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Report Highlights:
2013 will be a critically important year for the development of Vietnam's regulatory structure for biotechnology. Over the course of the next 12 months, components of The Bio Safety Decree (Decree 69) and the Food Safety Law, the two primary legal documents under Government of Vietnam (GVN) development that will regulate agriculture biotechnology (biotech) production, processing, and commercialization; govern the import of biotech products; and establish labeling requirements for food and agricultural products with biotech content will be finalized and implemented.

SECTION I: EXECUTIVE SUMMARY

2013 will be a critically important year for the development of Vietnam's regulatory structure for biotechnology. Over the course of the next 12 months, components of The Bio Safety Decree (Decree 69) and the Food Safety Law, the two primary legal documents under Government of Vietnam (GVN) development that will regulate agriculture biotechnology (biotech) production, processing, and commercialization; govern the import of biotech products; and establish labeling requirements for food and agricultural products with biotech content will be finalized and implemented.

This report outlines the responsibilities of relevant Vietnamese government agencies in the management of bio-safety and provides a status update on where each responsible government agency is in drafting the required governing regulations.

Decree 69, which was approved in June 2010 and entered into force in August 2010, provides the legal frameworks regarding risk assessment, research, field trial, commercialization and trade of Genetically Modified Organisms (GMOs). Three of its principal regulatory components—including a biosafety certificate (Circular on Procedure on Issuance and Withdraw of Bio-Safety Certificate for Genetically Modified Organisms; BSC), which is the governing certification for biotech events to be cultivated in Vietnam; a biotech feed approval certificate, and a biotech food approval certificate—are in the final stages of drafting, and will be implemented in 2013.

While the Ministry of Natural Resources and the Environment (MONRE) has overarching responsibility for Decree 69, the draft BSC is being developed by a committee comprised of GVN officials from MONRE, the Ministry of Agriculture and Rural Development (MARD), and the Ministry of Science and Technology (MOST).

On December 11, 2012, MARD's draft Circular on Approval of Genetically Modified Plants for Direct Use as Feed was officially notified to the WTO/SPS (G/SPS/VNM 38). The deadline for comments is February 9, 2013.

MARD indicated that the circular for certification for human food use would likely be released in 2013. According to MARD, the draft Circular for food use will be notified to the World Trade Organization as well.

SECTION II: PLANT BIOTECHNOLOGY TRADE AND PRODUCTION

Production of GM crops and trade in GM seeds are still not yet allowed in Vietnam as commercialization of a GM crop is not yet approved. MARD expects to release GM crops for cultivation in 2015, after issuance of Guidelines on Food/Feed Approval and Bio-Safety Certificate in 2013.

MARD, under the authority of Circulars 69 and 72 (see page 5), issued the first permission for conducting confined field trials of Bt corn to two companies in March 2010. Based on MARD's permission, in May 2010, the first ever field trials of Bt corn were launched in two locations, one in the North and one in the South. Later, in August 2010, a third company was granted permission for conducting confined field trials of Bt corn. All confined field trials of Bt corn were successfully completed in late 2010. MARD subsequently granted permission allowing the same three biotech companies to conduct multi-location field trials for the same Bt corn varieties initially approved by

MARD for confined field trials. All multi-location field trials of Bt corn were completed in late 2011. MARD is currently reviewing results from the multi-location field trials of GM corn.

On November 16, 2012, MARD issued another permit to a company to conduct a confined field trial for an additional biotech corn variety.

SECTION III: PLANT BIOTECHNOLOGY POLICY

Vietnam's Over-arching Bio-Safety Decree Approved

On June 21, 2010, Vietnam's Prime Minister approved Vietnam Bio-safety Decree 69/2010/ND-CP, replacing Vietnam's first ever Bio Safety Regulation approved in 2005 (VM5062). The new Bio-Safety provides legal frameworks for bio-safety management of genetically modified (GM) organisms, genetic specimen, 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 make it in compliance with provision of GM food management regulated in Vietnam Food Safety Law, on November 2011 Prime Minister Dung signed Decree 108, revising Decree 69, and changing the responsible Ministry for food certification from MOH to MARD. This bureaucratically resolved a problem created when Vietnam's Food Safety Law and Decree 69 granted the authority to regulate biotech agriculture food use certification. Food use certification authority now rests with MARD.

The Decree consists of nine chapters and five appendices.

Chapter I : General Provisions
Chapter II : Risk Assessment and Management of GMOs
Chapter III : Scientific Research and Technology Development of GMOs
Chapter IV : Trial of GMOs
Chapter V : Bio-Safety Certificate
Chapter VI : Approval of GMOs to Use as Food, Feed
Chapter VII : Production, Trade, Import, Export, Transportation, Storage of GMs and GM products
Chapter VIII : Information on GMOs and GM Products
Chapter IX : Implementation Provisions.

Appendix 1 : Required Information for Transportation, Transit; and Imports of GMOs
Appendix 2 : Application for Field Trial of GMOs
Appendix 3 : Field Trial Planning
Appendix 4 : Required Information for Risk Assessment Reports of GMOs to Environment and Biodiversity
Appendix 5 : Required Information for Risk Assessment Reports of GMOs to Human Health

Table 2: responsibilities of Vietnam's relevant government agencies in Management of Bio-Safety as described in Decree 69/2010/ND-CP

Government Agency	Role	Responsibilities
Ministry of Natural	- Acts as leading	1)- To issue **Bio-Safety Certificate** based on the following conditions:

Resources and Environment (MONRE)	government agency in Bio-safety Management;	- Request from Applicants - Results of field trial approved by Ministry of Agricultural and Rural Development (MARD) - To publish Applicant's information for public comments (for 30 days). - It takes 180 days from the date of receiving applications for processing-issuing of Bio-Safety Certificate 2- To withdraw Bio-Safety Certificate based on following conditions: • There is scientific evidence showing that it's not safe • Applicant provides misinformation • There is evidence that the decision of Bio-Safety Committee is not science based. 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 Agricultural and Rural Development (MARD)	To regulate field trial of GM crops. To approve GM products used for animal feed **NOTE: Decree 108/211 moved Food Certification Authority to MARD**	1. To issue **Permit for Field Trial** of GM crops 2. To accrediate MARD's agencies for conducting field trial of GM crops 3. To conduct Field Trial of GM crop 4. To approve GM products used for animal feed: GM products, that can be approved for use as animal feed, must meet the following conditions: a) application must be approved by Bio-Safety committee for animal feed that GM products does impose any harm to the environment; b) the GM products are approved for animal feed in at least five developed countries. In the case the GM product is already approved for food, it should be used for feed.
Formally: Ministry of Health (MOH) **now MARD** **NOTE: Decree 108/211 moved Food Certification Authority to MARD**	To approve GM products to use as food	1. To issue **Certificate for GM products used for food**. The GM product can be used as food only when: a) it is certified by Bio-safety Committee for Food to approve that meet requirement for being used as food; b) It is approved for food use in at least five developed countries. Registration dossier for GM product used as food including: Application; Report on Risk Assessment of GM products to human health in accordance with form stated in Appendix 5; and for GM products regulated in Item 2; Article 27 of the Decree must be approved for food use in at least 5 developed countries.
Ministry of Science and Technology (MOST)	MOST is key government agency to manage research and technology development of GMOs	1. Accrediation of GMOs researching labs; 2. Management of GMOs projects. 3. To coordinate with relevant government agencies on developing of labeling regulation
Ministry of Industry and Trade		To coordinate with relevant ministries including MARD to manage use of GM products as inputs in food processing industries

Although the Bio-Safety Decree 69/2010/ND-CP entered into force on August 10, 2010, regulations outlining the certification process for cultivation, feed, and food use have yet to be published. Therefore, the responsibilities, approval process, and conditions outlined above may be different from the responsibilities, approval process, and conditions outlined in each forthcoming MONRE and MARD Circular.

MOST Regulations on Laboratory Certification and Biosafety Management of Research and Development

In late August 2012, MOST published two draft regulations for comment: a guideline on Conditions and Procedures on Recognition of Laboratory for Research on GMOs and a circular on Biosafety Management of Research and Development of GMOs and GMO products. These two drafts can be found at: http://www.most.gov.vn.

MARD Regulation on Field Testing Of GM Crops

On October 27, 2009 MARD issued Circular 69/2009/TT-BNNPTNT to promulgate Regulation on Risk Assessment of GM Crops to Environment and Biodiversity providing the legal frame for conducting field trial of GM crops before releasing to commercial production. The Circular covers both confined and multi-location field trials.

The Circular consists of four chapters and six appendices:

Chapter I : General Provisions
Chapter II : Conducting Field Trial
Chapter III : Risk Management during Field Trial
Chapter IV : Implementation

Appendix 1 : Application for Field Testing
Appendix 2 : Registration Form for Field Testing
Appendix 3 : Plan for Confined Field Testing
Appendix 4 : Report of Confined Field Testing
Appendix 5 : Report of Multi Location Field testing
Appendix 6 : Form to Record Field Testing Result.

Each entity that wants to conduct field testing must meet requirements set in Chapter II of the Circular 69/2009/TT-BNNPTNT: "Acquiring sufficient facilities and techniques, and professional personnel appropriate for risk assessment of specific GM crops. Setting up methods applying risk supervision; and management methods for biosafety during trial period". Based on required criteria, MARD had approved the following institutes/agencies being eligible to conduct field trials:

- Agricultural Genetics Institute, and Plant Protection Institute, Vietnam Academy for Agriculture Science (VAAS)
- Northern and Southern New Seed Testing Centers, Crop Production Department
- Nha Ho Cotton Research Institute.

MARD also regulates which GM crops are allowed for field trials through MARD's Circular 72/2009/TT-BNNPTNT dated November 17, 2009. Accordingly, three GM crops, namely: Corn (*Zea may L.*), Cotton (*Gossypium spp.),* and Soybean [(*Glycline max* (L.) Merrill] are permitted to be field tested in Vietnam.

MONRE Development of Biosafety Certification Regulation

MONRE is developing Circular on Procedure of Granting, Revocation of the Biosafety Certificate for GMOs. The draft Circular is published on MONRE's website: http://www.monre.gov.vn/v35/default.aspx?tabid=671&CateID=126 for public comments. Although deadline for comments is not available, according to MONRE, MONRE planned to have it finalized by the end of 2012. The Final Circular will likely be published in the first three months of 2013. Un-official translation of the Final Circular will be available in a separate voluntary report once it is published.

MONRE's Circular regulates procedure to issue or revoke the Biosafety Certificate to an organization/individual that has performed the GMO trials in Vietnam, with MARD approval of the trial results.

The Draft Circular consists of four chapters, 22 articles, and 7 appendices as below:

Chapter I: General Regulation
Chapter II: Granting and Revoking Biosafety Certificate
(Note: According to Article 5, Chapter II, the submission dossiers for granting biosafety Certificate shall include: (1): One Application form (as required in Appendix 1); (2): Ten reports of trials approved by MARD; (3) Ten (reports of Risk Assessment of GMO to environment and biodiversity (as required in Appendix 3); and (4): One electric summary document of Risk Assessment report (as required in Appendix 4). Regarding revoking Biosafety Certificate, Item 1, Article 9 of this Chapter says: (a) there is new scientific proof of the risks of GMO; (b): Organization or individuals intentionally provide untruthful information which is decisive to the grant of the Biosafety Certificate; (d) There is a proof that the Biosafety Committee's conclusions lack of scientific grounds)
Chapter III: Organization and Operation of Permanent Biosafety Committee Authority; Biosafety Committee and Technical Advise Board.
Chapter IV: Operated Organization

Appendix 1: Application for granting Biosafety Certificate
Appendix 2: MONRE's form acknowledging to get dossiers validity for granting biosafety certificate
Appendix 3: Risk Assessment Report of GMOs to Environment and Biodiversity
Appendix 4: Summary of Risk Assessment report of GMOs to environment and biodiversity
Appendix5: Technical Expert's Board Evaluation Form
Appendix 6: Member of Biosafety Committee's Evaluation form of submission dossier for granting Biosafety Certificate
Appendix 7: BIOSAFETY CERTIFICATE

UPDATE: On November 30, 2011, Vietnamese Prime Minister Nguyen Tan Dung signed the Decree No.108/2011/ND-CP to revise some articles of the Decree 69/2010/ND-CP (the Bio-Safety Decree). Specifically, Decree 108 removes the Ministry of Health (MOH) as the certifying authority for biotech events for human consumption and replaces MOH with the Ministry of Agriculture and Rural Development (MARD). MARD is now responsible for drafting regulations governing both feed and food safety certification. While removing an additional ministry in the regulatory approval process likely reduced the burden placed on companies seeking biotech approvals; food and feed certifications remain two different certifications, a point of contention for the U.S. Government and biotech industry.

MARD Development of Feed Certification Regulation
On December 11, 2012, MARD's draft Circular on Approval Process of Genetically Modified Plants For Direct Use as Feed was officially notified to the WTO/SPS (G/SPS/VNM 38). The deadline for comment is February 9, 2013. This Circular will tentatively enter into force in April 2013.

MARD Development of Food Use Certification Regulation
MARD has not yet released the draft regulation for food certification. FAS-Hanoi has learned that MARD intends to publish the Food Use Certification Approval Regulation during 2013.

Labeling of GMOs and GM Products

Currently, both the Food Safety Law and Bio-Safety Decree have imposed labeling requirements for GMOs, GM food, and GM products. However, the provisions of labeling of GM products in the Food Safety Law and the Bio Safety Decree are not consistent. The Food Safety Law requires labeling only "high risk" GM food, while the Bio Safety Decree requires labeling all GMOs and products with GM content greater than 5 percent. The two laws also lay out two different agencies to manage labeling requirements. In the Food Safety Law, the Vietnam National Assembly (NA) assigned MARD responsibility for taking 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 taking lead in developing guidance to implement the labeling provision. To date, no legal documents guiding how to implement the labeling provisions regulated in the Food Safety Law and the Bio-Safety Decree are available.

The following table provides more details on different requirements of labeling of GMOs, GM products in the Food Safety Law and the Bio Safety Law.

	Vietnam Food Safety Law	**Bio Safety Decree 69/2010/ND-CP**
Approved date	June 17, 2010	June 21, 2010
Enforce date	July 1, 2011	August 10, 2010
Labeling requirement	Several GM foods that might be harmful to human health.	All GMOs and GM products with content of 5%, or more.
Implementing agency	Vietnam Government is assigned to develop list of high risk GM food for mandatory labeling. (MARD-lead)	Ministry of Science and Technology (MOST) is working with relevant ministries to develop guideline on labeling of GMOs, GM products.

Vietnam became a member of the Cartagena Protocol in April 2004. Vietnam Environment Administration (VEA) of MONRE is the Cartagena Protocol Focal Point of Vietnam. Although Vietnam is still in the learning stages of implementing of Cartagena Protocol, the Vietnamese government is actively incorporating requirements and obligations of the Protocol into regulations on Bio-Safety management. Vietnam regularly participates in the Cartagena Protocol Meeting of Parties.

SECTION IV: MARKETING ISSUES

Anti-biotech campaigns are increasing in Vietnam. In addition to the circulation of non-science based anti-biotech articles in a number of Vietnam websites and media, anti-biotech workshops and conferences have been held by Vietnamese or international NGOs in recent years. To date, these activities have not stopped the Vietnamese Government's strategy on biotechnology development, nor the development of Vietnam's regulatory framework to commercialize agricultural biotechnology.

It should be noted that Vietnam imports a large, and growing amount of GM products including soybeans, soybean meal, corn, distiller's dried grains (DDGs) to meet the rapidly growing demand in the animal feed sector. In 2011, Vietnam imported about 3.0 million metric tons (mmt) of soybean meal from different countries including key GM soybean growing countries namely Argentina, United States, and Brazil. Argentina was the biggest soybean meal supplier to Vietnam with total market share of 44.3%. The United States was the fourth largest soybean meal exporter to Vietnam with the export of 70 tmt or accounting for 2.33% of the market share (VM2018). Additionally, the United States supplied about 500,000 mt of DDGs to Vietnam in 2011. Virtually, all of the protein feed imported from Argentina, Brazil, and the United States (Vietnam's three largest suppliers of protein feed) is derived

from biotech agriculture.

SECTION V: CAPACITY BUILDING AND OUTREACH

During 2012, FAS/Vietnam and U.S. State Department continued to work with relevant Vietnamese agencies including MONRE, MOIT, MOH, MOST to support the development of pro-biotech regulations.

September 26-29, 2012, providing funding for an international expert to work with MONRE on the Draft Circular of Bio-safety Certificate.

September 16-20, 2012, provided funding for representatives from MARD and 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

August 17-September 2, 2012: under USDA's Cochran Fellowship Program, eight Vietnamese senior government officers representing MARD, MOH and MOST attended a training on approving GMOs for use as food or feed in Missouri, and the Washington, D.C.

August 6-9, 2012, 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 State Department's visitor program focused on SUPPORTING AGRICULTURAL BIOTECHNOLOGY THROUGH SCIENCE-BASED REGULATION that was conducted in the Washington, D.C. and Missouri.

August 16-17, 2011 under FAS funding, the Biotech- Safety Program organized a workshop on Net Mapping in Hanoi.

September 29 – October 1, 2010, funding from State Department, in coordination with Ho Chi Minh City Biotechnology and Crop Production Department, MARD, Economic Section – U.S. Embassy in Hanoi organized workshop on "Biotechnology III: Growing in Future."

September 7-8, 2010, utilizing funding from USDA and in coordination with MONRE, the International Service for Acquisition of Agribiotech Application (ISAAA) organized the Asia Regional Workshop on the Cartagena Protocol on Biosafety in Hanoi Vietnam. Participants from 13 countries from Asian countries and observers from the United States, Canada, Croplife Asia attended the workshop to discuss several provisions of Cartagena Protocol that would be addressed in the MOP5 held in Japan from October 11-15, 2010.

July 28-August 4, 2010, FAS/Vietnam and the New Technologies and Production Methods Division, Office of Science and Technical Affairs (FAS) supported a delegation from Ministry of Industry and Trade (MOIT) on a study tour of the U.S. The delegation met with U.S. biotech regulatory agencies including FDA, EPA and USDA to learn experience on regulatory policies on management of micro-organisms and other biological products. The delegation also visited universities and related industries to find opportunities for collaboration in this field.

June 15-19, 2010, a representative from Biodiversity Conservation Agency, VEA, MONRE attended a workshop of the Group of the Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Bio-Safety in Kuala Lumpur, Malaysia.

June 11-13, 2010, FAS/Vietnam provided funding for a representative from the Center for Science in the Public Interest to speak at s Liability & Redress workshop organized by MONRE in Hanoi.

May 27-30, 2010, under funding from USDA and USAID, three participants from Vietnam attended APEC High Level Policy Dialogue from May 29-30 and APEC Low Level Presence (LLP) Workshop from May 27-27, 2010, in Japan.

April 4-11, 2010, with financial support from USDA and State Department, a Biotechnology study tour to the U.S. was organized for 10 representatives from the Science, Technology and Environment Committee of Vietnam National Assembly. Due to the trip, the Committee was able to provide the NA's members with useful biotechnology information that made significant changes of proposed requirements on labeling GM food regulated in Vietnam Food Law.

March 23, 2010, under funding from USAID and Program for Bio Safety (PBS), MARD and MOIT organized a half day workshop on LLP in Hanoi, Vietnam.

December 3-5, 2009, USDA provided funding for a participant from Vietnam attend APEC High Level Policy Dialogue's Steering Committee meeting in Japan.

July 13-14, 2009, under funding from USDA, two VN government officials attended the APEC Workshop on LLP in Singapore.

June 17-28, 2009, FAS/Vietnam in coordination with the New Technology and Production Methods Division, Office of Science and Technical Affairs, FAS arranged a tour for a delegation from MONRE to study biotechnology management in the United States.

May 28-39, 2009, under funding from the FAS, Emerging Markets Proposal-Technical Issues Resolution Fund, a workshop on " Biotech Labeling: Considerations and Impacts" was held in Ho Chi Minh City with attendance of more than 80 participants from Vietnam Bio-Safety Decree drafting team, representatives from industries including food/animal feed traders and biotech researchers. The workshop's participants were provided with lessons on labeling of biotech products from EU, Australia, India and the United States. The latest version of the draft of Vietnamese Bio-safety Decree was also presented in the workshop and got a lot of comments from participants.