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Report Highlights: Vietnam has completed a new draft Biodiversity Law which is expected to be ratified by the National Assembly in October 2008. Chapter 6 of this law pertains to the management of Genetically Modified (GM) Organisms. The Implementing regulations to allow field trials of biotech crops have still not been approved, but the Ministry of Agriculture and Rural Development remains hopeful that it will be signed before the end 2008 so that field trials may begin this year. Vietnam will likely not achieve its targets to release GM crops for commercial production by 2010. Vietnam also has concerns about the lack of skilled biotech personnel and plans to send more students overseas for advanced degrees in biotech related fields.

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SECTION I: SITUATION AND OUTLOOK

Currently Vietnam has no restriction on the importation of Genetically Modified (GM) products and imports huge amounts of Bt cotton, soybeans, soybean meal and corn from the United States and other countries.

Production of GM crops and trade in GM seeds are still not yet allowed in Vietnam as the biotech regulations to allow these have yet to be approved. The Ministry of Agriculture and Rural Development (MARD) has already reported its draft regulations for biosafety management of genetically modified crops to WTO and received comments from various countries, including the United States. These regulations, when approved, will allow field trials of GM crops and ultimately commercialization of GM crops after a successful trial period. Notwithstanding the absence of approved biotech regulations, reports are that much of the cotton being grown in Vietnam is GM.

MARD anticipates approval of its biotech regulations later this year and will begin field testing as soon as the regulations are approved. Vietnam Food Administration (VFA) in the Ministry of Health has also reported its draft several regulations, which will control the import, export and trade of GM foods, to the WTO and received comments from the United States and other countries. VFA's draft regulations include provisions for risk assessment, labeling and certification of GM foods and food products that could be a hindrance to trade. Both MARD and VFA have confirmed that their regulations will not affect imports of bulk commodities like cotton, soybean meal or corn for the feed industry. VFA's regulations are concerned with packaged foods containing GM products and imported or locally produced GM crops for human consumption. Several Vietnam draft regulations, including a new draft Biodiversity Law, call for the labeling of GM foods or food products containing over 5 % GM products.

SECTION II: BIOTECHNOLOGY TRADE AND PRODUCTION

Vietnam remains keen to produce genetically modified (GM) crops, particularly soybeans, corn and cotton, in order to reduce the dependence on imports of these key commodities, used as inputs in Vietnam's large feed and textile industries. Although Vietnam ratified the Biosafety Regulation (VM5062) that provides the framework for research, production and trade of GM products in 2005, now three years on, Vietnam has yet to approve the implementing guidelines that would allow GM crops to be commercially produced and traded. It should be noted that, despite the lack of regulations, reportedly over 80% of the cotton grown in Vietnam is now Bt cotton, though the source of the seeds remains a mystery, given there is no legal GM seed trade in Vietnam. (VM8038)

The Ministry of Agriculture and Rural Development (MARD) has now reported its draft regulations for field testing and biosafety management of genetically modified crops (<u>VM8005</u>) to WTO and already received comments from various countries including the United States. MARD expects these regulations to be approved before the end of 2008. Scientists and policymakers have voiced concern that Vietnam needs to speed up the regulatory work and allow GM crops to be grown so that domestic production of food and feed may be increased.

The Vietnam Food Administration (VFA) in the Ministry of Health has also drafted regulations for the Management of the Safety and Hygiene of Foods Originated from Gene-Modified Organisms. These draft regulations, which cover the import, export and trade of GM foods, were notified to WTO earlier this year and comments from the United States and other countries have already been received. Approval of VFA's regulations is still pending.

Vietnam currently imports large quantities of agricultural biotech commodities including cotton, corn, soybeans and soybean meal. Vietnam's cotton lint imports for 2007/08 was 240 thousand metric tons, an increase of 7% over the previous market year. The United States and India, major Bt cotton growers are the two major suppliers of cotton to Vietnam. (<u>VM8038</u>) In 2007, Vietnam also imported 590 thousand metric of corn for animal feed; and U.S. Bt corn exports to Vietnam increased 41% over 2006 (<u>VM8023</u>). Vietnam's soybean meal imports for the animal feed industry was an estimated 2.2 million metric tons in 2007, much of which was Bt soybean meal largely from Argentina, the United States and Brazil.

Vietnam's biosafety regulations outline requirements for import permits and labeling that could prove disruptive to trade. A recent revision of these regulations, the Biodiversity Law, is expected to be passed by Vietnam's National Assembly at their next session in October 2008. Chapter VI, which covers the management of GM organisms, includes requirements for import permits, labeling and risk assessment of imported GM products. (see Policy section below)

SECTION III: BIOTECHNOLOGY POLICY

Vietnam National Assembly to ratify Biodiversity Law soon

In June 2008, Vietnam produced an updated version of the 2005 biosafety regulations, (<u>VM5062</u>) now called the Biodiversity Law, which was discussed by the National Assembly during its June 2008 session. It is expected that the National Assembly will ratify this new law, which will be the highest legislative document on biodiversity in Vietnam, at its next session in October 2008.

The Biodiversity Law consists of a total of 10 chapters, with chapter 6 focusing on the management of genetically modified organisms and safeguarding the environment against alien species. This new law has provisions for tight control of GM organisms and GM products, including requirements for risk assessment, labeling and certification of GM organisms and GM products.

- Chapter 1: General Provisions
- Chapter 2: Biodiversity reservation planning
- Chapter 3: Conservation and sustainable development of natural ecosystems
- Chapter 4: Conservation and sustainable development of biological organisms
- Chapter 5: Accessibility, evaluation of gene sources and benefits sharing: conservation and preservation of samples of heritage items
- Chapter 6: Management of the safety of genetically modified organisms and control of alien species from invading the environment.
- Chapter 7: International cooperation on biodiversity
- chapter 8: Mechanism and resources for sustainable development of bio-diversity
- Chapter 9: State management of bio-diversity
- Chapter 10: Implementation

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" (see <u>VM7059</u>)

On May 31, 2007, Prime Minister Nguyen Tan Dung signed Decree No. 79/2007/QD-TTg to promulgate the National Action Plan for implementation of the Convention on Biodiversity 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.

A number of objectives to be enacted by 2020 are also outlined in the Action Plan. Vietnam aims to strengthen the regulatory framework to manage GMOs and GM products so as to ensure the safety of human health and the environment, while also maintaining biological diversity. State of the Art laboratory facilities and the most up-to-date research methods and information systems are also projected as well as a database on the management of biodiversity and biosafety.

The Ministry of Environment and Natural Resources (MONRE) will take the lead on the implementation of the Plan. Several other ministries will participate in the implementation of the Plan, according to their area of responsibility; namely, the Ministries of Agriculture and Rural Development (MARD), Science and Technology (MOST), Education and Training (MOET), Culture and Information, Industry and Trade (MOIT), Finance (MOF) and the Ministry of Planning and Investment. Although the Plan became effective on July 7, 2007, thus far no Ministry has yet completed their implementing regulations for this Plan.

Vietnam unlikely to achieve its ambitious Biotechnology Plan by 2010 and 2020

Given that Vietnam still does not have approved biotech implementing guidelines, it is doubtful that Vietnam can meet the targets set for 2010 or 2020. The Ministry of Agriculture and Rural Development's (MARD) regulations to allow field trials of GM crops have yet to be approved. And, even assuming they were to be approved by the end of 2008, as projected, field trails are expected to run for at least two years before any GM crops would be released for commercial production. Furthermore, the draft of the regulations call for certification of the tested crops (corn, soybean) as safe for human consumption by the Vietnam Food Administration (VFA) in the Ministry of Health once MARD has completed its field trials and analysis. VFA's biotech regulations have also not yet been approved and given these two tiers of approval, it is highly doubtful that commercialization of locally grown GM crops will be in force by 2010 as planned.

The same can be said for the goals of Decree 11/2006/ND-TTg for "Key Programs and Application of Biotechnology in Agriculture to 2020" that was signed by the Prime Minister on January 12, 2006. Under this plan, Vietnam expects 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. A target annual investment of about VND100 billion (about \$6.3 million) in biotech programs is set for these programs. MARD is the lead agency 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. Vietnam expects to develop a variety of biotech seeds, including cotton, maize and soybeans, which would be commercially released by 2010, with biotech crop varieties accounting for about 70% of total crop production by 2020.

Vietnam's Labeling Regulation

Vietnam has several draft regulations that require GM foods and products be labeled. Both draft biotech regulations (MARD and VFA) and the draft Biodiversity Law call for labeling of goods containing GM organisms. Once the Biodiversity Law is passed by the National Assembly, it will affirm Vietnam Food Administration's (VFA) position that all foods or goods containing GM organisms must be labeled. Vietnam Food Administration, (VFA) the regulatory body within the Ministry of Health with oversight of food for human consumption, has drafted new labeling regulations for packaged foods. These draft regulations stipulate that labels (or sub-labels) are required for foods containing more than 5% of materials derived from gene technology and must clearly state, in Vietnamese, the phrase "using gene technology." (VM8020) Labeling of GM foods will be costly for consumers and traders and could also lead to misunderstanding about the safety of GM foods. VFA argues, however, that labeling of GM food merely provides the consumers with full information about the product so that he/she can make a more-informed decision, and it should not harm the market for GM food. VFA's stance on labeling is also supported by the Biosafety regulation approved in 2005 (VM5062); Vietnam Food Ordinance (VM3014); the Good Labeling Decree in 2006 (VM7037) and the National Action Plan (VM 7059). VFA's labeling regulations have not been notified to WTO and have also not vet been approved.

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.

In 2007, MARD added 22 plant species to the list of protected plant species, bringing the total of Vietnam's protected plant species to 38. Included among these species are rice, corn, soybean, peanut, cotton, sugarcane, tomato, potato, watermelon, cucumber, kohlrabi, cabbage, chili pepper, pumpkin, carrot, strawberry, onion, shallot, onion-shallot hybrids, bitter gourd, rose, chrysanthemum, gerbera, gladiolus, lilies, dianthus, marigold, grape, orange, mango, apple, banana, pomelo, papaya, dragon fruit, tea, rubber, coffee and ginger.

More and more plant breeders and traders are interested in certification of protected plant species. Since becoming a member of UPOV a year and a half ago, MARD has issued Plant Variety Protection Certificates for more than 11 rice varieties (hybrids) and 7 hybrid corn varieties. Both local and international organizations and individuals are owners of Plant Variety Protection Certificates in Vietnam.

Information relating to the PVPO's operations can be found at <u>http://pvpo.mard.gov.vn</u> in both Vietnamese and English.

SECTION IV: MARKETING ISSUES

There is no active anti-biotech campaign or groups in Vietnam to sway public opinion regarding adoption of biotechnology. As noted earlier, Vietnam currently imports huge quantities of commodities as inputs for its export industries, namely soybeans, soybean meal, corn and cotton. The current draft biotech regulations contain labeling and certification requirements which could put some restrictions on trade, but both MARD and VFA have avowed that neither of their regulations will impact these bulk commodities. Purportedly, it is packaged foods containing GM products that will be subject to the regulations, once they go into effect.

Vietnam has several research institutes, including the Institute of Biotechnology, the Vietnam Agricultural Science Institute, the Agricultural Genetics Institute and the Institute of Tropical Biology engaged in research on biotech crops in the laboratory. Biotech research is being done on rice, sweet potatoes, papaya, cotton, maize and flowers. Scientists anxiously await approval of MARD's regulations so that they may proceed with field trials. Several MARD research institutes are also working on proposals for field testing of soybeans, corn and cotton in preparation for field trials as soon as MARD's biotech regulations are approved.

Vietnam faces a number of challenges in the development of biotechnology, not least of which is the shortage of skilled or experienced scientists and personnel in the biotechnology field. Reportedly scientists of leading agricultural research institutes are bemoaning the lack of such skilled personnel to fully or effectively utilize improved equipment and laboratories at these institutes. Vietnamese scientists who receive advanced training overseas tend to leave public institutes for the private sector where salaries and working conditions are more attractive. Vietnam, nevertheless, continue to work to improve capacity in biotechnology and the government has plans to send up to 300 students abroad for Masters and doctoral degrees in biotechnology related field over the next 10 years.

SECTION V: CAPACITY BUILDING AND OUTREACH

During 2007 and the first half of 2008, FAS/Vietnam's biotechnology activities have focused on technical assistance to Vietnam's regulatory agencies (MARD and VFA) in order to both build the knowledge base and technical capacity and move the regulatory approval process forward, with the ultimate aim of creating a favorable environment for GM crop production and trade in Vietnam. Post also actively participated in and provided support to other biotechnology efforts spearheaded by other USG agencies in Vietnam, such as the Department of State's biotechnology outreach program and the biotechnology speaker's program.

Following is a list of Posts' principal biotech activities during this period:

? supported two senior officers from MARD and VFA to participate in the seventh APEC High Level Policy Dialogue on Agricultural Biotechnology (Policy Dialogue) held in Lima, Peru from February 26-28, 2008.

? supported two Vietnamese participants to attend the APEC Policy Dialogue workshop on Liability and Redress issues related to the Cartagena Protocol on Biosafety, held in Tokyo, Japan on February 13-14, 2008.

? coordinated a weeklong biotech study tour to Washington, DC and Missouri in December 2007 for eight senior Vietnam officials, including a Vice Minister, in collaboration with FAS/W, USSEC, Monsanto and the University of Missouri. Participants gained considerable insight into the U.S. biotech regulatory system from meetings with FDA, EPA and FAS and also made key connections with Monsanto and the University of Missouri, which culminated in an MOU for educational and scientific collaboration between MARD and the University of Missouri.

? secured funding for a 4-day workshop (December 5-8, 2007) on biotech food safety in Dai Lai, Vietnam for the benefit of the Vietnam Food Administration (VFA) which has regulatory oversight for the import, export and trade of GM foods. Drs. Paul Teng & Randy Hautea of ISAAA organized this workshop, which included speakers from the University of Illinois, the United Kingdom, India and the Philippines.

? coordinated an APEC High Level Policy Dialogue on Agricultural Biotechnology Workshop on Liability and Redress under the Biosafety Protocol held in Hanoi in September 2007 in collaboration with Vietnam's Environment Protection Agency (VEPA).

? 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.