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# Vietnam

# **Agricultural Biotechnology Annual**

# 2018

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# **Report Highlights:**

In 2017, the Ministry of Agriculture and Rural Development (MARD) continued its delay in the review and approval of genetically engineered (GE) events for food and feed use, including biotech hybrid corn varieties, with no new approvals since late 2016. MARD is also proposing to ban the use of the herbicide glyphosate following its suspension of this product's registration over a year ago. Vietnam remains a major importer of key biotech plant products, such as corn, distiller's dried grains with solubles (DDGS) for animal feed production, soybeans for oil crushing, and cotton for the textile industry.

# **EXECUTIVE SUMMARY**

Vietnam has continued or initiated a number of actions over the last year that have the potential to negatively impact the cultivation and trade of genetically engineered (GE) products.

# **Delay of GE Events and Biotech Crop Approval**

The Ministry of Agriculture and Rural Development (MARD) has delayed the review and approval of a large number of applications registering GE events for food and feed use. Between December 2016 and December 2017, developers submitted eight applications for new biotech hybrid corn varieties to MARD. However, as of October 2018, MARD has yet to approve any of these. Currently, MARD has approved only 21 out of 51 dossiers registering GE events for approval for use as food and feed with the remaining 30 cases still outstanding. Pending submissions for approval include events for corn, soybeans, canola, cotton, alfalfa, and sugar beets.

The delay in review and approval of new varieties and registrations for GE events could have resulted from a policy shift encouraging the production of agricultural commodities in which Vietnam has a competitive advantage to meet the demands of both domestic consumption and export. While biotech crops coexist with conventional and organic crops around the world, the government has also prioritized the production of organic crops. For example, the Government of Vietnam (GVN) issued Decree 109 to encourage organic production through support, such as subsidies and certification, as it continues look for solutions to address consumers' food safety concerns relating to the overuse of chemicals in Vietnamese agricultural production.

# Proposal to Ban Glyphosate

On April 12, 2016, MARD's Plant Protection Department (PPD) suspended new registrations of plant protection products containing glyphosate, stating that this chemical was pending renewal in the European Union (EU). However, this suspension remains in effect after the EU renewed the use of glyphosate for five years. After MARD announced its goal to reduce of the number of crop protection products registered for use in Vietnam by 30 percent, PPD accelerated the drafting of a proposal to ban glyphosate. Previously on February 8, 2017, MARD removed herbicide 2.4 D from the list of plant protection chemicals permitted for use in Vietnam. Industry is now requesting that MARD/PPD follow a transparent review process in line with internationally accepted methods and standards.

# Conditions for Trade, Production, and Import of GE Food and Feed

On September 17, 2018, GVN issued Decree 123/2018 amending and supplementing a number of conditions for trade and business in agriculture. This Decree consolidated the conditions for the import, production, and trade of GE food and feed. Accordingly, GE products must obtain a certificate satisfying conditions for food/feed use prior to importation, production, and trade in Vietnam. While MARD delays the approval of new GE events and GE crop varieties, the consolidation of the trade, production, and import conditions for GE food and feed into the new Decree could significantly impact the import of products containing unapproved GE events.

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# 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.

In early 2017, the second confined field trial of a biotech corn variety carrying an insect-resistant trait was completed. Although MARD's Biosafety Committee has completed its review of this field trial's report, their Ministry has yet to approve this variety for a multi-location field trial.

A report on a 2016 multi-location field trial for a GE corn variety carrying a single insect-resistant trait was also submitted to MARD in 2017; however, MARD's Bio-Safety Committee has yet to complete its review of this report.

# b) COMMERCIAL PRODUCTION:

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

MARD's Crop Production Department (CPD) reported that the biotech corn growing area in 2017 was approximately 28,500 hectares (ha), a decrease of 14 percent from the previous year. This reduction is on par with the overall reduction of the total corn growing area, from 1.15 million ha in 2016 to 1 million ha in 2017. Estimates for the 2018 biotech corn growing area are not yet available. However, industry sources expect the 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. This could be the result of the low price of imported corn and overall production trend of switching from corn to other higher value crops, such as fruits and vegetables. In addition, MARD's lack of approval of new biotech corn varieties since late

2016 has hindered the commercialization of new varieties. 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.

According to CPD data, Vietnam's total cultivated corn area in 2017 was 1.0 million ha, a decrease of 1.1 percent compared to 2016. The reduction is a result of farmers in the South East and Mekong River Delta switching some of their corn planted areas to higher-value crops, such as cassava, fruits, and vegetables.

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 had 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 with China, such as Son La. For more details on corn production and trade in Vietnam, please see GAIN report <u>VM8037</u>.

# 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; domestic supplies are unable to satisfy growth in these sectors.

According to Post's estimates, Vietnam's marketing year (MY) 2017/2018 corn imports are around 9.0 million tons, mostly from biotech corn growing countries including Brazil and Argentina. In MY 2017/18, U.S. corn exports to Vietnam reached 650,000 MT on competitive prices compared to South American corn (see GAIN report VM8037).

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 2017/18 will reach a new record level of about 710,000 MT or roughly 3.26 million bales, up 10 percent over MY 2016/17 (see GAIN report VM8020).

The United States continues to be the dominant supplier of distiller's dried grains with solubles (DDGS) to the Vietnam market. 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. Import volumes of DDGS in MY 2017/18 are estimated at 500,000 MT and forecasted to rise to 600,000 MT in MY 2018/19 (see GAIN report VM8037).

In the first six months of MY2017/18, the United States remained the leading soybean exporter to Vietnam due to its competitive prices with Brazil second. The market share for U.S. soybean exports increased to 61 percent from 47 percent in the previous year, Brazil at 31 percent, and 8 percent from other countries (see GAIN report VM8048).

# e) FOOD AID

Vietnam is not a food aid recipient, nor does it provide food aid for other countries. Historically Vietnam has made limited shipments of rice, however the country does not yet have concrete plans to provide food aid in the future.

#### f) TRADE BARRIERS

As of October 2018, no official trade barriers affecting GE agricultural products have been reported. However, biotechnology 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. Ultimately, this threatens investment and new technology development in Vietnam.

#### PART B: POLICY

#### a) REGULATORY FRAMEWORK

# Biosafety Decrees

Decree 69/2010 on Biosafety of GE organisms, genetic specimen, and products derived from GE organisms (see GAIN VM 2071)

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

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

Government	Role	Responsibilities
Agency		

Ministry of Natural Resources and Environment (MONRE)	Lead government agency in Biosafety Management.	<ol> <li>To issue a Biosafety Certificate</li> <li>To withdraw a Biosafety Certificate</li> <li>To develop a list of GE products granted Biosafety Certificate</li> <li>To develop regulations on the storage, package, and transportation of GE products specified in Article 1 of the Decree</li> <li>To develop and manage a database on GE products.</li> </ol>
Ministry of Agriculture and Rural Development (MARD)	Regulate field trials of GE crops and approves GE products used for animal feed and food (as a result of Decree 108).	<ol> <li>To issue a permit for field trials of GE crops</li> <li>To accredit MARD's agencies for conducting field trials of GE crops</li> <li>To conduct field trials of GE crops</li> <li>To approve GE products used for food and animal feed and GE products that can be approved for use as food and animal feed.</li> </ol>
Ministry of Science and Technology (MOST)	MOST is the key government agency managing the research and development of GE products.	<ol> <li>To accredit GE research labs</li> <li>To manage GE projects</li> <li>To coordinate with relevant government agencies to developing labeling regulations.</li> </ol>
Ministry of Industry and Trade (MOIT)	Comment: Although not officially stated, MOIT participates in the development of biosafety regulations.	To coordinate with relevant ministries including MARD and manage the use of GE products as inputs in food processing industries.

# 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.

In light of MARD's ongoing lack of approval of new biotech events, the ongoing consolidation of trade, production, and import conditions for GE food and feed under this new Decree could potentially impact the import of food and feed containing unapproved GE events.

# • Core Ministry Regulations Governing Commercialization of Agricultural Biotechnology

# MARD Food/Feed Use Certification Regulation

**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.

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 Biotechnology Center. For more details, please see <u>VM4020</u>.

**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.

# **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. 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).

**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 \$3,009 USD based on an October 15, 2018 exchange rate of \$1 USD = VND

23,265). 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. These regulations provided 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 and replaced 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 <a href="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.">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.</a>

# 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 Certificate of Biosafety, as well as 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, 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.

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 MARD's Department of Science, Technology and Environment (DOSTE) in reviewing the dossiers and 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.

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. DOSTE shall then submit a request to MARD's Minister for approval and issuance of a Decision on Exceptional Recognition.

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-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 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 abovementioned 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: <a href="http://antoansinhhoc.vn/Noi-dung/Thong-tu-so-23-2010-TT-BNNPTNT/2452598">http://antoansinhhoc.vn/Noi-dung/Thong-tu-so-23-2010-TT-BNNPTNT/2452598</a>.

# • 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/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 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.

# 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: <a href="http://antoansinhhoc.vn/upload/TT20\_2012\_BKHCN.PDF">http://antoansinhhoc.vn/upload/TT20\_2012\_BKHCN.PDF</a>.

# 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 (<a href="http://antoansinhhoc.vn/Noi-dung/Luat-Khoa-hoc-va-Cong-nghe-sua-doi2013/2452962">http://antoansinhhoc.vn/Noi-dung/Luat-Khoa-hoc-va-Cong-nghe-sua-doi2013/2452962</a>), Article 87 of the Environment Protection Law; Article 7 of Bio-Diversity Law (<a href="Luât số 20/2008/QH12">Luât số 20/2008/QH12 - hongchuyen.com | 2452579</a>), 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=d\_e\_tail&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-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 October 2018, MARD has approved 18 corn varieties for cultivation. The approved biotech corn varieties carry a trait tolerant to *lepidopteran* or *glyphosate* separately or both *lepidopteran* and *glyphosate* together.

MONRE does not issue any Biosafety Certificates:

MONRE has not issued any new Biosafety Certificates from November 2016 to October 2018. The current total remains at five, which 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). This Circular 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 October 2018, 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: <a href="http://www.agrobiotech.gov.vn/web/default.aspx?Lang=vi-VN.">http://www.agrobiotech.gov.vn/web/default.aspx?Lang=vi-VN.</a>

#### 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, and 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 <u>VM4020</u>), regulates procedures on 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

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, and
- 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 – corn (*Zea mays L.*), cotton (*Gossypium spp.*), and soybean [(*Glycline max (L.*) Merrill] – are approved for field testing. However, 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.

#### f) COEXISTENCE

On August 29, 2018, GVN issued Decree 109 on Organic Agriculture that aims to promote organic production in Vietnam. This Decree does not permit 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: <a href="https://luatvietnam.vn/nong-nghiep/nghi-dinh-109-2018-nd-cp-ve-nong-nghiep-huu-co-166604-d1.html">https://luatvietnam.vn/nong-nghiep/nghi-dinh-109-2018-nd-cp-ve-nong-nghiep-huu-co-166604-d1.html</a>.

# 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 contents 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 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 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 October 2018, 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 the Institute of Agricultural Genetics to develop a set of procedures and methodology to identify products originating from GE technology (in both quantity and quality). FAS will continue to monitor and update the development of this project.

# i) LOW LEVEL PRESENCE (LLP) POLICY

As of October 2018, Vietnam does not have a LLP policy, but MARD (when it conducts testing) is a frequent observer to the Global Low Level Presence Initiative meetings.

# i) 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=IN0000.

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/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: <a href="http://pvpo.mard.gov.vn/FileUpload/circular92.pdf">http://pvpo.mard.gov.vn/FileUpload/circular92.pdf</a>.

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 provide the list of protected plant species and designate MARD agencies approved to conduct DUS testing. These decisions and circulars are available at: <a href="http://pvpo.mard.gov.vn">http://pvpo.mard.gov.vn</a>.

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.

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 will 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".

<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: <a href="http://vanban.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class\_id=1&mode=detail&document\_id=189806">http://vanban.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class\_id=1&mode=detail&document\_id=189806</a>

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, <a href="www.antoansinhoc.vn">www.antoansinhoc.vn</a>, 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 management of MOH's Vietnam Food Administration: <a href="http://codexvn.org">http://codexvn.org</a>.

#### n) RELATED ISSUES

None at this time.

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. However, the GVN is increasing its focus 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 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.

# b) MARKET ACCEPTANCE/STUDIES

No known marketing studies exist on the acceptance of GE plants or products in Vietnam.

#### **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

# PART D: PRODUCTION AND TRADE

#### a) PRODUCT DEVELOPMENT

As of October 2018, 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

MARD notified the draft Animal Production Law as G/SPS/N/VNM/95 on March 12, 2018. This

current draft proposes to ban the "illegal import, production, release and use of GE animals and products of GE animals." This draft Law, currently under Vietnam's National Assembly (as of October 18, 2018), only allows the cloning of animals for study purposes and assigns the GVN to detail provisions on a risk assessment for GE animals. FAS continues monitor and will update on the development of this Law.

a) INNOVATIVE BIOTECHNOLOGY

None.

b) LABELING AND TRACEABILITY

None.

c) INTERLLECTUAL PROPERTY RIGHTS

None.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

None at this time.

b) MARKET ACCEPTANCE/STUDIES

None.