

Korea does not require re-registration.

xii. Approval/authorization limit

Korea requires renewal of an approved single event for food use every 10 years. Korea does not require renewal of approval for stacked events and events for feed use.

B) Approvals/Authorizations

As of October 2024, MFDS has granted food safety approval for 250 events, including 198 plant products, 41 food additives, and 11 microorganisms. RDA has approved 187 products for use in feed. See Appendix for a complete list of approved events.

Biotech products must undergo a food safety and environmental risk assessment (ERA). MFDS conducts the food safety assessment, consulting with RDA, NIE and NFRDI. While MFDS refers to the ERA 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. The committee reviewed only one product under this pilot project in 2016. The results of the pilot project demonstrated the committee achieved few efficiencies. 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. In response to demands for a predictable review process, an interagency effort led by MOTIE proposed a process to develop guidelines for ERA in 2023 and hosted the first joint government and industry meeting in February 2024. Korea's goal is to draft the guidelines that list all the required data for ERA to enhance predictability of data requirements and to avoid any redundant data requirements by different agencies involved in the ERA.

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 it notices other differences. However, industry 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 October 2024, RDA approved a total of 79 field trials, and in 2023, RDA authorized contained field trials for 85 products. RDA renews the field trial permits every year. According to the Consolidated Notice, RDA requires field trials 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 retains the authority to 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

See Part B: Policy A) Regulatory Framework viii. Pending Legislation for the latest on innovative biotechnologies.

F) Coexistence

As Korean producers do not grow any biotech crops, 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.). MFDS does not require supporting documents 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 does require manufactures 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 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, MFDS only accepts negative test results issued by an MFDS-

accredited laboratory. 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, MFDS will require companies marketing conventional potatoes and processed products containing conventional potato-derived ingredients 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 did not implement it following feedback from 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 parties made no tangible progress. 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 needs to revise relevant regulations to show details on implementation, such as timelines by product types.

In January 2021, MFDS proposed a draft revision to GE labeling requirements. The proposal allows 0.9 percent 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. As of October 2024, MFDS has not finalized the proposal.

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 (rice, wheat, etc.); other testing is mandatory (papaya).

In response to a finding of the release of unapproved GE zucchini seeds in local farms in March 2023, MAFRA introduced the following measures to prevent the release of unapproved GE seeds: 1) mandating a phytosanitary certificate for all imported seeds and quarantine inspection of seeds imported via postal package, 2) conducting LMO testing of eight seed products (soy, corn, canola, cotton, wheat, flaxseed, alfalfa and zucchini) in the first half of 2023, adding 5 seed products (tomato, melon, sweet pepper, paprika, and papaya) in the second half of 2023, and expanding LMO testing to 37 seed products that are commercially available worldwide by 2028, 3) mandating LMO test certificates for newly registered seeds, and 4) enhanced monitoring and testing of cotton, canola and zucchini seeds in a region where the unapproved zucchini event was planted.

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, Korea does not require additional registration 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, Korea has not approved GE products 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 actively participates 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 most of their proposed changes except for draft bills proposed by lawmakers 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 survey results, Korean consumers are generally aware of and hold a somewhat 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 still actively advocates for aligned positions with the National Assembly and MFDS.

Considering these sensitivities, many domestic food manufacturers are 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 products developed through innovative biotechnologies, 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

In 2023, the Consumer Union Korea (CUK) surveyed 1,000 Korean consumers and 426 farmers and the Korea Biosafety Clearing House (KBCH) completed its annual survey of 800 Korean consumers regarding their perceptions of biotechnology use across multiple industries. The Korean public largely holds positive views towards the application of biotechnology for medical and energy applications but more mixed views towards its use for agriculture and food.

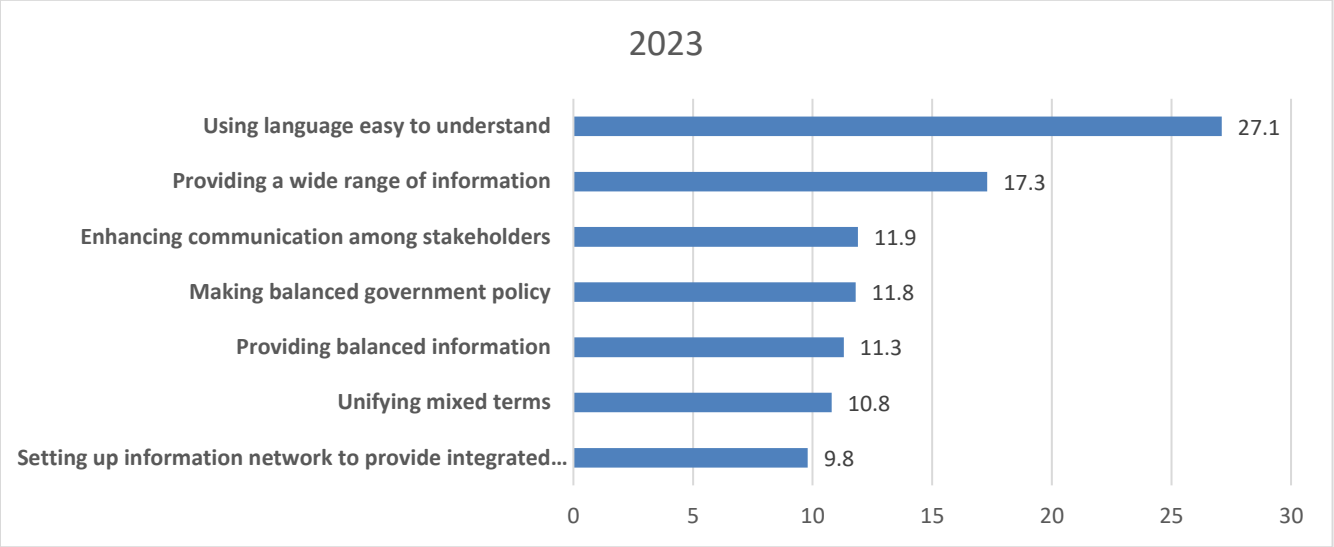
The CUK Survey showed that about 83 percent of respondents feel the use of biotechnology is necessary in the research and development process to secure quality seeds and maintain international competitiveness. Over 91 percent responded that GE product regulations are necessary to prevent any unintended effects of GE products. Consumers responded that they would buy GE products if they tasted better or were price competitive. Seventy three percent of farmers answered that they were willing to use agricultural biotechnology as a tool to deal with climate change if provided with enough relevant information. Contrastingly, however, only 26 percent of farmers responded that they were willing to plant GE products in Korea. Some farmers responded that they would grow GE products if it helped with weed and insect control as well as if it had health benefits. Both consumers and farmers answered that they are less concerned with GE products than contamination from pesticides and heavy metals. The survey found the most effective way to deliver information on agricultural biotechnology was through television programs and YouTube.

The KBCH survey showed consumer awareness of LMOs remains high, although it decreased from 82 to 73 percent compared to the previous year. Perceptions over biotechnology in general remain positive, however respondents identified GE food has the third-highest food safety concern, following radioactive contaminants and carcinogens. Seventy-three percent of respondents answered that biotechnology would be beneficial to humans for applications across all sectors of the economy. Of those who answered it was not beneficial, 35 percent questioned the safety to humans, and 16 percent thought that biotechnology is unnatural. Thirty-four percent believed biotechnology would have a harmful effect on the natural eco-system. For innovative biotechnologies, including gene scissors, less than half of the respondents were aware of this technology. Over 81 percent of respondents answered that regulations are necessary for innovative biotechnologies due to unintended effects and safety concerns with the technology. The major source of information was television and the internet.

Most respondents indicate the need for labeling of GE food and agricultural products and support strict controls on the research and development, imports, and marketing of these products. Fifty one percent of respondents expressed their willingness to buy GE food. The survey showed that consumers are more

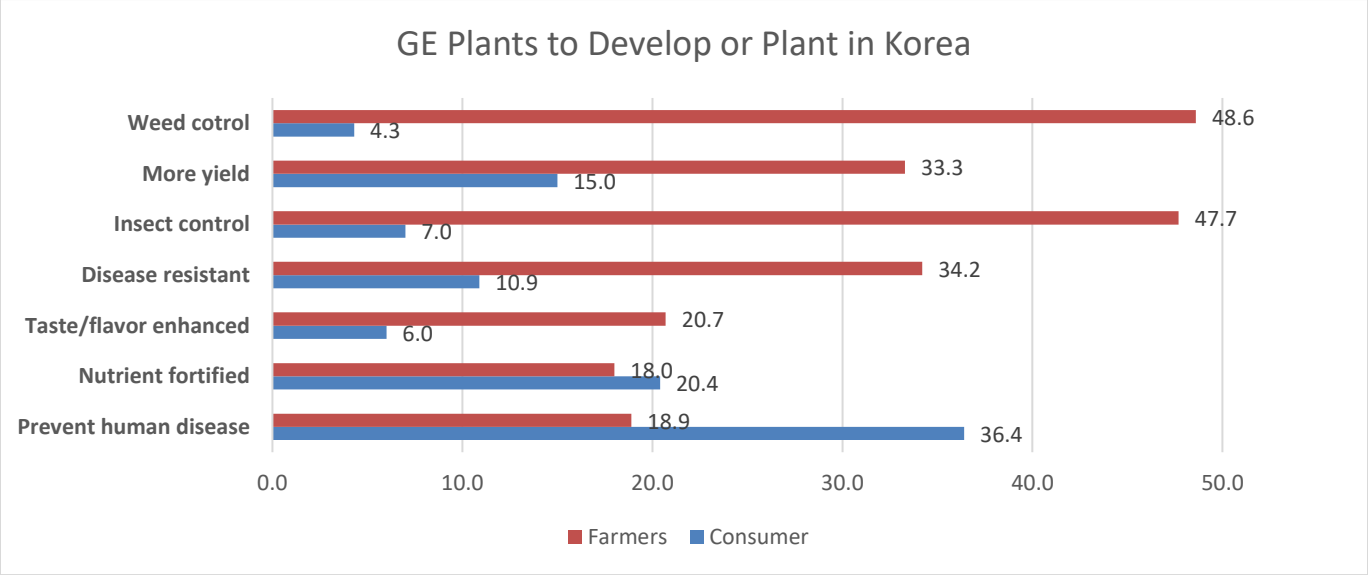
receptive to GE-derived food and agricultural products that have health benefits and are price competitive.

Figure 1: How to Improve Perception of Agricultural Biotechnology in Korea



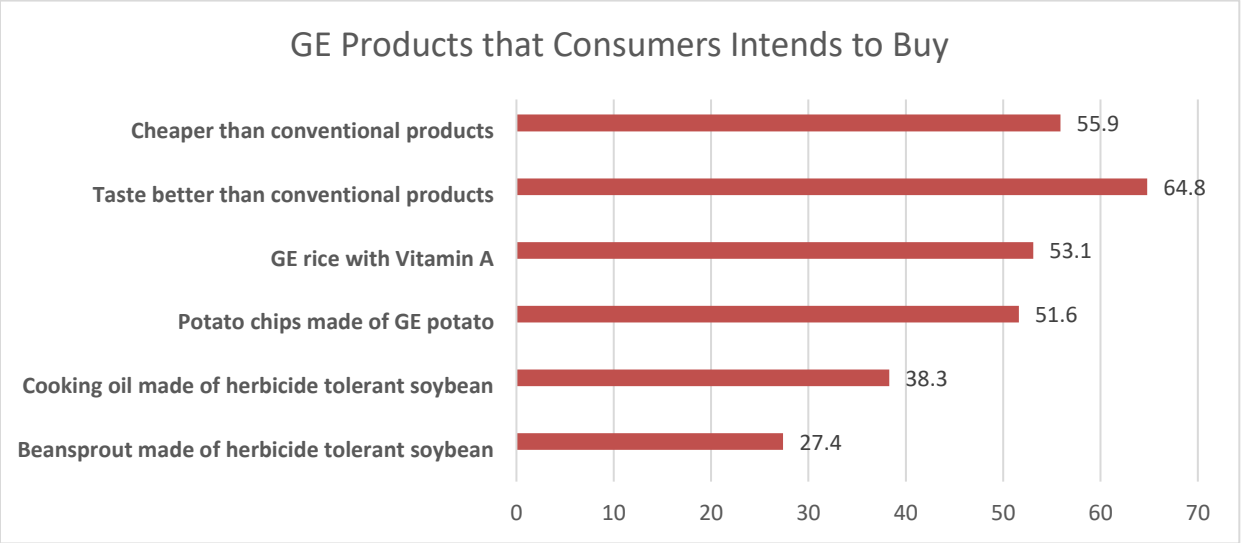
Source: Consumer Union Korea

Figure 2: Farmers and Consumers Preference for Development and Propagation of GE Plants in Korea



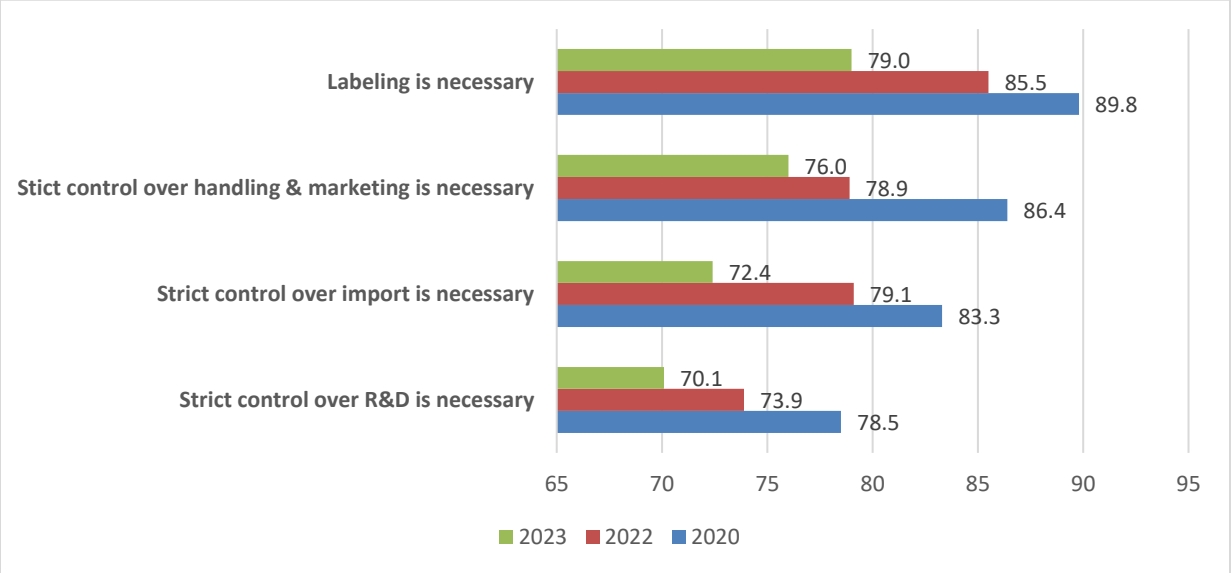
Source: Consumer Union Korea

Figure 3: GE Products that Consumers would Consider Purchasing



Source: Consumer Union Korea

Figure 4: Korea's Perspective on Biotech Regulations of Agricultural Products



Source: Korea Biosafety Clearing House

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. Several public and private entities are leading the research in Korea, 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 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.

In November 2023, RDA announced that they developed pigs expressing CRISPR associated protein 9 in its body. This development will help researchers check a gene function quickly and easily and utilize this technology to carry out Korea's native pig improvement project and research on human disease and pharmaceuticals. 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. 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 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 monthly and conducts GE testing.

Part E. Policy

A) Regulatory Framework

The LMO Act and its implementing regulations also applies to GE animals, but Korea has not established specific regulations for the management of GE animals. The Pharmaceuticals Affairs Act governs pharmaceuticals produced from GE animals.

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

See Part B: Policy A) Regulatory Framework viii. Pending Legislation in the Plant section of this report for the latest on innovative biotechnologies.

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 Korea has established no policy 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 (IPR)

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, 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 most of their proposed changes except for draft bills proposed by lawmakers and gather comments from trading partners. 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 energy or medical purposes but have more mixed views towards its use in the livestock sector and food. In the 2023 KBCH consumer survey, 52 percent of respondents answered that Korea may utilize GE technology in livestock. The survey showed that respondents are less likely to buy GE fish, such as salmon, compared to plant products derived from agricultural biotechnologies.

In the same survey, about 47 percent of respondents supported the application of gene editing technology in a livestock sector while only 14 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. However, 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

None.

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 the Act identifies biotech microbes as LMOs.

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

MFDS requires biotech microbes, developed domestically or imported, 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 does not require an environmental risk consultation. As of October 202, MFDS has granted food safety approval for 11 GE microbes and 41 microbial biotech-derived food ingredients. 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). Korea does not require biotech labeling for food products made from microbial biotech food ingredients.

D) Monitoring and Testing

No specific information is available.

E) Additional Regulatory Requirements

Korea requires a safety assessment for food ingredients 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 (IPR)

Domestic regulations protect IPR.

G) Related Issues

None.

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 items that humans consume directly, 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 sweetener 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 of microbial biotechnology are not readily available in Korea.

APPENDIX: APPROVED EVENT LIST

TABLE OF APPROVED PLANT BIOTECHNOLOGY PRODUCTS AS OF OCTOBER 2024

Note: Korea requires biotech products 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 (discontinued in 2022)
Soybean	MON87701	Monsanto	IR	Food & Feed	2011
Soybean	MON87769	Monsanto	SDA	Feed & Food	2012 & 2023
Soybean	MON87705	Monsanto	High oleic	Feed & Food	2012 & 2023
Soybean	MON87708	Monsanto	HT	Feed & Food	2012 & 2023*
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 & 2023*
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 (discontinued in 2023)
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	Monsanto	IR, HT	Food & Feed	2017

	MON87701 X MON87708 X MON89788				
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
Soybean	GMB151	BASF	HT, IR	Food & Feed	2023
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	2022* & 2004
Corn	Bt 11	Syngenta	HT, IR	Food & Feed	2023* & 2006
Corn	T25	Aventis / Bayer	HT	Food & Feed	2023* & 2004
Corn	MON863	Monsanto	IR	Food & Feed	2003 & 2004 (discontinued in 2013)
Corn	Bt176	Syngenta	HT, IR	Food & Feed	2003 & 2006 (discontinued in 2007)
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	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 (discontinued in 2019)
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 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	Monsanto	DR, HT, IR	Feed & Food	2012 & 2013

	MON88017				
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 & 2023*
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	2023* & 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	2024* & 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	2024* & 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
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 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-59122-7	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	Monsanto	HT, IR	Food and Feed	2019

	MON89034 X MON810 X MIR162 X MON87411 X MON87419				
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
Corn	DP-20221606	Corteva	Yield increase, HT	Food & Feed	2023 & 2022
Corn	3272 X Bt11 X MIR162 X MIR604 X TC1507 X 5307 X GA21	Syngenta	HT, IR, α-amylase activation	Food & Feed	2022
Corn	3272 X Bt11 X MIR162 X GA21	Syngenta	HT, IR, α-amylase activation	Food & Feed	2023
Corn	MON87429	Monsanto	HT	Food & Feed	2023
Corn	MON95379	Monsanto	IR	Food & Feed	2024
Corn	DP-915635-4	Corteva	HT, IR	Food & Feed	2024
Corn	DP-023211-2	Corteva	HT, IR	Food & Feed	2024
Corn	Bt11 X MIR162 X MZIR098 X DP-004114-3 X NK603	Syngenta	HT, IR	Food	2024
Cotton	Mon531	Monsanto	IR	Food & Feed	2023* & 2004
Cotton	757	Monsanto	IR	Food & Feed	2003 & 2004
Cotton	Mon1445	Monsanto	HT	Food & Feed	2023* & 2004
Cotton	15985	Monsanto	IR	Food & Feed	2023* & 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	2020 & 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	2022 & 2013
Cotton	GHB119	Bayer	HT	Feed & Food	2012 & 2023*
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	2023* & 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 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
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 & Feed	2021 & 2023
Cotton	281/3006 X COT102 X DAS-81910-7	Corteva	IR, HT	Food	2022
Cotton	GHB811 X T304-40	BASF	IR, HT	Food & Feed	2022

	X GHB119 X COT102 X MON88701				
Cotton	T304-40 X GHB119 X COT102	BASF	IR, HT	Food	2022
Cotton	GHB811 X LLCotton25 X MON88701	BASF	HT	Food & Feed	2022 & 2023
Cotton	MON88702 X MON15985 X COT102 X MON88701 X MON88913	Monsanto	IR, HT	Food & Feed	2022 & 2023
Cotton	T304-40	BASF	HT, IR	Food & Feed	2024 & 2023
Canola	RT73 (GT73)	Monsanto	HT	Food & Feed	2023* & 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 & 2023*
Canola	RF3	Bayer	HT	Feed & Food	2012 & 2023*
Canola	MON88302	Monsanto	HT	Feed & Food	2014 & 2024*
Canola	MON88302 X RF3	Monsanto	HT, Fertile restore	Food & Feed	2014 & 2015
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
Canola	MON94100	Monsanto	HT	Food & Feed	2024 & 2023
Canola	LBFLFK	BASF	HT, Fatty acid composition change	Food & Feed	2024

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: 198
Total Feed Approval: 187
* 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 2024

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
10	DS00002	Daesang	To produce D-ribose 5-phosphate isomerase (RPI) Host: Corynebacterium glutamicum Doner: RPI and Neomycin phosphotransferase II	Jan 2024
11	APC547	AP Technology	To produce fucosylactose Host: Corynebacterium glutamicum Doner: gmd, wcaG, lacY and npt II	Mar 2024

Total Biotech Microbe Approvals: 11

TABLE OF APPROVED MICROBIAL BIOTECH-DERIVED FOOD INGREDIENTS AS OF OCTOBER 2024

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
32	Matsurase FE	Matsutani	Activate D-allulose 3-epimerase	2023
33	Quara Boost	Novozymes	Activate phosphoinosited phospholipase C	2023
34	Quara Boost	Novozymes	Activate phospholipase C	2023
35	Optimax L-2500	Danisco	Activate pulluranase	2023
36	Powerfresh 3000	Danisco	Activate exo-maltotetrahydrolase	2024
37	YieldMax PF	Novozymes	To activate phospholipase	2024
38	Acrylaway HighT L	Novozymes	To activate asparaginase	2024
39	Novozym 270855	Novozymes	To activate glucoamylase	2024
40	LAMINEX MaxFlow 4G	Danisco	To activate xylanase	2024
41	CHY-MAX Supreme	Hwawoo	To activate chymosin	2024

Total Microbial Biotech-Derived Food Ingredient Approvals: 41

Attachments:

No Attachments