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Report Highlights:

As of October 2020, Vietnam has issued 45 Certificates of Food/Feed Approval for genetically engineered (GE) products for corn, soybeans, canola, sugar beets, alfalfa, and cotton. Among those, six cotton products and two alfalfa products were approved only for feed use. Biotech corn production area increased to 92 thousand hectares (ha) in 2019/2020, as Fall Army Worm (FAW) threats remain. Vietnam continues to amend Decree 69 on Biosafety to clarify provisions on environmental risk assessment for biotech crops. In addition, Vietnam extended the use of glyphosate until June 30, 2021. Vietnam remains a major importer of GE crops and products, including soybeans, corn, distiller's dried grains with solubles (DDGS), soybean meal, and cotton.

EXECUTIVE SUMMARY

MARD resumed the Approvals of GE Events for Food and Feed Use

From January to October 2020, the Ministry of Agriculture and Rural Development (MARD) issued Certificate of Food/Feed Safety Approvals for 14 outstanding GE products for corn, soybeans, canola, cotton, and sugar beets. Among those, six cotton products were approved only for feed use. These approvals bring the total number of products approved for food and feed use in Vietnam to 45. MARD acknowledged the receipt of four new submissions of GE corn and soybean products in May 2020 and completed the 30-day public comment period. As of October 2020, these submissions have been circulated for the GE Food and Feed Safety Committee's review.

Increased Adoption of Biotech Corn in Fighting Fall Army Worm

Vietnam has seen a significant increase in planting of insect-resistant GE corn as FAW threats remain. Industry's estimated GE corn areas, planted to seeds containing *Lepidoptera* pest protection and glyphosate tolerant technology, increased to 92,000 ha in 2020, accounting for about 10 percent of the total crop. GE corn area tends to increase more quickly in the south of Vietnam where farmers have larger production areas, are more receptive to new technologies, and enjoy substantial economic benefits. The 2019-2020 season marked a record growth of GE corn in the five years since Vietnam adopted the commercialization of GE corn.

Extension of Glyphosate Use

On April 24, 2020, the Ministry of Agriculture and Rural Development (MARD) issued Circular 06/2020 to extend the use of crop protection products containing glyphosate in Vietnam to June 30, 2021. This Circular took effect on June 9, 2020 and deactivated the previous ban under MARD's Decision 1186. The extension remains in MARD's Circular 10/2020 dated September 9, 2020, issuing the List of Permissible Pesticides and the List of Banned Pesticides in Vietnam. The United States continues to request that Vietnam postpone the ban until it conducts a thorough scientific review, consistent with international trade obligations.

Amendment of Environmental Risk Assessment Provisions in Decree 69

On October 2, 2020, the Government of Vietnam (GVN) issued Decree 118/2020 revising Decree 69/2010 on Biosafety. The revision focused on amending and supplementing provisions on field testing of GE crops for biosafety assessments. This Decree provides a regulatory basis to resume the field testing of GE corn for biosafety assessment, which had been suspended since 2017, due to the repeal of MARD's Circular 69/2009.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Despite the successful development of 16 GE crops from 2014-2015, the development of new crops has slowed down since late 2016. Since then, MARD suspended the receipt of new applications for confined-field testing for environmental risk assessment of GE crop varieties. MARD's Biosafety Committee, established in September 2017, has yet to complete its review of the multi-location field testing for an insect resistant hybrid corn, as MARD repealed Circular 69/2009, the regulatory base for field testing of GE crops for the environmental risk assessment.

As FAW spreads out across the country, damaging corn in all key production areas, farmers quickly switched to insect-resistant hybrid corn to minimize damage and reduce insecticide costs (VNM2020-0061). However, MARD continues delaying the recognition of *Bt* corn varieties, even though some of them are the most recently developed hybrid varieties containing traits resistant to FAW. During 2019 and 2020, the plant science industry collaborated with technical agencies at the provincial and central levels to conduct a series of demonstrations to showcase the effectiveness of the insect-resistant GE corn varieties that are approved for cultivation in Vietnam, in managing FAW.

As of October 2020, industry reported there are eight GE corn varieties pending for MARD's review for cultivation approval. Among those, four varieties contain traits resistant to FAW.

b) COMMERCIAL PRODUCTION

The GVN currently only approves the commercialization of GE corn. Up to date, MARD approved a total of 16 GE corn varieties, most of them with stacked traits, for commercialization in Vietnam. All of those were recognized in 2015-2016.

Since the fall-winter season of 2019, Vietnam has seen a significant increase in planting of insect-resistant GE corn as FAW threats remain. Industry's estimated GE corn area, planted to seeds containing Lepidoptera pest protection and glyphosate tolerant technology, is up to 92,000 ha in 2020, accounting for about 10 percent of the total crop. This increase marked a record growth in GE corn area in the five years since Vietnam adopted the commercialization of GE corn, especially given that total corn area has been declining since 2017. Farmers have been switching from corn to higher value crops, such as fruits and vegetables. GE corn area is expected to increase in 2021, as farmers get used to new technologies and enjoy the substantial economic benefits. A study published in September 2020¹, showed both economic and environmental benefits from the use of GE corn in Vietnam.

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,

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.

c) EXPORTS

There is no official data on Vietnamese corn exports. Post estimates annual corn exports at 500,000 metric tons (MT), including cross-border trade and regional exports. These exports could include GE corn, given that this crop is being grown in a number of border provinces. More details on corn production and trade in Vietnam is available in GAIN report VM2020-0028.

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.

According to Post's estimates, Vietnam's marketing year (MY) 2019/20 corn imports remain at 10.2 million metric tons (MMT) as the feed market is relatively flat due to the risk of African Swine Fever recurrence. Vietnam has been importing corn primarily from GE corn-growing countries in South America, with limited quantities from the United States and Eastern Europe. In MY19/20, Post forecasts imports rebounding to 10.5 MMT (GAIN report VM2020-0028).

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 strongly rebounded due to the high demand from the domestic feed industry. In MY19/20, Post estimates imports of about 1.2 MMT and forecasts MY20/21 imports up to 1.3 MMT (GAIN report VM2020-0028).

In MY2019/20, Post estimates soybean imports to reach 1.9 MMT due to the increasing soybean crush volume and steady annual increase in soybean demand for food use. The United States was the largest exporter of soybeans to Vietnam with more than 44 percent of the market share in MY 2018/19 (GAIN report VM2020-0026).

Vietnam imported 5 MMT of soybean meal in MY2018/19, increasing about 3 percent compared to MY2017/18. Post estimates soybean meal imports in MY2019/20 to increase to 5.2 MMT (GAIN report VM2020-0026).

The United States tops the list of cotton suppliers to Vietnam. Post estimates Vietnam's cotton imports for MY2019/20 down to 1.28 MMT, as the ongoing COVID-19 pandemic dragged down demand for apparel and has significantly affected cotton imports to Vietnam. U.S. cotton exports to Vietnam in MY2019/20 are estimated at 707,000 MT, down 15 percent from the previous year. For MY2020/21, Post forecasts that Vietnam's cotton imports will recover with 10 percent growth, importing about 1.42 MMT (GAIN report VM2020-0025).

e) FOOD AID

Vietnam is no longer a food aid recipient. Reportedly, Vietnam has made limited shipments of non-GE rice for food aid. In 2020, Vietnam provided 5,000 tons of rice for food aid to support Cuba during the COVID-19 pandemic.

f) TRADE BARRIERS

As of October 2020, no official trade barriers affecting GE agricultural products have been reported. However, the approval of outstanding GE products for food and feed use is still prolonged even when the technical review has been completed. These delays 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 GE hybrid corn varieties is hindering the ability of biotech companies to introduce new GE 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" 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, the Government of Vietnam (GVN) issued Decree 118/2020 revising Decree 69/2010 on Biosafety. The revision focuses on amending and supplementing provisions on field testing of GE crops for biosafety assessments. This Decree has provided a regulatory basis to resume the field testing of GE 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, the 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.

Core Ministry Regulations Governing Commercialization of Agricultural Biotechnology

Food and Feed Use Approval

MARD's Circular 2/2014/TT-BNNPTNT promulgating the approval process to issue and withdraw Certificates of Food and Feed Approval for GE crops.

On January 24, 2014, MARD issued Circular 2/2014 providing the approval process for issuing and withdrawing the certificate for GE crops for use as food and feed. The Circular entered into force on March 10, 2014.

According to this Circular, a GE product will be approved for food and feed use 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 crop 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 is established under MARD Circular 2/2014 with the tasks to advise MARD's leadership on issuance and revocation of Food and Feed Use Certificate. The Committee has 11

(eleven) members, including the Chairman and Vice-Chairman, and 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 field. The term of the Committee is three years.

MARD's Circular 6/2015/TT-BNNPTN extending the implementation deadline for Circular 2/2014/TT-BNNPNT to March 10, 2016.

On February 14, 2015, MARD issued Circular 6/2015 amending Clause 2, Article 18 of Circular 2/2014 extending the due date for application of GE crops for use as food and feed to March 10, 2016. MARD extended the submissions of GE events until November 2016, then did not receive applications for food/feed approval from 2017-2019.

MONRE Biosafety Certification

MONRE's Circular 8/2013/TT-BTNMT outlining the procedures for granting and revoking Certificates of Biosafety.

On May 16, 2013, MONRE published Circular 8/2013/TT-BTNMT, outlining the procedures for granting and revoking Certificates of Biosafety. A biosafety certificate is required in advance of the release of GE crops into environment in Vietnam. This Circular entered into force on July 1, 2013.

MARD's Exceptional Recognition of GE Crops for Cultivation

On September 5, 2014, MARD issued **Circular 29/2014/TT-BNNTPT** to amend and supplement Article 7 of MARD's Circular 23/2010/TT-BNNPTNT regarding the recognition of biotechnological advances in agriculture and rural development. Accordingly, a GE variety can be exceptionally recognized for cultivation in Vietnam, providing that the host variety is already recognized for cultivation, and meets the following conditions:

- i) the GE variety containing gene-transferred events that have been granted a Biosafety Certificate, as well as a Certificate for Food/Feed Use;
- ii) the GE crop variety has been compared with the host variety and undergone a risk assessment; and
- iii) the GE crop variety is similar to the host variety in key traits, except for those affected by the transgenic events.

In cases where the GE variety has undergone a risk assessment, to demonstrate equivalence with the host variety, the owner of the risk-assessed GE variety can submit a dossier applying for exceptional recognition as regulated in Article 5 of the Circular 23/2010. If a risk assessment field trial has not been done, the owner shall develop and submit a plan to the MARD Crop Protection Department (CPD) for field trials to demonstrate equivalency with the host variety in accordance with Appendix 7 of Circular 23/2010. The field trials shall 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.

MARD's Circular 23/2010/TT-BNNPTNT on the Recognition of Biotechnological Advances in agriculture and rural development.

On April 7, 2010, MARD issued Circular 23/2010/TT-BNNTPN regulating the procedures for the registration of recognition of biotechnological advances in the fields of agriculture, forestry, and fisheries that are under MARD's management.

Article 4 of the Circular regulates the criteria required for a biotechnological advance to be eligible for registration. Article 5 of the Circular regulates the order and registration procedures for the recognition of biotechnological advances developed in Vietnam or a foreign country.

The registration dossier for recognition of a biotechnological advance developed in a foreign country includes: 1) Application for recognition of a biotechnological advance developed in a foreign country (Appendix 1); 2) Report on research results and production trials of the registering organization (Appendix 2); 3) Recognition (or similar) document (issued by the original country); and 4) Results of field testing and crop variety testing, animal species, pesticides, fertilizer and soil enhancing product, animal feed, veterinary product, vaccine, products used in preservation, processing of agro-forestry, fishery products, and environmental treatment of registering organization. In addition to the abovementioned documents for the registration to recognize GE crops, GE animals, or GE micro-organisms, the registering dossier must include a copy of the biosafety certificate issued by a relevant Vietnamese agency.

Cultivation Approval for GE Crops under the Crop Production Law

According to the 2018 Law on Crop Production, which went into effect on January 1, 2020, GE varieties, whose host varieties are not approved for cultivation in Vietnam, like conventional varieties, are subject to field testing prior to applying for cultivation approval. The testing procedures include: 1) Testing for distinctness, uniformity, and stability of plant varieties; 2) Testing for the cultivating value and the use value of the variety includes: a) Controlled testing, b) Small-scale field testing; and c) Large-scale field testing. GE varieties must be tested for the environmental risk assessment in advance of the testing for cultivation recognition.

Per Decree 94/2020 dated December 13, 2019, guiding the Crop Production Law, GE varieties are permitted for import for field testing after obtaining both a Certificate of GE Food/Feed Approval and a Certificate of Biosafety.

Additional Ministry Regulations Governing Aspects of Agricultural Biotechnology

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. The full Circular (in Vietnamese) can be downloaded at: http://antoansinhhoc.vn/thong-tu-so-092012tt-btnmt/

The Circular applies to government agencies, local individuals, organizations, foreign individuals, and organizations carrying out activities related to the supply or exchange of information or databases on GE crops (as defined in the regulation). Information and databases on GE crops include:

- 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 kept by authorized agencies;
- 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 as regulated in Appendix I, II, III, and IX of 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

On November 20, 2012, MOST issued Circular 21/2012/TT-BKHCN regulating the Research and Development of Genetically Engineered Organisms in Vietnam. The Circular applies to individuals and organizations conducting research and development of GE crops and genetic specimen activities within Vietnam.

Article 4, Chapter I of Circular 21 regulates the principles of biosafety management for research on GE crops, stating that that all GE research must be in compliance with Item 19, Article 20 of the Science and Technology Law (http://antoansinhhoc.vn/luat-khoa-hoc-va-cong-nghe-sua-doi-2013-2/),

Article 87 of the Environment Protection Law; Article 7 of Bio-Diversity Law (http://antoansinhhoc.vn/luat-da-dang-sinh-hoc/), and Article 44 and 50 of the Vietnam Food Safety Law.

Research on GE crops must be implemented within the framework of science and technology development (project or research topics) and approved by the relevant competent authorities. All research on GE products must be carried out in MOST-certified laboratories in accordance with Circular 20/2012/TT-BKHCN.

b) APPROVALS

MARD suspended cultivation approval for GE hybrids.

During 2015-2016, MARD approved 16 corn varieties for cultivation in Vietnam. The approved GE corn varieties carry a trait tolerant to *lepidopteran* or *glyphosate* separately or both *lepidopteran* and *glyphosate* together. Since 2017, MARD has not approved any new GE corn varieties for cultivation in Vietnam.

MONRE has not issued any new Biosafety Certificates for release into the environment since late 2016

The total number of Biosafety Certificates issued by MONRE remains at five, all were issued before November 2016. As MARD repealed its regulation on field testing for environmental risk assessment of GE crops, there is a lack of regulations for MONRE to review field testing results and issue Biosafety Certificates. The list of GE traits granted a Biosafety Certificate is available at MONRE's website: http://antoansinhhoc.vn/gmo/danh-muc-da-cap-phep-vi/

MARD resumes approvals for Food and Feed Use

As of October 2020, MARD has approved 45 GE products for soybean, corn, alfalfa, sugar beets, and cotton for food and feed use. MARD regularly updates the lists of approved GE products and the list of received GE dossiers at: http://agrobiotech.gov.vn/Default.aspx

Below is the updated list of food and feed approvals:

Crop	Event	Date of Approval	Traits
Cotton	T304-40	Sep 14, 2020	Lepidopteran insect protected and Ammonium glufosinate tolerant
Cotton	LL Cotton 25	Sep 14, 2020	Ammonium glufosinate tolerant
Corn	MON 87411	Sep 14, 2020	Corn rootworm protected and glyphosate tolerant

Crop	Event	Date of Approval	Traits
Cotton	GHB 614	July 15, 2020 (only for feed)	Ammonium glufosinate tolerant
Cotton	COT 102	July 15, 2020 (only for feed)	Lepidoptera insect protected
Soybean	MON 87751	July 15, 2020	Lepidopteran insect protected
Soybean	FG 72	Feb 19, 2020	Glyphosate tolerance & Isoxaflutole herbicide tolerance
Canola	RF3	Feb 19, 2020	Ammonium glufosinate tolerant
Sugar beet	H7-1	Feb 19, 2020	Glyphosate tolerant
Canola	MON 88302	Feb 19, 2020	Glyphosate tolerant
Canola	RT 73	Feb 19, 2020	Glyphosate tolerant
Cotton	MON 15985	Jan 21, 2020 (only for feed)	Insect protected
Cotton	MON 88913	Jan 21, 2020 (only for feed)	Glyphosate tolerant
Canola	MS8	Jan 21, 2020	Ammonium glufosinate tolerant
Corn	DAS-40278-9	Sep 20, 2019	2.4-Dichlorophenoxyacetic herbicide tolerance
Soybean	DAS-68416-4	Sep 20, 2019	2.4-Dichlorophenoxyacetic herbicide tolerance, Glufosinate herbicide tolerance
Soybean	DAS-44406-6	Sep 20, 2019	2.4-Dichlorophenoxyacetic herbicide tolerance, Glyphosate herbicide tolerance, Glufosinate herbicide tolerance
Alfalfa	J101	Sep 20, 2019 (only for feed)	Glyphosate herbicide tolerance
Alfalfa	J163	Sep 20, 2019 (only for feed)	Glyphosate herbicide tolerance
Corn	3272	Feb 25, 2019	Expression of alpha-amylase AMY797E
Soybean	ОН2	Feb 25, 2019	Gluphosinate- ammonium tolerant and HPPD inhibitor
Soybean	CV 127	Feb 25, 2019	Herbicide tolerance
Soybean	DP-305423-1	Oct 25, 2018	Herbicide tolerance, fatty oil acid
Corn	DAS 59122-7	Oct 25, 2018	Herbicide tolerance, Insect tolerance
Corn	MIR604	Aug 12, 2016	Resistance to corn rootworm
Corn	5307	Jun 2, 2016	Resistance to corn rootworm

Crop	Event	Date of Approval	Traits
Corn	TC1507	Jan 19, 2016	Resistance to diseases and pests – Insects – Lepidoptera (butterflies and moths)
Corn	T25	Sep 9, 2015	Herbicide tolerant, glufosinate ammonium
Soybean	A5547-127	Sep 9, 2015	Herbicide tolerant, glufosinate ammonium
Soybean	A2704-12	Sep 9, 2015	Herbicide tolerant, glufosinate ammonium
Corn	MON87427	Sep 9, 2015	Herbicide tolerant – Glyphosate (commercial Roundup), modified for tissue selective glyphosate tolerance
Corn	MON87460	Sep 9, 2015	Drought-tolerant
Soybean	MON87769	Sep 9, 2015	Modified fatty acid composition to Omega 3
Corn	MON88017	Sep 9, 2015	Herbicide tolerant- Glyphosate and Resistance to Insects – provides protection against corn rootworm
Corn	MON810	Sep 9, 2015	Resistance to European corn borer
Soybean	40-3-2	April 20, 2015	Glyphosate herbicide tolerance
Soybean	MON87705	April 20, 2015	Increased oleic acid and Glyphosate herbicide tolerance (commercial Roundup)
Soybean	MON87701	April 20, 2015	Resistance to Insects – Lepidoptera
Soybean	MON87708	April 20, 2015	Dicamba Tolerant Soybean, Resistance to herbicides
Soybean	MON89788	Dec 24, 2014	Glyphosate herbicide tolerance
Corn	GA21	Dec 10, 2014	Resistance to herbicides – Glyphosate
Corn	MON89034	Aug 11, 2014	Resistance to diseases and pests – Insects – Lepidoptera (butterflies and moths)
Corn	NK603	Aug 11, 2014	Glyphosate herbicide tolerance
Corn	Bt11	Aug 11, 2014	Resistance to diseases and pests – Insects – Lepidoptera (butterflies and moths) Resistance to herbicides – Glufosinate
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/TT-BTNMT dated May 16, 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/TT-BNNPTNT, dated January 24, 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, biotech developers and MARD have only conducted field testing for corn varieties.

However, since late 2016, MARD suspended receipt of applications for field testing of GE crop varieties. Later, MARD repealed Circular 69/2009 regulating field testing for GE crop, causing a gap of regulations on field testing for GE crops in Vietnam. As the GVN recently renewed regulations on field testing in GVN's Decree 118/2020 dated October 2, 2020, the field testing of GE corn is expected to resume in 2021.

e) INNOVATIVE BIOTECHNOLOGIES

The Vietnam Agricultural Genetics Institute has conducted genome editing research 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 (https://www.usda.gov/media/press-releases/2018/11/02/wto-members-support-policy-approaches-enable-innovation-agriculture). 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 at: https://luatvietnam.vn/nong-nghiep/nghi-dinh-109-2018-nd-cp-ve-nong-nghiep-huu-co-166604-d1.html.

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 5 percent of the product's total ingredients. This calculation was stipulated in Inter-Ministerial Circular 45/2015/TTLBBNNPTNT-BKHCN, which detailed guidance for the labeling of pre-packed GE foods. Decree 15 also maintains labeling exemptions for GE food 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.

On April 14, 2017, the GVN issued Decree 43/2017/ND-CP on Good Labeling; the decree took effect on June 1, 2017 (see GAIN Report VM 7031). Regarding the labeling of GE food, the mandatory content of the label is detailed in Appendix 1 of the Decree. Accordingly, the mandatory content to be printed on label of the product must include: quantity, date of manufacture, expiration date, ingredients or ingredient quantities, and inscription of the phrase: "Thực phẩm biến đổi gen" or "biến đổi gen" ("Genetically modified food" or "genetically modified") beside the name of genetically engineered ingredients enclosed with the contents. However, the Decree does not specify a threshold for GE ingredients containing food that is required to be labeled as GE food products. After CropLife Vietnam raised concerns to MOST on this lack of a threshold, the GVN stated that GE food labeling is still subject to regulation stipulated by the Inter-Ministerial Circular 45/2015/TTLT-BNNPTNT-BKHCN, dated November 23, 2015 (see GAIN report VM 5088).

On November 23, 2015, MARD and MOST issued the Inter-Ministerial Circular 45/2015/TTLBBNNPTNT-BKHCN, detailing guidance for the labeling of pre-packed GE foods. Inter-Ministerial Circular 45 is applied to pre-packaged foods containing at least one GE ingredient having a content of 5 percent or higher of the total ingredients forming the product. Unlike Decree 14, this Circular does not contain guidance on labeling exemptions. In cases where Inter-Ministerial Circular 45 is applicable, the Vietnamese phrase "biến đổi gen" ("genetically modified") must be printed next to the GE ingredient on the Vietnamese secondary label affixed on the product. Circular 45 does not apply in the following cases:

- 1) Pre-packed food which contains GE ingredients that cannot be detected in the final product;
- 2) Fresh, raw, or unpackaged GE food; and
- 3) GE food products used in emergency cases, such as natural disasters or disease epidemics.

The Circular entered into force on January 8, 2016 and became fully effective on January 8, 2017. Please see FAS GAIN report VM 5088 for the full version of Circular 45.

h) MONITORING AND TESTING

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

As of October 2020, Vietnam has 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 2020, Vietnam does not have a 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, as well as detailing the process for obtaining Plant Variety protection. Part Four consists of the following chapters:

- Chapter XII: Conditions for Protection of Plant Varieties
- Chapter XIII: Establishing the Rights for Plant Varieties
- Chapter XIV: Contents and Limitations of Rights for Plant Varieties
- Chapter XV: Transfer of the Rights to a Plant Variety
- Chapter XIII (Section 2), which provides details on the application forms and process to obtain plant variety protection in Vietnam.

As stated in Article 174, the application must include: a) a registration form using the prescribed document; b) photo and technical questionnaires using the prescribed form; c) letter of authorization if the application form is to be completed by a representative; d) documents demonstrating the right to

register the variety, if the registrant has been transferred; e) documents justifying the claim for prioritization; and f) fee receipt.

Article 176 of the Law outlines the application review process, stipulating that after 15 days from the date of receiving the document a state competent authority will examine the application. That authority will then determine if the document qualifies for further processing, requires additional information, or should be rejected.

Article 178 outlines the content examination criteria and includes: a) examination for originality and the denomination and b) examination of the Technical Test results of the variety. The Technical Test is conducted to determine the Distinctness, Uniformity, and Stability (DUS) of the registered variety. A competent agency or institute assigned by MARD will perform this examination.

As stated in Article 169, 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/TT-BNNPTNT, 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.

1) CARTAGENA PROTOCOL RATIFICATION

MONRE establishes a steering committee for implementation of the Nagoya Protocol on Access and Benefit sharing.

On September 2017, the Minister of Natural Resources and Environment signed a decision to establish 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> <u>from Their Utilization</u>

On May 12, 2017, the GVN issued Decree No.59/2017/ND-CP, regarding the Management of Access to Genetic Resources and Benefit Sharing from Their Utilization. The Decree took effect on July 1, 2017 and consists of following five chapters:

- Chapter I: General Provisions
- Chapter II: Granting, Renewal and Withdrawal of Licenses to Access to Genetic Resources
- Chapter III: Sharing Benefits Arising from the Utilization of Genetic Resources
- Chapter IV: Information and Reporting
- Chapter V: Implementation Arrangement and Execution Provisions.

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.

The full Decree 59/2017/ND-CP (in Vietnamese) is available at the GVN website: http://vanban.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class_id=1&mode=detail&document_id=189806

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.

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. Although Vietnam is in the beginning stage of implementing the Cartagena Protocol, it actively tries to incorporate requirements and obligations of the Protocol into its biosafety management regulations.

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's corn growing regions are open to adopting GE corn varieties. They are 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 public concern on food safety resulting in their delay in review and commercialization approval of new biotech varieties and events.

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. However, Post forecasts that Vietnam's cotton imports will decrease in MY20/21 due to COVID-19 with a drop in consumer demand in the main export markets for Vietnamese textiles.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Cloned animals

The National Institute of Animal Science (NIAS)/MARD 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 mastered the technology of creating cloned pig embryos by using somatic cell nuclear transfer and succeeded in transferring cloned embryos into surrogate sows.

GE animals

On May 12, 2020, <u>Kraig Biocraft Laboratories</u>, a company working on GE spider silk production, announced that it will transfer production back to Prodigy Textiles, its Vietnamese subsidiary. During the COVID-19 lockdown, the company shifted its spider silk production operations focus to its U.S. research facility. The company plans to transition its production back to Vietnam as the silkworm rearing cycle allows.

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 using 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 engineered livestock animals.

b) INNOVATIVE BIOTECHNOLOGY

No information available.

c) LABELING AND TRACEABILITY

No information available.

d) INTERLLECTUAL PROPERTY RIGHTS

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 is no official report on commercial production of products derived from microbial biotechnology in Vietnam.

b) EXPORTS

There is no official report on exports of products derived from microbial biotechnology in Vietnam. However, Vietnam exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

c) IMPORTS

According to Trade Data Monitor, imports of enzymes and enzyme preparations into Vietnam under the HS code 350790, were valued at \$70 million USD in 2019. Post estimates most of the imports are products used in food and feed industries and derived from microbial biotechnology, given 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, and feed industries consume the rest.

d) TRADE BARRIERS

As of October 2020, 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. Products derived from genetically engineered (GE) microorganisms, such as enzymes, food substances for seasoning, coloring, and flavoring, are 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; and iv) to register or declare conformity with technical regulations prior to market sale. According to the FSL, the Ministry of Health (MOH) is the specialized ministry in charge of food safety for food additives.

Food Additives Management

On August 30, 2019, MOH issued Circular 24 to renew regulations on food additives in Vietnam (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.

Currently, there are several enzymes listed on the List of Permissible Food Additives, including alphaamylase 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.

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 may find the use of microbial biotechnology and associated fermentation technologies accessible. 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. Food and beverage products fortified with vitamins and nutrients are increasingly popular in Vietnam.

Attachments:

No Attachments