**Required Report:** Required - Public Distribution **Date:** November 13, 2023

**Report Number:** VM2023-0059

# **Report Name:** Agricultural Biotechnology Annual

**Country:** Vietnam

**Post:** Hanoi

**Report Category:** Biotechnology and Other New Production Technologies

**Prepared By:** Thu Pham

**Approved By:** Ralph Bean

**Report Highlights:**

This report provides updated information about the adoption of agricultural biotechnology in Vietnam. In the first six months of 2023, Vietnam approved six outstanding biotech corn hybrids for cultivation after the country suspended its appraisal process since 2017. Biotech corn continues to be adopted in a wide range of regions in the country due to its resilience in the face of pests and climate impacts. 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 Approved Outstanding Biotech Corn Hybrids for Cultivation

As of June 2023, the Ministry of Agriculture and Rural Development (MARD) approved six outstanding biotech corn hybrids for cultivation. They were the latest approvals after 7 years since the Ministry suspended its appraisal process in 2017. According to MARD, these hybrids, containing stacked-events resistant to glyphosate and Lepidoptera, were approved under Circular 29/2014 on Exceptional Recognition of Biotechnology Advantages. These hybrids were tested in field trials and went through the MARD Biosafety Committee review in 2016.

### MARD Acknowledged New Applications for Food and Feed Use

MARD resumed the acknowledgement of new applications for food and feed use in 2023. The Ministry opened public consultations for the first batch of four applications in April 2023. This included two applications of herbicide resistant traits for canola and two applications of herbicide and pest resistant traits for cotton. In the second batch of acknowledgement in September, MARD accepted three more applications, including two biotech events for corn and one event for soybeans. As of October 2023, public consultations for the second batch of applications are ongoing. At the same time, MARD invited new technical advisors for the GE Food and Feed Safety Committee to review these applications. To date, MARD has approved 52 biotech events for food and feed use in corn, soybeans, alfalfa, cotton, canola, and sugar beets.

### Biotech Corn Continued to Gain Public Acceptance

Cultivation of biotech corn continues to grow in the main corn-producing regions as it has proven effective in combating pests, including fall armyworm (FAW). In 2022, industry estimated the biotech corn area at around 220,000 hectares (ha) while demand for GE seed is increasing. Biotech corn is gaining popularity as farmers appreciate the benefits of the technology in mitigating damage caused by harmful pests, reducing insecticide costs, and resilience to drought conditions.

**TABLE OF CONTENTS**

# CHAPTER 1: PLANT BIOTECHNOLOGY

## *PART A: PRODUCTION AND TRADE*

### a) RESEARCH AND PRODUCT DEVELOPMENT

Vietnam has developed a key program on the application of biotechnology in agriculture with the aim of creating new plant varieties with high productivity, improved quality, and which improve the competitiveness of farm produce. In 2020, MARD reported several research projects using genetic engineering (GE) in plants: i) Research on drought-tolerant events in corn; ii) Designing transgenic vectors to create insect-resistant soybeans; iii) Research on selecting and creating GE soybean lines resistant to stem borers and fruit borers; iv) Research on creating breeding lines in corn with enhanced starch synthesis. However, according to MARD, these research projects for GE plants were conducted in the laboratory and have not yet reached the stage of commercial production.

Regarding innovative biotechnology, Vietnam reported several research activities using CRISPR/Cas9: i) Using genome editing to improve aroma and blight resistance traits on key rice varieties; ii) Research on improving the sugar and amino acid content of tomato through gene mutation using the CRISPR/Cas9 system; iii) Using CRISPR/Cas9 system to improve resistance to ringspot virus in papaya; iv) Using CRISPR/Cas9 system to create cucumber varieties with virus-resistance.

In terms of field testing for risk assessment of GE crops, Vietnam first allowed field testing of GE corn in 2010. Field testing must be conducted in confined fields on a large-scale, and under MARD's strict control. During 2010-2016, MARD issued field testing permits for GE corn and recognized field-testing results for five biotech events resistant to herbicides and Lepidotera. That allowed biotech developers to apply for Certificates of Biosafety for these recognized events, then conduct field trials for the purpose of cultivation for GE corn hybrids containing the recognized events.

MARD approved 16 biotech corn hybrids, containing recognized events, for cultivation during 2014-2016. After that, the Ministry suspended issuance of field testing permits and delayed the approval process for cultivation during 2017-2022.

MARD recently resumed the approval process for cultivation since GE corn has continued to prove productive and effective, especially in combating FAW. In the first six months of 2023, MARD approved six outstanding GE corn hybrids, including five hybrids containing stacked events resistant to herbicide and Lepidotera, and one hybrid containing a single event resistant to herbicide. In March 2023, MARD recognized the field-testing results, conducted in 2016, of MIR162, a biotech event reported resistant specifically to FAW in corn. This will allow the developer of MIR162 to apply for a Certificate of Biosafety and initiate the commercialization of GE corn hybrids containing this event in Vietnam.

In addition to GE corn, Vietnam allows field testing for risk assessment of GE cotton and soybeans, but there were no applications on field testing of GE cotton and soybean. As of October 2023, there are no new applications on field testing for risk assessment of GE corn in Vietnam.

b) COMMERCIAL PRODUCTION

Vietnam currently only approves the cultivation of GE corn. To date, MARD has approved a total of 22 biotech corn hybrids for commercialization in Vietnam. Most of them contain stacked events resistant to insects and herbicides. However, only nine varieties have been commercialized in the local market. Since MARD recently approved six GE corn hybrids for cultivation, industry expects some of them will be commercialized next year.

There has been a significant increase in planting of insect-resistant biotech corn since 2019, after FAW started to spread in the country. 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 2023, industry estimates show that the biotech corn area maintained around 220,000 ha even though the overall total corn production area continued to decline during recent years (GAIN Report VM2023-0019).

Biotech corn is mainly produced for feed use, either for grains or as silage, due to high demand in the feed and livestock industry. During recent years, corn growers reported benefiting from higher prices in the domestic market due to global supply chain disruptions. According to the industry, the adoption levels of biotech corn varies among different geographical areas in Vietnam. Biotech corn area is largest in the Central Highland and Mekong Delta regions, where FAW exists at high levels, and GE corn significantly helps to increase farmers' income. The Northwest and North Central regions of Vietnam have also seen high levels of GE corn adoption due to its effectiveness in saving costs for herbicides and pesticides.

Most GE corn seed used in the domestic market is produced domestically. Major developers reported they domestically produce up to 100% of GE seeds in the Vietnam market and partly for export to other ASEAN countries.

A study on the economic and environmental benefits of GE corn in Vietnam was published in September 2020.[1] The report showed that GE corn varieties out-performed conventional varieties in 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). Approximately 60 percent of farmers also reported an improvement in grain

[1] 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

quality that is likely related to 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.

Vietnam exported 250,000 metric tons of corn in 2022, down 53 percent compared to the previous year, due to lower imports and less demand in Association of Southeast Asian Nations (ASEAN) countries. These exports are mainly re-exports of imported corn, given that the domestic production is mainly consumed locally. (GAIN Report VM2023-0019).

Vietnam exported about 59,000 metric tons of soy oil in MY 2021/22 with South Korea accounting for 77 percent of total exports (GAIN Report VM2023-0015). According to the Food Safety Law, Vietnam issues certificates of free sale, health certificates, or other certification for exports upon request by 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 2021/22** | **MY 2022/23 (estimated)** |
| Corn | 9.2 | 10.5 |
| DDGS* | 1.31 | 1.2 |
| Soybeans | 1.84 | 2.0 |
| Soybean meal | 5.16 | 5.2 |
| Cotton | 1.44 | 1.37 |

Source: GAIN Report VM2023-0019, VM2023-0013, VM2023-0015
** Data reported for calendar year*

e) FOOD AID

Reportedly, Vietnam provided food aid for some countries for the purpose of humanitarian assistance. In April 2023, Vietnam donated 5,000 tons of rice to Cuba following an announcement made during the 2022 visit of the Cuban Prime Minister to Vietnam.

f) TRADE BARRIERS

As of October 2023, 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.

## *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 organisms" ("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, that took effect on July 1, 2009, provides a legal basis for the GVN to outline the approval process and responsibilities of line ministries.

| **Legal term (in official language)** | **Legal Term (in English)** | **Laws and Regulations where term is used** | **Legal Definition (in English)** |
|---|---|---|---|
| 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. |
| Sản phẩm của sinh vật biến đổi gen | Products of GMOs | Decree 69/2010 guiding the Law on Biodiversity on Biosafety for GMOs, Genetic Specimens and Products of GMOs - Article 3.2 | Products of GMOs are products that wholly or partly contain ingredients originating from GMOs, including genetic specimens of GMOs that can't themselves create new organisms under natural conditions |

## 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, GE products, and the approval of GE plants for food and feed use as well as for cultivation. Decree 69 was revised in 2011 after the Food Safety Law (FSL) re-assigned the food safety management of GE plants 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 plants 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 assessments which was suspended since 2017. In addition, this decree details provisions on the renewal of Certificates for Food and Feed Approval and Certificates of Biosafety in the case of a change to an applicant's 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 Certificates of Food and Feed Approval for GE crops is regulated under MARD's Circular 2/2014/TT-BNNPTNT. This 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. Circular 2/2014 also provides the procedure to revoke Certificates of Food and Feed Approval for GE crops in accordance with Decree 69/2010.

### *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 a term of three years and includes twelve members, from MARD, Ministry of Natural Resources and Environment (MONRE), Ministry of Health (MOH), the Ministry of Science and Technology (MOST), the Ministry of Industry and Trade (MOIT) and some experts in relevant fields. The current committee was established on December 9, 2020. The committee retained its chairman and vice chairman from the previous term and added four new members from technical agencies under MARD. As of October 2023, MARD stated that they are in the process of re-organizing the committee since some members are no longer eligible.

## **Biosafety Approval for Environmental Release**

### *Field Testing 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. 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 plants into the environment in Vietnam. The procedure for granting and revoking the 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 an application for the Biosafety Certificate after

MARD approves field testing results for the biotech event. In 2014-2016, MONRE issued Biosafety Certificates for 5 biotech events in corn 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 (CPL)*

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, the Ministry of Science and Technology (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 the 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. In 2023, industry continues to seek more guidance on DUS testing for GE corn from the MARD.

## Additional Regulations Governing Aspects of Agricultural Biotechnology

**Master Plan for Development of Agricultural Bioindustry to 2030**

On March 24, 2021, the GVN issued a master plan to outline the development of the agricultural bioindustry in Vietnam to 2030. This master plan was developed as a 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 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 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.

Furthermore, the plan covers 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-BKHCN 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 Food Safety Law (FSL). All research on GE products must be carried out in MOST certified laboratories in accordance with Circular 20/2012/TT-BKHCN.

b) APPROVALS/AUTHORIZATIONS

**Approval for Environment Release**

During 2014-2016, MONRE issued biosafety certificates for five biotech events in corn. The list of GE traits granted a biosafety certificate is available (in Vietnamese) at: http://antoansinhhoc.vn/gmo/danh-muc-da-cap-phep-vi/

MONRE is currently reviewing the application of Biosafety Certificate for MIR162 since MARD approved the field-testing result of the event. The public consultation for the event was closed in July 2023.

**Approval for Cultivation**

MARD resumed the cultivation approval for GE corn hybrids in 2023. To date, MARD approved 22 GE corn hybrids for cultivation in Vietnam. Most approved biotech corn varieties carry stacked events tolerant to both *lepidopteran* and *glyphosate*, but a small number of approved varieties carry a single event tolerant to *lepidopteran* or *glyphosate* separately.

**Food and Feed Use Approval**

MARD accepted 4 new applications of biotech events for canola and cotton in April 2023. These applications are currently under MARD's review process for approval. As of August 2021, MARD has approved a total of 52 biotech events for soybeans, corn, alfalfa, sugar beets, and cotton. All of these biotech events for soybean, corn, canola and sugar beet are approved for food and feed use, but those for cotton and alfalfa are approved only for feed use.

According to Circular 2/2014 on Food and Feed Approval, MARD keeps updating the lists of approved GE events and the list of received GE dossiers (in Vietnamese) on the website: 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 (only for feed) | Glyphosate herbicide tolerance |

| | | | | |
|---|---|---|---|---|
| 27. | Corn | 3272 | Feb 25, 2019 | Expression of alpha-amylase AMY797E |
| 28. | Soybean | OH2 | Feb 25, 2019 | Gluphosinate- 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 plant bearing a molecular stacked event is subject to the approval of a biosafety certificate. The approval procedure for GE plants 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 testing for the purpose of biosafety evaluation and commercialization for three GE crops – corn (*Zea mays L*.), cotton (*Gossypium spp*.), and soybeans *[(Glycline max (L*.) Merrill]. To date, MARD has only issued permits for conducting field trials of GE corn.

Field testing of GE crops is currently regulated under Decree 69/2010 guiding the Law on Biodiversity and Decree 118/2020 amending a number of articles of Decree 69/2010. During 2010-2016, MARD issued field testing permits for GE corn under its Circular 69/2009, but the Ministry repealed this circular in 2020. MARD did not issue any new permits for field testing during 2017-2022. e) INNOVATIVE BIOTECHNOLOGIES

Vietnam has expanded its outreach to explore regulatory approaches for gene editing and innovative biotechnologies. MARD continues to participate in the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) with high interest in regulatory approaches for gene editing and gene-edited products. As discussed in the gene editing webinar hosted by the Foreign Agricultural Service (FAS) Hanoi in July 2022, one of the key policy advisors called on regulatory managers that Vietnam should develop a regulation to pave the way for the adoption of new breeding technologies, such as gene editing.

In terms of regulatory consultation, BCA/MONRE, hosted a series of workshops to discuss the approach to research, application, and commercialization of gene-edited crops. At the first workshop held in October 2022, BCA shared their viewpoints about reviewing the Cartagena Protocol and the Law on Biodiversity. Post will continue to participate in the workshops held by MONRE to learn more about their perspective.

Previously, Vietnam supported 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 AND TRACEABILITY

Vietnam does not require labeling for bulk commodities and raw materials but requires labeling for packaged food and feed containing GE ingredients. According to MOST, goods containing GE ingredients must follow labeling requirements provided in Decree 69/2010 on Biosafety for GMOs and Products of GMOs, Decree 43/2017 on Goods Labeling, and Decree 15/2018 guiding the Food Safety Law.

Article 43 of Decree 69/2010, applicable for goods in general, provides that "…*goods containing GMOs or products thereof exceeding 5% of each constituent shall, apart from complying with the law on goods labeling, show information related to the GMOs on the goods labels*".

Decree 15/2018/ND-CP, specifically for foods, requires that "…*foods containing at least one GM ingredient that exceeds 5% of the total ingredients, must represent information related to the GMOs*" (GAIN Report VM8016). In addition, Decree 43/2017 requires a statement of "*Thực phẩm biến đổi gen*" or "*biến đổi gen*" ("Genetically modified food" or "genetically modified") must represent in accompany with the names of GE ingredients on labels of packaged foods containing the GE ingredients.

On the other hand, Decree 15/2018 states that labeling is not required in the following cases:

- 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.
- 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, MOST 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.

In 2023, MARD continues to develop standards of detection methods for GE events in corn and soybeans. According to MARD, since they established the National Laboratory for GMO Testing, they need to standardize detection methods for GMOs in the fields of agriculture. MARD first opened the public consultation for four standards in January 2023 and continued posting two drafts for public comments in August 2023. The standards are still in the drafting process and will be submitted to MOST for their final review and approval per the Law on Standards and Technical Regulations.

i) LOW LEVEL PRESENCE (LLP) POLICY

Vietnam does not have an LLP policy. MARD is a frequent observer at the Global Low-Level Presence Initiative meetings.

j) ADDITIONAL REQULATORY 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=IN00000305

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. As of October 2023, Decree 88/2010 remains unchanged.

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 (NFP) 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 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, corn growers' acceptance for GE corn has increased significantly since FAW established in Vietnam. Major developers reported the ratio of GE seeds accounted for up to 50 percent, or event higher, of their total sales of corn seeds. Corn growers 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).

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 suppliers being countries producing GE corn, 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) RESEARCH AND 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 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**

In January 2023, Kraig Biocraft Laboratories, announced that the company delivered the first two hybrid-cross silkworm strains to its production partner in Vietnam. These strains were developed in the company's hybridization program, which aims to create GE silkworm strains adapted to the local production environment. As of May 2023, the company reported that its cross-breeding program to create commercial lines of spider silkworm is ongoing. Previously, Kraig Biocraft Laboratories announced that the company was granted a business license to begin its operations for silk production in Lam Dong Province.

b) COMMERCIAL PRODUCTION

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

c) EXPORTS

No information available.

d) IMPORTS

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.

| **Legal term (in official language)** | **Legal Term (in English)** | **Laws and Regulations where term is used** | **Legal Definition (in English)** |
|---|---|---|---|
| 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 | Law on Animal Husbandry (Article | Cloning of domesticated |

| | | | |
|---|---|---|---|
| | animals | 17.3) | 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 microbial biotechnology products in Vietnam. Vietnam reported several research to create recombinant enzymes or proteins for food use or industrial production, but most research reached at a laboratory scale and have not progressed to commercial production.

b) EXPORTS

There are neither official statistics nor estimates on export of microbial biotechnology products from Vietnam. However, according to Trade Data Monitor (TDM), in 2022, Vietnam exported more than $400,000 USD of enzymes and prepared enzymes (HS code 3507), mainly to Asian countries. There are no reports of exporting products under HS code 3507 exported to the United States in 2022. Vietnam also exports products that may contain microbial biotech-derived food ingredients, like beverage, dairy products, and processed products.

c) IMPORTS

There are neither official statistics nor estimates on import of microbial biotechnology products in Vietnam. However, according to TDM, imports of enzymes and enzyme preparations to Vietnam under the HS code 3507, were valued at $83.6 million USD in 2022. 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. Likewise, Vietnam imports alcoholic beverages, dairy products, and products that may contain micro biotech-derived food ingredients.

d) TRADE BARRIERS

There are no reports on trade barriers affecting products derived from microbial biotechnology reported in Vietnam.

### *PART H: POLICY*

a) REGULATORY FRAMEWORK

Currently, biotech-derived microbes are regulated under the Law on Biodiversity as the law provides general requirements on “genetically modified organisms”. In addition, the Food Safety Law provides general requirements on food safety for “genetically modified food” that cover microbial biotech-derived food ingredients. However, the FSL does not require pre-market approval for biotech-derived microbes food ingredients such as enzymes, coloring, flavoring, nutrients, sweeteners, thus MOH

currently manages these products based on their purpose of use as food additives.

| Legal term (in official language) | Legal Term (in English) | Laws and Regulations where term is used | Legal Definition (in English) |
|---|---|---|---|
| Sinh vật biến đổi gen | Genetically modified organisms (GMOs) | Law on Biodiversity - Article 3.27 | Genetically modified organism means an organism whose genetic structure has been modified by the gene transfer technology. |
| Sản phẩm của sinh vật biến đổi gen | Products of GMOs | Decree 69/2010 guiding the Law on Biodiversity on Biosafety for GMOs, Genetic Specimens and Products of GMOs - Article 3.2 | Products of GMOs are products that wholly or partly contain ingredients originating from GMOs, including genetic specimens of GMOs that can't themselves create new organisms under natural conditions |
| Thực phẩm biến đổi gen | Genetically modified food (GM food) | Law on Food Safety - Article 2.24, Article 15 | Genetically modified foods are foods that contain one or several ingredients that are modified by gene technology. |

**Biodiversity Law**

Under the Law on Biodiversity, the GOV issued Decree 69/2010 on June 21, 2010, which specifies requirements on biosafety approval for "GMOs" and "Products of GMOs". However, according to MARD and MONRE, these requirements are aimed more at GE crops, thus they are not technically applicable for biotech-derived microbes. These ministries affirmed that they received a few requests regarding the biosafety approval for biotech-derived microbes and products thereof, but they are still exploring Decree 69/2010 for application.

**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. Currently, the FSL provides a definition of "GM foods" at Article 2.24, that covers microbial biotech-derived food ingredients. Accordingly, Article 15 of the FSL requires "GM food" must comply with i) general requirements for conventional food provided at Article 10 of the FSL; ii) regulatory requirements on ensuring the safety for human health and environment stipulated by the GOV. In addition, the FSL also requires GMs food to bear a Certificate of Free Sale or

Health Certificate for the importation to Vietnam.

Under the FSL, the GOV currently provides Decree 15/2018 guiding the FSL, but this decree continues to refer to Decree 69/2010 guiding the Law on Biodiversity regarding "Products of GMOs" which are more applicable to products of GE crops.

Since the FSL and Decree 15/2018 provides no further requirements on pre-market approval for food ingredients like enzymes, coloring, flavoring, nutrients, sweeteners derived from genetically engineering microbes, MOH, the single ministry in charge of food safety for food additives, currently manages these products based on their purpose of use as food additives.

Article 17 of the FSL sets safety requirements 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.

**Food Additives Management**

Food additives are currently regulated under MOH's Circular 24/2019 (GAIN report VM2019-0066). This circular, taking 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.

Vietnam first notified a draft circular amending the Food Additives Circular to the World Trade Organization (WTO) on August 12, 2021, as G/SPS/N/VNM/123. Vietnam re-notified the draft circular amending the Food Additives Circular as G/SPS/N/VNM/140 on July 29, 2022.

As of October 2023, MOH updated that it has issued the Amendment of Circular 24/2019. The new circular, which allows an automatic update of the List of Permissible Food Additives according to the latest Codex standards on food additives, will take effect from November 9, 2023.

b) APPROVALS

Vietnam has no regulations in place on pre-market approval for biotech-derived microbes and microbial biotech-derived food ingredients.

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 microbial biotech-derived food ingredients or food products.

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

Vietnam has a long history of consuming fermented foods, such as alcohol, soy sauce, fish sauce, fermented pork, etc., thus consumers are familiar with products of microbial technology. Dairy products, beverages, and bakery products are popular among young consumers in Vietnam. Post is not aware of any public concerns regarding microbial biotech-derived food ingredients.

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