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### **Report Highlights:**

This report provides updated information about the adoption of agricultural biotechnology in Vietnam. Since approving all outstanding applications for food and feed use in August 2021, Vietnam has not resumed its regulatory process for acknowledging and reviewing new applications. Biotech corn area has increased to 180,000 hectares, but no new cultivation approvals for commercialization have been issued since 2016. As of October 2022, Vietnam made no changes to its regulatory system for agricultural biotechnology. The country remains a major importer of biotech crops and products, including soybeans, corn, distiller's dried grains with solubles (DDGS), soybean meal, and cotton.

## ***EXECUTIVE SUMMARY***

### **MARD Has Not Acknowledged New GE Applications for Food and Feed Use**

As of October 2022, the Ministry of Agriculture and Rural Development (MARD) has not acknowledged the submission of new applications for food and feed use since the last approvals were granted in August 2021. MARD has indicated that it will reopen the registration, but the timeline is unclear. To date, MARD approved 52 biotech events for food and feed use. MARD has also not acknowledged or reviewed new applications for cultivation. The food and feed approval is required for GE products prior to importation and trade in Vietnam (GAIN Report [VM2022-0039](#)).

### **Record Biotech Corn Area**

Vietnam has seen a significant increase in planting of biotech corn hybrids, as they are a proven tool to combat fall army worm (FAW). In 2021, industry estimated the biotech corn area reached a record of 180,000 hectares (ha), 5.5 times higher than the biotech corn area in 2016. Biotech corn is gaining popularity as farmers understand the benefits of the technology in mitigating damage caused by harmful pests and reducing insecticide costs. Post expects the production of biotech corn in Vietnam will continue to increase while still facing potential regulatory challenges as Vietnam has not approved new biotech varieties and does not have transparent guidance for product development.

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## CHAPTER 1: PLANT BIOTECHNOLOGY

### *PART A: PRODUCTION AND TRADE*

#### a) PRODUCT DEVELOPMENT

Despite the approval of 16 biotech crops in 2014-2015, the approval of new crops for cultivation has been on hold since late 2016. Since then, MARD suspended both the confined-field testing and large-scale testing for biosafety risk assessment of biotech events. MARD has yet to re-establish the GE Risk Assessment Committee, although the Government of Vietnam (GVN) renewed its biosafety regulations in October 2020, which allows the re-establishment of the Committee. This has delayed the review of biosafety assessment reports for biotech events conducted since 2017, as well as prevented the submission of new applications for field testing. Industry also reported that the national standards of field-testing for value of cultivation and use, issued in 2021, do not provide sufficient guidance on testing for resistant traits in biotech corn, which will impact the appraisal of testing results and the registration of new varieties.

According to MARD, FAW has decreased across the country in terms of both infested areas and severity, however FAW continues to spread in all key production areas. That encourages farmers in Vietnam to switch to corn hybrids resistant to FAW to minimize damage and reduce insecticide costs. However, MARD continues to delay the review of field-testing results for *Bt* corn varieties, including one variety containing traits specifically resistant to FAW. This prevents farmers from accessing the advanced technologies.

As of October 2022, industry reported several corn varieties pending MARD's review for cultivation approval. Among those, four varieties contain biotech traits resistant to FAW.

#### b) COMMERCIAL PRODUCTION

Vietnam currently only approves the commercialization of biotech corn. To date, MARD has approved a total of 16 biotech corn varieties, most of them stacked events, for commercialization in Vietnam. However, only nine varieties have been commercialized in the local market. The latest variety was approved in 2016.

Since the fall-winter season of 2019, Vietnam has seen a significant increase in planting of insect-resistant biotech corn as FAW threats remain. The biotech corn area marked record growth in 2020, exceeding one hundred thousand hectares for the first time since Vietnam adopted the commercialization of biotech corn. In 2021, industry revised its estimates for biotech corn area up to 180,000 ha, 5.5 times the area of biotech corn in 2016. That shows a significant growth in biotech corn production, even though the overall total corn production area has declined during recent years, down to 820,000 ha in 2021 (GAIN Report [VM2022-0026](#)).

Industry reports that farmers are switching to high yield and insect resistant corn varieties to benefit from the increase in corn prices in the domestic market. This is due to higher demand in the feed and livestock industry as impacts from global supply chain disruptions and high feed prices make domestic corn more competitive with imported corn.

Different levels of adoption of biotech corn are seen in different geographical areas in Vietnam. Biotech corn area is highest in the Mekong delta, where local authorities recognize GE corn as a solution to help the transition from rice farming to the cultivation of higher value crops. The adoption of GE corn created a higher value per unit of cultivated area, in terms of income, productivity, and economic benefits for farmers, as well as providing a solution to climate change in this area. Biotech corn is also grown in the north, central, and southeast regions due to increases in biomass production and demand for fodder for dairy and ruminant livestock.

However, since Vietnam banned the use of glyphosate in July 2021, industry reported lower biotech corn area in Son La, one of the largest corn producing provinces in North Vietnam, as the ban prevented farmers from accessing the benefits of technology.

A study on the economic and environmental benefits of GE corn in Vietnam was published in September 2020.<sup>1</sup> The report showed that GE corn varieties out-performed conventional varieties in terms of yield by 15 percent and reduced the cost of production by between \$26.47- \$31.30 USD per ha. The average amount of herbicide used in the GE planting area was 26 percent lower than the average value for the conventional corn area. Overall farm income of farms that planted GE corn increased between \$196 USD per ha (relative to equivalent conventional varieties) and \$330 USD per ha (average of all conventional varieties). 60 percent of farmers also reported an improvement in grain quality that is likely related to the reduced levels of mycotoxins in GE corn compared with conventional corn hybrids.

### c) EXPORTS

There is no official data on Vietnam's exports of GE products. Vietnam does export corn and soy oil. Vietnam's soybean crushers rely on imported soybeans.

In marketing year (MY) 2021/22, Post estimated Vietnam corn exports down to 400,000 metric tons, due to Vietnam's lower imports and lower demand in Association of Southeast Asian Nations (ASEAN) countries and limited cross border trade with China. These exports are mainly re-exports of imported corn, given that the domestic production is mainly consumed locally. More details on corn trade in Vietnam is available in GAIN Grain and Feed Annual Report [VM2022-0026](#).

Soy oil exports accounted for 36 percent of the total vegetable oil export value of Vietnam in MY 2020/21([VM2022-0067](#)). In MY2021/22, South Korea and Cambodia were the top export markets for

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<sup>1</sup> Graham Brookes & Tran Xuan Dinh (2021) The impact of using genetically modified (GM) corn/maize in Vietnam: Results of the first farm-level survey, GM Crops & Food, 12:1, 71-83, DOI: 10.1080/21645698.2020.1816800

Vietnam’s soy oil. According to the Food Safety Law, Vietnam issues certificates of free sale, health certificates, or other certification for exports upon the request of importing countries.

#### d) IMPORTS

Vietnam imports a number of GE plant products, including soybeans, soybean meal, soybean oil, corn, distiller’s dried grains with solubles (DDGS), cotton, and alfalfa. Excluding imported cotton used in the textile industry, and soybean oil, the majority of Vietnam’s GE product imports are utilized as feed for the country’s growing livestock and aquaculture sectors. Vietnam is increasingly dependent upon imported GE feed ingredients as domestic supplies are unable to satisfy growth in these sectors. GE products must be approved for food and feed use by MARD before importation.

The following table shows imports of GE products and byproducts to Vietnam. The United States is the dominant supplier of DDGS, soybeans, and cotton, while Argentina and Brazil are the two largest suppliers of corn and soybean meal.

Commodity	Quantity (million tons)	
	MY 2020/21	MY 2021/22
Corn	13.3	9.9
DDGS*	1.1	1.2
Soybeans	1.9	2.0
Soybean meal	5.1	5.0
Cotton	1.6	1.7

Source: GAIN Report [VM2022-0067](#), [VM2022-0026](#), [VM2022-0021](#)

\* Data reported for calendar year

#### e) FOOD AID

Vietnam is no longer a food aid recipient. Reportedly, Vietnam has made limited shipments of rice for food aid. In October 2022, Vietnam announced a donation of 5,000 tons of rice for Cuba during the visit of the Cuban Prime Minister to Vietnam.

#### f) TRADE BARRIERS

As of October 2022, no official trade barriers affecting GE agricultural products have been reported. However, since Vietnam remains a major importer of biotech crops and related products it is one of the main markets where developers are seeking approval in advance of commercialization in producing countries. The prolonged review and approval period for food and feed use continues to raise concerns about unpredictable procedures, which could disrupt trade and increase the likelihood of unapproved varieties entering the market. Additionally, the suspension of cultivation approval for new biotech hybrid corn varieties and the continued delays in development of field-testing regulations have prevented biotech companies from introducing new biotech hybrids to farmers.

## ***PART B: POLICY***

### **a) REGULATORY FRAMEWORK**

#### **Law on Biodiversity**

The Law on Biodiversity, ratified by the National Assembly in 2008, is the first law legalizing provisions of “genetically modified organism” (“GMO”) and risk management of “GMO” in Vietnam. Previously, Vietnam managed “GMOs” under the 2005 Regulation on Biosafety, but this regulation did not detail the approval process for GE organisms and GE-derived products. The Law on Biodiversity, taking effect on July 1, 2009, provides a legal basis for the GVN to outline the approval process and responsibilities of line ministries.

<b>Legal term (in official language)</b>	<b>Legal Term (in English)</b>	<b>Laws and Regulations where term is used</b>	<b>Legal Definition (in English)</b>
Sinh vật biến đổi gen	Genetically modified organism (GMO)	Law on Biodiversity (Article 3.27)	Genetically modified organism means an organism whose genetic structure has been modified by the gene transfer technology.

#### **Biosafety Decrees**

##### ***Decree 69/2010 on Biosafety of GE Organisms, Genetic Specimen, and Products Derived from GE Organisms***

On June 21, 2010, the GVN issued Decree 69/2010/ND-CP on Biosafety, replacing the 2005 Biosafety Regulation. Decree 69 provides a framework on the management of GE organisms, genetic specimens, and the approval of GE crops for food and feed use as well as for cultivation. Decree 69 was revised in 2011, because the Food Safety Law (FSL) re-assigned the food safety management of GE crops from the Ministry of Health (MOH) to MARD. Since Decree 108 (revising Decree 69) took effect on January 15, 2012, MARD became the sole ministry responsible for reviewing and issuing Certificates for Food and Feed Approval for GE crops in Vietnam.

##### ***Decree 118/2020 revising Decree 69 on Biosafety***

On October 2, 2020, GVN issued Decree 118/2020 revising Decree 69/2010 on Biosafety. The revision focuses on amending and supplementing provisions on field testing of biotech crops for biosafety assessments. This Decree has provided a regulatory basis to resume the field testing of biotech corn for biosafety assessment which was suspended since 2017 due to the repeal of MARD’s Circular 69/2009.

In addition, this Decree details provisions on renewal of Certificates for Food and Feed Approval and Certificates of Biosafety in case of change of applicants' information.

### ***Decree 123/2018 Amending and Supplementing Conditions for Trade and Business in Agriculture***

On September 17, 2018, GVN issued Decree 123/2018 amending and supplementing a number of conditions for trade and business in agriculture. This Decree amended Articles 37, 38, 39, and 40 of Decree 69/2010 on biosafety to consolidate the conditions for import, production, and trade of GE food and feed. Decree 123 maintains the requirements that GE products used for food and feed must obtain a certificate of food/feed approval prior to importation, production, and trade in Vietnam.

### **Food and Feed Import Approval**

The review and approval process to issue and revoke Certificates of Food and Feed Approval for GE crops is regulated under MARD's Circular 2/2014/TT-BNNPTNT. The Circular entered into force on March 10, 2014. According to this Circular, a GE event is approved for food and feed use if it meets one of the following conditions: either it has been approved for use as food and/or feed in five developed countries (defined as a country with advanced biotechnology policies in the OECD and/or in the G20) or the GE Food and Feed Safety Committee concludes that the GE product does not contain uncontrolled risks to humans and/or the environment. All submissions of GE products must be posted on MARD's website for a 30-day public comment period. After that, the submissions must be circulated for the GE Food and Feed Safety Committee's review before being submitted to MARD's leadership for approval.

### ***GE Food and Feed Safety Committee***

This Committee was established under MARD Circular 2/2014 to advise MARD's leadership on the issuance and withdrawal of Food and Feed Use Certificates. The Committee has twelve members, including representatives of MARD, MONRE, MOH, the Ministry of Science and Technology (MOST), the Ministry of Industry and Trade (MOIT) and some experts in the relevant fields. The term for the current Committee started on December 9, 2020. The Committee retains the Chairman and Vice Chairman from the previous term and added four new members from technical agencies under MARD. The Committee has a term of three years.

### **Biosafety Approval for Environmental Release**

#### ***Field Trials for Risk Assessment***

According to Decree 69/2010 on Biosafety, GE crops must be tested in-field, in both confined-field and large-scale trials, to evaluate their effects on the environment and biodiversity in specific conditions in Vietnam, in advance of rearing, planting, and purposeful release into the environment. The procedure for biosafety field-testing, revised under Decree 118/2020, stipulates that MARD is responsible for granting and revoking a permit for field-testing. The results of field-testing must be reviewed and approved by the Committee of GE Crop Risk Assessment established by MARD.



### ***GE Crop Risk Assessment Committee***

The GE Crop Risk Assessment Committee, first established in 2014, reviewed and approved the biosafety field-testing for five GE events in corn for the purpose of cultivation in Vietnam. The Committee ended its term in September 2020. Even though the GVN issued Decree 118 in 2020, Revising and Supplementing Provisions for GE Crop Risk Assessments, MARD has yet to re-establish the Committee. As of October 2022, MARD communicated that the Committee is in the process of being reformed to review an application submitted in 2017. However, MARD noted that due to Decree 118, the Committee will be ad-hoc, with members nominated once MARD acknowledges a submission, and the Committee will be dissolved after completing its appraisal.

### ***MONRE Biosafety Certification***

A Certificate of Biosafety is required for the release of GE crops into the environment in Vietnam. The procedure for granting and revoking Certificate of Biosafety is regulated under MONRE's Circular 8/2013/TT-BTNMT. This Circular entered into force on July 1, 2013. Accordingly, MONRE shall establish its National Biosafety Committee to review developers' applications after the developers complete their field trial for risk assessment and MARD approves these results. Prior to 2016, MONRE issued five Biosafety Certificates based on MARD's approval of risk assessment results.

### **Cultivation Approval**

Currently, all GE hybrids adopted for cultivation in Vietnam were recognized as exceptional cases under MARD's Circular 29/2014. The Crop Production Law (CPL), that went into effect on January 1, 2020, provides provisions related to field trials, breeding, trading, and quality management of GE varieties. However, the CPL does not clarify the procedures for cultivation approval for GE varieties. The CPL continues to refer to the Biodiversity Law regarding risk assessments and biosafety certifications for GE crops.

### ***Exceptional Approvals for GE Hybrids***

According to MARD's Circular 29/2014 on Exceptional Recognition of Biotechnology Advantages, a GE hybrid must be tested in field trials to demonstrate its equivalence with its host variety, except for those affected by the transgenic events. The demonstration trial of GE hybrids can be conducted at the same time as the risk assessment.

Accordingly, a GE hybrid can be exceptionally recognized for cultivation in Vietnam, providing that its host variety is already recognized for cultivation, and meets the following conditions:

- i) the GE hybrid containing gene-transferred events that have been granted a Biosafety Certificate, as well as a Certificate for Food/Feed Use.
- ii) the GE hybrid has been compared with the host variety and undergone a risk assessment; and

iii) the GE hybrid is equivalent to the host variety in the main characteristic morphological traits, except for those affected by the transgenic events.

In cases where the GE hybrid has undergone a risk assessment, the owner of the GE hybrid can apply for a demonstration trial with the host variety. The demonstration trial must be conducted on both a small and large scale. The small-scale field trial will be conducted during one crop season in two different places. The large-scale field trial will be conducted during one crop season at one location of at least one hectare. The small-scale field trial can be conducted before or at the same time as the large-scale field trial.

### ***Cultivation Approval Under the Crop Production Law***

According to the CPL, a plant variety is subject to field testing prior to applying for cultivation approval. The testing procedures include: 1) Testing for distinctness, uniformity, and stability (DUS) of plant varieties; 2) Testing for the cultivating value and the use value (VCU) of the variety, which includes: a) Controlled testing, b) Small-scale field testing; and c) Large-scale field testing. The CPL requires GE varieties to undergo an environmental risk assessment in advance of the testing for cultivation recognition.

Since the CPL provides general provisions on the field testing and cultivation approval for plant varieties, there are disparities in interpretation of the Law regarding GE crops. Industry expects that MARD will approve GE varieties for cultivation under the same procedures with conventional varieties, MARD still refers to the Law on Biodiversity and the Law on Science and Technology for GE variety approvals. Decree 94/2020 dated December 13, 2019, guiding the CPL, stipulates that GE varieties are permitted for import for field testing (for the purpose of cultivation registration) after obtaining both a Certificate of GE Food/Feed Approval and a Certificate of Biosafety.

### ***National Standards for DUS and VCU testing***

In October 2021, MOST issued the National Standards for DUS testing (TCVN 13382) and VCU testing (TCVN 13381) for corn and rice, which were drafted by the National Testing Center for Plant Varieties, MARD. The standards are the key requirements for demonstration trials of new varieties for cultivation approval under the CPL. However, during the development of the standard TCVN 13881 Part 2 for corn, industry was concerned about lack of necessary guidance for examination of resistant traits in biotech varieties, which will challenge the design of field trials as well as the appraisal of testing results for new variety recognition. Industry is seeking more guidance from the MARD.

## **Additional Regulations Governing Aspects of Agricultural Biotechnology**

### **Master Plan for Development of Agricultural Biotechnology to 2030**

On March 24, 2021, the GVN issued a Master Plan to outline the development of agricultural biotechnology in Vietnam to 2030. This Master Plan was developed in follow-up to the GVN's Decision

on Restructuring in Agriculture, and in accordance with the Law on High Technology and the Law on Science and Technology. This Master Plan aims to: i) facilitate research and application and of biotechnology in a group of key agricultural products to increase quality and productivity, adapt to climate change, and resist pests and disease; ii) increase investment in local agricultural biotechnology industries; and iii) upgrade capacities in plant breeding technologies, gene technologies, and animal and plant cell technologies.

Regarding plant breeding, this Plan sets objectives in applying gene technologies, plant cell technologies and new technologies to create new varieties with high-quality, high-yield, climate-resilient and disease-resistant traits for key crops. The Plan sets an objective to approach and master techniques in genome editing, and to develop a genomic selection system in plant breeding. The Plan also highlights areas for international cooperation to support the adoption of new technologies in Vietnam, including the development of biosafety assessment policies and regulations in harmonization with international regulations; technical exchanges and training in genome editing and new breeding technologies; outreach to stakeholders and policy makers about the benefits of new technologies.

### **MONRE Regulations on Providing and Exchanging Information and Databases on GE Organisms**

On August 22, 2012, MONRE issued Circular 09/2012/TT-BTNMT on the Regulation of the Provision and Exchange of Information and Databases on GE Organisms. The Circular entered into force on October 8, 2012. According to this Circular, MONRE is responsible for developing a database on GE organisms, including:

- Bilateral or multilateral agreements on the biosafety of GE organisms that Vietnam participates in or has already signed.
- Current regulations on GE organisms.
- Results of research projects and programs on the safety of GE products.
- Biosafety Certificates, Food/Feed Approval Certificates and Permits for Field Testing, Validation of Field-Testing results, Decisions to accredit or revoke laboratories qualified for conducting research on GE products, Decisions on which facilities are allowed to conduct GE crop field testing, Permit or Decision on Imports of GE products that are not on the list of GE products allowed for use as food/feed.
- Reports on field-trials for risk assessment as regulated in Decree 69; and
- Information on field testing of GE organisms, planting areas of GE crops, and the list of local/foreign consultants on biosafety, and modern biotechnology and other biotech related information or documents.

### **MOST Regulation on Guidance to Certify Laboratories Qualified for GE Research**

On October 20, 2012, MOST issued Circular 20/2012/TT-BKHCHN regarding the Regulation of Procedures to Certify a Lab for Permission to Conduct GMO Research. The full Circular (in

Vietnamese) can be found at: <https://thuvienphapluat.vn/van-ban/linh-vuc-khac/thong-tu-20-2012-tt-bkhcn-huong-dan-dieu-kien-trinh-tu-va-thu-tuc-cong-nhan-162294.aspx>

## **MOST Regulation on Biosafety Management of GE Research and Development**

The principles of biosafety management for research on GE crops are provided in MOST's Circular 21/2012 regulating the Research and Development of Genetically Engineered Organisms in Vietnam.

Accordingly, research on GE crops must be implemented within the regulatory framework of science and technology, including the Law on Science and Technology, the Law on Biodiversity, and the FSL. All research on GE products must be carried out in MOST certified laboratories in accordance with Circular 20/2012/TT-BKHCN.

### **b) APPROVALS**

MARD approved 16 corn varieties for cultivation in Vietnam. The approved biotech corn varieties carry a trait tolerant to *lepidopteran* or *glyphosate* separately or both *lepidopteran* and *glyphosate* together. Since the last approval in 2016, MARD has not approved any new biotech corn varieties for cultivation in Vietnam.

MONRE issued five Biosafety Certificates for the release of GE crops. All of them were issued before November 2016. As MARD suspended its review of field testing for environmental risk assessment of biotech crops, developers are unable to submit new applications for Biosafety Certificate to MONRE. The list of GE traits granted a Biosafety Certificate is available (in Vietnamese) at MONRE's website: <http://antoansinhhoc.vn/gmo/danh-muc-da-cap-phep-vi/>

As of October 2021, MARD has approved a total of 52 biotech events for soybeans, corn, alfalfa, sugar beets, and cotton for food and feed use. The lists of approved GE events and the list of received GE dossiers can be found at (in Vietnamese): <http://agrobiotech.gov.vn/Default.aspx>

Below is the current list of food and feed approvals:

No.	Crop	Event	Date of Approval	Traits
1.	Corn	MZIR098	Aug 24, 2021	Insect protected
2.	Corn	MON 87419	Aug 23, 2021	Dicamba and glufosinate tolerant
3.	Soybean	DAS-81419-2	June 23, 2021	Glufosinate tolerance and Lepidopteran insect protected
4.	Corn	DP ØØ 4114-3	June 23, 2021	Glufosinate tolerance & Lepidoptera & Coleoptera tolerance

5.	Cotton	T304-40	Sep 14, 2020 (only for feed)	Lepidopteran insect protected and Ammonium glufosinate tolerant
6.	Cotton	GHB 119	Dec 16, 2020 (only for feed)	Insect protected and ammonium glufosinate tolerant
7.	Cotton	MON 88701	Dec 16, 2020 (only for feed)	Dicamba and glufosinate tolerant
8.	Alfalfa	KK 179	Dec 16, 2020 (only for feed)	Reduced Lignin
9.	Cotton	LL Cotton 25	Sep 14, 2020 (only for feed)	Ammonium glufosinate tolerant
10.	Corn	MON 87411	Sep 14, 2020	Corn rootworm protected and glyphosate tolerant
11.	Cotton	GHB 614	Jul 15, 2020 (only for feed)	Ammonium glufosinate tolerant
12.	Cotton	COT 102	Jul 15, 2020 (only for feed)	Lepidoptera insect protected
13.	Soybean	MON 87751	Jul 15, 2020	Lepidopteran insect protected
14.	Soybean	FG 72	Feb 19, 2020	Glyphosate tolerance & Isoxaflutole herbicide tolerance
15.	Canola	RF3	Feb 19, 2020	Ammonium glufosinate tolerant
16.	Sugar beet	H7-1	Feb 19, 2020	Glyphosate tolerant
17.	Canola	MON 88302	Feb 19, 2020	Glyphosate tolerant
18.	Canola	RT 73	Feb 19, 2020	Glyphosate tolerant
19.	Cotton	MON 15985	Jan 21, 2020 (only for feed)	Insect protected
20.	Cotton	MON 88913	Jan 21, 2020 (only for feed)	Glyphosate tolerant
21.	Canola	MS8	Jan 21, 2020	Ammonium glufosinate tolerant
22.	Corn	DAS-40278-9	Sep 20, 2019	2,4-Dichlorophenoxyacetic herbicide tolerance
23.	Soybean	DAS-68416-4	Sep 20, 2019	2,4-Dichlorophenoxyacetic herbicide tolerance, Glufosinate herbicide tolerance
24.	Soybean	DAS-44406-6	Sep 20, 2019	2,4-Dichlorophenoxyacetic herbicide tolerance, Glyphosate herbicide tolerance, Glufosinate herbicide tolerance
25.	Alfalfa	J101	Sep 20, 2019 (only for feed)	Glyphosate herbicide tolerance
26.	Alfalfa	J163	Sep 20, 2019	Glyphosate herbicide tolerance

			(only for feed)	
27.	Corn	3272	Feb 25, 2019	Expression of alpha-amylase AMY797E
28.	Soybean	OH2	Feb 25, 2019	Glufosinate- ammonium tolerant and HPPD inhibitor
29.	Soybean	CV 127	Feb 25, 2019	Herbicide tolerance
30.	Soybean	DP-305423-1	Oct 25, 2018	Herbicide tolerance, fatty oil acid
31.	Corn	DAS 59122-7	Oct 25, 2018	Herbicide tolerance, Insect tolerance
32.	Corn	MIR604	Aug 12, 2016	Resistance to corn rootworm
33.	Corn	5307	Jun 2, 2016	Resistance to corn rootworm
34.	Corn	TC1507	Jan 19, 2016	Resistance to diseases and pests – Insects – Lepidoptera (butterflies and moths)
35.	Corn	T25	Sep 9, 2015	Herbicide tolerant, glufosinate ammonium
36.	Soybean	A5547-127	Sep 9, 2015	Herbicide tolerant, glufosinate ammonium
37.	Soybean	A2704-12	Sep 9, 2015	Herbicide tolerant, glufosinate ammonium
38.	Corn	MON87427	Sep 9, 2015	Herbicide tolerant – Glyphosate (commercial Roundup), modified for tissue selective glyphosate tolerance
39.	Corn	MON87460	Sep 9, 2015	Drought-tolerant
40.	Soybean	MON87769	Sep 9, 2015	Modified fatty acid composition to Omega 3
41.	Corn	MON88017	Sep 9, 2015	Herbicide tolerant- Glyphosate and Resistance to Insects – provides protection against corn rootworm
42.	Corn	MON810	Sep 9, 2015	Resistance to European corn borer
43.	Soybean	40-3-2	Apr20, 2015	Glyphosate herbicide tolerance
44.	Soybean	MON87705	April 20, 2015	Increased oleic acid and Glyphosate herbicide tolerance (commercial Roundup)
45.	Soybean	MON87701	April 20, 2015	Resistance to Insects – Lepidoptera
46.	Soybean	MON87708	April 20, 2015	Dicamba Tolerant Soybean, Resistance to herbicides
47.	Soybean	MON89788	Dec 24, 2014	Glyphosate herbicide tolerance
48.	Corn	GA21	Dec 10, 2014	Resistance to herbicides – Glyphosate
49.	Corn	MON89034	Aug 11, 2014	Resistance to diseases and pests – Insects – Lepidoptera (butterflies and moths)
50.	Corn	NK603	Aug 11, 2014	Glyphosate herbicide tolerance
51.	Corn	Bt11	Aug 11, 2014	Resistance to diseases and pests – Insects – Lepidoptera (butterflies and

				moths) Resistance to herbicides – Glufosinate
52.	Corn	MIR162	Aug 11, 2014	Resistance to diseases and pests – Insects – Lepidoptera (butterflies and moths)

c) STACKED or PYRAMIDED EVENT APPROVALS

According to MONRE’s Circular 8/2013, a GE crop bearing a molecular stacked event is subject to the approval for Biosafety Certificate. The approval procedure for GE crops bearing stacked events is regulated under the same procedure for single events. Similarly, MARD Circular 2/2014, regulates the certification of food and feed approval for both single and stacked events.

d) FIELD TESTING

According to Circular 72/2009, dated November 17, 2009, MARD allows field trials for the purpose of biosafety evaluation and commercialization for only three GE crops – corn (*Zea mays L.*), cotton (*Gossypium spp.*), and soybeans [*Glycine max (L.) Merrill*]. MARD has only issued permits for conducting field trials of GE corn.

However, since late 2016, MARD suspended receipt of applications for field testing of biotech crop varieties. Later, MARD repealed Circular 69/2009 regulating field testing for biotech crops, causing a gap in regulations on field testing for biotech crops in Vietnam. Although the GVN renewed regulations on field testing in GVN’s Decree 118/2020, the field testing of biotech corn has yet to resume.

e) INNOVATIVE BIOTECHNOLOGIES

The Vietnam Agricultural Genetics Institute, the Institute of Biotechnology at the Vietnam Academy Science and Technology, and other research institutes in Vietnam have conducted several genome editing research studies applying CRISPR/Cas9 in rice, soybeans, cassava, and other crops. Vietnam is also one of the countries supporting the International Statement on Agricultural Applications of Precision Biotechnology submitted to the World Trade Organization Committee on the Application of Sanitary and Phytosanitary Measures in November 2018. This is a non-binding document that reiterates high-level approaches regarding the fair, science-based treatment of precision biotechnology.

f) COEXISTENCE

On August 29, 2018, the GVN issued Decree 109 on Organic Agriculture that aims to promote organic production in Vietnam. This Decree bans the use of GE technology and inputs in organic production systems. In addition, this Decree allows the GVN to provide up to 100 percent funding to identify areas eligible for organic production and certify products conforming to Vietnamese standards on organic

agriculture. This decree is available (in Vietnamese) at: <https://luatvietnam.vn/nong-nghiep/nghi-dinh-109-2018-nd-cp-ve-nong-nghiep-huu-co-166604-d1.html>.

As of November 2020, MARD reported that Vietnam's organic farming area had significant growth from 2016-2020 ([GAIN Report VM2021-0069](#)). Organic cultivation area reached 63,000 ha in 2021. A set of national standards for organic production was issued in 2017, but industry reports a lack of an effective and widely recognized organic certification mechanism.

#### g) LABELING

On February 2, 2018, the GVN issued Decree 15/2018/ND-CP to regulate the implementation of a number of articles of the FSL ([GAIN Report VM8016](#)). This Decree maintains requirements for the labelling of foods containing at least one GE ingredient that exceeds five percent of the product's total ingredients. This calculation was in the Inter-Ministerial Circular 45/2015 dated November 23, 2015, which provides guidance on the labeling of pre-packed GE foods ([GAIN report VM 5088](#)).

A statement of "*Thực phẩm biến đổi gen*" or "*biến đổi gen*" ("Genetically modified food" or "genetically modified") is required on labels of GE pre-packaged foods according to Decree 43/2017 on Goods Labeling. Other mandatory contents to be printed on the label includes, quantity, date of manufacture, expiration date, ingredients, or ingredient quantities.

Both Decree 15/2018 and Joint Circular 45/2015 state that labeling is not required in the following cases:

- Pre-packaged food containing GE ingredients without detection of the modified genes or products of the modified genes in the food.
- Fresh GE foods and unpackaged processed GE foods sold directly to consumers; and
- GE foods used in emergencies, such as natural disasters or epidemics.

#### h) MONITORING AND TESTING

Currently, Vietnam does not have a monitoring or testing regime in place to evaluate the biotech content in imported food products or food products domestically produced for consumption in Vietnam.

In 2019, Vietnam issued Standard TCVN 12613 on the Methods of Analysis for the Detection of Genetically Modified Organisms and Derived Products. This standard, developed by the National Institute of Food Control (NIFC/MOH), is based on International Organization for Standardization (ISO) Standard 21570:2005. The standard provides a framework of quantitative methods, using the polymerase chain reaction (PCR) and real time PCR, for the detection of "GM" corn, rice, soybeans, and tomatoes in food. Per the Law on Standards and Technical Regulations, this standard is not mandatory, but laboratories, approved by MOST, can apply this standard for quantitative detection or monitoring of "GM" content in food and feed. NIFC has been approved by MOST for quantitative testing of "GM" content in food and feed.



#### i) LOW LEVEL PRESENCE (LLP) POLICY

As of October 2022, Vietnam does not have an LLP policy. MARD is a frequent observer to the Global Low-Level Presence Initiative meetings.

#### j) ADDITIONAL REGULATORY REQUIREMENTS

None at this time.

#### k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Under the Intellectual Property Law (IPL) 50/2005/QH11, Vietnam has a regulatory structure in place to protect the rights of plant variety developers. The IPL provides the foundation for intellectual property rights protection in Vietnam and covers plant varieties, including those derived from agricultural biotechnology. The IPL was ratified by the National Assembly (NA) in 2005 and entered into force on July 1, 2006.

Part Four of the Law outlines the rights and protections for plant varieties and details the process for obtaining Plant Variety Protection.

According to the IPL, the Certificate of Plant Variety Protection is valid for 25 years for trees and grapes; and 20 years for other crops. The Certificate applies for the whole of Vietnam.

The full IP Law 50/2005/QH11 in English can be found at:

<http://pvpo.mard.gov.vn/DetailInfomation.aspx?InfomationID=IN00000037>

Government Decree 88/2010/ND-CP, published on August 16, 2010, provides additional clarification on aspects of the IPL as it relates to plant variety protection. The full Decree 88 in English is available at:

<http://pvpo.mard.gov.vn/DetailInfomation.aspx?InfomationID=IN000000305>

On February 28, 2013, MARD issued Circular 16/2013, which stipulates the Guidelines on the Protection of Plant Variety Rights. The Circular guides the implementation of a number of established content rights for plant varieties, representing rights to plant varieties, assessment of plant variety rights, and forms of protection of plant varieties. MARD issued Circular 03/2021 dated June 21, 2021, to revise and supplement some provisions of Circular 16/2013 regarding the registration procedures for plant protection.

In June 2022, the National Assembly adopted a revision of IPL 07/2022/QH15 that amends and supplements provisions on trademark registration and plant variety protection. According to the GVN, a new Decree amending Decree 88/2010 will be issued by the end of 2022.

#### l) CARTAGENA PROTOCOL RATIFICATION

Vietnam became a member of the Cartagena Protocol in April 2004 and regularly participates in meetings. As stipulated by the Cartagena Protocol, the Vietnam Environmental Administration (VEA) is the Cartagena Protocol Focal Point of Vietnam. MONRE has developed a website (<http://antoansinhhoc.vn/en/>) to serve as the Biosafety Clearing-House for biotech information, regulations, and Certificates issued by MONRE and MARD per Article 20 of the Cartagena Protocol.

### **Steering Committee for the Implementation of the Nagoya Protocol on Access and Benefit Sharing**

On March 17, 2014, the Vietnamese Prime Minister signed Resolution 17/NQ-CP regarding Vietnam joining the Nagoya Protocol, which covers access to genetic resources, equitable sharing, and reasonable interests arising from the use of genetic resources within the Biodiversity Convention.

On September 2017, MONRE established a Steering Committee for the implementation of the Nagoya Protocol on Access and Benefit Sharing (ABS). The Committee is chaired by a MONRE Vice-Minister with representatives from the VEA and relevant agencies of MONRE, MARD, MOST, and Lao Cai Province. MONRE implemented the ABS project to support the implementation of Nagoya Protocol from 2017-2020. In September 2020, MONRE issued Circular 10/2020 on Reporting Access to Genetic Resources and Sharing Benefits from the Use of Genetic Resources.

### **GVN Decree 59/2017/ND-CP on the Management of Access to Genetic Resources and Benefit Sharing from Their Utilization**

On May 12, 2017, the GVN issued Decree 59/2017/ND-CP, regarding the Management of Access to Genetic Resources and Benefit Sharing from Their Utilization. As regulated in Article 5 of the Decree, MONRE is the National Focal Point (NFP) for the Nagoya Protocol. The NFP is responsible for implementing the unified management and monitoring of activities relating to the granting, renewal, and withdrawal of licenses for access to genetic resources. The NFP is responsible for liaising, providing information, and coordinating the information exchange with the Secretariat of the Convention on Biological Diversity via the Access and Benefit-Sharing Clearing-House in accordance with the Nagoya Protocol.

Regarding the granting, renewal, and withdrawal of licenses to access genetic resources, Article 6 of the Decree states:

- MARD shall grant, renew, and withdraw licenses to access genetic resources of agricultural crop varieties, livestock, aquatic species, and forest seedlings; and
- MONRE shall grant, renew, and withdraw licenses to access genetic resources other than those specified in Clause 1 of this Article.

#### m) INTERNATIONAL TREATIES and FORUMS

Vietnam became a member of Codex Alimentarius in 1989 and the International Plant Protection Convention in 2005. The Vietnam Codex Office is under the management of the Ministry of Health's Vietnam Food Administration: <http://codex.gov.vn/vi/news/van-phong-ub-codex-viet-nam/>

#### n) RELATED ISSUES

No information available.

### *PART C: MARKETING*

#### a) PUBLIC/PRIVATE OPINIONS

According to industry, farmers in Vietnam have started planting GE corn since the invasion of FAW, as it shows more effective resistance than conventional varieties. One of the major developers reported that during recent years, GE seeds accounted for up to 90 percent of their total sales of corn seeds. Farmers are also interested in better profit margins due to improved crop yields and lower input costs of pesticides and labor. Most farmers who have grown GE corn expressed high levels of satisfaction with the technology, with less than 10 percent of users indicating that the additional cost of the seed was too high. However, farmers also cited the higher price of GE seeds in relation to conventional seeds as one of the reasons for not trying the new technology ([Brookes and Tran, 2020](#)).

There is no available data on consumer attitude or public acceptance of GE food in Vietnam. However, MARD has cited concerns on biodiversity impacts, resulting in their delay for review and commercialization approval of new biotech varieties.

#### b) MARKET ACCEPTANCE/STUDIES

The market continues to grow for imported biotech corn, soybeans, and DDGS to meet the increasing demands of the livestock and aquaculture feed industry. Vietnam remains a major importer with most supplier being countries producing GE corn and soybean and related products. As the GVN stated that Vietnam is not competitive in producing corn and soybeans, Vietnam has enhanced bilateral activities to ensure the trade flow of these products, with the high level of acceptance of GE products. The GVN reduced the Most-Favored-Nation (MFN) tariff on corn from 5 to 2 percent on December 30, 2021 (GAIN Report [VM2021-0097](#)).

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### *PART D: PRODUCTION AND TRADE*

#### a) PRODUCT DEVELOPMENT

##### **Cloned Animals**

In March 2021, the National Institute of Animal Science (NIAS)/MARD reported successfully cloning a local specialty pig breed from somatic cells of ear tissue. The institute launched the project in 2017, to study the cloning of pigs by somatic cell nuclear transfer technology. According to NIAS, the success has opened up research opportunities to apply cloning technology in conservation of endangered animals and breeding valuable livestock.

Previously, NIAS reported success in improving the freezing process of embryos in vivo and in vitro and transferring embryos to dairy cows and pig sows for reproduction. The Institute also successfully cloned pig embryos using somatic cell nuclear transfer and succeeded in transferring cloned embryos into surrogate sows.

In a webinar on Animal Biotech held by Post in August 2022, the Institute of Biotechnology (IBT) noted its research on the application of animal reproductive biotechnology (ART) for conservation of endangered species.

## **GE Animals**

As of September 2022, [Kraig Biocraft Laboratories](#) announced that the company was granted a business license to begin its operations for silk production in Lam Dong Province. The company reported that it started rearing the second generation of recombinant silkworms at their breeding and production center in Quang Nam province. The company also stated in 2021, that it delivered the first fabric samples to “Spydasilk,” a Singapore-based company for developing the first line of recombinant spider silk apparel.

### **b) COMMERCIAL PRODUCTION**

No commercial licenses of cloned animals or GE animals have been issued in Vietnam.

### **c) EXPORT**

No information available.

### **d) IMPORT**

No information available.

### **e) TRADE BARRIERS**

No information available.

## ***PART E: POLICY***

### **a) REGULATORY FRAMEWORK**

#### **Law on Biodiversity 2008 and Decree 69/2010**

The Law on Biodiversity adopted in 2008, and Decree 69/2010 regulate both GE plants and GE animals.

However, the implementation of the Law on Biodiversity focuses on GE plants. MONRE and MARD have not provided any guidance on GE animals in Vietnam.

### **Law on Animal Husbandry and Decree Guiding the Law on Animal Husbandry**

Vietnam’s National Assembly passed the Law on Animal Husbandry (AHL) in November 2018. This Law, like the Law on Biodiversity, provides a definition of genetically modified livestock animals as “Genetically modified domesticated animal means domesticated animal whose genetic structure has been modified by the use of gene transfer technology.” The AHL bans the “illegal import, production, release, and use of genetically modified animals and products of genetically modified animals.” The AHL allows the cloning of animals for study purposes and assigns the GVN to detail provisions on a risk assessment for genetically modified animals.

The GVN issued Decree 13 on January 21, 2020, to detail the implementation of the AHL. Decree 13 provides provisions on the conservation of genetic resources of livestock breeds but has no further details on genetically modified livestock animals.

<b>Legal term (in official language)</b>	<b>Legal Term (in English)</b>	<b>Laws and Regulations where term is used</b>	<b>Legal Definition (in English)</b>
Vật nuôi biến đổi gen	Genetically modified domesticated animal	Law on Animal Husbandry (Article 17.1)	Genetically modified domesticated animal means livestock whose genetic structure has been modified by the gene transfer technology.
Nhân bản vô tính vật nuôi	Cloning of domesticated animals	Law on Animal Husbandry (Article 17.3)	Cloning of domesticated animals means the use of cloning techniques to create domesticated animal clones from somatic cells.

#### **b) APPROVALS/AUTHORIZATIONS**

No information available.

#### **c) INNOVATIVE BIOTECHNOLOGY**

No information available.

#### **d) LABELING AND TRACEABILITY**

No information available.

e) **ADDITIONAL REGULATORY REQUIREMENTS**

No information available.

f) **INTERLLECTUAL PROPERTY RIGHTS (IPR)**

No information available.

g) **INTERNATIONAL TREATIES and FORUMS**

No information available.

h) **RELATED ISSUES**

No information available.

***PART F: MARKETING***

a) **PUBLIC/PRIVATE OPINIONS**

No information available.

b) **MARKET ACCEPTANCE/STUDIES**

No information available.

**CHAPTER 3: MICROBIAL BIOTECHNOLOGY**

***PART G: PRODUCTION AND TRADE***

a) **COMMERCIAL PRODUCTION**

There are neither official statistics nor estimates on commercial production of food ingredients derived from microbial biotechnology in Vietnam.

b) **EXPORTS**

According to Trade Data Monitor (TDM), in 2021, Vietnam exported around \$340,000 USD of enzymes and prepared enzymes (HS code 3507), mainly to Asian countries. There is a limited number of products under HS code 3507 exported to the United States. In 2021, Vietnam exported around \$961 million USD worth of cheese, wine and beer, processed foods, fruit juices, sauces and condiments, and infant products that may contain microbial-derived food ingredients.

c) **IMPORTS**

According to TDM, imports of enzymes and enzyme preparations to Vietnam under the HS code 3507, were valued at \$80.8 million USD in 2021, an increase of 12 percent compared to the previous year.

Post estimates most of the imported enzymes, used in the food and feed industry, are derived from microbial technology, given that the main suppliers for Vietnam are the United States, China, and the EU. Industry sources reported about 60 percent of the imports are consumed in the food manufacturing sector, mainly in the brewing and bakery segment, while the feed industry consumes the rest.

According to TDM, Vietnam imported \$1.85 billion USD worth of cheese, wine and beer, processed foods, fruit juices, sauces and condiments, and infant products in 2021, an increase of 18.9 percent compared to the previous year. Most of these products may contain microbial-derived food ingredients, and among those processed products under HS codes 2106, 1904 and 1905, were valued at \$1.3 billion USD.

#### d) TRADE BARRIERS

As of October 2022, no official trade barriers affecting products derived from microbial biotechnology have been reported in Vietnam.

### ***PART H: POLICY***

#### a) REGULATORY FRAMEWORK

Vietnam currently has no regulations on pre-market approval for products derived from microbial biotechnology. Food ingredients, such as enzymes, food substances for seasoning, coloring, and flavoring, regardless of being derived from conventional or “genetically engineered microorganisms” (GEMs), are considered as food additives and regulated under the same provisions for food additives in the FSL and pursuant regulations.

#### **Food Safety Law**

The FSL, entered into force on July 1, 2011, provides an overview framework to ensure the safety of foods and food ingredients in Vietnam. The FSL sets safety conditions for food additives including: i) To conform with technical regulations on food additives and food processing aids; ii) To have use instructions written on their labels in Vietnamese and the language of the country of origin; iii) To be on the List of Food Additives Permitted for Use in Vietnam; iv) To register or declare conformity with technical regulations prior to market sale. According to the FSL, the MOH is the specialized ministry in charge of food safety for food additives.

#### **Food Additives Management**

Food additives are currently regulated under MOH’s Circular 24/2019 (GAIN report [VM2019-0066](#)). Circular 24/2019, which took effect on October 16, 2019, provides the List of Food Additives Permitted for Use in Vietnam and safety conditions for food additives use. Accordingly, food additives on the permissible list are allowed for import to Vietnam, providing that importers self-declare product conformity.

There are several enzymes listed on the List of Permissible Food Additives, including alpha-amylase from *Aspergillus oryzae var.*, alpha-amylase from *Bacillus subtilis*, carbohydrase from *Bacillus licheniformis*, protease from *Aspergillus oryzae var*, bromelain, lysozyme. Other substances such as riboflavin, colorings, flavorings, etc. are also included in the permissible list. MOH shall review the list of permissible food additives every two years and update the list based on the requests of food enterprises.

On August 12, 2021, Vietnam notified a draft Circular amending the Food Additives Circular as G/SPS/N/VNM/123. The draft Amendment proposed an automatic update of the List of Permissible Food Additives according to the latest Codex standards on food additives. Vietnam re-notified a draft Circular amending the Food Additives Circular as G/SPS/N/VNM/141 on July 29, 2022. This amendment is expected to be finalized and issued at the end of 2022.

#### b) APPROVALS

Vietnam has no regulations in place on pre-market approval for products derived from microbial biotechnology.

#### c) LABELING and TRACEABILITY

In addition to mandatory labeling requirements for food, according to the FSL and GVN's Decree 15 guiding the FSL, a phrase "genetically modified food" must be displayed on labels of foods containing "GMOs" or products of "GMOs" exceeding five percent of total ingredients.

#### d) MONITORING AND TESTING

Vietnam has no regulations on testing and monitoring of products derived from microbial biotechnology.

#### e) ADDITIONAL REGULATORY REQUIREMENTS

No information available.

#### f) INTELLECTUAL PROPERTY RIGHTS (IPR)

No information available.

#### g) RELATED ISSUES

No information available.

### **PART I: MARKETING**

#### a) PUBLIC/PRIVATE OPINIONS



There is no report on public opinions about microbial biotechnology products. As Vietnam has a long history of consuming fermented foods, such as alcohol, soy sauce, fish sauce, fermented pork, etc., consumers are familiar with products of microbial technology. Dairy products, beverages, and bakery products are popular among young consumers in Vietnam.

**b) MARKET ACCEPTANCE/STUDIES**

The market continues to grow for enzymes and enzyme preparations to meet the increasing demands of the food and feed industry in Vietnam. The main consumers of enzymes and enzyme preparations in Vietnam are the brewing, beverage, bakery, food processing, and feed segments.

**Attachments:**

No Attachments