United States Department of Agriculture (USDA)

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

Report on Genetically Engineered (GE) Plant Imports: Current and Future

January 2012

Purpose

The USDA Office of Inspector General (OIG) conducted an audit of controls over the importation of transgenic plants and animals that began October 1, 2007 and was concluded April 7, 2008 (50601-17-Te). OIG found that USDA agencies' controls are appropriate for the current risk associated with transgenic biotechnology; however, OIG also found that USDA has no controls in place that would identify undeclared, regulated transgenic plants or identify a shipment of undeclared transgenic plants unknown to the U.S. regulatory system. OIG developed three recommendations:

Recommendation 1: Formalize, at the department level, a control policy for all transgenic imports.

Recommendation 2: Develop and implement a strategy for monitoring the development of transgenic plants and animals in foreign nations.

Recommendation 3: Develop procedures for regular interagency USDA consultations coordinated by the Office of the Secretary on potential actions that may be appropriate to address any emerging risks that particular new foreign transgenic plants or animals might pose to the United States.

In June 2010, USDA submitted final responses for Recommendations 2 and 3; these actions were accepted by the Office of the Chief Financial Officer (OCFO) in July 2010. In summary, USDA committed to a plan that includes the following actions:

- Coordinating among agencies
- Working with other international entities
- Bilateral and multilateral efforts with other countries involved in biotechnology research
- Vulnerability assessment
- Input from non-governmental organizations

APHIS committed to follow through with these recommendations, including a commitment to perform the afore-mentioned vulnerability assessment of the potential for unapproved genetically engineered plants to be imported into the United States, and to draft potential import control policies to respond specifically to outstanding recommendation #1. The policy and primary strategy for control of transgenic imports will be based on information gathering from publicly available databases and advance intelligence gathering through the USDA field offices in foreign nations. In addition, an increase in USDA outreach efforts to impart understanding of our regulatory requirements by participation in global fora, engagement with regulatory officials from other countries to promote information exchange, and discussions with U.S. agricultural commodity importers to increase awareness of USDA regulations and the importance of regulatory compliance with those regulations will minimize the potential for unapproved GE plants to be imported into the United States.

Background

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for enforcing regulations governing the import of plants and animals and certain agricultural products. Biotechnology Regulatory Services (BRS) is responsible for enforcing regulations governing the import of transgenic (genetically engineered) organisms which might pose risks as plant pests. APHIS undertook a detailed vulnerability assessment to provide baseline of the potential for genetically engineered (GE) plants produced outside the United States that have not been

deregulated by APHIS to enter the United States as plants (including seed, viable grain, whole plants, or other viable plant products). To gauge the potential for entry of regulated GE plants, APHIS surveyed the approvals for environmental release and the status of GE crop production worldwide using information available from a variety of sources. This report describes the methodologies used to perform the baseline analysis and provides a subjective assessment of the value of several publicly available databases and reporting mechanisms as tools to monitor the development and production of GE crops internationally. This work is the logical extension of the 2010 vulnerability assessment described in Appendix D begun in response to recommendations 2 and 3.

Vulnerability Assessment Methodology

APHIS conducted an analysis of approvals for environmental release and the production of GE crops in foreign countries to assess the potential for unapproved GE plants to be imported into the U.S. We relied on the following data sources:

- Center for Environmental Risk Assessment (CERA) GM Crop Database (http://cera-gmc.org). CERA was established by the non-profit International Life Sciences Institute (ILSI) in March, 2009.
- The Biosafety Clearing House (BCH) (http://bch.cbd.int/about/). The BCH was established as a mechanism for international communication regarding biotechnology under the Cartagena Protocol on Biosafety. The BCH is based upon information submitted by each country and reflects national decisions regarding the transboundary movement of GE organisms, also known as Living Modified Organisms (LMOs) under the terminology of the Protocol.
- The GM Approval Database maintained by the International Service for the Acquisition of Agri-biotech Applications (ISAAAA) (http://www.isaaa.org/). This database features biotechnology/GM crop events and traits approved for commercialization and planting and/or for import for food and feed use. The data is derived from the BCH (listed previously) and country regulatory websites.
- The USDA Foreign Agricultural Service (FAS) Global Agriculture Information Network (GAIN) (http://gain.fas.usda.gov/Pages/Default.aspx). GAIN provides timely information on the agricultural economy, products and issues in foreign countries since 1995 that are likely to have an impact on United States agricultural production and trade. U.S. Foreign Service officers working at posts overseas collect and submit information on the agricultural situation in more than 130 countries to USDA's Foreign Agricultural Service (FAS), which maintains the GAIN reports. GAIN reports are documents that capture insight and intelligence garnered by FAS Ag Attaches in country, utilizing local sources of information. GAIN includes reports on biotechnology and other new technologies.

Disclaimer: Each data source provided valuable information, and each source also has its limitations. In some cases, we found discrepancies between data sources; in such cases, we relied on the information in the FAS GAIN Reports to provide context. APHIS was not able to fully utilize the information in the GAIN network due to a lack of resources; APHIS acknowledges the utility of the GAIN data and in the future, envisions a more thorough analysis of the information contained in GAIN reports as a way to validate findings in subsequent revisions.

APHIS began its analysis by examining the CERA database for a list of all GE events or transformation lines approved for environmental release by a foreign country. The CERA database was the initial data source considered because it is primarily keyed on crop and event. Other sources contain this information as well, but this vital information is not as accessible. As of June 2011, this database contained information on the following crops:

Sugar Beets
Argentine Canola
Polish Canola
Papaya
Chicory
Squash
Carnations
Soybeans
Cotton
Sunflower
Lentil
Flax
Alfalfa
Tobacco
Rice
Plum
Potato
Wheat
Maize

While the list of crops was short, the combinations of crops, events, and multiple countries that had approved these events made it extremely difficult to assess the data and cross reference it to other data sources. Therefore, as a next step, APHIS compared the list of products and lines approved in a foreign country to the APHIS list of deregulated products and eliminated the deregulated events and lines. This work was cross checked with the BioSafety Clearing House as a secondary check. From this list, APHIS removed all the events that are outside the authority of USDA as defined in 7CFR340. For example, USDA does not regulate products derived from mutagenesis that generate novel traits; stacked traits and/or conventional breeding using deregulated lines. In addition, APHIS utilized information in the GAIN reports to identify additional events that had been approved for environmental release by a foreign government but information about these events were not available on either CERA or the BCH. This 'first pass' yielded the following results, representing those countries that have approved a line or event that has not been deregulated by USDA:

Country	**Commodity**	**Transformation Event or Line**
Australia	Carnation	4,11,15,16
Australia	Carnation	66
Brazil	Soybean	BPS-CV127-9
Canada	Canola	OXY-235
Canada	Sugar beet	H7-1
Colombia	Carnation	959A, 988A, 1226A, 1351A, 1363A, 1400A
European Union	Potato	Event EH92-527-1
European Union	Carnation	66

Country	Commodity	Transformation Event or Line
European Union	Carnation	959A, 988A, 1226A, 1351A, 1363A, 1400A
India	Cotton	Event 1
India	Cotton	GFM
India	Cotton	CICR
India	Cotton	Event 9124
Japan	Canola	OXY-235
Japan	Canola	PHY14, Phy35
Japan	Canola	PHY36
Japan	Sugar beet	H7-1

Next, APHIS examined the ISAAA database to generate a list of countries that produce biotech crops. According to the ISAAA website, the database includes biotechnology/ GM crop events and traits approved for commercialization and planting and/or for import for food and feed use; but it does not distinguish between the two uses. This distinction is important because importation of an import into a foreign country for food and feed use is not an important pathway for GE crops unapproved by the United States to make it into the U.S. import stream. The ISAAA data also does not include specific information about events or lines in use within a particular country. Nonetheless, it serves as a useful framework. This analysis yielded the following result:

Country	Commodity	Country	Commodity
Argentina	Soybean	Czech Republic	Maize
Argentina	Maize	Czech Republic	Potato
Argentina	Cotton	Egypt	Maize
Australia	Cotton	Germany	Potato
Australia	Canola	Honduras	Maize
Bolivia	Soybean	India	Cotton
Brazil	Soybean	Mexico	Cotton
Brazil	Maize	Mexico	Soybean
Brazil	Cotton	Myanmar	Cotton
Burkina Faso	Cotton	Pakistan	Cotton
Canada	Canola	Paraguay	Soybean
Canada	Maize	Philippines	Maize
Canada	Soybean	Poland	Maize
Canada	Sugar beet	Portugal	Maize
Chile	Maize	Romania	Maize
Chile	Soybean	Slovakia	Maize
Chile	Canola	South Africa	Maize
China	Cotton	South Africa	Soybean
China	Tomato	South Africa	Cotton
China	Poplar	Spain	Maize
China	Papaya	Sweden	Potato
China	Sweet Pepper	Uruguay	Soybean

Colombia	Cotton	Uruguay	Maize
Costa Rica	Cotton		
Costa Rica	Soybean	**Note: Table excludes U.S.**	Note: Countries <0.1 million hectares in blue

Based upon ISAAA data as of 2010, 29 countries, including the United States, produce crops developed using biotechnology (genetic engineering), and the top ten countries each grew more than 1 million hectares.[1] Adoption of plant biotechnology is increasing as more countries begin growing GE crops and new products are developed. To date the majority of the GE crops in production around the world are corn, soybean, and cotton; all have multiple transformation events which were deregulated for environmental release by APHIS. These GE plants that have been approved for environmental release by another country have already been deregulated by APHIS and are therefore not a concern in the import stream.

Our next step was to consider the data collected against the existing APHIS regulations that cover importation of material into the United States. We identified plant admissibility for planting, and fresh fruits and vegetables for consumption to be imported into the country under current quarantine restrictions. Apart from the APHIS regulations for GE organisms, APHIS has additional import requirements to provide safeguards to U.S. agriculture and natural resources from the introduction of foreign plant pests. Under 7 CFR 319.37, certain agricultural commodities must meet entry requirements to be imported into the United States, while others are prohibited. Under 7 CFR 319.56, agricultural commodities intended for consumption, such as fresh fruits, vegetables, and other unprocessed articles, irrespective of whether they are GE or not, are not authorized entry unless the risk of plant pest introduction has been evaluated and mitigated. We reviewed the entry requirements for propagative plant material (whole plants, seeds, and tissue cultures) and fresh fruits and vegetables for each crop species from the countries that had approved environmental release or documented production of a genetically engineered plant. This analysis did not include processed products such as oils, corn meal, cut flowers, or other non-viable material; nonviable products are outside the scope of 7 CFR 340, the APHIS regulations governing GE organisms. Entry requirements for propagative material are contained in Plant Protection and Quarantines' (PPQ) Nursery Stock Manual, while admissibility requirements for fresh fruits and vegetables are reflected in the fruits and vegetables import requirement database (FAVIR).

Lastly, we analyzed the potential for regulated GE plants approved in other countries to be imported into the United States. We also ascertained if such GE plants were currently under review for deregulation by APHIS. In some instances where there was insufficient specificity of the GE plant variety under consideration, we were unable to determine if the GE plant had been deregulated by APHIS using these data sources exclusively. To obtain further details about specific GE lines or transformation events in a particular country, we referenced the GAIN reports prepared by USDA's Foreign Agricultural Service staff overseas.

Results and Key Findings

[1] Appendix B, Table 2 represents countries that, according to ISAAA, had production of biotech crops in 2009. The table also provides details on admissibility of the commodities into the United States. The most recent data for the 2010 report can be found online at http://www.isaaa.org/resources/publications/briefs/42/default.asp

Appendices A and B list the crops from the CERA/BCH databases and the ISAAA database (respectively) which are approved in a foreign country but are still subject to regulation in the United States under the APHIS biotechnology regulations (7CFR340). The last three columns provide information about enterability (as described above). The largest potential for unapproved GE crop import is from countries that produce a GE crop and have at least one GE plant line or variety approved for environmental release that has not been deregulated by APHIS.[2] In these situations, further information is needed to determine if the specific GE plant is actually in production in the foreign country. It is also important to determine if the GE plant is currently undergoing APHIS regulatory review for nonregulated status. We note that new GE varieties may have been produced in 2010. Information about these GE crops was obtained from the GAIN reports and is addressed later in the analysis. It is also important to note that the analysis of the potential for unapproved GE crops to be imported into the country includes admissibility based upon relevant quarantine regulations. If the GE crop is not allowed to be imported into the United States due to phytosanitary restrictions, the potential for unapproved GE plants to enter the United States, at least in a viable form, is low. The following are key findings within each of these scenarios.

Countries With GE Crops that May Include U.S. Regulated Events

CERA/BCH Database Results (Appendix A) Against U.S. Import Requirements

Canola – Canada is producing OXY-235 which is still regulated in the US and APHIS has not received a petition for deregulation. Japan has approvals in place for various canola events, but the 2010 GAIN report indicates that Japan does not produce canola, but is an importer. Thus, canola from Japan is not likely to be imported to the U.S.

Carnations – Australia, Columbia, and the European Union all have approved events in carnations. An initial analysis of information at the Florigene website indicates that flower production occurs in Australia, Colombia, and Ecuador; the products are imported into countries in South America and the European Union. Carnations are enterable as both seeds and whole plants. However, based upon ISAAA data, GE carnations were not produced within the relevant country in 2009, limiting the potential for unapproved imports into the United States. The GAIN reports provide additional and sometimes conflicting information about the production of these carnations. The 2010 GAIN report for Columbia indicates in 2009 4 hectares of blue carnations were produced for export to Europe. The 2009 GAIN report for the EU states GE carnations are approved for import use and not cultivation.

Cotton – India is producing several events that are not approved in the U.S. This will be discussed more fully in the following section, incorporating ISAAA findings.

Potatoes – GAIN reports indicate that the Amflora potato is being produced in several countries within the European Union. In 2010 the European Union approved a GE potato (event EH92-527-1), otherwise known as the Amflora potato, for environmental release. The potato was

[2] Appendix A, Table 1 represents events that have been approved for environmental release by foreign countries but have not been deregulated by APHIS that may act as a pathway for unapproved GE imports to enter the country. This table excludes varieties that are the result of crosses between events that APHIS approved (i.e. stacks) or conventional breeding.

approved for growing in the European Union for processing into starch, and small scale production (225 ha) is reported only in the Czech Republic, Germany, and Sweden. Potato propagative material is prohibited and material for consumption from Europe is not admissible into the United States.

Soybeans – Brazil is producing Event BPS-CV127-9. This will be discussed more fully in the following section, incorporating ISAAA findings.

Sugar beet – Seed and plants are enterable from Japan but unprocessed material for consumption is not. Currently, Japan does not produce any GE crops.

ISAAA Database Results (Appendix B) Against U.S. Import Requirements and Other Data Sources

The ISAAA data does not report on specific events, but when we cross-referenced the countries that are producing biotech products around the world (Appendix B) to the CERA database, we found that most countries were producing biotech crops that are approved in the U.S. Exceptions included soybeans from Brazil and canola from Canada. The CERA database did not contain entries for Bolivia, Chile, Costa Rica, Egypt, and Honduras. The CERA database did include entries for the EU for maize, which includes the countries of the Czech Republic, Poland, Portugal, Romania, and Slovakia. The CERA database also did not contain entries for poplar or sweet pepper.

When cross-referenced with the GAIN reports, we were able to determine whether the reported GE crop variety had been reviewed by APHIS. In some cases we were still unable to obtain information about the GE crop in production. Therefore APHIS is unable to determine if the GE crop has been deregulated by APHIS. These include: Bolivia (soybean), Chile (corn and canola), Costa Rica (cotton), and Czech Republic (corn). Lastly, there are several countries that have approved GE crops, but they were not produced in 2009. In one case, production of a GE crop in 2010 was reported by the GAIN report.

- Chile - Produces GE soybean seed as well as other varieties, but only for seed multiplication and/or re-export, often to the United States. Information about the specific events is not readily available. Soybean seed is admissible from Chile, but other propagative materials are prohibited and unprocessed material for consumption is not authorized. Corn seed for planting and ears for consumption are enterable, while other propagative material is prohibited.

- Costa Rica - Produces GE soybean seed as well as other varieties, but only for seed multiplication and/or re-export, often to the United States. Information about the specific events is not readily available. Soybean seed is admissible from Costa Rica but other propagative materials are prohibited and unprocessed material for consumption is not authorized.

- Egypt - Produces GE corn according to ISAAA; however, the GAIN report notes that only MON810 corn are in field trials. APHIS approved Mon-810 corn for nonregulated status in 1995. Therefore, corn imports that may contain this event are not a concern. Egypt is a net importer of corn, and does not export corn to the United States.

- Honduras - There are 3 varieties of GE corn (Mon-810, NK 603, and Herculex I) grown in Honduras. All three GE varieties have been deregulated by APHIS.

The GAIN network does not contain information about crops produced in Brazil, Canada, China, and India that may be imported ("enterable") under APHIS phytosanitary regulations into the United States, and these may include GE varieties approved for environmental release in the foreign country but not deregulated by APHIS.

The following list of countries outlines the crops that may be of most concern, based on the data sources examined to date.

Brazil: Soybean seed from Brazil is generally enterable, but other propagative material is prohibited and is also not authorized entry as an unprocessed article for consumption.
Of the four GE soybean transformation events approved for environmental release in Brazil, the event BPS-CV127-9, developed in Brazil, has not been deregulated by APHIS. APHIS has received a petition for deregulation of this event, but it is still under review. The Brazil 2011 Annual Oilseeds GAIN report indicates that imports from Brazil of soybean seed are minimal (2009: 100 metric tons)

Canada: Canada is a large producer of GE crops. In general, agricultural imports from Canada have fewer quarantine concerns than other countries around the world, and therefore have fewer restrictions. In general, GE crops approved for environmental release in Canada have also been deregulated by APHIS. There are several GE crops in production with the potential to contain unapproved GE plants:

- Canola - Enterable as seed and other propagative material but not authorized entry as an unprocessed article for consumption. Canola (OXY-235) is still regulated under APHIS biotech regulations, and APHIS has not received a petition for deregulation.
- Sugar Beets – Enterable in all forms for both propagation and consumption; Roundup Ready sugar beet is in production in Canada. Sugar beet (H7-1) was deregulated by APHIS but was brought back under regulation in 2010 as the result of a court order to prepare an EIS. APHIS anticipates the completion of an EIS and the issuance of a Record of Decision (ROD) in May 2012.

China: The rules of admissibility of plant material from China are diverse. Cotton seed for planting is enterable with a permit, while other propagative material is prohibited. Similarly, poplar seeds are admissible, but other propagules are prohibited. Papaya seeds may be imported, but other viable plant material for growing requires additional inspection and monitoring through PPQ's post-entry quarantine program. Papayas for consumption are not authorized for entry into

United States. Lastly, sweet pepper and tomatoes may be imported as propagative material but are not admissible as fruits and vegetables for consumption.

There are five GE crop varieties in production in China. APHIS has not deregulated any GE varieties of poplar and sweet pepper; therefore any imports of viable GE plants would require a APHIS permit or notification. Of the other three crops--cotton, tomato, and papaya-- APHIS has deregulated GE events in these crops. However, due to a lack of publicly available information the specific GE transformation events grown in China are unknown. Through an ongoing bilateral relationship[3] with Chinese officials, APHIS is aware that Biosafety certificates have been issued by China's Ministry of Agriculture for Bt-rice and phytase-corn, but neither has yet received the necessary approvals that would be needed for commercial-scale production in China. Neither corn nor rice is admissible from China.

India: In India, currently the only GE crop in production is cotton. Six GE events have been approved for environmental release, of which two have been deregulated by APHIS. Event 1, CICR, and Event 9124 were developed in India, and GFM was sourced from China (according to the 2010 GAIN report). Due to quarantine concerns, only cotton seed may be imported into the United States under a PPQ permit.

Vulnerability Assessment Conclusions

There are GE crops approved for environmental release in other countries that are currently not in production or are not admissible due to phytosanitary concerns. Our analysis indicates that Brazil, Canada, China, and India produce GE crops and some of them may not be deregulated in the United States. Additional analysis of the quarantine requirements indicates either propagative or consumption material of some of these GE crops are enterable and therefore may be imported into the United States.

Anyone who wishes to import a regulated GE plant or viable plant part into the United States must have an APHIS permit or notification under the regulations found at 7 CFR Part 340. USDA's Office of Inspector General questioned whether USDA can be sure that all foreign governments would have the motivation or means to assure that there are no regulated GE crops in commodities or seeds that we import. However, we believe the current potential for unapproved imports is low, because the majority of GE crops approved for environmental release by foreign countries have been deregulated by APHIS.

It will be important to conduct an ongoing regular analysis of foreign approvals and crops in production to determine their potential for importation, and what regulatory requirements would be relevant. For example, a determination of the number of shipments to the United States from the countries with the highest potential for GE plant imports will provide a more comprehensive look at the potential for GE plant imports to occur. If importations increase from the identified countries, the potential for regulated GE plants to enter into the United States and U.S. agriculture will increase as well.
Furthermore, more extensive analysis of the information in the GAIN network will serve as an important validation to the data presented here. Appendix C represents the beginning of this

[3] Due to the information source (bilateral relationship) neither the Bt-rice nor the phytase-corn are listed on Appendix A or Appendix B.

analysis, but additional analysis is needed to validate this compilation of information from the GAIN reports.

Both CERA and BCH databases used to determine environmental approvals are external to USDA. The CERA database is updated regularly, but it is based upon publicly available or published information; that is, ILSI policy is to update the data included in CERA when they can confirm information independently from a variety of sources. The BCH is based upon information submitted by each country and is not independently verified. The information about production was obtained from the ISAAA and reflects information from 2009, and the accuracy of the information is unknown. Further information was obtained from the 2010 USDA GAIN reports, which were developed by USDA officials in foreign postings. In several cases, it was difficult to reconcile conflicting information about approvals and production from the various data sources.

Even so, the data available in publicly accessible databases about biotechnology production serves as a good starting point for analysis. The information contained in the databases helped focus the analysis on the countries that have approvals that are still regulated in the United States, as well as countries with known production that may lend to imports of the unapproved products into the United States. In some instances, we were unable to determine if the GE plant has been deregulated by APHIS due to the lack of information available about either the GE plant in production and/or GE crops approved for environmental release in a country using these data sources exclusively. The GAIN reports provided more up-to-date information than what was available in the other databases. We were able to use the GAIN reports to obtain the most current status of GE crop production and approvals in countries identified in the analysis.

USDA Import Control Policy Implications

OIG Audit (50601-17-Te) found that USDA has insufficient controls in the event that a country was attempting to import GE plants into the United States. In fact, the current 340.0 regulation restricts the introduction of a regulated article: "No person shall introduce any regulated article unless: (1) Such introduction is authorized by a permit; and (2) such introduction is in conformity with all of the other applicable restrictions in this part. A regulated article is defined as: "any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in Part 340.2….." This is the first, and most important control that USDA has in place to regulate GE agricultural imports. Of course, its effectiveness relies on the degree of awareness foreign entities and domestic importers have regarding our regulatory procedures.

Over the years, APHIS has participated in numerous global fora to describe our regulatory system, and we host numerous international visitors from other governments to impart understanding of regulatory requirements. During these engagements, we seek to more fully understand the mechanics and nuances of other countries' regulatory systems. APHIS and the Foreign Agricultural Service (FAS) have agricultural attachés assigned to U.S. Embassies around the world who keep abreast of agricultural developments in country, including biotechnology developments. Both FAS and International Services (IS) employees are trained by APHIS about biotechnology regulations implemented by APHIS, so that FAS and IS officers can provide this information to relevant foreign developers and exporters of GE crops. APHIS participated in the

training of FAS and IS officers for the past three years, and we anticipate continuation of this training to effectively engage foreign developers and exporters about regulatory requirements.

In the fall of 2009, APHIS began a pilot Project using ARGUS to more efficiently and effectively gather information about the development of GE organisms in foreign countries. Project Argus[4] is a prototype bio-surveillance system designed to detect and track biological events that may threaten human, plant, and animal health globally. The approach is based on monitoring local, native-language media reports around the world including traditional print and electronic media, internet-based newsletters, and blogs. The timely reporting from ARGUS seems to be an effective way to track field tests of new GE organisms, approvals of GE organisms for commercial use, changes in regulations or laws that might mark a change in use of GE organisms in other countries, and also accidental releases or any apparent unexpected observations associated with the use of GE organisms abroad. This type of information can be used to identify countries and crops where we should target out attention. This type of data increases the effectiveness of our system and allows greater confidence that we are aware of developments with GE organisms abroad and ultimately helps us achieve our goal of protecting American agriculture.

The USDA import control policy must, of necessity, include the activities described in Recommendation #2 (Monitoring) and Recommendation #3 (USDA Coordination). It is the integration of these efforts, along with pro-active engagement with our regulatory counterparts in other countries, particularly those that we have identified in our baseline vulnerability assessment that will yield the best chance for heading off the import of unapproved events into the United States. We propose that on an annual basis, USDA will prepare a vulnerability assessment using the data sources currently available, incorporating new data sources and systems as they become available. This assessment will then serve to guide our interactions and efforts on the countries that pose the greatest risk, and will guide us in efforts to work with these countries to provide information to their domestic developers about the U.S. regulatory requirements for GE organisms and the information needed to navigate the U.S. regulatory system. APHIS and FAS have ongoing mechanisms for information exchange with the countries (China, Canada, Brazil, and India) that appear to be the most likely sources for imports of biotech crops imported into the United States in the near term. Currently, APHIS and FAS effectively receive real-time intelligence from USDA employees posted in these countries, and have established mechanisms to share that information and to collaborate on appropriate actions that USDA will undertake in response to what we learn. In addition, APHIS leads ongoing formal bilateral technical discussions with regulatory counterparts in Canada and China.

USDA should also increase its efforts to reach out to U.S. importers of agricultural commodities and seeds for fruits and vegetables that historically have had few GE varieties in commercial production to date. During the early years of the APHIS regulations governing GE organisms,

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[4] Hartley, DM, NP Nelson, R Walters, R Arthur, R Yangarber, L Madoff, JP Linge, A Mawudeku, N Collier, JS Brownstein, G Thinus, and N Lightfoot. 2010. Landscape of international event-based biosurveillance. Emerging Health Threats Journal 2010, 3:e3. doi: 10.3134/ehtj.10.002, Copyright 2010 DM Hartley et al.; licensee Emerging Health Threats Journal.

APHIS spent considerable time to inform relevant individuals and organizations about the regulations with a view toward achieving compliance that was practical in light of existing mechanisms for research, development, and trade of plants. More recently, APHIS has reinvigorated these efforts in a more systematic approach through its Biotechnology Quality Management System (BQMS) designed for compliance assistance. Now in its third year, BQMS is increasing the number of participating public and private institutions, and there may be opportunities to use BQMS as a means to reach out additionally to relevant organizations that are involved in the development of GE plants outside of the United States.

APPENDIX A

Table 1: Events approved around the world but not deregulated by USDA (APHIS biotechnology regulations, 7 CFR Part 340)

Country	**Commodity**	**Transformation Event or Line**	**Q37** - Seed	**Q37** - All Propagules except seed	**Q56**
Australia	Carnation	4,11,15,16	Admissible	Admissible	Not admissible
Australia	Carnation	66	Admissible	Admissible	Not admissible
Brazil	Soybean	BPS-CV127-9	Admissible	Admissible	Not admissible
Canada	Canola	OXY-235	Admissible	Admissible	Not admissible
Canada	Sugar beet	H7-1	Admissible	Admissible	Admissible
Colombia	Carnation	959A, 988A, 1226A, 1351A, 1363A, 1400A	Admissible	Admissible	Not admissible
European Union	Potato	Event EH92-527-1	Prohibited	Prohibited	Not admissible
European Union	Carnation	66	Admissible	Admissible	Not admissible
European Union	Carnation	959A, 988A, 1226A, 1351A, 1363A, 1400A	Admissible	Admissible	Not admissible
India	Cotton	Event 1	Admissible	Prohibited	Not admissible
India	Cotton	GFM	Admissible	Prohibited	Not admissible
India	Cotton	CICR	Admissible	Prohibited	Not admissible
India	Cotton	Event 9124	Admissible	Prohibited	Not admissible
Japan	Canola	OXY-235	Admissible	Admissible	Not admissible
Japan	Canola	PHY14, Phy35	Admissible	Admissible	Not admissible
Japan	Canola	PHY36	Admissible	Admissible	Not admissible
Japan	Sugar beet	H7-1	Admissible	Admissible	Not admissible

APPENDIX B

Table 2: Production of biotech products around the world[5]

Country	Commodity	Transformation Event or Line	Q37 Seed	Q37 All Propagules except seed	Q56
Argentina	Soybean	Unknown	Admissible	Prohibited	Not admissible
Argentina	Maize	Unknown	Admissible	Prohibited	Admissible
Argentina	Cotton	Unknown	Admissible	Prohibited	Not admissible
Australia	Cotton	Unknown	Admissible	Prohibited	Not admissible
Australia	Canola	Unknown	Admissible	Admissible	Not admissible
Bolivia	Soybean	Unknown	Admissible	Prohibited	Not admissible
Brazil	Soybean	Unknown	Admissible	Prohibited	Not admissible
Brazil	Maize	Unknown	Admissible	Prohibited	Admissible
Brazil	Cotton	Unknown	Admissible	Prohibited	Not admissible
Burkina Faso	Cotton	Unknown	Admissible	Prohibited	Not admissible
Canada	Canola	Unknown	Admissible	Admissible	Not admissible
Canada	Maize	Unknown	Admissible	Admissible	Admissible
Canada	Soybean	Unknown	Admissible	Admissible	Not admissible
Canada	Sugar beet	Unknown	Admissible	Admissible	Admissible
Chile	Maize	Unknown	Admissible	Prohibited	Admissible
Chile	Soybean	Unknown	Admissible	Prohibited	Not admissible
Chile	Canola	Unknown	Admissible	Admissible	Not admissible
China	Cotton	Unknown	Admissible	Prohibited	Not admissible
China	Tomato	Unknown	Admissible	Admissible	Not admissible
China	Poplar	Unknown	Admissible	Prohibited	Not admissible
China	Papaya	Unknown	Admissible	Postentry	Not admissible
China	Sweet Pepper	Unknown	Admissible	Admissible	Not admissible
Colombia	Cotton	Unknown	Admissible	Prohibited	Not admissible
Costa Rica	Cotton	Unknown	Admissible	Prohibited	Not admissible
Costa Rica	Soybean	Unknown	Admissible	Prohibited	Not admissible
Czech Republic	Maize	Unknown	Admissible	Prohibited	Not admissible
Egypt	Maize	Unknown	Prohibited	Prohibited	Not admissible
Honduras	Maize	Unknown	Admissible	Prohibited	Admissible
India	Cotton	Unknown	Admissible	Prohibited	Not admissible

[5] James, Clive. 2010. Global Status of Commercialized Biotech/GM Crops: 2010. ISAAA Brief No. 42. ISAAA: Ithaca, NY.

Country	**Commodity**	**Transformation Event or Line**	**Q37** Seed	**Q37** All Propagules except seed	**Q56**
Mexico	Cotton	Unknown	Admissible	Prohibited	Not admissible
Mexico	Soybean	Unknown	Admissible	Prohibited	Not admissible
Paraguay	Soybean	Unknown	Admissible	Admissible	Not admissible
Philippines	Maize	Unknown	Prohibited	Prohibited	Not admissible
Poland	Maize	Unknown	Admissible	Prohibited	Not admissible
Portugal	Maize	Unknown	Admissible	Prohibited	Not admissible
Romania	Maize	Unknown	Admissible	Prohibited	Not admissible
Slovakia	Maize	Unknown	Admissible	Prohibited	Not admissible
South Africa	Maize	Unknown	Prohibited	Prohibited	Not admissible
South Africa	Soybean	Unknown	Admissible	Prohibited	Not admissible
South Africa	Cotton	Unknown	Admissible	Prohibited	Not admissible
Spain	Maize	Unknown	Admissible	Prohibited	Not admissible
Uruguay	Soybean	Unknown	Admissible	Prohibited	Not admissible
Uruguay	Maize	Unknown	Admissible	Prohibited	Admissible

Appendix C
GAIN reports - FAS website
Summaries of biotechnology trade and production from all the countries
June 17, 2011

Australia: Besides the US produced biotech cotton and canola that is grown commercially, carnations and roses are the only crops approved for commercial release. A number of canola, Indian mustard, wheat, sugarcane, white clover, grapevines, pineapple, papaya, and barley varieties are being field tested at different locations in Australia.

U.S. export opportunities are restricted for GMOs that have not received regulatory approval in Australia. For the United States, the commercial impact of this constraint is most pronounced for feed grains, e.g. whole corn, and soybeans as these products have not yet received Australian regulatory approval.

Bosnia and Herzegovina: *Bosnia and Herzegovina (BiH) does not produce biotech crops and there are no biotech crops under development.* However, a new law passed on GMO allows the intentional release of biotech products into the environment and field trials under license.

Brazil: Brazil is now the second largest producer of plant biotech crops in the world after the United States. Brazil has in the pipeline other **plant biotech crops waiting for commercial approvals, mostly for sugar cane, dry edible beans, potatoes, papaya and eucalyptus.**

As of July 2010, there are 21 genetically engineered crops approved in Brazil: 11 for corn, 6 for cotton and 4 for soybeans most of which are US developed and exported to Brazil.

Burkina Faso: Burkina Faso remains the only francophone West African country in the region with an operational framework for the production and marketing of GMOs. Burkina Faso is becoming a large scale producer of GMO cotton growing about 400,000 ha in 2010. Insect resistant Bt cowpea, is likely the next biotech crop to be tested in Burkina Faso. The report does not indicate where the GMO cotton or Bt cowpea was developed.

Canada: Canada produces mainly GE corn, canola, and soybean and a small amount of sugarbeets. A number of field trials of GE alfalfa, camelina, canola and corn are on-going. Because of regular bilateral and trilateral meetings with Canada, APHIS will be aware of the latest developments in Canada.

Caribbean Basin: *The islands in the Caribbean Basin do not commercially produce any biotechnology crops.*

Chile: Chile does not produce any crops for sale domestically. However, Chile allows the production of GE crops for multiplication of seeds, under strict field controls, for life sciences companies such as Monsanto, Pioneer, etc. Those seeds must be exported to the country of origin and can not be sold or consumed by the Chileans. The new administration in Chile is seen as enthusiastic to push forward regulations in Congress so that Chilean farmers may benefit from

this technology. Chile has begun to do landmark research (non-bulk commodities), in crops such as salmon, pine, stone fruit, apples, and grapes.

There were biotechnology crops developed outside the U.S. and have not passed through the U.S. regulatory system and that was produced in Chile in 2009. These crops were: Barley, p607 from Hungry, Raps, VC-LJB1327-1 from Germany, Soybean LL2704_12; TG GM 13; TG GM 6 and TG GM 23 from Canada.

China: China has approved six genetically modified plants since 1997 (cotton, tomato, sweet pepper, petunia, poplar, and papaya). China is now the sixth largest producer of agricultural biotechnology crops in the world. In 2009, the Ministry of Agriculture (MOA) granted biosafety certificates to two insect resistant rice varieties and a high phytase corn variety and we are not sure if these are grown commercially.

According to MOA publications, other major crops undergoing the field trial stage of development (which is either the intermediary experiment or environmental release stage) include insect resistant corn, high lysine corn, wheat resistant to pre-harvest germination, and insect resistant soybeans. In addition to the crops mentioned above, other crops in advanced research and developmental stage include wheat, peanuts, and cabbage. FAS - Beijing believes that the central government's primary interest in biotechnology is to address food security. Almost all biotech research and development is carried out by public-funded research institutes and universities, and there are a number of advanced trials going on at the current time.

Colombia: Colombia grows US developed and approved insect-resistant cotton and herbicide-tolerant corn at a large scale. Australian developed blue carnations and chrysanthemum continue to be approved for commercial production for export to Japan and Europe.

Colombia is currently working on several biotechnology crops for regulatory approvals such as virus resistant sugarcane, insect resistant coffee, insect resistant potato, rice, grazing grass, cassava, and chrysanthemums with blue petals.

Costa Rica: Costa Rica does not produce GE crops for domestic consumption, but reproduces GE cotton and soybean seed entirely for export to the country of origin -- the United States. Costa Rican researchers are working on the development of genetically modified rice (resistance to virus and herbicides), and bananas (resistance to black Sigatoka). The development of these products is at the field trial stage. The most advanced project is in bananas, but it is not expected to come to market during the next year.

Croatia: *There are neither commercially produced biotech crops nor seeds and there are no biotech crops under development.* Croatia does not import any biotech crops or products for market use.

Czech Republic: The Czech Republic is one the few growers of genetically modified crops within the European Union. Czech farmers started growing genetically modified Bt corn in 2005. In 2010, they started growing Amflora potato. The Czech Republic Ministry of Agriculture is promoting policies to provide additional support for applied research in biotechnology.

Ecuador: *Ecuador does not have the capacity to conduct any GEO-related research or produce GE crops.* Ecuador does not allow the importation of seeds containing any GM organisms.

El Salvador: El Salvador does not produce any genetically modified crops and there are no crops under development that would be in the market in the coming year. Field testing of two U.S. developed genetically modified corn was started recently.

EU-27: There are currently two biotech products approved for cultivation in the European Union (EU). MON810 corn, approved in the US, was approved in 1998. It is planted in six Member States (MS), including Spain, the Czech Republic, Portugal, Poland, Slovakia, and Romania. The Amflora starch potato has not been through the US regulatory process for determination of deregulation. It was approved for cultivation in March 2010, and is estimated to be grown on about 225 ha in the Czech Republic, Sweden, and Germany.

Agricultural biotechnology research is stated as a priority of the European Commission and many member States. Intimidation by anti-biotech activist NGOs and field destructions the permit requests to conduct field trials have fallen dramatically since 2007. In Austria, Bulgaria, Greece, Ireland, and Italy field trials are not conducted at this time. However, Belgium, Czech Republic, France, Germany and Slovakia have marginal field trials, ranging from 1 to 25 plots.

France: *France does not produce any genetically engineered crops.* Last year, the Ministry of Agriculture approved 38 varieties of biotech corn, including 36 MON810 (Monsanto) and 2 T25 (Bayer Crop Science) events, but cultivation of these corn varieties is not expected in the near future, as France imposes a national ban on MON810 cultivation and the company producing T25 products, BayerCropScience. These varieties have been approved in the US.

Ghana: *Ghana does not currently produce any biotechnology crops commercially.* Some contained experiments using modern biotechnology methods are being conducted at the Crops Research Institute and BNARI. These include virus disease resistance in cassava, pest and disease resistance in cowpea and improvement of lysine strain in corn.

Guatemala: *Guatemala does not produce any biotechnology crops.* In 2004, Guatemala approved field trials of the Yieldgard gene in corn for Lepidopteron resistance, and the Liberty gene in cotton for glufosinate resistance, which are both deregulated events in the U.S. Del Valle University of Guatemala also developed ring-spot resistant papaya which has not received approval to be tested in the field.

Honduras: Honduras is the only country in Central America and one of the five countries in Latin America that allows the commercial production of biotechnology crops. US approved and imported crops such as Bt, RR and Ht corn are both field-tested and grown at the commercial scale in Honduras.

Hong Kong: Hong Kong does not commercially produce any biotechnology crops, nor does it conduct field trials. Farming is insignificant in Hong Kong. Hong Kong carries out research on biotech rice at the Chinese University of Hong Kong, but field trials are conducted in China.

Hungary: Officially, there is no commercial production of any biotech crop. The Ministry of Agriculture issued a statement on its official website announcing the launch of a safeguard procedure for a new biotechnology potato variety (BASF developed *Amflora* starch potato) recently approved by the EU Commission. This is consistent with Hungary's five years moratorium on the MON810 biotechnology corn strain.

India: Currently, Bt cotton is the only commercially approved biotech crop in India. Two of the approved Bt cotton hybrids are from Monsanto events that are already approved in the United States, one from approved event sourced from China and three locally developed.
Final approval of indigenously developed Bt eggplant is still pending. Many genetically engineered crops are at various stages of development but regulatory procedures are not conductive to commercialization of these products. Private seed companies and public sector research institutions are working on the development of biotech banana, cabbage, cassava, cauliflower, chickpea, cotton, eggplant, rapeseed/mustard, okra, papaya, pigeon pea, potato, rice, tomato, watermelon and wheat crops mainly for traits such as pest resistance, nutritional enhancement, drought tolerance and yield enhancement.

Indonesia: Indonesia has not yet produced any crops at a large scale that involve transgenic processes. However, Indonesia will likely have the capacity to multiply transgenic seeds or commercialize transgenic crops in the coming year.

Currently the Government of Indonesia (GOI) has carried out confined field-testing on several transgenic crops including rice (resistant to biotic stress), sugar cane (tolerant to biotic stress and modification of high glucose content), cassava (modification of amylase), potato (resistant to biotic stress), and tomato (resistant to biotic stress). Additional GOI research projects on transgenic plants such as virus resistance in tomatoes and potatoes, delayed ripening for papaya, pest resistant sweet potato, drought tolerant rice, and pest resistant soybeans, remain ongoing but at a relatively modest pace. Bt corn, bt cotton, RR corn, and RR soybeans seeds have passed the biosafety assessment process.

Italy: There is no official report of production of GE crops. Despite Italy's ban on biotech field trials, many Italian companies are developing biotech plant varieties able to resist pests or enhance growth during drought or low-nutrient soil conditions. In the future, agricultural biotechnology could also lead to a new generation of crops designed to improve biofuel production. Even though these varieties cannot yet be cultivated in Italy, there are a variety of indirect ways that Italian agriculture already uses biotechnology, such as internationally traded feedstock is produced through biotechnology.

Japan: Japanese companies have developed a few ornamental flowers that have been genetically engineered for color. In 2009, Suntory, a major beer brewery and liquor manufacturer, started producing "blue rose", making it Japan's first domestically produced biotech crop. Cut flower carnations are imported from Australia and Colombia.

Ministry of Agriculture (MAFF) is devoting significant resources towards genomics and biotech crop development research. Traits planned for research include high yield multi-disease resistant rice (for feed and/or biofuel production), drought tolerant rice and wheat, nutritionally altered rice (value added/function food, or pharmaceutical), and heavy metal accumulating rice (phyto-remediation). However, due in part to regulatory costs, it is becoming increasingly clear that this research will not be commercialized in Japan.

Jordan: Jordan does not produce any biotech crops. To date, no biotech crops have been introduced or approved in the country. There is a small amount of resources devoted to biotechnology research by some universities working in cooperation with the National Center for Agricultural Research and Extension (NCARE) and regional institutions such as the International Center for Agricultural Research in the Dry Areas (ICARDA).

Kenya: Currently, Kenya does not produce transgenic crops but the situation is expected to improve as its biosafety regulations have been recently approved. Information provided by the Kenya Agriculture Research Institute indicates trials on virus-resistant sweet potato and cassava, insect resistant cotton and corn, fortified sorghum and drought resistant corn.

Korea, Republic of: Korea recently approved three single trait biotech crops - MIR 162 (corn), DP-098140-6 (corn), and GHB614 (cotton) and two stacked corn events for imported food and feed use. Several of these crops are scheduled for commercialization in the United States in 2011.

Malaysia: Malaysia has not yet produced a biotechnology crop commercially, although several genetically modified crops containing valuable traits have been produced at the experimental stage. Malaysia's has a National Biotechnology Policy -- a three-phase program over 15 years to establish the country as a global leader in the field. During the first phase (2006-2010), they have been focusing on capacity and infrastructure building. The second phase (2011-2015), is geared to create business out from science and they plan to put measures in place to launch local research and products on the global market. To date, none of the biotechnology research involving the Malaysian oil palm sector (which is often considered to be the most advanced in the world) has gone beyond the experiment stage.

The current approved list of GM products for imports into Malaysia is as follows: Rounduo Ready™GTS 40-3-2 Soybean (Monsanto), MON 810 YieldGard™ Corn (Monsanto), NK603 Roundup Ready™Corn (Monsanto), MON 863 YieldGard™ Corn (Monsanto) and ISP type III HPLC 12 Glacein™-Ice-Structuring Protein (Unilever). Malaysia does not grow corn or soybeans on an appreciable level.

Mexico: Mexico does not commercially produce any biotechnology crops. However, 26 permits for genetically-modified corn for resistance to insects, tolerance to herbicides, and a combination of the two events, have been granted for their experimental release into the environment. Dow, Monsanto and Pioneer are the three companies involved in testing. Pioneer was granted approval to test in Puerto Vallarta, Jalisco but the work did not progress further. All biotechnology crops that are being tested in Mexico were developed in the United States and

have passed through the U.S. regulatory system. The United States has excellent bilateral and trilateral relationships with Mexican regulatory officials and it is encouraging Mexico to become more engaged in biotech research and development.

Morocco: Currently, Morocco does not produce any biotech crops.

New Zealand: **T**he New Zealand Government maintains a very comprehensive and rigorous approval regime for genetically modified organisms, and to date, the Environmental Risk Management Authority (ERMA) has approved several contained field trials but there has been no approval of a conditional or full-scale commercial release of a GM organism in New Zealand. Research projects include GM plants with improved characteristics for biofuel production, plants modified to produce pharmaceuticals and crops modified to produce higher levels of nutrients. The focus of the research is on high-impact traits that cannot be achieved through conventional breeding – traits that can reduce environmental impacts of agriculture and increase on-farm productivity. The research crops include potatoes, onions, broccoli, cabbage, cauliflower, forage kale and pine.

Nicaragua: Nicaragua does not produce any biotechnology crops.

Nigeria: Nigeria does not currently produce any biotechnology crops commercially but the need to commercialize of GM crops with high industrial uses was identified. Research using modern agricultural biotechnology methods is being conducted at the International Institute for Tropical Agriculture (IITA) in Nigeria. The institute is doing preliminary work on cassava and bio-engineered cowpea. The Bio-cassava Plus undergoing trials was developed in United States, while the Cowpea was developed in Australia. However, there is no biotechnology crop under development in Nigeria that will be on the market in the coming year.

Pakistan: There are no endogenously produced GE crops in Pakistan. However, Pakistan grows a large acreage of US produced Bt cotton and herbicide tolerant Flex cotton. In addition to Bt cotton and Roundup Ready Flex (herbicide tolerant) cotton, Bt /heat tolerant corn is also undergoing trial and expected to be released in 2011/2012. GE potato, sugarcane, chickpea, sunflower, chilies, tomato, cucurbits, tobacco, and groundnut (peanut) are undergoing laboratory/green house/field testing and some could be commercialized in the future.

Panama: *No biotech products are developed or consumed in Panama.*

Peru: *Peru does not commercially produce any biotechnology crops.* The International Potato Center (CIP - Centro International de la Papa) in Lima has developed a genetically modified potato engineered to repel the potato moth but has not gone through any regulatory approvals for field trials.

Poland: Officially, there is no production of any biotech crops. Poland's parliament is considering a restrictive new law on cultivating agricultural biotechnology, which also includes restrictive coexistence measures on the crops.

Russian Federation: *Currently Russia does not allow the cultivation of genetically engineered plants*. However, as of July 2010, there are 17 genetically engineered crops that can be legally imported to Russia for food use, including nine corn varieties, four soybean varieties, one rice variety, one sugar beet variety, and two potato varieties. Of these 17 varieties, eight corn varieties, and all four soybean varieties are also registered for feed use.

Saudi Arabia: Saudi Arabia is not a producer of biotech crops and import of GE seeds into the country is banned.

Senegal: No commercial production of biotech crops. There is some research on Bt cowpeas and cotton but no commercial production of any transgenic varieties are in the near future.

Serbia: There is no commercial production of any genetically modified organism (GMO) crops since 2009 and no biotechnology varieties are permitted for imports to Serbia.

South Africa: South Africa is the eighth largest producer of biotech crops in the world. Corn, soybean, and cotton that is commercially produced in South Africa was developed in the United States and SA does not produce any biotechnology crops where the events were developed outside of the United States. South Africa is the major exporter of corn in the Africa continent and 95 percent of South African corn exports are destined for African countries in Africa.

Testing of transgenic grapevines, cassava, and sorghum in a contained greenhouse facility is approved by South Africa. Research is continuing on corn and cotton for evaluation of insect resistance and/or herbicide tolerance and the long-awaited drought tolerance in corn as well as for the evaluation of GM sugarcane with altered sugar content and growth rate. The Agriculture Research Center is also testing transgenic virus resistant selections of an ornamental bulb species, *Orinthogalum*, a type of hyacinth (Chinkerinchee or Sun Star).

Sweden: Amflora potato, which is not yet approved in the US, has been reported to be planted in Sweden, besides Czech Republic and Germany in the EU. According to media reports, the Swedish food retail industry is moving towards GMO-free supply.

Taiwan: *There are no biotechnology crops under development on Taiwan that is expected to be commercialized in the near future.* Taiwan has established public field trials facilities at Council of Agriculture (COA) affiliated research institutes. Taiwan's existing biotech regulations only regulate biotech corn and soybeans and their products for food, feed and processing use. Therefore, it requires prior market approval for GM soybeans and corn imports for food, feed or processing use (FFP use), but doesn't require market approval for GM cotton imports because cotton is not for food use.

Taiwan has established field testing regulations for plants. However, there are no domestically developed GM events that have completed the field trials and in the pipeline for commercialization. Currently, seven events are undergoing field testing for biosafety assessment and they are:

1. Sweet rice for processing developed by Academia Sinica
2. Latoferri rice developed by National Chung Hsing University

3. Delay-ripening broccoli developed by Academia Sinica
4. Phytase potato developed by Academia Sinica
5. Cucumber mottle mosaic virus-resistant tomato developed by Asia Vegetable Research Development Center (AVRDC)
6. Eucalyptus for pulping developed by COA affiliate Taiwan Forestry Research Institute
7. New developed ring spot and leaf distortion mosaic virus-resistant papaya

Currently Taiwan does not allow the growing of GM crops outside of field trials. However, they have drafted regulations governing commercial production of biotech plants that is still pending for approvals.

Thailand: There is no commercial production of transgenic crops. Earlier field-testing was conducted for Flavr Savr tomato, Bt cotton, Bt corn, Round-up ready cotton, Round-up ready corn, Antisense RNA tomato, and ring-spot virus resistant papaya but further efforts were abandoned due to environmental and human health concerns, and the Thai government issued a blanket ban on all field trials.

Tunisia: Tunisia does not produce any biotech crops.

Turkey: There is no information if any biotech crops are grown or imported into Turkey.

Ukraine: At present, no GM plant varieties are approved for commercial planting or sale in Ukraine. However, because of a weak regulatory system and a lack of field surveillance programs till recently, doubts exist as to the "GMO-free" status of agricultural plantings in Ukraine. It is estimated that over half of Ukraine‟s soybean production are Round-up Ready Soybeans. Other plantings of biotech crops are also suspected (corn, sugar beets, etc.)

United Arab Emirates: None of the five Gulf Cooperation Council (GCC-5) countries covered by ATO Dubai have any biotech-enhanced crops under commercial production.
However, there is growing interest in utilizing biotechnology to address issues like soil salinity and pest resistance, particularly in date palms, and UAE researchers have established ties with a U.S. university in biotech research. The GCC-5 import biotech crops such as corn, soybeans and their products from a number of countries including the United States

Venezuela: There are no commercial plant biotechnology events under development and Venezuela does not produce crops using modern methods of genetic engineering. In recent years, programs have been initiated, usually in research or teaching institutes, to develop genetic transformation of plants, but the republic has not granted approval for plant biotechnology crops from any source.

Country	Production		Research	
Australia	Yes	U.S produced biotech cotton and canola carnations and roses	Yes	Canola, indian mustard, wheat, sugarcane, white clover, grapevines, pineapple, papaya, barley varieties
Belgium	No		Some	Small, unspecified field trials
Bosnia/ Herzegovina	None		None	
Brazil	Yes	11 corn, 6 cotton and 4 soybeans most of which are US developed	Yes	Sugar cane, dry edible beans, potatoes, papaya and eucalyptus awaiting commercial approval
Burkina Faso	Yes	Cotton – report does not specify where developed	Yes	Cowpea – report does not specify where developed
Canada	Yes	Corn, canola, soybean, sugar beets	Yes	Alfalfa, camelina, canola, corn – US and Canada hold regular meetings to ensure USDA is aware of developments in Canada
Caribbean Basin	None		None	
Chile	Yes	Barley p607 from Hungary Raps VC-LJB1327-1 from Germany Soybean: LL2704_12, TG GM 13, TG GM 6, TG GM 23 from Canada GE crops for seed for Monsanto, Pioneer, etc. that must be exported to the country of origin	Yes	Pine, stone fruit, apples,salmon, grapes

China	Yes	Cotton, tomato, sweet pepper, petunia, poplar, papaya In 2009, MOA granted biosafety certificates to two insect resistant rice varieties and a high phytase corn variety – uncertain if they are grown commercially	Yes	Insect resistant corn, high lysine corn, wheat resistant to pre-harvest germination, insect resistant soybeans in field trial. Crops in advanced research stage include wheat, peanuts, cabbage
Columbia	Yes	US developed insect-resistant cotton and herbicide-tolerant corn Blue carnations and chrysanthemum from Australia for export to Japan and Europe	Yes	Virus resistant sugarcane, insect resistant coffee, insect resistant potato, rice, grazing grass, cassava, and chrysanthemums with blue petals
Costa Rica	Yes	GE cotton and soybean seed for export to the country of origin (US)	Yes	Rice resistant to virus and herbicides Bananas resistant to black sigatoka
Croatia	None		None	
Czech Republic	Yes	Bt corn (MON810) Amflora potato	Some	Small unspecified field trials
Ecuador	None		None	
El Salvador	No			Field testing of two U.S. GE corn varieties began recently
European Union		**See individual states**		
France	None		Some	Small unspecified field trials
Germany		Amflora potato	Some	Small unspecified field trials

Ghana	No		Yes	Virus disease resistant cassava, pest and disease resistant cowpea Lysine improved corn
Guatemala	No		Yes	Lepidopteron resistant corn (Yieldgard) – approved in US Glufosinate resistant cotton (Liberty) – approved in US Del Valle University of Guatemala developed ring-spot resistant papaya but not approved for field trials
Honduras	Yes	Bt corn, Round-up Ready corn, herbicide tolerant corn approved in US in field trials	Yes	Bt corn, Round-up Ready corn, herbicide tolerant corn approved in US in field trials
Hong Kong	None		See Note	Research on biotech rice by Chinese University of Hong Kong but field trials conducted in China
Hungary	None		None	
India	Yes	Bt cotton – two from Monsanto and approved in US, one approved event sourced from China, three events locally developed	Yes	Bt eggplant still pending Private seed companies and public sector research institutions working on banana, cabbage, cassava, cauliflower, chickpea, cotton, eggplant, rapeseed/mustard, okra, papaya, pigeon pea, potato, rice, tomato, watermelon and wheat crops mainly for traits such as pest resistance, nutritional enhancement, drought tolerance and yield enhancement

Indonesia	No		Yes	Biotic Stress Resistance: rice, potato, tomato, sugar cane (also modified high glucose content) Cassava – amylase modification Virus resistance in tomatoes and potatoes Delayed ripening for papaya Pest resistant sweet potato and soybeans Bt corn, bt cotton, RR corn, RR soybeans seeds have passed the biosafety assessment process
Italy	No		See Note	Some Italian companies thought to be developing plant varieties resistant to pests or able to withstand drought or low-nutrient soil conditions
Japan	Yes	Blue Rose (Suntory)	Yes	High yield multi-disease resistant rice Drought tolerant rice and wheat Nutritionally altered rice Heavy metal accumulating rice Due in part to regulatory costs, it is becoming more clear that this research will not be commercialized in Japan
Jordan	No		See Note	Small amount of research in national or regional institutes
Kenya	No		Yes	Trials on virus-resistant sweet potato and cassava, insect resistant cotton and corn, fortified sorghum and drought resistant corn

Korea, Republic of	See Note	GAIN reports approval of Corn - MIR 162, DP-098140-6, two stacked events for imported food and feed use Cotton - GHB614 in 2010 The ROK is not a large producer of corn or cotton; it does produce significant soybeans and varieties have been approved in the past. Assumption is that ROK produces GE soybeans	No	
Malaysia	None		See Note	Malaysia is building capacity to begin research on the Malaysian oil palm, one of its biggest agricultural crops
Mexico	No		Yes	26 permits for genetically-modified corn for resistance to insects, tolerance to herbicides, and a combination of the two events, have been granted for experimental release Crops tested in Mexico have passed through the U.S. regulatory system
Morocco	None		None	
New Zealand	No		Yes	Plants with improved traits for biofuel production Pharmaceutical Plants Crops producing higher levels of nutrients Research crops include potatoes, onions, broccoli, cabbage, cauliflower, forage, kale and pine

Nicaragua	None		None	
Nigeria	No		Yes	Bio-cassava Plus developed in US Cowpea developed in Australia
Pakistan	Yes	Cotton: Bt and Roundup Ready Flex (herbicide tolerant) developed in US	Yes	Bt /heat tolerant corn expected to be released in 2011/2012 Potato, sugarcane, chickpea, sunflower, chilies, tomato, cucurbits, tobacco, and groundnut (peanut) are undergoing laboratory/green house/field testing
Panama	None		None	
Peru	None		See Note	International Potato Center has developed genetically modified potato engineered to repel the potato moth but not gone through regulatory approvals for field trials
Poland	See Note	Conflicting GAIN reports – one report indicates limited BT corn (MON810) while others indicate no GE crop production	No	
Portugal	See Note	EU-27 report indicates production of BT corn (MON810)	No	
Romania	See Note	EU-27 report indicates production of BT corn (MON810)	No	
Russian Federation	None		None	
Saudia Arabia	None		None	

Senegal	No		Yes	Bt cotton and cowpeas
Serbia	None		None	
Slovakia	See Note	EU-27 report indicates production of BT corn (MON810)	Some	Small unspecified field trials
South Africa	Yes	Corn, soybean, and cotton varieties all developed and approved in the U.S.	Yes	Testing of transgenic grapevines, cassava, and sorghum in contained facility Corn and cotton - insect and/or herbicide tolerance and drought tolerance in corn Sugarcane with altered sugar content and growth rate virus resistant ornamental bulb *Orinthogalum*, a hyacinth
Spain	See Note	EU-27 report indicates production of BT corn (MON810)		
Sweden	See Note	Amflora potato is said by some to be planted in Sweden	No	
Taiwan	No		Yes	Sweet rice by Academia Sinica Latoferri rice by National Chung Hsing University Delay-ripening broccoli developed by Academia Sinica Phytase potato developed by Academia Sinica Cucumber mottle mosaic virus-resistant tomato by Asia Vegetable Research Development Center Eucalyptus by Taiwan Forestry Research Institute

				New developed ring spot and leaf distortion mosaic virus-resistant papaya
Thailand	None		None	
Tunisia	None		None	
Turkey	None		None	
Ukraine	See Note	No GM plant varieties are approved for commercial planting but a weak regulatory system and lack of surveillance programs have led to doubts about the GMO-free status of planting Some experts estimate that over half of the soybean production is Round-up Ready Soybeans. Other plantings of biotech crops are also suspected (corn, sugar beets, etc.)	No	
United Arab Emirates	None		None	
Venezuela	None		None	

APPENDIX D

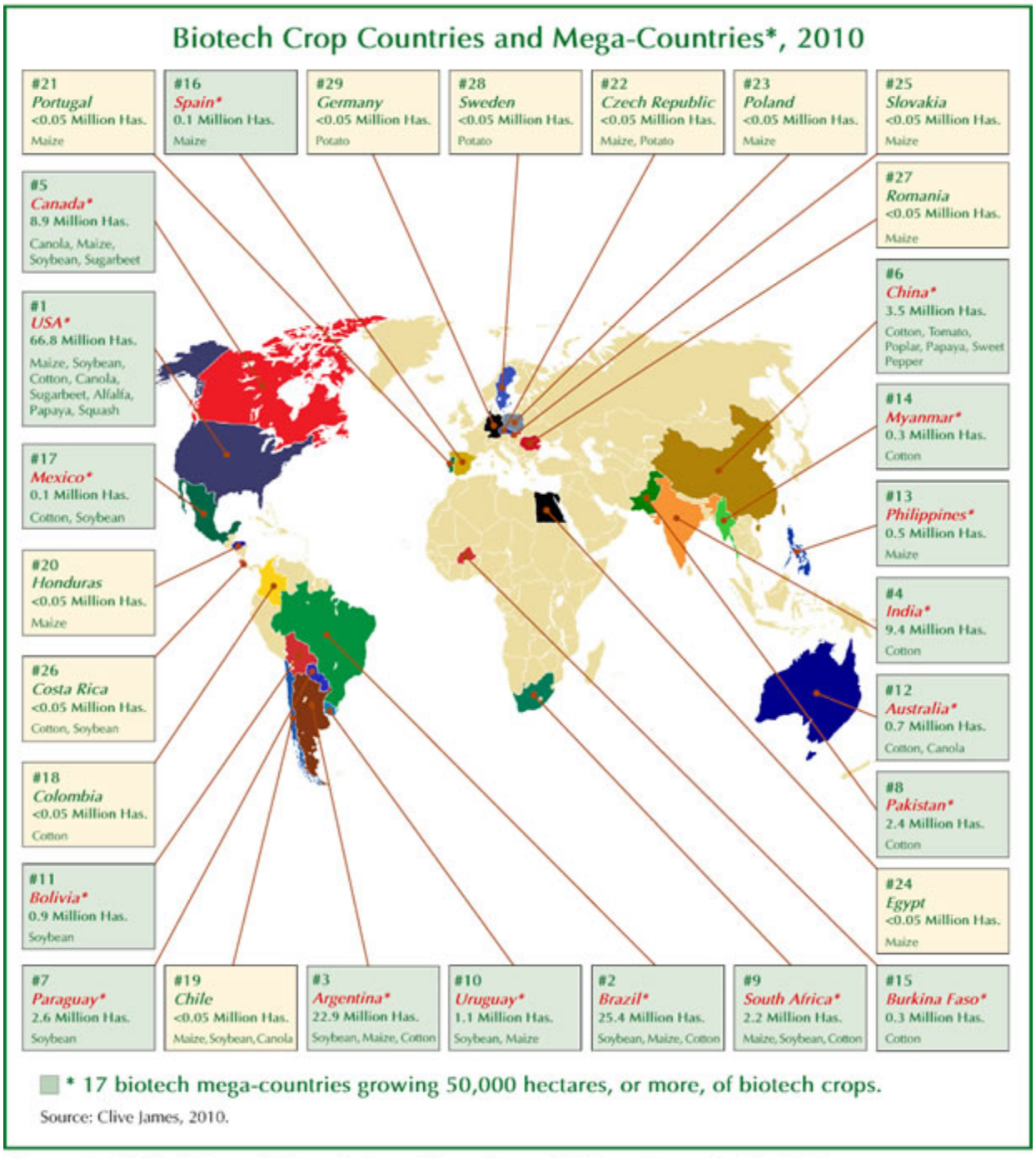

Figure 1. Global Map of Biotech Crop Countries and Mega-Countries in 2010

Appendix E – USDA Actions to Address Recommendations 2 and 3

USDA Monitoring Strategy and Implementation Plan for Transgenic Plants and Animals

Accepted by OCFO July 12, 2010

The following strategy will be employed for monitoring the development in foreign nations of transgenic plants and live animals that are nearing commercialization that may be imported into the U.S. It is intended to help ensure the safety of U.S. agriculture consistent with the recommendation of the Office of the Inspector General.

Two points related to transgenic animals are important to note to place this strategy in context. First, while this strategy applies to importation of transgenic plants and animals, determining the safety of foods that are derived from or contain ingredients from transgenic animals is the responsibility of the Food and Drug Administration (FDA). Such genetic modifications are regulated as New Animal Drugs under the Food, Drug and Cosmetic Act and are subject to mandatory pre-market approval by FDA. FDA approval is required before such animals can be imported into the United States. Information about approved New Animal Drugs is made available by FDA. FSIS will not allow the importation of meat, poultry, or egg products containing ingredients from genetically engineered animals that have been determined unfit for human consumption by FDA into the United States. Second, APHIS has a rigorous system to safeguard U.S. livestock from animal diseases and pests through regulation of animal imports. These same controls will be applied to any GE animals that might be developed abroad and imported into the United States. Our approach will include the following elements:

Coordinating among agencies. USDA will coordinate among its research, regulatory, and marketing agencies by including information sharing regarding new transgenic plants or live animals nearing commercialization in other countries as a regular (at least bimonthly) topic on the meeting agenda of the Biotechnology Coordinating Group. In addition, to broaden coordination outside of USDA, the Chair of the interagency Agricultural Biotechnology Working Group[6] (ABWG) led by the White House Office of Science and Technology Policy has been approached and has agreed to put this topic as a regular agenda item on monthly ABWG meetings.

Working with other international entities. On a regular basis, USDA agencies (typically, APHIS, FAS, ARS, and FSIS, as appropriate) will reach out specifically to organizations such as the Food and Agriculture Organization of the United Nations (FAO) (which is building a database on biotech plants that have been authorized in accordance with Codex plant guidance) for information and food safety updates. These interactions will also cover other plant and animal focused organizations, such as the International Plant Protection Convention (IPPC) and the World Organisation for Animal Health (OIE), as well as Codex Alimentarius, should any of these organizations begin to gather relevant information. Additionally, USDA will maintain contacts on an informal basis with other international organizations that conduct research and/or track commercial development of genetically engineered organisms, such as the Consultative Group on International Agricultural Research (CGIAR) and the International Service for the Acquisition of Agri-biotech Applications (ISAAA).

Bilateral and multilateral efforts with other countries involved in biotechnology research. USDA regulatory and trade agencies (APHIS and FAS) will seek opportunities to use bilateral and multilateral meetings with other countries as occasions for inquiries about progress of biotechnology research programs and the status of any transgenic organisms under development in those countries with respect to their possible commercialization (and for FSIS, for transgenic animals from which meat, poultry, and egg

[6] The ABWG includes representatives from OSTP, OMS, USDA, FDA, EPA, USTR, the Department of Commerce, the Department of State.

products might be exported to the United States). In addition, we will continue to conduct specific engagements, for example, with our North American partners Canada and Mexico through the North American Biotechnology Initiative, which usually meets at least once yearly, to share information the three nations have gathered about progress in other nations. We will also continue ongoing bilateral activities with China. U.S. regulatory agencies are also exploring ways to disseminate information to other countries to facilitate compliance with U.S. regulatory requirements.

Vulnerability assessment. In order to accurately assess potential vulnerabilities, USDA agencies have begun organized data gathering both to establish a baseline "snapshot" of the products that are currently available or that may be available in the near future, as well as to provide regular reports from other countries about relevant development progress on transgenic plants and animals. This data gathering will supplement information obtained through any of the consultations described in the sections above and below. Specifically:

- APHIS has gathered information on transgenic plants that might be in the product development pipeline in other countries and that could be imported into the United States. This information establishes a baseline which will be supplemented with information gathered in routine ongoing activities such as post reporting described below.

- FAS has amended its reporting instructions to its foreign posts so that posts in yearly reports are to identify transgenic organisms and products therefrom that are in advanced stages of development in their respective countries. The first round of information gathered in this way will be analyzed during the second half of 2010. FDA determines the safety of foods that are derived from or contain ingredients from genetically engineered animals and makes a food-safety determination based upon procedures established under the New Animal Drug provisions of the Federal Food Drug and Cosmetic Act. USDA and FDA routinely exchange information on GE animals that may be advancing in their development.

As information is gathered on various transgenic plants and animals, agencies may then be able to identify certain organisms that may merit additional monitoring. This would be based on any safety concerns related to the biology of the organism along with consideration of the likelihood that it might be imported into the United States.

Overall vulnerability will then be reviewed at least once per year by the Biotechnology Coordinating Group, though specific assessments regarding particular products may occur at any time based on information that arises. The results of all such assessments will be shared with senior officials and significant identified risks will be discussed in ABWG meetings as well.

Input from non-governmental organizations. In addition to information gathered from the snapshot, APHIS will also reach out on a regular basis (at least once yearly) to a range of non-governmental groups for information they may have on genetically engineered plants and animals that are in commercial production or nearing commercialization in other countries. Examples of such groups and organizations may include:

- Commodity-specific groups and trade associations
- Food safety and environmental organizations
- The Biotechnology Industry Organization and its members
- The Public Research and Regulation Initiative (PRRI), an international consortium of public sector scientists engaged in biotechnology research

Sources

Center for Environmental Risk Assessment (http://www.cera-gmc.org/)

Biosafety Clearing House (http://bch.cbd.int/)

Nursery Stock Manual
(http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/nursery_stock.pdf)

Fruits and Vegetables Import Requirement (FAVIR) database
(http://www.aphis.usda.gov/import_export/plants/plant_imports/quarantine_56/favir.shtml)

GMO crop production in the European Union: http://www.gmo-compass.org/eng/grocery_shopping/crops/18.genetically_modified_maize_eu.html

James, Clive. 2010. Global Status of Commercialized Biotech/GM Crops: 2010. ISAAA Brief No. 42. ISAAA: Ithaca, NY. (http://www.isaaa.org/resources/publications/briefs/42/default.asp)

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