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Report Highlights:

In 2021, Vietnam completed its approvals for the outstanding product applications for food and feed import. Vietnam continues to benefit from biotech corn as a sustainable tool in the fight against fall army worm (FAW) and increased the production area to more than one hundred thousand hectares (ha) in 2020/2021. Growing domestic production also helps meet demand for local feed materials. Vietnam 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 completed the approval of all outstanding GE events

From December 2020 to August 2021, the Ministry of Agriculture and Rural Development (MARD) issued Certificate of Food/Feed Safety Approvals for the last seven remaining biotech events for corn, soybeans, cotton, and alfalfa. These approvals bring the total number of events approved for food and feed import in Vietnam up to 52. MARD also re-established the GE Food and Feed Safety Committee for review and approvals of biotech events in December 2020. Industries expect to submit new dossiers soon as MARD reopens its application process.

Biotech corn continued expanding and contributed to local feed supply

Vietnam has seen a significant increase in planting of insect-resistant biotech corn as FAW threats remain. Industry's estimated biotech corn area, planted with seeds containing *Lepidoptera* pest protection, increased to 112,000 ha in 2021 and accounted for about 12 percent of the total crop. Biotech corn is well adopted in the areas where farmers are facing the pressure of harmful pests and are more receptive to new technologies. Biotech corn also contributes to local supply of fodder feed for ruminant livestock and grains for pigs and poultry. Post expects that the production of biotech corn in Vietnam will continue increasing gradually but still faces potential regulatory challenges, as the country suspended the approval for new biotech varieties and does not have transparent implementation of field-testing regulations.

GVN issued a Master Plan for Development of Agricultural Biotechnology to 2030

In March 2021, the Government of Vietnam (GVN) issued a Master Plan to outline the development of agricultural biotechnology in Vietnam to 2030. 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 with climate changes, and increase resistance to 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. MARD is the focal point and responsible for collaborating with line ministries to implement this Master Plan.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Despite the successful development of 16 biotech crops from 2014-2015, the development of new crops has slowed down since late 2016. Since then, MARD suspended both the confined-field testing and large-scale testing for environmental risk assessment of biotech crop varieties. MARD has yet to reestablish the GE Risk Assessment Committee, dissolved in September 2020, thus, industries are not able to submit applications for field testing of new hybrids in 2021. The development of field-testing regulations, according to the Law on Crop Production, has been delayed since MARD continues to review the requirements for examining specific traits such as pest or disease resistance in testing of distinctness, uniformity, and stability (DUS), and value of cultivation and use (VCU).

As FAW spread out across the country damaging corn in all key production areas, farmers in Vietnam quickly switched to insect-resistant hybrid corn to minimize damage and reduce insecticide costs (VNM2020-0061). However, the recognition for field testing results of *Bt* corn varieties and traits resistant to FAW - even though some of them are the most recently developed hybrid varieties - continues to be suspended. That prevents both developers and local companies in the development of new varieties.

As of October 2021, industry reported there are several varieties pending for MARD's review for cultivation approval. Among those, four varieties contain biotech traits resistant to FAW.

b) COMMERCIAL PRODUCTION

Vietnam currently approves only the commercialization of biotech corn. To date, MARD has approved a total of 16 biotech corn varieties, most of them are stacked events, for commercialization in Vietnam. However, only 8 varieties have been commercialized in the local market. The latest variety was approved in March 2018.

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, nearly doubling the total area since Vietnam adopted the commercialization of biotech corn. In 2021, industry estimated the biotech corn area reached 112,000 ha, an increase of twenty percent compared with the production area in 2020. That shows a tentatively sustainable growth trend in biotech corn production, even though the overall total corn production area has been declining during recent years. Industries also reported different trends in adoption of biotech corn among different geographical areas. The coverage of biotech corn was reported at high levels in the Mekong delta, where farmers are more receptive in adoption of technologies and local authorities recognize GE corn as a solution to help the transition from inefficient rice farming to cultivation of high 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 responsive solution to climate change in this area. Biotech corn also achieved sustainable growth in the North Central and Southeast regions due to its high biomass growth rate, which is effective in providing fodder for dairy and ruminant livestock.

According to a study published in September 2020¹, the adoption of GE corn showed both economic and environmental benefits in Vietnam. Farmers reported 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. Reportedly, the average amount of herbicide used in 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.

Industries also reported a growth of GE seed production in Vietnam for local production and export. One of the major developers stated that they can domestically produce up to 90 percent of GE seed for distribution in Vietnam, and plan to expand its production for export.

c) EXPORTS

There is no official data on Vietnamese corn exports. Post estimates Vietnam corn exports for MY20/21 at 800TM on higher demand from the Association of Southeast Asian Nations (ASEAN) countries and cross border trade with China. These exports are mainly re-export of imported corn, given that the domestic production is not price-competitive and mainly consumed locally. More details on corn production and trade in Vietnam is available in GAIN report VM2021-0025.

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.

Post estimates Vietnam's marketing year (MY) 2020/21 corn imports increased to 13 million metric tons (MMT) as the feed market is gradually recovering after having been hit hard by African Swine Fever (ASF). The main suppliers for Vietnam in MY2020/21 are biotech corn planting countries, with increased market share from the United States. However, in MY2021/22, Post forecasts Vietnam imports down to 11.5 MMT on high stocks and disruptions throughout the livestock and feed industries

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

due to the continuing Covid-19 outbreaks and large-scale social distancing lockdown measures (<u>GAIN</u> report VM2021-0078).

Vietnam's calendar year (CY) 2020 DDGS imports reached approximately 1.1 MMT. The United States continues to be the dominant supplier of DDGS. After MARD lifted its import suspension of U.S. DDGS in September 2017, imports have strongly rebounded due to the high demand from the domestic feed industry. In CY2020, DDGS imported from the United States accounted for 98.2 percent of the Vietnam market (GAIN report VM2021-0025).

As of August 31, Vietnam soybean imports reached 1.39 MMT, an increase of five percent compared to the same period in MY2019/20. The United States is the largest soybean exporter with 49.1 percent of the market share while Brazil held 45.1 percent of market share. However, Post revises estimates of total soybean imports down to 1.9 MMT and 2.05 MMT in MY2020/21 and MY2021/22 respectively as the fourth Covid-19 outbreak has negatively affected livestock and aquaculture sectors (GAIN report VM2021-0082).

As of July 31, Vietnam imported about 3.3 MMT of soybean meal (SBM), an increase of about four percent compared to the same period of MY2019/20. Argentina is the largest supplier accounting for almost 65.2 percent of the SBM imports due to lower prices. The second largest SBM supplier to Vietnam is Brazil accounting for 21.3 percent of the total market share. The United States is the third largest SBM supplier to Vietnam. U.S. SBM exports to Vietnam were up by almost 228 percent compared to the same period in MY2019/20. Post keeps SBM imports estimated in MY2020/21 at 5.1 MMT due to future contracts signed. However, Post revises the SBM import forecast up to 5.2 MMT in MY2021/22 due to the forecasted increase in total feed demand (GAIN report VM2021-0082).

Post estimates Vietnam's cotton imports for MY2020/21 up to 1.48 MMT, due to high demand for apparel from China and South Korea. The United States tops the list of cotton suppliers to Vietnam. However, Post estimates that U.S. cotton exports to Vietnam will decline by 10 percent in MY2020/21, as Vietnamese spinners are encountering difficulties in buying U.S. cotton due to major purchases by China. Brazil is using this opportunity to increase its cotton exports to Vietnam and will see its market share continue to grow in in MY2020/21. Post forecasts Vietnam's cotton imports for MY2021/22 up to 7.1 million bales or about 1.55 MMT (GAIN report VM2021-0029).

e) FOOD AID

Vietnam is no longer a food aid recipient. Reportedly, Vietnam has made limited shipments of rice for food aid. In 2021, Vietnam announced a donation of 12,000 tons of rice and 100 tons of hybrid corn seed to support Cuba to mitigate the impacts of the COVID-19 pandemic.

f) TRADE BARRIERS

As of October 2021, no official trade barriers affecting GE agricultural products have been reported. However, as Vietnam remains a major importer of biotech crops and related products, it has become one

of the main markets that developers are seeking for its approvals in advance of the commercialization in production countries. The prolonged review period and approval for food and feed use continues to raise concerns about unpredictable procedures, which could cause potential trade disruptions and increase the likelihood that there are 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 organisms" ("GMOs") and risk management of "GMOs" 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 took effect on July 1, 2009 and provides a legal basis for the GVN to outline the approval process and responsibilities of line ministries.

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 Law on Food Safety 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 withdraw 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 and import if it meets one of the following conditions: either it has been approved for use as food, feed in five developed countries (defined as a country that has an advanced biotech background in the OECD and 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 of 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 issuance and withdrawal of Food and Feed Use Certificate. MARD re-established the Committee of GE Food and Feed Safety on Dec 9, 2020. 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 new Committee retains its Chairman and Vice Chairman from the previous term but renews four members from technical agencies under MARD. The Committee has a term of three years.

Biosafety Approval for Environmental Release

Field Trial 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 release, including rearing, planting, and purposefully releasing 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.

Committee of GE Crop Risk Assessment

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 last Committee ended its term in September 2020, given that MARD suspended its operation from 2018, resulting in the delay of reviewing multi-location field testing for GE events. Even though the GVN issued Decree 118 in 2020, revising and supplementing provisions for GE crops risk assessment, MARD has yet to re-establish the Committee.

MONRE Biosafety Certification

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 the MONRE's Circular 8/2013/TT-BTNMT. This Circular entered into force on July 1, 2013. Accordingly, MONRE shall establish its Biosafety Committee to review developers' applications after the developers complete their field trial for risk assessment and MARD approves these results. Up 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), coming into effect from January 1, 2020, provides provisions related to field trial, breeding, trading, and quality management of GE varieties. However, this Law does not clarify the procedures on cultivation approval for GE varieties. The CPL continues to refer to the Biodiversity Law regarding risk assessment and biosafety certification of GE crops.

Exceptional Approval 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 with 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 risk-assessed GE hybrid can apply for demonstration trial with the host variety. The demonstration trial must be conducted on a small and large scale. The small-scale field trial shall be conducted during one crop season in two places. The large-scale field trial shall be conducted during one crop season and on 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. Regarding GE varieties, the CP Law provides that GE varieties must be tested for the 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. While industries expect MARD will approve GE varieties for cultivation under the same procedures with conventional varieties, the Ministry still refers to the Law on Biodiversity and the Law on Science and Technology in terms of GE varieties. 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 2021, MARD drafted national standards of DUS and VCU testing for main crops, corn and rice. The standards will be the key requirements for demonstration trials of plan varieties for cultivation approval under the CPL. Given the importance of these standards, industries have worked closely with MARD to request the recognition of examination criteria on specific characteristics such as resistance to pests and diseases. However, as of September 2021, industries reported that the drafts have yet to provide necessary guidance for examination of resistant traits. Post continues to monitor the development of these standards and support industries in engagement with 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 with

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. Remarkably, the Plan sets an objective to approach and master techniques in genome editing to develop a genomic selection system in plant breeding. This Plan also highlights some areas for international cooperation to support the adoption of new technologies in Vietnam, such as development of biosafety assessment policies and regulations in harmonization with international regulations; technical exchange and training in genome editing and new breeding technologies; communications with stakeholders and policy makers about the benefits of new technologies.

Post will continue monitoring the implementation of this Master Plan and support the collaboration with MARD in terms of regulatory development and technical exchange.

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 to develop a database on databases 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, the Ministry of Science and Technology (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 Law on Food Safety. 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 March 2018, 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 submits 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 soybean, corn, alfalfa, sugar beets, and cotton for food and feed use. MARD regularly updates the lists of approved GE events and the list of received GE dossiers 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 & Lepidoptera & Coleoptera torlerance

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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	ОН2	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
	Com	77111102	1105 11, 2011	moths)

c) STACKED or PYRAMIDED EVENT APPROVALS

According to MONRE's Circular 8/2013, a GE crop bearing a stacked event is also subject to the approval for Biosafety Certificate. The approval procedure for stacked events is regulated under the same procedure for single events.

Similarly, MARD Circular 2/2014, regulates the procedures for the certification of food and feed approval for both single and stacked events. In both instances, MARD and MONRE will review each individual trait in a stack variety and approve, if each of the individual traits is approved in Vietnam.

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 soybean [(*Glycline max (L.*) Merrill]. Up to date, MARD just 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 crop, causing a gap of 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 in 2021.

e) INNOVATIVE BIOTECHNOLOGIES

The Vietnam Agricultural Genetics Institute has conducted several genome editing research studies applying CRISPR/Cas9 in rice, soybean, and cassava. 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. 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 during 2016-2020 (GAIN Report VM2021-0069). A national standard for organic production was issued since 2017, but there is still a lack of an effective and widely recognized mechanism in organic certification. However, the promotion of organic production at policy-level has resulted in a decline of outreach activities for biotech crops.

g) LABELING

On February 2, 2018, GVN issued Decree 15/2018/ND-CP to regulate the implementation of a number of articles on the Food Safety Law (see 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 detailed in Inter-Ministerial Circular 45/2015 dated November 23, 2015, which detailed guidance for 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 also required on labels of GE pre-packaged foods according to Decree 43/2017 on Good Labeling. Other mandatory contents to be printed on the label of the product must include quantity, date of manufacture, expiration date, ingredients or ingredient quantities.

Both Decree 15/2018 and Joint Circular 45/2015 provide that labeling is not applied 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 – 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 an overall framework of quantitative methods, using the polymerase chain reaction (PCR) and real time PCR, for the detection of "genetically modified" ("GM") corn, rice, soybeans, and tomatoes in foodstuffs. 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" contents in food and feeds. Up to date, NIFC has been approved by MOST for quantitative testing of "GM" contents in food and feed.

i) LOW LEVEL PRESENCE (LLP) POLICY

As of October 2021, Vietnam does not have an LLP policy. MARD is a frequent observer to 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 agricultural biotechnology. The IPL was ratified by the National Assembly (NA) in 2005 and entered into force on July 1, 2006.

Part Four (of Six) 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 Law in English can be found at:

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

Government Decree 88/2010/ND-CP was published on August 16, 2010 and 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.

1) 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 VEA is the Cartagena Protocol Focal Point of Vietnam. MONRE has already developed a website, http://antoansinhhoc.vn/en/ which serves as the clearinghouse for biotech information, regulations, and Certificates issued by MONRE and MARD.

MONRE establishes a Steering Committee for 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 Vietnam Environmental Administration (VEA) and relevant agencies of MONRE, MARD, MOST, and Lao Cai Province. MONRE has 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.

<u>GVN Decree 59/2017/ND-CP on the Management of Access to Genetic Resources and Benefit Sharing</u> 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 also acts as a focal point 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/

n) RELATED ISSUES

No information available.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

According to industry, farmers in Vietnam have actively adopted GE corn since the invasion of FAW as it shows more effective resistance than conventional varieties. One of the major developers reported that during two recent years, GE seeds accounted 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 only 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 seed in relation to conventional seeds as one of the reasons for not trying the new technology (Brookes and Tran, 2020).

On the other hand, 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, soybean, and DDGS to meet the increasing demands of livestock and aquaculture feed industries. Vietnam remains a major importer with most suppliers are countries producing GE corn and soybean and related products. As the GVN states that this country has no competitiveness 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.

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 a success in cloning a local specialty pig breed from somatic cells of ear tissue. The institute launched the project to study the

cloning of pigs by somatic cell nuclear transfer technology since July 2017. 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 reported the successful creation of cloned pig embryos by using somatic cell nuclear transfer and succeeded in transferring cloned embryos into surrogate sows.

GE animals

As of September 2021, <u>Kraig Biocraft Laboratories</u> announced that it is now rearing the second generation of recombinant silkworms at the new production headquarters for Prodigy Textiles ("Prodigy"), the Company's Vietnamese subsidiary in Quang Nam province. The company also stated 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 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 livestock are livestock whose genetic structure has been modified by the use of gene transfer technology." This Law bans the "illegal import, production, release, and use of genetically modified animals and products of genetically modified animals." This Law allows the cloning of animals for study purposes and assigns the GVN to detail provisions on a risk assessment for genetically modified animals.

Government's Decree guiding the Law on Animal Husbandry

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

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 2020, Vietnam exported a very small amount of enzymes and prepared enzymes (HS code 3507), mainly to Asia countries. There is no export of products under HS code 3507 to the United States. In 2020, this country exported around \$854 million USD worth of dairy products, alcoholic beverages, 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 into Vietnam under the HS code 3507, were valued at \$71.9 million USD in 2020. Post estimates most of the imported enzymes, used in food and feed industries, are derived from microbial technology given that the main suppliers for Vietnam are U.S., Chinese, and European companies. Industry sources reported about 60 percent of the imports are consumed in food industries, mainly brewing, bread, and bakery industries, while feed industries consume the rest.

Likewise, TDM reported that Vietnam imported around \$1.6 billion USD worth of dairy products, alcoholic beverages, processed foods, fruit juices, sauces and condiments and infant products in 2020. Most of these products may contain microbial-derived food ingredients, among those, processed products, under HS codes 2106, 1904 and 1905, reached over \$1 billion USD.

d) TRADE BARRIERS

As of October 2021, 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 deriving from conventional or "genetically engineered microorganisms" ("GEMs"), are considered as food additives, and regulated under the same provisions for food additives

in the Food Safety Law and pursuant regulations.

Food Safety Law

The Food Safety Law (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, 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 announce the self-declaration of 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 Food Additives Circular as G/SPS/N/VNM/123. The draft Amendment will expand regulations on food additives approval as it proposes a real-time update of the List of Permissible Food Additives according to the latest Codex standards on food additives.

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 alcohols, soya sauces, fish sauces, fermented pork, etc., consumers are familiar with products of microbial technology. Dairy products, beverages, and bakery products are well-received by young consumers in Vietnam.

b) MARKET ACCEPTANCE/STUDIES

The market continues to grow for enzymes and enzyme preparations to meet the increasing demands of food and feed industries in Vietnam. The main consumers of enzymes and enzyme preparations in Vietnam are currently brewing and beverages, bread and bakery, food processing, and feed industries.

Attachments:

No Attachments