



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report - public distribution

Date: 7/20/2007

GAIN Report Number: VM7048

Vietnam

Biotechnology

Update

2007

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Report Highlights: Although Vietnam approved the biosafety regulations for management of genetically modified organisms and their products two years ago, these regulations are still not yet in force, due to slow progress on the implementing guidelines. The Ministry of Agriculture and Rural Development (MARD) expects to have its guidelines for risk assessment and field trials approved soon. Regulations for commercial production and trade of biotech crops and products are still a long way off, however. Several new regulations or Plans call for labeling, testing and registration of biotech products; if enforced, such measures could prove disruptive to Vietnam's huge imports of biotech products.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Hanoi [VM1]
[VM]

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Section I: Biotechnology Trade and Production

Vietnam remains keen to produce genetically modified (GM) crops, particularly soybean, corn and cotton, so as to reduce the dependency on imports of these vital commodities. However, now more than 2 years after the government decree providing the legal framework for research, production and trade of GM products (see VM5062) was ratified, the implementing regulations have yet to be approved. Thus, field trials or commercial production of GM (or Bt) crops are still not allowed in Vietnam. The Ministry of Agriculture and Rural Development (MARD) has drafted bio-safety regulations for field trials of biotech crops, but they remain to be approved. The Vietnam Food Administration (VFA) must also prepare regulations or work with MARD on regulations that will provide the guidelines for commercial production and trade of biotech crops and products containing genetically modified organisms (GMO).

Notwithstanding the lack of regulations, reports are that Bt cotton is being produced in the Tay Nguyen Central Highlands, the main cotton region of Vietnam. A survey conducted by one of MARD's research institutes found that farmers in the Tay Nguyen Central Highlands have been commercially growing biotech (Bt) cotton. The report did not, however, reveal how farmers obtained the Bt cottonseeds, which are not legally available for sale in Vietnam. (refer to cotton report VM7035)

Vietnam currently imports large quantities of biotech agricultural commodities as raw material for its burgeoning industries. In 2006, Vietnam imported around 190 thousand metric tons of cotton lint from around the world. The United States and India, two major producers of Bt cotton, supplied more than 38% of this amount. Similarly, Vietnam's animal feed industry relies heavily on imports of feed ingredients, including soybean meal and corn. According to Post's estimates, Vietnam's 2006 soybean meal import set a record at more than 1.5 million metric tons (see VM7002). Argentina and the United States, two major users of biotech varieties, were key suppliers of Vietnam's soybean meal imports. Vietnam also imported about 660 thousand metric tons of corn from several countries, including Thailand, Argentina and China, in 2006 (see VM7021).

While currently Vietnam does not restrict the import of biotech products, the new biotech decree outlines requirements for import permits and labeling that could prove disruptive to trade. Further, in the newly approved National Action Plan on the Implementation of the Convention on Bio-diversity and the Cartagena Protocol (see policy section below), Vietnam's plan to label and conduct risk assessments of all GM organisms and products might hamper, if not outrightly disrupt trade of GM products in Vietnam. Post will continue to follow this issue.

Section II: Biotechnology Policy

Vietnam ratified the "National Action Plan on Biological Diversity to 2010 and the Strategy for implementation of the Convention on Biological Diversity and the Cartagena Protocol on Biodiversity to 2020"

On May 31, 2007, Prime Minister Nguyen Tan Dung signed Decree No. 79/2007/QĐ-TTg to promulgate the National Action Plan for implementation of the Convention on Bio-Diversity and the Cartagena Protocol, with targets for 2010 and 2020. The Action Plan covers all aspects of biological diversity including management of genetically modified organisms (GMO) and GM products. Under the Plan, Vietnam's targets set for 2010 include conducting risk assessments, labeling, and monitoring and inspecting of all GM organisms and products marketed in Vietnam. It is doubtful these objectives can be met within the prescribed timeframe, particularly given the pace of progress on the regulations for commercialization.

Moreover, these proposed activities assume a capacity of trained personnel and research facilities, which are still lacking in Vietnam. Strict implementation of the Plan would, in fact, seriously impact the animal feed and livestock industries, not to mention the fishery and textile industries, two major export income earners for Vietnam.

Also outlined in the Action Plan are a number of objectives to be enacted by 2020. With regard to the management of GMOs and GM products, Vietnam aims to strengthen the regulatory framework to ensure the safety of human health and the environment, with care taken to maintain biological diversity. Appropriate regulations to address the management of GMOs and GM products will be created. Vietnam will also invest in getting the most up-to-date information and research methods in order to manage GM organisms and GM products safely. Laboratory facilities will be upgraded or modernized and new scientific facilities will also be constructed to conduct risk assessment on GMO products. A database relevant to the management of biodiversity and biosafety is also included in the targets set for 2020.

The Ministry of Environment and Natural Resources (MONRE) has been assigned the lead for the implementation of the Plan. However, several other ministries, namely the Ministry of Agriculture and Rural Development (MARD), Ministry of Fishery, Ministry of Science and Technology, Ministry of Education and Training, Ministry of Culture and Information, Ministry of Trade, Ministry of Finance, Ministry of Planning and Investment, and others, will participate in the implementation of the Plan, according to their area of responsibility. While, in theory, the Plan became effective on July 7, 2007, each ministry or agency is required to create implementing guidelines for the area of the Plan under their authority before it can be put in practice. No Ministry has yet completed implementing regulations for this Plan.

Post will provide a report with the Action Plan as soon as the English version becomes available.

Vietnam's Biosafety regulation approved

Decree 212/2005/QĐ-TTg, ratified in 2005, is a testament to the Vietnamese government's strong commitment to implementing the Cartagena Protocol on biosafety that it signed in 2004. Responsibilities of each ministry and agency are clearly identified in the Decree. The Ministry of Natural Resources and Environment is assigned to coordinate regulations between the various government entities involved. The Ministry of Science and Technology is responsible for management of research on GMOs. Food safety is the concern of the Ministry of Health. The Ministry of Agriculture and Rural Development (MARD) is responsible for managing field-testing and production of biotech crops (see VM 5062).

Ministry of Agriculture and Rural Development (MARD) will likely approve Regulation for Risk Assessment Trials of Genetically Modified crops soon.

As soon as the Biosafety regulation was approved in 2005, MARD began working on its regulations for risk assessment and field trials of biotech crops. The primary aims of the regulations are to provide the legal framework for field-testing of GMOs and to certify the biosafety of GMOs being released for commercial production. According to the latest draft, MARD's biotech regulations have the following structure:

- Chapter 1: General Provision
- Chapter 2: Field Testing
- Chapter 3: Evaluation of Field Test Results and granting bio-safety certificates
- Chapter 4: Production, trade, import/export and management of GM crops
- Chapter 5: Government Management of Biosafety of GM crops
- Chapter 6: Executive Provision

These regulations apply to both imported GM varieties and GM varieties developed in Vietnam. Field-testing procedures for imported Bt varieties can be described as follows:

The company or agency wishing to import Bt varieties to Vietnam will submit an application for field-testing to the Department of Science and Technology at MARD (MARD/DST). After a favorable review of the application, DST will grant the applicant a permit for testing. The applicant must then work with a research agency, accredited by MARD, to conduct the field trial(s). At the end of the allowed trial phase, a biosafety committee will convene to evaluate the field trial results. Based on the findings of this committee's evaluation, the applicant will/will not be granted a biosafety certificate for further trials. Fields trials that are deemed safe for the environment will be granted a biosafety certificate for further field-testing in different ecological zones of Vietnam so that the seeds may receive certification. Such testing will be conducted by a National Center for Evaluation and Seed Certification authorized by MARD. The seed variety may be released for commercial production only after being granted a seed certificate by a National Center for Evaluation and Seed Certification. Additionally, the tested seed will be subject to certification by the Vietnam Food Administration (VFA) of the Ministry of Health, which must approve it or the ensuing crop as safe for human health.

VFA is currently working on its regulations relevant to the management of GM foods. Its major concern relates to how to do risk assessments of GM foods.

MARD, VFA and Vietnam Environment Protection Agency (VEPA) recently met to consider how best to move forward on the regulations relevant to the management of GM crops and GM products. It was unofficially reported that these three agencies agreed to work on an inter-ministerial agreement that would clearly delineate the responsibilities of each ministry or agency relevant to the management of GM crops and GM products

Post will update when this document becomes available.

Vietnam unlikely to achieve its ambitious Biotechnology Plan by 2020

Given the delay in implementation of the Biosafety Regulations, approved in 2005, it seems doubtful that Vietnam can meet its targets for 2010 and 2020. Scientists have been urging the relevant government agencies to speed up their regulatory work to legalize the production of Bt crops in Vietnam, fearing that Vietnam may be left behind in adopting biotechnology in agriculture.

On January 12, 2006, the Prime Minister signed Decree 11/2006/ND-TTg on "Key Programs and Application of Biotechnology in Agriculture to 2020." The primary objective is to create new plant varieties, animal breeds and biotech products through application of biotechnology, so as to enhance the competitiveness of Vietnam's agricultural and fishery products, both domestically and internationally. To this end, Vietnam plans to invest about VND100 billion (about \$6.3 billion) in biotech programs, annually. MARD has been assigned the lead agency role for these programs, and must coordinate the work of the Ministry of Science and Technology, the Ministry of Industry, the Ministry of Planning and Investment and local authorities.

Government plans call for commercial release by 2010 of a number of biotech seeds developed by Vietnamese scientists, including cotton, maize and soybeans. By 2020, the government hopes biotech crop varieties will account for 70% of total crop production.

Vietnam's Labeling Regulation

On August 30, 2006, Prime Minister Nguyen Tan Dung signed Decree No. 89/2006/ND-CP on goods labeling. This replaces Prime Minister Decision No. 178/1999/QDTTg of August 30, 1999 that promulgated the Regulation on labeling of domestically circulated and exported and imported goods, and Decision No. 95/2000/QD-TTg of August 15, 2000 that provided adjustments and supplements to it. The new decree would normally have been effective in March 2007, six months after publication in the Official Gazette, but due to delay in issuing the implementing guidelines, it will not go into effect until September 2007. (see VM7037)

In April 2007, the Ministry of Science and Technology (MOST) issued implementing regulations (see VM7038) for that portion of the goods labeling decree under its control. Vietnam Food Administration (VFA) of the Ministry of Health is responsible for the implementing guidelines for food products, including GM foods. VFA has not yet completed its labeling guidelines for food products.

Vietnam will likely require that GM food products be labeled. The recently approved National Action Plan to implement the convention on biological diversity calls for Vietnam to label all GM organisms and GM products that are circulated in the market by 2010. The "Ordinance on Food Hygiene and Safety" that became effective on Nov.1, 2003 (see VM 3014) also support labeling GM foods. In Article 20 of Chapter II, it asks that genetically modified food or genetically modified food materials have inscribed on their labels in Vietnamese the phrase "food containing biotech products". This is also supported by the biotech decree, which reiterates the need for labeling of biotech products. While indications made during Vietnam's WTO Accession would seem to allay fears of labeling disrupting trade, current sentiments and the strong position taken by VFA on labeling for GM products give cause for concern.

Intellectual Property Rights Law

In November 2005, the Vietnam National Assembly passed a comprehensive Intellectual Property Rights law. Part four of the law covers Intellectual Property Rights for plant varieties. It closely follows the International Union for the Protection of New Varieties of Plants (UPOV) guidelines. Vietnam officially became a member of UPOV in December 2006.

On September 22, 2006, Prime Minister Nguyen Tan Dung signed Decree No. 04/2006/ND-CP, which provides detailed guidelines for implementation of the chapters on Plant Variety Rights in the Intellectual Property Law. The Decree offers guidance on the execution of articles on Plant Variety Rights, including State management of Plant Variety Protection; the order and procedures for defining plant variety rights; rights and obligations of plant variety certificate holders and plant variety creators; and the transfer or assignment of rights' licenses for protected varieties.

The Ministry of Agriculture and Rural Development (MARD) has the lead on Intellectual Property Rights for plant varieties and was responsible for drafting the law and implementing regulations. MARD established Vietnam's Plant Variety Protection Office (PVPO) under the Department of Crop Production (DCP) in 2004. PVPO actively participated in drafting Vietnam's Intellectual Property Rights for plant varieties and the procedures for Vietnam to become a member of the UPOV. Information relating to the PVPO's operations can be found at <http://pvpo.mard.gov.vn> in both Vietnamese and English.

Within a month of Vietnam becoming a member of UPOV, MARD registered and issued Plant Variety Protection Certificates for two hybrid-corn and hybrid-rice varieties. The Plant Variety Protection office (PVPO) reports getting more and more applications for Plant Variety

Protection from plant breeders and traders as they now see the benefit of having their plant varieties protected by law.

USDA and the American Seed Trade Association provided technical assistance to Vietnam to assist the PVP office with more efficient implementation of the Intellectual Property Rights law for plant varieties. Two staff members of the PVPO received training on the U.S. systems for plant variety protection in the United States under the auspices of USDA's Cochran Fellowship Program. In March 2007, an American consultant came and worked with Vietnam's PVPO on a survey of the status of breeding and development of new plant varieties in Vietnam. Vietnam's plant breeders and regulatory officers were most appreciative of the efforts and recommendations of this consultant. The PVP office is currently working to implement one such recommendation by seeking permission from the government to establish a Patent Division under the Plant Variety Protection office. The current Intellectual property rights for plant varieties do not include patent protection. Plant breeders, especially breeders of high valuable plant varieties, including vegetative propagation crops, inbred lines and GM event traits, will welcome this protection.

Section III: Marketing

In Vietnam, there is not an active anti-biotech campaign underway to sway public opinion away from adoption of biotechnology.

Currently, several of Vietnam's research institutes, including the Institute of Biotechnology, the Vietnam Agricultural Science Institute, the Agricultural Genetics Institute, and the Institute of Tropical Biology, are conducting research on biotech crops in laboratories. Experimental biotech crops include rice, sweet potatoes, papaya, cotton, maize and flowers. Scientists are anxiously awaiting approval of MARD's regulations so that they may proceed with field trials.

There are a number of challenges relating to the development of biotechnology in Vietnam. Not least among them is the lack of understanding about biosafety among scientists and the media. A shortage of appropriately trained personnel to develop and implement biosafety regulatory mechanisms, as well a lack of adequate facilities for analyzing risk also impede the development of biotechnology in Vietnam.

Section IV: Capacity Building and Outreach

Foreign Agricultural Service (FAS) in Vietnam has been working closely with the government, namely the Ministry of Agriculture and Rural Development (MARD), Vietnam Food Administration (VFA) of the Ministry of Health, and Ministry of Environment and Natural Resources, to advance the development of biotechnology in Vietnam. Since June 2006, a number of activities involving technical assistance, exchange-visits, workshops and seminars have been organized. Following are some of the key biotech activities:

- Under the auspices of the United States government and in coordination with Vietnam's Environment Protection Agency of the Ministry of Natural Resources and Environment, an APEC High Level Policy Dialogue on Agricultural Biotechnology Workshop on Liability and Redress under the Biosafety Protocol will be held in Hanoi in September 2007
- In May 2007, USDA sponsored a delegation of high-ranking Vietnam officials (including a Vice Minister) to attend BIO 2007, the International convention on

biotechnology, held in Boston, MA. The U.S. Agriculture Counselor to Vietnam accompanied the group.

- In May 2007, USDA provided funding for the Director of Vietnam's Biotechnology Institute to attend the Steering Committee Meeting of APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) in Brisbane, Australia.
- In April 2007, MARD's Department of Science and Technology and ISAAA jointly organized a workshop on "Implementing Biosafety Regulations to Release and Commercialize GM crops in Vietnam, which was partly funded by FAS.
- In January 2007, FAS/Hanoi, in conjunction with the Economic Section of the Embassy arranged meetings with various Ministries, including a Vice Minister of MARD, for a senior biotech advisor from the State Department to discuss the benefits of biotechnology and the status of Vietnam's efforts.
- In December 2006, USDA sponsored two senior officers from MARD and the Ministry of Science and Technology (MOST) to attend the 2006 APEC High Level Policy Dialog on Biotechnology in Canberra, Australia.
- In early December 2006, Post funded three participants from Vietnam Farmers' Union and Vietnam Television to attend a workshop on "Promoting Farmer's Role in Policy Advocacy, Capacity Building and Technology Use for Agricultural Development" held in the Philippines.
- In June 2006, USDA & USAID sponsored the Director of MARD's Biotechnology office to attend a workshop in the Philippines on "Commercialization of Biotechnology Crops in Asia – Moving from ideas to useful products in farmers' fields" organized by Asia Biobusiness, ISAAA and the Singapore National Institute of Education.