

Required Report: Required - Public Distribution

Date: February 04,2020

Report Number: VM2019-0052

Report Name: Agricultural Biotechnology Annual

Country: Vietnam

Post: Hanoi

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Pham Minh Thu and Sarah Gilleski

Approved By: Robert Hanson

Report Highlights:

The Ministry of Agriculture and Rural Development (MARD) issued Certificates of Food and Feed Safety Approvals for ten genetically engineered (GE) events for corn, soybeans, and alfalfa in 2018-2019. However, MARD continues to delay the approval of biotech corn varieties for commercialization. In April 2019, MARD removed glyphosate from the list of pesticides approved for use in Vietnam and gave only a one-year grace period for domestic use. Vietnam remains a major importer of key biotech plant products, such as soybeans, distiller's dried grains with solubles (DDGS), corn, and cotton.

EXECUTIVE SUMMARY

Approvals of Outstanding Events in Corn, Soybean and Alfalfa

From October 2018 to September 2019, MARD issued ten Certificates of Food and Feed Safety Approvals for outstanding biotech events. The approved events included, three corn events, five soybean events, and two alfalfa events. The approval of these events, which in some cases have been pending approval for almost four years in Vietnam, despite being commercially adopted in the United States and other countries, provides much needed assurance to producers that the trade in these products can continue.

However, as of October 2019, industry reports there are 21 events awaiting approval. Among those, MARD officially acknowledges only 17 events that were submitted before 2017. Submissions pending for review and approval include events for corn, soybeans, canola, cotton, alfalfa, and sugar beets.

Potential of Biotech Corn in Fighting Fall Army Worm

As of August 2019, MARD reported 15,000 hectares of the current corn crop is infected by fall armyworm (FAW) in 40 provinces in Vietnam. Post estimates the total FAW infected corn area since the first detection in April is 35,000 hectares. The most infected areas are in the northwest and central highlands. Industry has engaged with MARD to conduct field trials to show the effect of GE corn hybrids in combating FAW.

Ban on Glyphosate

On April 10, 2019, MARD announced Decision 1184 to remove glyphosate from the list of approved pesticides, stating their concerns on human safety and the pressures they are facing from the public and their legislature. The removal decision halted imports of glyphosate from June 10, 2019 and gave a one-year grace period for domestic use. While MARD pledged the ban would not impact the trade of U.S. products, the United States continues to request that Vietnam postpone the ban until it conducts a thorough scientific review consistent with international trade obligations.

Delays in recognition of new biotech corn varieties

Since 2017, MARD has not approved any new biotech corn varieties for commercialization. Currently, there are eight biotech corn varieties pending MARD's review and/or commercialization approval. Among those, four varieties contain biotech traits resistant to FAW. In September 2018, MARD repealed Circular 69/2009 regulating field trials for environmental risk assessment before commercialization, causing a gap in regulations on field trials and biosafety certification for biotech crops in Vietnam. There is also concern that a draft Government Decree guiding the implementation of the new Cultivation Law, taking effect on January 1, 2020, lacks guidance on biotech crop recognition and biotech seed importation.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY	4
<i>PART A: PRODUCTION AND TRADE</i>	4
<i>PART B: POLICY</i>	6
<i>PART C: MARKETING</i>	17
CHAPTER 2: ANIMAL BIOTECHNOLOGY.....	17
<i>PART D: PRODUCTION AND TRADE</i>	17
<i>PART E: POLICY</i>	18
<i>PART F: MARKETING</i>	18

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Since late 2016, MARD has not received any new applications for confined-field trials of biotech crop varieties. MARD has yet to approve a multi-location field trial for the completed confined field trial of insect-resistant corn. MARD's Biosafety Committee has not completed its review of the completed multi-location field trial for one biotech corn variety, because MARD repealed Circular 69/2009, a regulatory base for environmental risk assessment field trials, in September 2018.

However, in April 2019, MARD officially confirmed that the presence of FAW has caused thousands of hectares of damage to corn nationwide. The plant science industry in Vietnam has collaborated with technical agencies at the provincial and central levels to conduct more than 70 bio-efficacy demonstrations to showcase the effectiveness of insect-resistant biotech corn varieties in managing FAW.

As of October 2019, industry reported there are 8 biotech corn varieties pending for MARD's review for cultivation approval. Among those, four varieties contain biotech traits resistant to FAW.

b) COMMERCIAL PRODUCTION

The Government of Vietnam (GVN) currently approves only the commercialization of biotech corn. MARD approved a total of 16 biotech corn varieties to be grown in Vietnam in 2015-2016.

There is no official data on biotech corn growing area in 2018. Industry estimates were 40,000 hectares (ha) in 2018, around four percent of the total corn growing area. Estimates for the 2019 biotech corn growing area are not yet available. Industry sources expect the area to increase slightly due to FAW that is leading producers to switch from conventional corn to biotech corn varieties, which are resistant to FAW. Industry also stated that GE hybrid corn cultivated in Vietnam has a higher profit margin than host hybrid varieties due to the reduction of pesticides and labor costs since the GE varieties are resistant to stem borers, maize borer, and glyphosate-tolerant herbicides. Additionally, biotech hybrid corn has experienced higher yields compared to those of host hybrid corn varieties. However, as MARD has removed glyphosate from the list of pesticides approved for use in Vietnam and provided only a one-year grace period for domestic use until June 2020, that calls into question the policy on commercialization of biotech corn varieties in Vietnam.

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

c) EXPORTS:

Although official data on Vietnamese corn exports to China is unavailable, trade contacts estimate annual corn exports to China at 500,000 metric tons (MT), mainly via border trade. These exports could include GE corn, given that this crop is being grown in a number of provinces that border China, such as Son La. For more details on corn production and trade in Vietnam, please see GAIN report [VM9014](#).

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, 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) 2018/19 corn imports are around 10.2 million metric tons (MMT), mostly from biotech corn growing countries including Brazil Argentina and the United States (GAIN report [VM9014](#)). In MY19/20, Post forecasts imports down to 10 MMT due to the expected spread of African Swine Fever.

The United States has topped the list of cotton suppliers to Vietnam for nearly a decade. Post estimates that U.S. cotton exports to Vietnam in MY 2018/19 will reach 803,000 MT, an increase of ten percent over MY 2017/18 (see GAIN report [VM9019](#)).

The United States continues to be the dominant supplier of DDGS. After MARD lifted its import suspension of U.S. DDGS in September 2017, imports have strongly rebounded due to the high demand from the domestic feed industry. The import volume of DDGS in MY 2018/19 is estimated at 960,000 MT and forecasts to rise to 1.2 MMT in MY 2019/20 (see GAIN report [VM9014](#)).

In MY 2017/18, the United States was the leading soybean exporter to Vietnam, with the export volume reaching 1.27 MMT. Post estimates MY 2018/19 soybean imports at 1.80 MMT and a slight increase in MY 2019/20 to 1.83 MMT (see GAIN report [VM9013](#)).

e) FOOD AID

Vietnam is not a food aid recipient. Historically, Vietnam has made limited shipments of rice for food aid, however the country does not yet have concrete plans to provide food aid in the future.

f) TRADE BARRIERS

As of October 2019, no official trade barriers affecting GE agricultural products have been reported. However, biotechnology companies continue to raise concerns about MARD's delay in approvals of outstanding biotech events for food and feed use. These delays have started to cause trade disruptions and raise the likelihood that there are unapproved varieties entering the market. Additionally, the delay in the approval of recognition for new biotech hybrid corn varieties is hindering the ability of biotech companies to introduce new biotech hybrid seed corn to farmers.

PART B: POLICY

a) REGULATORY FRAMEWORK

Biosafety Decrees

Decree 69/2010 on Biosafety of GE organisms, genetic specimen, and products derived from GE organisms

On June 21, 2010, Vietnam's Prime Minister approved the Biosafety Decree 69/2010/ND-CP, replacing the GVN's 2005 Biosafety Regulation. 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 on 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.

Decree 123/2018 amending and supplementing a number of conditions for trade and business in agriculture

On September 17, 2018, GVN issued Decree 123/2018 amending and supplementing a number of conditions for trade and business in agriculture. This Decree amended Articles 37, 38, 39, and 40 of Decree 69/2010 on biosafety and consolidated the conditions for import, production, and trade of GE food and feed. Accordingly, organizational/individual producers of GE products for use in animal feed must obtain a certificate satisfying conditions for use as food and feed prior to importation, production, and trade in Vietnam.

Core Ministry Regulations Governing Commercialization of Agricultural Biotechnology

MARD Food and Feed Use Certification

MARD's Circular 2/2014/TT-BNNPTNT promulgating the approval process of issuing and withdrawing certification for GE plants for use as food and feed.

On January 24, 2014, MARD issued Circular 2/2014 providing 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.

Due to this Circular, a GE event will be approved for use as food and feed 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 Food and Feed Safety Committee concludes that the GE plant does not contain uncontrolled risks to humans and/or the environment. Circular 2/2014 stipulates the Department of Science Technology and Environment (DOSTE) to organize a Food and Feed Safety Committee to review and evaluate biotech applications before submitting them to MARD's Minister for his approval.

MARD's Circular 6/2015/TT-BNNPTN extending the implementation deadline for Circular 2/2014/TT-BNNPTN 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 plants for use as food and feed to March 10, 2016. However, MARD has suspended receiving applications for food/feed approval as of the beginning of 2017.

MONRE Biosafety Certification Regulation

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, as well as a certificate on food and feed approval are both required for recognition of biotech varieties cultivated in Vietnam. Circular 8 lays out the regulatory structure to evaluate the biosafety of agricultural traits derived from biotechnology. This Circular entered into force on July 1, 2013.

MARD's Biotech Crop Varieties Recognition

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. As a result, Circular 23/2010's Article 7 is amended 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 (hereinafter referred to as the host variety). Host varieties contain gene-transferred events that have been granted a Biosafety Certificate, as well as a Certificate for Food/Feed Use, and meet the following conditions:

- i) the GE crop variety has been compared with the host variety and undergone a risk assessment; and
- ii) 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 MARD/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.

Circular 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-BNNTPTNT 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 trials 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 above-mentioned documents for the registration to recognize GE plants, GE animals, or GE micro-organisms, 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/thong-tu-so-232010tt-bnnptnt/>

Additional Ministry 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/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:

- 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 and 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, and 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; and
- Local GE crop databases developed and managed by Provincial/People's City Committees.

Ministry of Science and Technology (MOST) Regulation on Guidance to Certify Laboratories Qualified for GE Research

On October 20, 2012, MOST issued Circular 20/2012/TT-BKHCHN regarding the Regulation of Procedures to Certify a Lab for Permission to Conduct GMO Research. The full Circular (in Vietnamese) can be found at: <https://thuvienphapluat.vn/van-ban/linh-vuc-khac/thong-tu-20-2012-tt-bkhcn-huong-dan-dieu-kien-trinh-tu-va-thu-tuc-cong-nhan-162294.aspx>

MOST Regulation on Biosafety Management of GE Research and Development

On November 20, 2012, MOST issued Circular 21/2012/TT-BKHCHN 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

(http://vanban.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class_id=1&_page=3&mode=detail&document_id=96032)

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-BKHCHN.

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_BKHCHN.PDF

b) APPROVALS

According to industry sources, MARD approved 16 corn varieties for cultivation in 2015-2016. The approved biotech 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 biotech corn varieties for cultivation in Vietnam.

MONRE has not issued any new Biosafety Certificates for cultivation since late 2016.

The current total of Biosafety Certificates issued by MONRE remains at five, all were issued before November 2016. MARD has repealed its regulation on field trials for environmental risk assessment of biotech crops, causing a gap in regulations for MONRE to issue new 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 issues new approvals for Food and Feed Use in 2018-2019

As of October 2019, MARD has approved 31 biotech events for soybean, corn, and alfalfa for import, and recognized receiving 17 outstanding events. In September 2019, MARD approved five events, one corn, two soybean and two alfalfa (GAIN report [VM2019-0012](#)). The lists of approved GE events and the list of received GE dossiers are available at MARD's website:

<http://agrobiotech.gov.vn/Default.aspx>

c) STACKED or PYRAMIDED EVENT APPROVALS

According to MONRE's Circular 8/2013/TT-BTNMT dated May 16, 2013, a stacked event variety derived from biotechnology is similar to single event varieties. Stacked events are permitted to be considered for a Biosafety Certificate under the same procedure for single events.

Similarly, MARD Circular 2/TT-BNNPTNT, dated January 24, 2014, regulates the procedures for the certification of GE plants for food and feed use for 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 [*Glycine max (L.) Merrill*]. Up to date, biotech developers and MARD have only conducted field trials for corn varieties.

Although, in September 2018, MARD repealed Circular 69/2009 regulating biotech field trials before commercialization, causing a gap of regulations on field trial for biotech crops in Vietnam.

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. 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 does not permit the use of GE technology and inputs in organic production. In addition, the GVN will provide 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 five 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-BKHCHN, dated November 23, 2015 (see GAIN report [VM 5088](#)).

On November 23, 2015, MARD and MOST issued the Inter-Ministerial Circular 45/2015/TTLBNNPTNT-BKHCHN, 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. 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” (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 October 2019, 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. Previously, in 2017, MARD assigned the Agricultural Genetics Institute to develop a set of procedures and methodology to identify products originating from GE technology. FAS will continue to monitor and update the development of this project.

i) LOW LEVEL PRESENCE (LLP) POLICY

As of October 2019, Vietnam does not have a LLP policy, but MARD is a frequent observer to the Global Low Level Presence Initiative meetings.

j) ADDITIONAL REGULATORY REQUIREMENTS

None at this time.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Under the Intellectual Property Law (IPL) 50/2005/QH11, Vietnam has a regulatory structure in place to protect the rights of plant variety developers. The IPL provides the foundation for intellectual

property rights protection in Vietnam and covers plant varieties, including 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/DetailInformation.aspx?InformationID=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.

I) 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.

The total funding for the ABS project is about \$2 million; \$1.2 million is from the Global Environment Facility (GEF) via the United Nations Development Program (UNDP). The Vietnamese Government and other international organizations provide the remaining funds. The project continues to be implemented over a four-year period with Lao Cai province 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. 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, 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, 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://codexvn.org>.

n) RELATED ISSUES

No information available.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

According to industry, farmers in Vietnam's corn growing regions – especially in mountainous areas – are open to adopting biotech corn varieties. They are interested in better profit margins due to improved crop yields and lower input costs of pesticides and labor. Biotech companies regularly organize field visits for corn farmers to demonstration fields of biotech varieties to display the advantages of biotech corn. Sources also noted that some biotech corn varieties are better for biomass production; therefore, many farmers in Vietnam's northern mountain areas prefer to grow these varieties to use the biomass as dairy cattle feed.

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. Vietnam's cotton import forecast continues to increase in order to capture business opportunities created from joining free trade agreements such as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and the EU-Vietnam Free Trade Agreement (EVFTA).

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

As of October 2019, there is no report on the GVN's plan 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, no commercial licenses 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

Vietnam National Assembly adopted the Law on Animal Husbandry in November 2018. This Law shall ban the “illegal import, production, release and use of GE animals and products of GE animals.” This Law, only allows the cloning of animals for study purposes and assigns the GVN to detail provisions on a risk assessment for GE animals. Currently, a draft Government Decree guiding the Law on Animal Husbandry, which was notified to WTO in May 2019, has no provisions on animal biotechnology.

a) INNOVATIVE BIOTECHNOLOGY

Unknown.

b) LABELING AND TRACEABILITY

No information available.

c) INTERLECTUAL PROPERTY RIGHTS

No information available.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

No information available.

b) MARKET ACCEPTANCE/STUDIES

No information available.

Attachments:

No Attachments