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Required Report - public distribution

Date: 7/8/2015

GAIN Report Number: VM5042

Vietnam Agricultural Biotechnology Annual 2015

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Report Highlights:

In March 2015, the Crop Production Department (CPD) of the Ministry of Agriculture and Rural Development (MARD) approved three genetically modified corn varieties for commercial planting. This is the final step in the regulatory approval process for Vietnam to commercialize biotech corn. In April 2015, the approved GM corn varieties were planted making Vietnam the 29th country to commercialize a biotech crop in the world. Concerning feed / food safety registration, the regulatory process to approve individual biotech traits for food and feed use in Vietnam, MARD extended the deadline to submit dossiers one additional year to March 10, 2016.

Section I. Executive Summary:

By the first quarter of 2014, the Government of Vietnam had published all the necessary regulations required to review and approve biotech traits for commercialization, and biotech developers began submitting application dossiers for Bio-Safety and Food/Feed approval. To date, MONRE has issued four (4) Bio-Safety Certificates for two biotech developers. On August 27, 2014, MONRE issued the first Bio-safety Certificate for a GM corn trait tolerant to *Lepidopteran*. Two other Bio-Safety Certificates for GM corn traits tolerant to *glyphosate* were granted to two biotech developers on November 3, 2014. On January 14, 2015, MONRE issued the fourth Bio-Safety Certificate for a GM corn trait tolerant to *Lepidopteran*.

Earlier, on September 5, 2014 MARD had issued Circular 29/2014/TT-BNNPTNT regarding the exceptional recognition of biotechnological advances. Accordingly, the owner of crop variety carrying the approved GM event is eligible to register for exceptional recognition as a new crop variety which is allowed to grow without further field testing if the host variety of that GM trait is already tested for comparison with the host variety via confined and multi-location field trials, regulated by MARD (see VM2071). It is noted that the approved event carrying the host variety must be on the List of crop varieties approved for cultivation in Vietnam. If the host variety is not on the List of crop varieties approved for cultivation in Vietnam, the variety must go through separate field testing for approval as a new crop variety first. This requirement is regulated in MARD's Decision 95/2007/QD-BNN dated November 27, 2007 regarding the Regulation on recognition of new agricultural crop variety. Decision 95/2007/QD-BNN in Vietnamese is available on CPD's website:

http://cuctrongtrot.gov.vn/ctt/vbpl/DetailDocument.aspx?ObjectID=379

According to biotech companies operating in Vietnam, most of the host varieties of GM corn traits being evaluated by MARD and MONRE are already on the List of crop varieties approved for cultivation in Vietnam. As regulated in MARD's Circular 29/2014/TT-BNNPTNT, for this kind of field trial, each GM corn variety must go through a small scale trial (in two places) and a large scale trial (in one place) for comparison testing. Some crops of this field testing will be harvested by the end of June 2015, after which, those varieties could also be commercialized.

On August 11, 2014, MARD issued the first Food/Feed Use Certificates for GM corn traits tolerant to *glyphosate;* or to *Lepidopteran;* or to both *Lepidopteran and glyphosate.* MARD extended the deadline to submit dossiers for Food/Feed Use Certification to March 10, 2016 as stated in MARD's Circular 6/2015/TT-BNNPTNT to ensure that all the commercially traded corn, soybean, and other agricultural traits are submitted before the deadline. So far, approximately 22 dossier applications for Food/Feed Use Certificates for corn, soybean, and cotton products have been submitted to MARD. Of the ten applications that have been approved by MARD, six certificates are for corn and four certificates are for soybean events.

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Product Development & Approval

Vietnam Ministry of Natural Resources and Environment (MONRE) issues Bio-Safety Certificates:

As of June 15, 2015 MONRE had issued Bio-Safety Certificates for four (4) GM corn events including single events and one stacked event. The single events contain a trait resistant to *glyphosate* or *Lepidopteran*. The stacked event contains traits resistant to both *glyphosate* and *Lepidopteran*. The list of GM traits granted a Bio-Safety Certificate is available at MONRE's website: http://antoansinhhoc.vn/Noi-dung-don/Danh-muc-GMO/2452502.

These events are approved by MONRE in accordance with Circular 8/2013/TT-BTNMT regarding the Procedure on issuing/revoking bio-certificate (see <u>VM3042</u>). As stated in MONRE's Circular 8/2013/TT-BTNMT, biotech developers are only eligible to submit Bio-Safety Certificate applications for GM events that are already approved by MARD for use as food and feed.

MARD issues Certificate on Approval of GM plants for Use as Food and Feed:

Since MARD's Circular 2/2014/TT-BNNPTNT promulgating the Regulation on the approval of GM plants for use as food and feed entered into force on March 10, 2014 (see <u>VM 4020</u>), MARD has issued Certificates for six (6) corn events and four (4) soybean events.

The list of GM events granted certification for use as food and feed is available on MARD's website: http://www.mard.gov.vn/Pages/news_detail.aspx?NewsId=37520&Page=1

- b) Commercial Production: The first ever genetically modified corn was planted in Vietnam in April 2015 shortly after MARD's Decision 69/QD-CT-CLT permitting its biotech developer to grow three GM corn varieties. It is reported that demonstration plots of the approved GM corn varieties were planted in various regions in Vietnam. The first harvest of these corn varieties was conducted at the end of June 2015. According to the biotech company, the approved GM corn varieties are growing well and demonstrating potential for higher yields.
- c) Exports: Vietnam does not export GE products.
- **d) Imports:** Vietnam is importing GM plant products including soybeans, soybean meal, soybean oil, corn, distillers dried grains, cotton, alfalfa, and canola. The majority of Vietnam's GM product imports are utilized as feed for the livestock and aquaculture sectors. Vietnam is increasingly dependent on imported GM feed ingredients to fuel these sectors' growth.

Vietnam's total import of soybean meal and soybean flour in MY 2014/15 is estimated to be 3.75 MMT up from 3.64 MMT MY 2013/14. Additionally, Vietnam is forecast to import 1.6 MMT of soybeans in MY 2014/15 up from 1.56 MMT the previous MY. Key suppliers of soybean meal and soybeans are mainly GM soybean growing countries, including: Argentina, Brazil, and the United States (for more

detail, see VM5019).

Vietnam's MY 2014/15 corn imports are estimated at 2 MMT. In addition to corn, in CY 2014, Vietnam imported about 600 TMT of DDGS for the animal and aquaculture industries. Much of Vietnam's corn imports and nearly 100 percent of Vietnam's DDG imports are GM (for more detail, see VM5025).

e) Food Aid Recipients: Vietnam is not a food aid recipient.

Part B: Policy

a) Regulatory Framework / b) Approvals:

*¹MARD'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 02/2014 regarding the Approval process of issuing and withdrawing Certification for GM plants for use as food and feed. Accordingly, the deadline for submission of food/feed approval dossiers for all biotech events was extended to March 10, 2016 from the previous deadline of March 10, 2015.

*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 as the host variety) containing gene transferred events that have been granted a Certificate of Biosafety and a Certificate for Food / Feed Use and meet the following conditions: 1) the GM crop variety has been compared with the host variety and undergone a risk assessment test; 2) the GM crop variety is similar to the host variety in term of key traits, except for those affected by the transgenic events.

- a) In cases where the GM variety has undergone a risk assessment to compare with the host variety, the owner of the risk assessed GM variety can submit dossiers applying for exceptional recognition as regulated in Article 5 of the Circular 23/2010.
- b) In cases where the GM variety has not undergone the Risk Assessment field trial, the owner of the GM variety shall develop and submit to CPD a plan for field trials to compare the GM

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¹ *Indicates update from last Biotechnology Annual Report.

variety with the host variety in accordance with Appendix 7 of Circular 23/2010. The field trials shall be conducted on a small scale and a 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 having a minimum area of 1 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 twenty (20) working days upon receipt of a valid dossier, CPD shall take the lead to coordinate with the Department of Science and Technology and Environment (DSTE) in reviewing the dossiers and submit a request to MARD to establish a Review Council. Members of the Review Council shall evaluate the Dossier in accordance with Article 9 of Circular 23/2010.

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

Circular 29/2014 in Vietnamese is available at:

 $\underline{\text{http://www.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class_id=1\&mode=detail\&document_id=175906}$

*MARD's Circular 23/2010/TT-BNNPTNT on 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 of agriculture and rural development sector. The Circular regulates the order, procedures on registration, and the recognition of biotechnological advances in the field of agriculture, forestry, and fishery that are under MARD's management.

<u>Article 4 of the Circular</u> regulates the criteria required for a biotechnological advance eligible for the registration. Accordingly, biotechnological advances that are developed in Vietnam or overseas can be registered for recognition. The biotechnological advances developed in foreign countries shall be only eligible for registration if it was already recognized as effective for use in foreign countries and is on the list of high technology and products of high technology encouraged for investment and use in Vietnam.

<u>Article 5 of the Circular</u> regulates the order and procedure on registration for the recognition of a biotechnological advance developed in Vietnam or a foreign country.

The dossier registering for the 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) Document on the 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 agroforestry, fishery products, and environment treatment of registering organization. For registration to recognize GM plants, GM animals, and GM 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.

The registering dossier (one original and ten copies) shall be sealed and submitted to DSTE by mail or directly.

The recognition, suspension and cancellation of the recognition are regulated in Chapter III. The recognition can be done via three methods: 1) Exceptional recognition as described in MARD's Circular 29; 2) Review by an independent technical team; or 3) Review by the Science and Technology Committee.

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

*Vietnam Ministry of Finance's (MOF) Circular 36/2014/TT-BTC promulgating the regulation on payment fee for Bio-Safety Certificate. On March 24, 2014 MOF issued Circular 36/2014 regarding the Regulation on Collection, Payment, Management and Use of Fee for Appraisal of Dossiers Applied for Bio-Certificate of GM Plants. The fee for each Appraisal is set at VND 70 million (\$3,300 at the exchange rate of 1\$ for VND 21,200 as of July 11, 2014). The Circular entered into force on May 15, 2014.

As stipulated by the Circular, 20 percent of the fees collected for the appraisal of each application will go to the Government budget, while the remaining 80 percent will be managed by the appraisal agency (MONRE) for expenses relating to reviewing dossiers.

Vietnam's Over-arching Bio-Safety Decree (see VM 2071)

On June 21, 2010, Vietnam's Prime Minister approved the Bio-Safety Decree 69/2010/ND-CP, replacing Vietnam's Bio-Safety Regulation approved in 2005, which was the first-ever biotech regulation in Vietnam (VM5062). The Bio-Safety Decree provides the legal framework for bio-safety management of genetically modified organisms (GMO), genetic specimens, and products derived from GMOs. This Decree does not regulate pharmaceutical products originating from GMOs. The Decree entered into force August 10, 2010. In order to bring Decree 69 in compliance with provisions on the management of food derived from agricultural biotechnology as regulated under the Vietnam Food Safety Law, in November 2011, Prime Minister Dung signed Decree 108 revising Decree 69 and changing the responsible Ministry for 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	Acts as lead government agency in Bio-	1. To issue Bio-Safety Certificate
Resources and	safety Management;	
Environment (MONRE)		2. To withdraw Bio-Safety Certificate
		3. To develop list of GM products granted Bio- Safety Certificate
		4. To develop regulation on storage, package and transportation of GMOs specified in the Article 1 of the Decree.
		5. To develop and manage database on GMOs
Ministry of Agriculture and Rural Development	To regulate field trial of GM crops. To approve GM products used for animal	1. To issue Permit for Field Trial of GM crops
ana Karai Developmeni (MARD)	feed and food (as a result of Decree 108)	2. To accredit MARD's agencies for conducting
	yeed and jood (as a result of Beeree 100)	field trial of GM crops
		3. To conduct Field Trial of GM crop
		4. To approve GM products used for food and
		animal feed; GM products that can be approved
		for use as food and animal feed
Ministry of Science and Technology (MOST)	MOST is the key government agency to	1. Accreditation of GM research labs
	manage research and development of GMOs	2. Management of GM projects
		3. To coordinate with relevant government
		8
		agencies on developing of labeling regulation
Ministry of Industry and		1. To coordinate with relevant ministries
Trade (MOIT)		including MARD to manage use of GM products
		as inputs in food processing industries.

Core GVN Regulations Governing Commercialization of Agricultural Biotechnology

MONRE Biosafety Certification Regulation

On May 16, 2013, the Ministry of Natural Resources and Environment (MONRE) published Circular 8/2013/TT-BTNMT, providing the procedure 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 detail).

MARD approves Food/Feed Use Certification Regulation

On January 24, 2014, the Ministry of Agriculture and Rural Development (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 (see VM 4020). The Circular provides the Approval Process of Issuing and Revoking the Certificate for Genetically Modified (GM) Plants to be Used as Food and Feed. The Circular entered into force on March 10, 2014.

MARD formed a Committee to review and evaluate the dossiers. The Committee consists of 11 experts and scientists representing various Ministries and related organizations, including MONRE, MARD, MOH, MOIT, the Vietnam Academy of Sciences, the Vietnam Academy of Agricultural Sciences, and Ho Chi Minh City's Biotechnology Center. For more details, please see *VM4020*.

Additional GVN Regulations Governing Aspects of Agricultural Biotechnology

MONRE Regulation on Supplying, Exchanging Information, and Databases on GMOs

On August 22, 2012, MONRE issued Circular 09/2012/TT-BTNMT on the Regulation of Providing and Exchanging Information, and Databases on GMOs. The Circular entered into force on October 8, 2012.

The full Circular in Vietnam can be downloaded from: http://antoansinhhoc.vn/upload/Thong%20tu%2009.2012.TT-BTNMT.pdf

The Circular is applied to government agencies, local individuals, organizations, foreign individuals, and organizations operating activities related to providing or exchanging information, and databases on GMOs (as defined in the regulation).

Information and databases on GMOs include: 1) bilateral or multilateral agreements on Biosafety of GMOs that Vietnam participates in or has already signed; 2) Current regulations on GMOs; 3) Results of research projects and programs on safety of GMOs kept by authorized agencies; 4) Bio-Safety 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 GMOs; Decisions on which facilities are allowed to conduct GMO field trials; Permit or Decision on Imports of GMOs that are not on the list of GMOs allowed for use as food /feed; 5) Reports as regulated in Appendix I, II, III, IX of Decree 69; and 6) Information on field trials of GMOs, GM crop growing areas, and the list of local/foreign consultants on biosafety - and modern biotechnology and other biotech related information or documents.

GMO databases are grouped into: National GMO database developed and managed by the Vietnam Environment Administration (VEA), MONRE; Sectorial GMO databases developed and managed by related ministries; Local GMO databases developed and managed by Provincial/City People's Committees.

MOST Regulation on Guidance to Certify Laboratories Qualified for GMO Research

On October 20, 2012, MOST issued Circular 20/2012/TT-BKHCN regarding the Regulation of the Procedure to Certify a Lab Allowed 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 GMO Research and Development

On November 20, 2012, the Ministry of Science and Technology (MOST) issued Circular 21/2012/TT-BKHCN regulating the Research and Development of Genetically Modified Organisms in Vietnam. The Circular applies to individuals and organizations conducting research and development of GMOs and genetic specimen activities within Vietnam.

Article 4, Chapter I of Circular 21 regulates the principles of biosafety management for research on GMOs and states that all GMO 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-doi-2013/2452962); Article 87 of the Environment Protection Law; Article 7 of Bio-Diversity Law (Luât số-20/2008/QH12-hongchuyen.com | 2452579); and Article 44 and 50 of the Vietnam Food Safety Law (http://antoansinhhoc.vn/Noi-dung/Luat-An-toan-thuc-pham-/2452601). Research on GMOs must be implemented within the framework of science and technology development (project or research topics) approved by relevant competent authorities. All research on GMOs 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. The Circular in Vietnamese can be downloaded from:

http://antoansinhhoc.vn/upload/TT21_2012_BKHCN.PDF.

c) Field Testing

MARD Regulation on Field Testing of GM Crops (see VM2071)

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 the criteria to evaluate entities and facilities that wish to conduct biotech field trials. Based on this those criteria, MARD has approved the following MARD institutes/agencies to conduct agricultural biotech field trials:

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

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

Although, Vietnamese regulations allow for field trials of these three biotech crops (corn, soybeans, and cotton), so far, biotech developers and MARD have only conducted field trials for corn varieties.

- d) Stacked Event Approvals: According to the Ministry of Natural Resources and Environment's (MONRE) Circular 8/2013/TT-BTNMT dated May 16, 2013, the stacked event varieties derived from Biotechnology are also permitted to be considered for a Bio-Safety Certificate. The procedure of issuing the Bio-Safety Certificate is described in detail in VM3042. Similarly, MARD Circular 2/TT-BNNPTNT dated January 24, 2014 (See VM4020), regulates procedures on issuance of Certification on Approval of GM plants allowed to use as food and feed for both single and stacked event plants derived from biotechnology. In both instances, MARD and MONRE will review each individual trait in the stack and will approve the stacked variety if the individual traits that make up the stack are approved in Vietnam.
- **f)** Coexistence: There is a small market for certified organic products in Vietnam. However, the market potential for organic products remains very limited due to the low average income level in Vietnam. Currently, there is no market for identity preserved food products.

g) Labeling

Labeling of GMOs and GM Products (as defined in Decree 69).

The Inter-Ministerial Circular on Labeling of GMOs and GM Products is going to be issued in the coming months by MARD and the Ministry of Science and Technology (MOST). According to different sources, the Inter-Ministerial Circular is already approved by MARD and now is waiting for approval from MOST. Post will continue to monitor the status of this Circular.

The draft of the Inter-Ministerial Circular on Labeling of GMOs and GM products was notified as G/TBT/N/VNM/51 on October 9, 2014. The U.S. Government provided comments on the Draft of the Circular in December 2014, and received a written response from Vietnam's TBT Office on January 19, 2015.

There remains a discrepancy in two Vietnamese legal documents regarding GMO labelling. The Food Safety Law requires labeling only "high risk" GM foods while the Bio Safety Decree requires labeling of all GMOs and products with GM content greater than 5 percent. In the Food Safety Law, the Vietnam National Assembly (NA) assigned MARD responsibility for taking the lead and coordinating with Ministry of Science and Technology (MOST) in providing detailed guidelines on the labeling of foods containing GMOs and GM products. While in the Bio Safety Decree, the Ministry of Science and Technology (MOST) is tasked to take the lead in developing guidance to implement the labeling provision.

- **h) Trade Barriers:** As of July 2015, there are no trade barriers in place affecting GE agricultural products.
- i) Intellectual Property Rights (IPR)

<u>Intellectual Property Law (IPL) 50/2005/QH11</u>: In principle, 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.

The Law consists of six parts and Part Four outlines the rights and protections for plant varieties. Part Four covers the process for obtaining and the rights of Plant Variety protection and consists of four chapters (Chapters XII to XV) as follows:

- 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

Section 2 of Chapter XIII provides details on the application forms and the process to obtain plant variety protection in Vietnam.

As stated in the Article 174, the application must include: a) a registration using the prescribed form; b) photo and technical questionnaires using the prescribed form; c) letter of authorization if the application form is 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 documents, the application will be examined by a state competent authority to see if it is qualified for further processing, requires additional information, or should be rejected.

Article 178 outlines the content examination criteria and includes: a) examination for novelty 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. The Technical Test will be done by a competent agency or institute assigned by MARD.

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. 88-2010-ND-CP.pdf

The fee for registration for Certificate for Plant Variety Protection is stipulated in the Ministry of Finance's (MOF) <u>Circular 92/2002/TT-BTC</u>, 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. MARD's 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 provide the list of plant species protected and designates 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 <u>Circular 16/2013/TT-BNNPTNT</u> which stipulates the Guidelines on 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.

j) Cartagena Protocol: Vietnam joins the Nagoya Protocol.

On March 17, 2014, Prime Minister Dung signed Resolution 17/NQ-CP regarding Vietnam joining the Nagoya Protocol, which covers access to genetic resources and equitable sharing and reasonable interests arising from the use of genetic resources within the Biodiversity Convention. Accordingly, MONRE is assigned to coordinate with relevant agencies to evaluate Vietnam's collaboration with foreign organizations and individuals regarding the access to genetic resources in Vietnam for the period of 2000-2013; and to develop a project on "Enhancing capacity on management of access to genetic resources and equitable sharing, reasonable benefits arising from the use of genetic resources", that was reported to the Prime Minister in the fourth quarter of 2014; as well as to develop a Decree on the "management of access to genetic resources and equitable sharing, reasonable benefits arising from the use of genetic resources" for submission to the Government in the third quarter of 2015. The Ministry of Foreign Affairs is assigned to complete all necessary diplomatic procedures in accordance with existing law and regulations.

So far, no details on how Vietnam plants to implement the Protocol have been released. Contacts report that instead of developing a separate Decree to implement the Nagoya Protocol, Vietnam may consider amending the Bio-Safety Decree 69/2010/ND-CP (VM2071) and add a section on Liability and Redress as recommended by some international consultants.

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 at the beginning stages of implementing the Cartagena Protocol, the Vietnamese Government actively tries to incorporate requirements and obligations of the Protocol into regulations on bio-safety management.

- **k) International Treaties/Fora:** Vietnam became a member of International Plant Protection Convention in 2005. Also, Vietnam became a member of Codex Alimentarius in 1989. The Vietnam Codex Office is under management of the Vietnam Food Administration, Ministry of Health: http://codexvn.org.
- **I) Monitoring and Testing:** As of June 2015, 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.
- **m)** Low Level Presence: As of June 2015, Vietnam does not have a policy for Low Level Presence (LLP). However, Vietnam frequently participates as an observer at Global Low Level Presence Initiative meetings.

PART C: MARKETING

a) Marketing Acceptance / b) Public/Private Opinion:

In the period of July 2014 to June 2015, anti-biotech campaigns remained active in Vietnam. A number of unscientific articles were published on different media criticizing the technology. Despite an active anti-biotech campaign, the Vietnamese government actively recognizes the importance of GE crops in the agricultural and manufacturing economy in Vietnam. The Minister of MARD has publicly expressed support for the cultivation of GE agriculture in Vietnam. The livestock, fishery, and textile / garment industries depend heavily on imported materials including soybean, soybean meal, corn, and cotton of which the majority is derived from agricultural biotechnology, and the GVN, led by MARD, clearly understands that necessity. The level of anti-biotech activity following Vietnam's issuance of the first Bio-Safety and Feed / Food Use Certificates followed by commercialization of a few corn events was localized within a few NGOs and could be characterized as soft.

PART D: CAPACITY BUILDING AND OUTREACH

Activities: During July 2014-June 2015, FAS/Vietnam and the U.S. State Department continued to work with Vietnamese agencies to support the development of the biotech regulatory framework and biotech acceptance. The following were some of the key activities in that effort:

<u>June 8-12, 2015</u>: Three senior officers from MARD and MONRE attended the APEC High Level Policy Dialogue on Biotechnology themed on the topic of "Fostering the Benefits of Innovation in Plant Breeding and Science Communication" held in the Philippines from June 8-12, 2015. USDA provided funds for their attendance.

May 30-June 4, 2015: Under funding from the USDA, a technical team member of the Ministry of Natural Resources and Environment's (MONRE) Bio-Safety Committee was invited to attend Biotechnology Literacy Project Boot camp 2015 held at the University of California – Davis from May 30 – June 4, 2015.

<u>September 14-15, 2014</u>: USDA sponsored travel of the chairman of MARD's committee on approval of GM plants for use as food/feed to attend the Asia-Pacific Economic Cooperation Workshop on Plant Biotechnology Life Cycle that was held in Beijing, China from September 14-15, 2014.

August 11-22, 2014: Under funding from the USDA, three officers representing MARD and the Agricultural Economic Department of Vietnam's National Central Committee attended the training course on Biotechnology Regulation Immersion Course 2014 conducted at the University of Missouri (MU), Columbia, USA from August 11-22, 2014.

<u>August 18-19, 2014</u>: Under funding from the State Department, two outreach workshops titled: "Vietnam Biotech: Growing the Future" were conducted in Can Tho University on August 18 and in Ho Chi Minh City on August 19, 2014, respectively. FAS/Hanoi staff co-organized and participated.

June 21 and June 23, 2014: Under funding from USDA, in collaboration with the Vietnam Academy of Agricultural Sciences (VAAS), the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) organized two Symposia on Agricultural Biotechnology and its Benefits for Vietnam" in Hanoi on June 21 and June 23, 2014. Participants attending the June 21st Symposium were members from Committee of Science, Technology and Environment of the Vietnam National Assembly, while attendees of the Symposium conducted on June 23rd were senior officials from key corn growing provinces in Vietnam.

<u>June 8-14, 2014</u>: Four senior officers from MARD, MOIT, MOH and MONRE attended the international training on agricultural biotechnology in Bogor Agricultural University in Indonesia. The training was organized and conducted by Michigan State University in partnership with USDA and ISAAA.

<u>September 23-24, 2013</u>: Two workshops under the theme "Growing the Future" were held in Hanoi using funding from the State Department. The workshop's participants ranged from senior government regulatory officers and scientists to journalists and students. Significant favorable media coverage was generated.

<u>August 12-23, 2013</u>: Under funding from the U.S. Soybean Export Council, FAS-Vietnam helped to recruit four participants; including two lecturers from Hanoi Agricultural University, one official from the Vietnam Women's Union, and one participant from the Ministry of Industry and Trade to attend a short course titled, "2013 Agricultural Biotechnology Regulation Immersion Course" at the University of Missouri in Columbia, Missouri.

<u>August 4-17, 2013</u>: Under USDA's Cochran Fellowship Program, eight Vietnamese government extension officers representing the National Agricultural Extension Center (NAEC) of MARD and Agricultural Extension Centers of some provinces attended training titled, "How to Educate Farmers about Biotech Crops" in Missouri and Iowa.

<u>July 6-20, 2013</u>: Under USDA's Cochran Fellowship Program, nine Vietnamese journalists working for different agricultural newspapers participated in a short course titled, "Training Journalists on Benefits

Biotechnology" in Tennessee, Missouri, and Iowa.

May 9-14, 2013: In coordination with FAS/Vietnam, the International Food Information Council Foundation (IFIC) conducted a series of Risk Communication Workshops on Agricultural Biotechnology in Hanoi and Ho Chi Minh City, respectively. Participants included regulatory officers and researchers from agricultural institutes and universities. A half-day workshop, titled "Media Workshop on Food Science" was also organized in Hanoi and in HCMC. Targeted participants for these workshops were journalists.

<u>February 15- April 12, 2013</u>: Under USDA's Borlaug Fellowship Program, the Deputy Head of the Department of Molecular Biotechnology Institute of Biotechnology at Can Tho University was selected for a fellowship focused on the "Identification of genetically engineered in foods." He was trained on Rice Breeding and Pathology at the USDA-ARS Dale Bumpers National Rice Research Center (Stuttgart, Arkansas), and on Genetically Modified Plant Identification and Regulation at Monsanto in St. Louis, Missouri.

<u>September 26-29, 2012</u>: FAS-Vietnam received a FAS Emerging Markets Program (EMP) Grant, funding an international expert to visit Vietnam to work with MONRE on the Draft Circular on the procedure to issue the Bio-Safety Certificate.

<u>September 16-20, 2012</u>: FAS-Vietnam provided funding for international airfares to a representative from MARD and a representative from MONRE to attend the 12th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO 12) hosted by the International Society for Biosafety Research in St. Louis, Missouri.

<u>August 6-9, 2012</u>: Under funding from State Department and FAS/Hanoi, a series of workshops on Biotech: Growing in Future were held at Can Tho University and Ho Chi Minh City.

April 7-14, 2012: Ten Vietnamese government officials representing MARD, MONRE, and Ministry of Industry and Trade (MOIT) attended a State Department sponsored Volunteer Visitor's Program focused on supporting agricultural biotechnology through science-based regulation that was conducted in Washington, D.C. and Missouri.

Strategies and Needs: Vietnamese regulatory Ministries are focused on building the capacity of the individuals on the technical review committees who are evaluating the Food / Feed Certificate and Bio-Safety Certificate Dossiers. Additionally, focus has been placed on conducting outreach to producers and consumers of products derived from agricultural biotechnology to highlight the benefits of the biotechnology.

Chapter 2: Animal Biotechnology

PART E: PRODUCTION AND TRADE

a) Product Development: As of July 2015, GVN and MARD do not have legal regulations in place

governing the research and development or regulatory approval process for animal biotechnology applications. However, there is some research on gene technology for improving animal productivity, animal disease treatment, and production of vaccine for animals utilizing biotechnology.

- **b)** Commercial Production: As there are no regulations in place to govern animal biotechnology, there is no commercial production in Vietnam.
- c) Exports: None.
- d) Imports: None.

PART F: POLICY

- a) Regulation: No regulations cover animal biotechnology.
- b) Labeling and Traceability: None.
- c) Trade Barriers: None.
- d) Intellectual Property Rights (IPR): None.
- e) International Treaties/Fora: None.

PART G: MARKETING

- a) Market Acceptance: Not applicable.
- b) Public/Private Opinions: None at this time.
- c) Market Studies: None.

PART H: CAPACITY BUILDING AND OUTREACH

- a) Activities: None to date.
- b) Strategies and Needs: None at this time.