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Report Highlights:
In 2016, estimates for Vietnam's growing areas of biotech crop (corn) were at 35,000 ha, accounting for about 3 percent of the total cultivated corn area. Post notes its concern that the Ministry of Agriculture and Rural Development's (MARD) procedures on reviewing and approval of genetically engineered (GE) events for food/feed use; and biotech hybrid corn variety slowed down significantly over the last year with no new approvals granted for submissions registering GE events for food/feed use or new biotech corn variety since early 2017. Post believes this slowdown may be a result of an ongoing reorganization in MARD. Vietnam remains a major importer of key biotech plant products such as corn, DDGS, soybeans for animal feed production and cotton for textile industry.

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SECTION I: EXECUTIVE SUMMARY

According to International Service for the Acquisition of Agri-biotech Applications (ISAAA), Vietnam's 2016 biotech corn growing area was estimated at 35,000 hectares (ha), accounting for about 3 percent of the total cultivated corn area. Official data on biotech corn production for 2016 is not available, however, according to industry, 2017 biotech corn growth is expected at the same level or slightly lower than 2016 levels due to an overall production trend of farmers switching from corn to other crops, such as cassava, due to better prices.

MARD's approval of new biotech corn varieties has been slowing since late 2016 with Vietnam failing to approve any new biotech corn varieties since December 2016. Between December 2016 and December 2017, eight applications to register new biotech hybrid corn varieties were submitted to MARD for approval, however, as of December 2017, the Government of Vietnam (GVN) has yet to approve any of these.

Similarly, MARD has also delayed the review and approval of a large number of applications registering GE events for food/feed use. As of November 2017, MARD has approved only 21 out of 51 dossiers registering GE events for approval for use as food and feed, with 30 cases still outstanding. Pending submissions for approval include events for corn, soybeans, canola, cotton, alfalfa, and sugar beets.

Post believes that the slowdown in review and approval of new varieties and registrations for GE events may be the result of an ongoing reorganization in MARD. Dr. Nguyễn Cường became MARD Minister in July 2016 and has led a major reorganization of his ministry over the last year.

As of early December 2017, Vietnam has approved 18 biotech corn varieties to be grown in Vietnam. The approved biotech corn varieties carry a GE corn trait tolerant to either *Lepidopteran* or *glyphosate* separately or *Lepidopteran* and *glyphosate* together. According to biotech companies, the majority of

approved biotech corn varieties being commercialized in Vietnam are stacked corn events, mainly due to farmer preferences.

Registration procedures for GE events for food/feed use is regulated by MARD's Circular 02/2014/TT-BNNPTNT dated April 14, 2014 the Approval Process of Issuing and Withdrawing Certification for Genetically Modified Plants for use as Food and Feed (see GAIN Report VM 4020). Under Circular 02/2014, the deadline for submission of registration dossiers for GE events (that were present in products exported to Vietnam) was March 10, 2015. However, per requests from animal feed industry and to avoid trade interruption, MARD issued Circular 6/2015 on February 14, 2015, amending Clause 2, Article 18 of Circular 02/2014 and extending the deadline for submission of food/feed approval dossiers for all GE events to March 10, 2016 (see GAIN Report VM5042). However, MARD continues to receive applications from biotech companies despite the passing of the March 2016 deadline. As of November 2017, there were 51 submissions for approval of GE events for food/feed use, of which 21 submissions have been approved and 30 applications are still pending. All approved applications are for corn and soybean GE events while pending GE events are for different crops such as cotton, canola, sugar beet, and alfalfa, in addition to other corn and soybean events.

Labeling of GM food products is still stipulated under Inter-Ministerial Circular 45/2015/TTLT-BNNPTNT-BKHCN. On November 23, 2015, MARD and the Ministry of Science and Technology (MOST) issued Inter-Ministerial Circular 45/2015/TTLT-BNNPTNT-BKHCN guiding the labeling of pre-packaged food products containing at least 5 percent of GE ingredients (determined by volume). Circular 45/2015, went into effect on January 8, 2015, and applies to pre-packed foods containing at least one GE ingredient that is at least 5 percent of the total ingredients of the product. In instances where Circular 45 is applicable, the Vietnamese phrase "*biến đổi gien*" (aka: "genetically engineered") must be printed next to the GE component on the ingredient listing of the Vietnamese-language secondary label that is affixed on a product.

Circular 45/2015 does not apply to: 1) pre-packaged food products containing GE ingredients that cannot be detected in the final product; 2) fresh, un-packaged GE food products; and 3) GE food used in emergency cases, such as natural disasters or disease epidemics. For more information, please see GAIN report VM5088.

On April 12, 2016, MARD's Plant Protection Department (PPD) issued the Official Letter 611/BVTV-QLT suspending any new registrations of plant products containing the active ingredients *Glyphosate*, *Diazinon*, *Malathion*, and *Tetrachlorvinphos*. This suspension still remains in effect (as of December 2017).

Background:

By the first quarter of 2014, the GVN had published all the necessary regulations required to review and approve biotech traits for commercialization, and biotech developers began submitting application dossiers for biosafety and food/feed approval.
On September 5, 2014, MARD issued Circular 29/2014/TT-BNNPTNT regarding the exceptional recognition of biotechnological advances. As a result, the owner of a crop variety carrying an approved GE event may register for the status of "exceptional recognition" which permits new crop varieties to be grown without requiring further field-testing. For a crop to be eligible for this status, its host variety

for the GE trait must already have been tested for comparison with the original variety (without the GE trait) via confined and multi-location field trials, as regulated by MARD (see VM2071). This Circular streamlined the approval process, making further field-testing minimal after a GE event has been evaluated for safety and approved. Please note that an approved event carrying the host variety must be on the List of crop varieties approved for cultivation in Vietnam and, if not, then the variety must first go through separate field-testing for approval as a new crop variety. This requirement is regulated in MARD's Decision 95/2007/QD-BNN dated November 27, 2007 regarding the regulation on recognition of a new agricultural crop variety. Decision 95/2007/QD-BNN is available in Vietnamese on MARD's Crop Production Department (CPD)'s website at:
http://cuctrongtrot.gov.vn/ctt/vbpl/DetailDocument.aspx?ObjectID=379

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Field Trials:

Since late 2016, MARD has not received any new applications for confined field trials of biotech crop varieties.

In early 2017, the second confined field trial of a biotech corn variety carrying an insect-resistant trait was completed. This field trial's report had already been submitted to MARD's Biosafety Committee for review, approval, and for an issuance of permission for a multi-location field trial. The first confined field trial of this biotech corn variety was conducted between March to July, 2016, following MARD's granting of permission in early 2016.

One biotech company plans to submit a report to MARD on a 2016 multi-location field trial for a GE corn variety carrying a single insect-resistant trait. MARD's Bio-Safety Committee will review the report and, following their approval, the company shall then forward the report to the Ministry of Natural Resources and Environment (MONRE) for an issuance of a Biosafety Certificate.

Vietnam Ministry of Natural Resources and Environment (MONRE) does not issue any Biosafety Certificates in 2017:

Since November 2016, MONRE has not issued any new Biosafety Certificates. Before then (between June 2015 to November 2016), MONRE had issued biosafety certificates for five GE corn events (one single event and four stacked events). The single event contains a trait resistant to *glyphosate* or *Lepidopteran* with the stacked events containing traits resistant to both *glyphosate* and *Lepidopteran*. The list of GE traits granted a Biosafety Certificate is available at MONRE's website:
http://antoansinhhoc.vn/Noi-dung-don/Danh-muc-GMO/2452502

MONRE approves events in accordance with Circular 8/2013/TT-BTNMT covering procedures for issuing and revoking bio-certificates (see GAIN VM3042) which states that biotech developers are only eligible to submit applications for Biosafety Certificates for GE events that MARD has already approved for use as food and feed.

MARD issues Certificates on the Approval of GE plants for Use as Food and Feed:

According to industry sources, as of November 2017, there were 51 dossiers registering for GE events submitted to MARD for food/feed approval. However MARD has approved only 21 cases so far, with 30 submissions still pending for approval, including GE events for corn, soybeans, cotton, canola, sugar beets, and alfalfa. Post notes a significant slowdown in MARD's review and approval process for new GE events for food/feed use, with no new approvals since March 2017. Industry has raised concerns that MARD's slowdown in approvals could create trade disruptions for products that do not comply with Vietnam's regulations on bio-safety management as they contain unapproved GE events.

MARD also published an list of dossiers of 18 GE events that were approved for food/feed approval and an list of dossiers of 27 GE events received by MARD. The approved GE events are for corn and soybean while the dossiers pending for approval include GE events for corn, soybean, canola, cotton, sugar beet and alfalfa. The lists are available at MARD's website: http://www.agrobiotech.gov.vn/web/default.aspx?Lang=vi-VN

b) COMMERCIAL PRODUCTION:

The GVN currently only allows biotech corn varieties to be grown in Vietnam.

According to ISAAA, Vietnam's 2016 biotech corn growing area was estimated at 35,000 ha, around 3 percent of the total cultivated corn area. Although 2016 biotech corn production data is unavailable, industry states that GE hybrid corn cultivated in Vietnam has a higher profit margin than host hybrid varieties due to lower production costs due to less expensive inputs, such as herbicides and labor costs, due to better weed control. Additionally, biotech hybrid corn has experienced higher yields compared to those of host hybrid corn varieties.

2017 estimates for Vietnam's biotech corn growing area are unavailable, but industry sources expect this area to remain the same or slightly decrease from last year's levels due to an ongoing reduction in Vietnam's overall corn growing area.

According to MARD data, Vietnam's total cultivated corn area in 2016 was 1.15 million ha, a decrease of 1.1 percent compared to 2015 as a result of farmers in the South East and Mekong River Delta regions switching some of their corn planting areas to higher-value crops, such as cassava.

In practice, the biotech corn varieties commercialized in Vietnam are mainly stacked events due to the preference of farmers. Industry sources also report that approved biotech corn is being grown in all regions of Vietnam where host varieties had been cultivated.

c) EXPORTS:

Official data on Vietnamese corn exports to China is unavailable, however, according to traders, annual Vietnam corn exports to China are estimated at 500,000 metric tons, mainly via border trade. These exports could include GE corn given that this crop is being grown in a number of provinces, such as Son La, that border with China. For more details on corn production and trade in Vietnam, please see GAIN report VM7035.

d) IMPORTS

Vietnam imports a number of GE plant products, including soybeans, soybean meal, soybean oil, corn and distillers dried grains, cotton, alfalfa, and canola. Excluding imported cotton used in the textile industry, 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 on imported GE feed ingredients as domestic supplies are unable to fuel these sectors' growth.

According to Post's estimates, Vietnam's MY 2016/2017 corn imports are around 8.0 million tons, of which 6.3 million metric tons are from biotech corn growing countries, including Brazil and Argentina (see GAIN report VM7035).

The United States has topped the list of cotton suppliers to Vietnam for nearly a decade. In CY 2017, U.S. cotton exports to Vietnam are expected to climb up to 730,000 tons, a 36 percent increase over the year before (see GAIN report VM7055).

Vietnam's imports of DDGS are estimated to increase to 1 million metric tons in 2018, a 25 percent increase compared to the previous year (see VM7051). Although the United States is a key supplier of DDGS to Vietnam, 2017 exports were significantly restricted due to a December 2016 decision by MARD to suspend these products as a result of quarantine pest detections. Vietnam's imports of U.S. DDGS are now recovering following MARD's lifting of its suspension on September 1st, 2017 (for more details, please see GAIN report VM7052).

In CY 2016, Vietnam imported 1.542 million metric tons of soybeans with Brazil as the biggest supplier (55 percent of total imports), followed by the United States (with a 22 percent market share [see GAIN report VM7052]).

e) FOOD AID

Vietnam is not a food aid recipient.

f) TRADE BARRIERS

As of November 2016, no official trade barriers affecting GE agricultural products have been reported. However, biotech companies are concerned about the increasing delay in MARD's approval of pending submissions to register GE events for food and feed use. Industry sources are concerned that such a delay may restrict the use of GE events in products intended for the Vietnamese market. Additionally, the delay in the approval of registrations for new biotech hybrid corn varieties is hindering the ability of biotech companies to introduce new biotech hybrid seed corn to farmers.

Post also notes that MARD's announced intention to develop an extensive organic agriculture industry may lead to less GVN resources and priority given to agricultural biotechnology.

PART B: POLICY

a) REGULATORY FRAMEWORK

***[1]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 regarding the approval process for issuing and withdrawing certifications for GE plants for use as food and feed. MARD extended this deadline to March 10, 2016, however despite the passing of this date, MARD continues to receive applications for food/feed approval dossiers.

MARD's 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.

On September 5, 2014, MARD issued Circular 29/2014 to amend and supplement some parts of Circular 23/2010 regarding the Recognition of biotechnological advances in agriculture and rural development and applying Circular 23/2010 to biotech seed varieties. Accordingly, Circular 29/2014 amends and supplements Article 7 of Circular 23/2010 as follows:

The exceptional recognition of biotechnological advances shall be applied for a crop variety that is on the list of crop varieties allowed for production and trade in Vietnam (here referred to as the host variety) containing gene-transferred events which have been granted a Certificate of Biosafety and a Certificate for Food/Feed Use and meet the following conditions: 1) the GE crop variety has been compared with the host variety and undergone a risk assessment; and 2) 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 in order to compare 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 the GE variety has not yet undergone a risk assessment field trial, the owner of the GE variety shall develop and submit to MARD/CPD, a plan for field trials to compare the GE variety 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.

The processing time to review a dossier for exceptional recognition takes about 20-25 working days. Within 20 working days upon receipt of a valid dossier, CPD shall take the lead and coordinate with DOSTE in reviewing the dossiers and shall submit a request to MARD to establish a Review Council.

Members of the Review Council will evaluate the dossier in accordance with Article 9 of Circular 23/2010.

[1] *Indicates an update from Post's previous Annual Biotechnology Report.

Within five working days of the Review Council's conclusion regarding the dossier, CPD will provide DOSTE with the following documents: 1) the Letter of Submission; 2) the Notes on Appraising Council's meeting; 3) CPD's appraising report; 4) the Dossier registered for exceptional recognition; and 5) a draft of the Decision on exceptional recognition. Within five working days of receiving documents from CPD, DOSTE shall lead and coordinate with the Legal Department to review all documents provided by CPD in order to submit a request to MARD's Minister for approval and issuance of a Decision on Exceptional Recognition.

Circular's 29/2014 is available (in Vietnamese) at:

http://www.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class_id=1&mode=detail&document_id=175906

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 regarding the Recognition of Biotechnological Advances in Agriculture and Rural Development. The Circular regulates the procedures for the registration of recognition of biotechnological advances in the field of agriculture, forestry, and fishery 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 trials, crop variety testing; animal species; pesticides; fertilizer, soil enhancing product; animal feed, veterinary product, vaccine, products used in preservation, processing of agro-forestry, fishery products, and environment treatment of registering organization. For registration to recognize GE plants, GE animals, or GE micro-organisms, in addition to the above-mentioned documents, the registering dossier must include a copy of the biosafety certificate issued by a relevant Vietnamese agency.

Circular 23/2010 is available (in Vietnamese) at MONRE's biosafety website:
http://antoansinhhoc.vn/Noi-dung/Thong-tu-so-23-2010-TT-BNNPTNT/2452598

*** Vietnam Ministry of Finance (MOF) Circular 186/2016/TT-BTC regarding the regulation on payment fees for a Bio-Safety Certificate review.** On November 08, 2016, Vietnam's MOF issued Circular 186/2016/TT-BTC regarding the regulation on "Collection, Payment and Management and Use of Fees paid for the Appraisal for the Bio-Certification of a Genetically Modified Organisms (GMO)." Accordingly, the fee for each appraisal is VND 70 million (around $3,087 USD, based on a November 21, 2017 exchange rate of $1 USD = VND 22,675). As regulated in the Circular, 100 percent of the fees shall be paid to the GVN budget. MONRE's Bio-Diversity Conservation Agency (BCA) has been assigned to collect the fee with guidelines on the fee's use regulated by Clause 1,

Article 4; and Article 5 of the GVN's Decree No.120/2016/ND-CP, dated August 23, 2016, providing details and guidance on the implementation of a number of provisions of the Law on Fees and Charges.

The Circular took effect on January 1, 2017, replacing MOF's Circular 36/2014/TT-BTC, dated March 24, 2016, to promulgate the Regulation on payment fees for Bio-Safety Certificate review. The full Vietnamese version of the Circular 186/2016/TT-BTC is available at https://thuvienphapluat.vn/van-ban/Thue-Phi-Le-Phi/Thong-tu-186-2016-TT-BTC-phi-tham-dinh-ho-so-cap-giay-chung-nhan-an-toan-sinh-hoc-bien-doi-gen-319382.aspx.

Vietnam's Over-arching Biosafety Decree (see GAIN VM 2071)

On June 21, 2010, Vietnam's Prime Minister approved the Biosafety Decree 69/2010/ND-CP, replacing Vietnam's 2005 Biosafety Regulation, its first ever such document (see VM5062). The Biosafety Decree provides the legal framework for the biosafety management of genetically engineered organisms, genetic specimens, and GE-derived products (with the exception of pharmaceutical products originating from GE). Although Decree 69 entered into force August 10, 2010, it was revised by Decree 108 in 2011 to make it compliant with provisions of Vietnam's Food Safety Law on the management of food derived from agricultural biotechnology. Additionally, Decree 108 moved the responsibility of certification for food use from the Ministry of Health (MOH) to MARD.

***Table 1**: Responsibilities of Vietnam's Government Agencies in Management of Bio-Safety as described in Decree 69, and amended by Decree 108*

Government Agency	***Role***	***Responsibilities***
Ministry of Natural Resources and Environment (MONRE)	*Acts as lead government agency in Biosafety Management;*	1. *To issue a Biosafety Certificate* 2. *To withdraw a Biosafety Certificate* 3. *To develop list of GE products granted Biosafety Certificate* 4. *To develop regulation on storage, package and transportation of GE products specified in the Article 1 of the Decree.* 5. *To develop and manage database on GE products*
Ministry of Agriculture and Rural Development (MARD)	*To regulate field trials of GE crops. To approve GE products used for animal feed and food (as a result of Decree 108)*	1. *To issue a Permit for Field Trial of GE crops* 2. *To accredit MARD's agencies for conducting field trial of GE crops* 3. *To conduct Field Trials of GE crops* 4. *To approve GE products used for food and animal feed; GE products that can be approved for use as food and animal feed*

Ministry of Science and Technology (MOST)	*MOST is the key government agency managing the research and development of GE products*	1. *Accreditation of GE research labs* 2. *Management of GE projects* 3. *To coordinate with relevant government agencies on developing of labeling regulation*
Ministry of Industry and Trade (MOIT)	*Post comment: Although not officially stated, MOIT's role is to participate in the development of biosafety regulations.*	1. *To coordinate with relevant ministries including MARD to manage use of GE products as inputs in food processing industries.*

Core GVN Regulations Governing Commercialization of Agricultural Biotechnology

MONRE Biosafety Certification Regulation

On May 16, 2013, MONRE published Circular 8/2013/TT-BTNMT, outlining the procedures for granting and revoking Certificates of Biosafety. Circular 8 lays out the regulatory structure to evaluate the biosafety of agricultural traits derived from biotechnology. A biosafety certificate is required before an agricultural biotech event can be commercially cultivated in Vietnam. This Circular entered into force on July 1, 2013 (see VM3042 for more details).

MARD approved Food/Feed Use Certification Regulation

On January 24, 2014, MARD issued Circular 2/2014/TT-BNNPTNT to promulgate the Approval Process of Issuing and Withdrawing Certification for Genetically Modified Plants for use as food and feed. The Circular provides the approval process for issuing and revoking the certificate for GE plants for use as food and feed. The Circular entered into force on March 10, 2014.

MARD formed a committee to review and evaluate the dossiers consisting of 11 experts and scientists representing different Ministries, including MONRE, MARD, MOH, MOIT, the Vietnam Academy of Sciences, the Vietnam Academy of Agricultural Sciences, and the Ho Chi Minh City's Biotechnology Center. For more details, please see VM4020.

Additional GVN Regulations Governing Aspects of Agricultural Biotechnology

MONRE Regulations on Providing and Exchanging Information and Databases on GE Products

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 crops. The Circular entered into force on October 8, 2012. The full Circular (in Vietnamese) can be downloaded at:
http://antoansinhhoc.vn/upload/Thong%20tu%2009.2012.TT-BTNMT.pdf
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: 1) bilateral or multilateral agreements on the biosafety of GE plants that Vietnam participates in or has already signed; 2) Current regulations on GE plants; 3) Results of research projects and programs on the safety of GE products kept by authorized agencies; 4) Biosafety Certificates; Food/Feed Approval Certificates, Permits for Field Trials; Validation of Field Trial 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 trials; Permit or Decision on Imports of GE products that are not on the list of GE products allowed for use as food/feed; 5) Reports as regulated in Appendix I, II, III, IX of Decree 69; and 6) Information on GE crop field trials and growing areas, and the list of local/foreign consultants on biosafety - and modern biotechnology and other biotech related information or documents.

GE crop databases are grouped into: the National Genetically Modified Organism (GMO) Database (developed and managed by the Vietnam Environment Administration [VEA] of MONRE; Sectorial GE crop databases developed and managed by related ministries; Local GE crop databases developed and managed by Provincial/ People's City Committees.

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: http://antoansinhhoc.vn/upload/TT20_2012_BKHCN.PDF.

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/Noi-dung/Luat-Khoa-hoc-va-Cong-nghe-sua-doi2013/2452962); Article 87 of the Environment Protection Law; Article 7 of Bio-Diversity Law (Luật số 20/2008/QH12 - hongchuyen.com | 2452579); and Article 44 and 50 of the Vietnam Food Safety Law:
http://vanban.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class_id=1&_page=3&mode=de tail&document_id=96032

Research on GE crops must be implemented within the framework of science and technology development (project or research topics) 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.

Please contact FAS-Vietnam if you need further information regarding this Circular which can be found (in Vietnamese) at: http://antoansinhhoc.vn/upload/TT21_2012_BKHCN.PDF.

b) APPROVALS

According to industry sources, as of December 2017, MARD has approved a total of 18 corn varieties to be grown in Vietnam. The approved biotech corn varieties carry a trait tolerant to *Lepidopteran* or *glyphosate* separately or both *Lepidopteran* and *glyphosate* together. However, according to industry, farmers prefer to use the nine biotech corn varieties carrying stacked events as they believe there are more benefits in growing stacked events corn varieties.

Vietnam Ministry of Natural Resources and Environment (MONRE) does not issue any Biosafety Certificates:

MONRE has not issued any new Biosafety Certificates between November 2016 to December 2017, therefore the current total remains at five that were issued before November 2016. The list of GE traits granted a Biosafety Certificate is available at MONRE's website: http://antoansinhhoc.vn/Noi-dung-don/Danh-muc-GMO/2452502.

MONRE approves these events in accordance with Circular 8/2013/TT-BTNMT covering procedures for issuing and revoking bio-certificates (see GAIN VM3042) which states that biotech developers are only eligible to submit applications for Biosafety Certificates for GE events that are already approved by MARD for use as food and feed.

MARD issues Certificates on the Approval of GE plants for Use as Food and Feed:

As of December 2017, MARD has received 51 applications for the registration for approval for GE events for food and feed use. However, MARD has only approved 21 applications to date with 30 cases still pending. The approved submissions were for GE corn and soybean events, with pending cases including GE events for soybeans, corn, canola, sugar beets, and alfalfa. The lists of approved GE events and the List of received GE dossiers are available at MARD's website: http://www.agrobiotech.gov.vn/web/default.aspx?Lang=vi-VN

c) STACKED or PYRAMIDED EVENT APPROVALS

According to MONRE's Circular 8/2013/TT-BTNMT dated May 16, 2013, similar to single event varieties, a stacked event variety derived from biotechnology is permitted to be considered for a Biosafety Certificate. The procedure of issuing a Biosafety Certificate is described in detail at VM3042.

Similarly, MARD Circular 2/TT-BNNPTNT, dated January 24, 2014 (see GAIN report VM4020), regulates procedures on the issuance of the certification of approval of GE plants allowed for use as food and feed for both single and stacked events derived from biotechnology. In both instances, MARD and MONRE will review each individual trait in a stack variety and will approve it if each of the individual traits is approved in Vietnam.

d) FIELD TESTING

On October 27, 2009, MARD issued Circular 69/2009/TT-BNNPTNT outlining the regulatory process for conducting agricultural biotech field trials before commercialization. The Circular covers both confined and multi-location field trials. Circular 69 established criteria to evaluate entities and facilities

that wish to conduct biotech field trials. Based on these requirements, MARD has approved the following institutes/agencies to conduct agricultural biotech field trials:

- The Agricultural Genetics Institute (AGI) and the Plant Protection Institute (PPI), both of which are part of the MARD Vietnam Academy for Agriculture Science (VAAS)
- The Northern and Southern New Seed Testing Centers, Crop Production Department, MARD
- The Nha Ho Cotton Research Institute

MARD also regulates which GE crops are allowed for field trials, and ultimately, commercialization, through Circular 72/2009/TT-BNNPTNT dated November 17, 2009. Thus far, only three GE crops namely: Corn (*Zea mays L.*), Cotton (*Gossypium spp.*), and Soybean *[(Glycline max (L.)* Merrill] are approved for field testing.

Although, Vietnamese regulations allow for field trials for the three aforementioned crops at this time, biotech developers and MARD have only conducted field trials for corn varieties.

e) INNOVATIVE BIOTECHNOLOGIES

According to MARD, one of its genetic research institutes is carrying out a research project that applies genome editing technology. The project objective is to develop a rice variety that is resistant to rice blight disease and exhibits a good aroma. The research will be carried out from 2017 until 2020.

In addition, several workshops that introduced the application of genome editing in agriculture were also reported to have been held in Vietnam in 2017.

f) Coexistence

MARD is currently drafting a Decree on the Production of Agricultural Organic Products. The draft decree consists of 6 Chapters, 20 Articles, and two Appendices that cover the production, certification, labeling, logo, traceability, and trade of organic products in areas of crop production, animal husbandry, forestry, aquaculture, inspection and policy promoting organic agriculture. The draft decree is available on the Vietnam Chamber of Industry and Commerce's website:http://vibonline.com.vn/du_thao/du-thao-nghi-dinh-san-xuat-nong-nghiep-huu-co?download=yes

Once approved (expected in 2018), this decree will serve as a legislative document for MARD to develop a national organic agriculture program for the period of 2018-2025.

g) LABELING

On April 14, 2017, Vietnamese Government issued Decree 43/2017/ND-CP on Good Labeling, with the decree taking took effect on June 1, 2017 (see VM 7031). Regarding the labeling of genetically engineered food, the mandatory content of the label is detailed in Appendix-1 of the Decree. Accordingly, the mandatory contents to be printed on label of the product and must include: Quantity; Date of manufacture; Expiration date; Ingredients or ingredient quantities; 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 contents. However, the Decree

does not specify a threshold for GE ingredients containing food that is required to 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 five percent or higher of the total ingredients forming the product. In cases where Inter-Ministerial Circular 45 is applicable, the Vietnamese phrase "biến đổi gien" (aka: "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

As of December 2017, Vietnam does not have a monitoring or testing regime in place to evaluate the biotech content in imported or exported food products or food products domestically-produced for consumption in Vietnam. However, in 2017, MARD assigned one of its research institutes to develop a set of procedures and methodology to identify products originating from GE (in both quantity and quality). The expected results include a set of procedures and methodology to identify GE products shall be tested for more than 500 different samples with an accuracy rate of 99 percent; the operational procedures will be for a GE testing lab that is certified for ISO17025. The project will be implemented from 2017 to 2019.

i) LOW LEVEL PRESENCE (LLP) POLICY

Although, as of November 2017, Vietnam does not have a LLP policy, it 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 four 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 the 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 to see if it 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=IN0000

Government Decree 88/2010/ND-CP: Decree 88 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/ImageNews/201308090928Decree_No._88-2010ND-CP.pdf

The registration fee for the Certificate for Plant Variety Protection is stipulated in the Ministry of Finance's (MOF) Circular 92/2002/TT-BTC, dated October 12, 2002. The full Circular in English is available at: http://pvpo.mard.gov.vn/FileUpload/circular92.pdf.

To implement the IPL and Decree 88, MARD has also issued a number of Circulars. Circular 56/2007/QĐ-BNN, dated June 12, 2007; Decision 103/2007/QD-BNN, dated December 25, 2007; Circular 33 /2009/TT-BNNPTNT, dated June 10, 2009; and Circular 11/2013/TT-BNNPTNT, dated February 6, 2013, all of which provide the list of plant species protected and designate MARD agencies

approved to conduct DUS testing. These decisions and circulars are available at: http://pvpo.mard.gov.vn

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.

l) CARTAGENA PROTOCOL RATIFICATION

Ministry of Natural Resources and Environment (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.

The total funding for the ABS project is about $2 million, of which $1.2 million is from the Global Environment Facility (GEF) via the United Nations Development Program (UNDP), with the Vietnamese Government and other international organizations providing the remaining funds. The project will be implemented over a four year period with Lao Cai province being selected for the project location. According to the GEF, the project's key objective is to "develop and implement a national ABS framework, build national capacities, and support an ABS Agreement based on Traditional Knowledge and Public-Private Partnership"

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

On May 12, 2017, the GVN issued Decree 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, with the responsibility to implement 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 that:

1) MARD shall grant, renew, and withdraw licenses to access genetic resources of agricultural crop varieties, livestock, aquatic species, and forest seedlings; 2) 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 Cartagena Protocol Meetings. As stipulated by the Cartagena Protocol, the Vietnam Environment Administration (VEA) of MONRE is the Cartagena Protocol Focal Point of Vietnam. MONRE has already developed a website: www.antoansinhoc.vn 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, its government actively tries to incorporate requirements and obligations of the Protocol into its regulations on biosafety management.

m) INTERNATIONAL TREATIES/FORA

Vietnam became a member of Codex Alimentarius in 1989 and a member of International Plant Protection Convention in 2005. The Vietnam Codex Office is under management of MOH's Vietnam Food Administration: http://codexvn.org.

n) RELATED ISSUES

None at this time

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS; b) MARKET ACCEPTANCE/STUDIES

According to biotech companies, farmers in Vietnam's corn growing regions, especially in mountainous areas, are gradually preferring to use biotech corn varieties thanks to better profit margins due to improved crop yields and lower costs of inputs, such as pesticides and labor. However, there is a trend by the GVN to focus more on the promotion of organic agriculture in Vietnam, which may lead to a decrease in support and resources for the development and application of biotechnology in agriculture.

Biotech companies regularly organize field visits for corn farmers to field demos of biotech corn varieties to show farmers advantages of biotech corn to compare with other corn varieties. It was also reported that some biotech corn varieties has advantages in biomass production therefore farmers in North Mountain areas prefer to grow for biomass used to feed dairy cattle.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

As of December 2017, the GVN and MARD do not have any plans to develop regulations for the management of research or approval of animal biotechnology applications.

b) COMMERCIAL PRODUCTION

As there are no regulations in place to govern animal biotechnology, there is no commercial production in Vietnam.

c) EXPORT

None

d) IMPORT

None

e) TRADE BARRIERS

None

PART E: POLICY

a) REGULATORY FRAMEWORK

No regulations cover animal biotechnology.

b) INNOVATIVE BIOTECHNOLOGY

None

c) LABELING AND TRACEABILITY

None

d) INTERLLECTUAL PROPERTY RIGHTS

None

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

None at this time

b) MARKET ACCEPTANCE/STUDIES

None