Report on Genetically Engineered Plant Imports: Current and Future
FY13

Executive Summary

USDA analyzed databases as well as USDA country-specific reports focused on biotechnology to assess the likelihood of the unauthorized importation of genetically engineered (GE) plants (including seed, viable grain, whole plants or other viable plant products) subject to USDA's Animal and Plant Health Inspection Service – Biotechnology Regulatory Services (APHIS-BRS) regulations found at 7 CFR part 340. In addition to these regulations for GE organisms, USDA's Animal and Plant Health Inspection Service – Plant Protection and Quarantine (APHIS-PPQ) administers regulations governing the importation of plants and plant products to prevent the introduction of plant pests and noxious weeds into the United States.

The purpose of this 2013 report is to identify the development and commercialization of GE plants in foreign nations, and to analyze the likelihood of the unauthorized importation of those GE plants that are still subject to APHIS regulations found at 7 CFR part 340. We identified 47 GE plants authorized for commercial cultivation in other countries that are likely to be regulated articles subject to the APHIS regulations found at 7 CFR part 340 in the United States. APHIS-BRS typically authorizes importation of relatively small quantities of GE plants for research purposes, yet commercial scale production of GE crops in other countries might result in the inadvertent unauthorized importation of GE plants. The majority of global GE crop production consists of GE crops derived from GE plants that have nonregulated status in the United States and are no longer regulated by APHIS regulations found at 7 CFR part 340.

In assessing the likelihood that any of these 47 GE plants could enter the United States as unauthorized imports, USDA considered two factors: (1) the extent of cultivation of the GE plant in foreign countries; and (2) the admissibility of imports under APHIS-PPQ quarantine regulations found at 7 CFR part 319. Based on these two criteria, the likelihood is extremely low that any of these 47 GE plants could enter the United States as unauthorized imports.

In addition, this report identifies regional GE crop production as an important emerging trend that may become the most likely source of unauthorized imports in the future. Specifically, regional GE crop development, defined as GE plants developed to meet local or regional demand, continues to expand in Brazil, China and India. A continued focus on tracking the development and deployment of these regional GE crops will be required to guard against unauthorized imports.

While this report is focused on GE plants authorized for cultivation in other countries, the possibility for unauthorized import of GE plants not authorized for cultivation in other countries is also briefly discussed. The two potential sources of such unauthorized imports are: (1) illegal GE crop production; and (2) failure of confinement methods in regulated confined field trials (CFTs).

INTRODUCTION

Under regulations found at 7 CFR part 340, APHIS-BRS regulates the importation, interstate movement, and release into the environment of certain GE organisms which might pose a plant pest risk. These regulations include provisions for a petition procedure whereby APHIS may determine nonregulated status for GE organisms. GE organisms with nonregulated status are no longer subject to these regulations. To date, APHIS has made determinations of nonregulated status in response to 103 petitions, representing 16 plant species. An APHIS determination of nonregulated status also applies to all progeny of the GE plant derived via traditional plant breeding methods. Most of the GE crop varieties cultivated commercially in other countries are the offspring of GE crops for which APHIS has previously determined nonregulated status.

In addition to these regulations for GE organisms, APHIS-PPQ administers additional regulations governing the importation of plants and plant products to prevent the introduction of plant pests and noxious weeds into the United States. The APHIS-PPQ regulations found at 7 CFR §319.37 and 7 CFR §319.56 cover the importation of propagative plant material and fruits and vegetables for consumption, respectively. In assessing the likelihood of unauthorized imports of GE plants still subject to APHIS regulations found at 7 CFR part 340, USDA considered two factors: (1) the extent of cultivation of the GE plant in foreign countries; and (2) the admissibility of imports under APHIS-PPQ quarantine regulations found at 7 CFR §319.37 and 7 CFR §319.56. USDA also considered the APHIS-PPQ regulations specific to the importation of corn (7 CFR §319.41) and rice (7 CFR § 319.55).

In 2012, USDA developed a vulnerability assessment (VA) as an initial baseline of the likelihood for the importation of unauthorized GE plants. Consistent with the scope of the APHIS regulations cited above, the assessment included plants, seed, viable grain, whole plants, or other viable plant products (USDA-APHIS, 2012a). This 2013 annual VA builds upon the 2012 report.

USDA developed the first annual VA in 2012 in response to the USDA Office of Inspector General (OIG) audit of controls over the importation of transgenic plants and animals that was conducted in 2007-2008 (50601-17-Te). The OIG audit recommended that USDA develop and implement a strategy for monitoring the development of transgenic plants and animals in foreign nations. The 2012 and 2013 VAs both use the term GE rather than transgenic because GE is the term used in the APHIS regulations found at 7 CFR part 340. Additional information about the OIG audit recommendations can be found in Appendix A.

Global production of GE crops has increased steadily over the past 20 years; in 2012, farmers in 28 countries grew more than 170M ha of GE crops (ISAAA, 2013). Nearly all of the global GE crop production consists of GE corn, GE cotton, GE canola and GE soybean that are derived from GE plants that were first developed in the United States and that are no longer regulated by APHIS regulations found at 7 CFR part 340.

Purpose

The purpose of this 2013 VA is to identify the development and commercialization of GE plants in foreign nations, and to analyze the likelihood of the unauthorized importation of those GE plants that are still subject to APHIS regulations found at 7 CFR part 340.

TERMINOLOGY

Several terms used in this analysis warrant some explanation. For the purpose of this report, these are defined as follows[1]:

Asynchronous Approval – An approval for commercial cultivation in another country in cases where APHIS has received a petition for a determination of nonregulated status. In these cases, APHIS has the full data package required for environmental risk assessment (ERA) of the GE plant.

Asymmetric Approval – An approval for commercial cultivation in another country in cases where APHIS has not received a petition for a determination of nonregulated status. In these cases, APHIS does not have the full data package required for ERA of the GE plant.

Biosafety Certificate – Regulatory documents in the Chinese system for regulating GE plants. Time-limited (typically 5 years) biosafety certificates are issued at various stages in the development of the GE plant (ex. laboratory tests, environmental tests, production tests). While information is often lacking as to the stage of development authorized by a specific biosafety certificate, in the present analysis we assume that a biosafety certificate is an authorization for commercial cultivation.

Confined Field Trial (CFT) – A regulated field trial (environmental release) of GE plants. While not a common term in the US, CFT is the accepted global term for these regulated field activities.

Variety Registration – The formal process of registering specific varieties for cultivation in a country. In most countries, variety registration is required before seed can be sold, regardless of whether or not the seed is GE. In these countries, commercial cultivation of GE plants requires both the approval for cultivation of the GE plant and the registration of varieties of the GE plant. Lack of variety registration is partial evidence that seed of the GE plant is unlikely to be marketed in the current planting season.

METHODOLOGY

The results presented below are the outcome of a two-step process, starting with a data collection phase followed by an analysis phase.

Data Collection

[1] Please note that some of the terms listed below are defined for the purposes of this paper in a slightly different manner than common usage.

The data collection phase had three distinct goals: (1) to identify all GE plants approved for commercial cultivation in other countries but still subject to APHIS regulations found at 7 CFR part 340; (2) to compile brief synopses of GE crop development by country; and (3) to identify countries with illegal cultivation of unauthorized GE crops.

To achieve the first goal, USDA generated a list of all GE plants that have received determinations of nonregulated status under APHIS regulations found at 7 CFR part 340. This was followed by a review of the following three online global databases to generate the list of GE plants approved for commercial cultivation in other countries but still subject to APHIS regulations found at 7 CFR part 340:

- The International Society for the Acquisition of Agri-Biotech Applications (ISAAA) GM approval database
- The Center for Environmental Risk Assessment (CERA) GM crop database
- The Biosafety Clearing-House Living Modified Organism (LMO) Registry

Information from all three databases was used to generate a complete list of GE plants approved for commercial cultivation in other countries and still subject to APHIS regulations found at 7 CFR part 340. Each of the databases provided useful information, and analyzing multiple databases allowed discrepancies to be detected and clarified. A detailed description of each database is presented in Appendix B.

When APHIS-BRS makes a determination of nonregulated status the determination applies to all of the progeny of the GE plant. Developers are then free to use conventional plant breeding to combine two or more GE plant events into a single GE plant line. While these so-called breeding stacks are not regulated by APHIS-BRS, many countries do regulate breeding stacks. Since all three of the databases include approvals for breeding stacks, we reviewed each approval to ensure that each component of the stack had been granted non-regulated status by APHIS-BRS. Similarly, products of mutagenesis are also not regulated by APHIS-BRS under 7 CFR part 340; however they are included in the CERA database because they are regulated in Canada. These products of mutagenesis were also eliminated from the present analysis.

Three primary resources were used to achieve the second goal of generating the brief synopses of GE plant development by country:

- The annual ISAAA report on the global status of commercialized GE crops
- Biotechnology-focused reports found in the USDA Foreign Agricultural Service's Global Agriculture Information Network (GAIN)
- The USAID Development Experience Database

The annual ISAAA report (ISAAA, 2012) provides commercial production details of GE crops by country. In some cases, the GAIN reports provided more up-to-date information on the extent of commercial

production. The GAIN reports, together with results from the USAID database, were used to assess the level of GE crop development in each country, with emphasis on authorized CFTs. The USAID database was a useful source of information for GE crop development by public institutions and regional seed companies, particularly those funded by USAID.

In addition to the regulatory approval of the GE crop, most countries require variety registration which often adds 2-3 years to the commercialization timeframe. The Canadian Food Inspection Agency (CFIA) database of Plants Evaluated for Environmental and Feed Safety was particularly useful for assessing the commercial status of some GE crops because it includes information on variety registration in Canada. For countries other than Canada, the GAIN reports sometimes provided details about variety registration timelines in each country.

In addition to the unauthorized importation of GE plants approved in other countries, we recognize the possibility of the unauthorized importation of GE plants that remain regulated in the country of origin. The two potential sources of such unauthorized imports are: (1) illegal GE crop production; and (2) failure of confinement methods in CFTs. While it was not possible to fully analyze the likelihood of these events, available information on illegal production and CFTs is included in the brief synopses of GE plant development by country.

Analysis

The primary goal of the analysis phase was to evaluate the likelihood that the GE plants identified in the data collection phase could enter the United States as imports. This included consideration of the following factors that influence this likelihood: (1) the extent of commercial cultivation of the GE plant in foreign countries; and (2) the admissibility of imports under APHIS-PPQ quarantine regulations found at 7 CFR part 319.

APHIS-PPQ phytosanitary regulations found at 7 CFR §319.37 and 7 CFR §319.56 were reviewed to determine the entry requirements (admissibility) of imports for each crop/country combination. Under 7 CFR §319.37, certain agricultural commodities imported into the United States and intended for planting must meet entry requirements, 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. The entry requirements for propagative material were obtained from the Plants for Planting Manual (USDA-APHIS, 2012b), and the entry requirements for fruits and vegetable were obtained from the Fruits and Vegetables Import Requirements (FAVIR) database (USDA-APHIS (2012c). Since nonviable products are outside the scope of 7 CFR part 340, the analysis of entry requirements did not include processed products such as oils, corn meal, cut flowers, or other non-viable material.

The GAIN reports were the primary source of information used to assess the commercial status of each GE plant identified in the data collection phase. This was supplemented with information obtained

through direct communication with APHIS personnel in key countries, and in some cases by direct communication with the developers of the GE plant. When available, press releases were obtained to provide evidence for delayed commercialization plans.

RESULTS and ANALYSIS

Our analysis identified 47 GE plants that are authorized for commercial cultivation in other countries but are still subject to APHIS regulations found at 7 CFR part 340 (Table 1). In the following discussion, we will often refer to the GE plant line by the name of the transformation event listed in Table 1. Each transformation event is unique and all countries regulate at the level of the transformation event.

Table 1. Complete list of GE plants approved for commercial cultivation in other countries but still subject to APHIS regulations found at 7 CFR part 340.

Crop	Applicant	OECD Unique ID	Event	Cultivation Approvals
Canola	Bayer	ACS-BNØ11-5	Oxy-235	Canada, Japan
Canola	Bayer	NONE	PHY14	Japan
Canola	Bayer	NONE	PHY23	Japan
Canola	Bayer	NONE	PHY35	Japan
Canola	Bayer	NONE	PHY36	Japan
Carnation	Florigene	FLO-ØØØØ4-9	4	Australia, EU
Carnation	Florigene	FLO-ØØØ15-2	15	Australia, EU
Carnation	Florigene	FLO-ØØØ16-3	16	Australia
Carnation	Florigene	FLO-ØØØ66-8	66	Australia
Carnation	Florigene	FLO-Ø7442-4	11 (7442)	Australia, EU, Japan
Carnation	Florigene	FLO-11226-8	1226A	EU
Carnation	Florigene	FLO-4Ø619-7	123.2.2 (40619)	Australia, Japan
Carnation	Florigene	FLO-4Ø644-4	123.2.38 (40644)	Australia, EU, Japan
Carnation	Florigene	FLO-4Ø689-6	123.8.12	Japan
Carnation	Florigene	FLO-4Ø685-1	123.8.8 (40685)	Australia, Japan
Carnation	Florigene	FLO-11351-7	1351A (11351)	Colombia
Carnation	Florigene	FLO-11363-1	1363A	Australia, EU, Japan
Carnation	Florigene	FLO-114ØØ-2	1400A (11400)	Colombia
Carnation	Florigene	FLO-11959-3	959A (11959)	Colombia, EU
Carnation	Florigene	FLO-11988-7	988A (11988)	EU
Corn	DAS	DAS-40278-9	DAS-40278-9	Canada, Japan
Corn	Origin Agritech (China)	NONE	BVLA430101	China
Cotton	Chinese Acad Ag Sci	NONE	SGK321	China
Cotton	Chinese Acad Ag Sci	NONE	GK12	China
Cotton	CICR (India)	NONE	BNLA-601	India
Cotton	Cotton and Sericulture Dept (Burma)	NONE	Ngwe China 6 Bt	Burma
Cotton	JK Agri Genetics Ltd (India)	NONE	Event 1	India

Crop	Applicant	OECD Unique ID	Event	Commercial Approvals
Cotton	Metahelix Pvt Ltd (India)	NONE	MLS 9124	India
Cotton	Nath Seeds (India)	GTL-GFM311-7	GFM Cry1A	India, Pakistan
Dry Edible Bean	EMBRAPA (Brazil)	EMB-PVØ51-1	EMB-PVØ51-1	Brazil
Papaya	South China Ag U	NONE	Huanong No. 1	China
Petunia	Beijing U (China)	NONE	Petunia-CHS	China
Poplar	Res Inst of Forestry (China)	NONE	Bt Poplar	China
Poplar	Res Inst of Forestry (China)	NONE	Hybrid Poplar Clone 741	China
Potato	BASF Plant Science	BPS-25271-9	EH92-527-1	EU
Rice	Ag Biotech Res Inst (Iran)	NONE	Tarom molaii + cry1Ab	Iran
Rice	Huazhong Ag U (China)	NONE	GM Shanyou 63	China
Rice	Huazhong Ag U (China)	NONE	Huahui-1/TT51-1	China
Rice	Nat Inst Ag Sci (Japan)	NONE	7Crp#10	Japan
Soybean	BASF	BPS-CV127-9	BPS-CV127-9	Brazil, Canada
Soybean	DAS	DAS-68416-4	DAS-68416-4	Canada, Japan
Soybean	Monsanto	MON-877Ø8-9	MON 87708	Canada, Japan
Sweet Pepper	Beijing U (China)	NONE	PK-SP01	China
Tobacco	SNETA (France)	NONE	C/F/93/08-02	EU
Tomato	Beijing U (China)	NONE	PK-TM8805R	China
Tomato	Huazhong Ag U (China)	NONE	Huafan No 1	China
Tomato	Inst Microbiology, CAS (China)	NONE	Da Dong No 9	China

Not all of the 47 GE plants are produced commercially in the countries listed in Table 1. Some are older products that have been discontinued, while others are newer products that have not yet been commercialized. Lack of variety registration for older GE plants is evidence that seed of those GE plants is no longer sold, while lack of variety registration for newly developed GE plants is partial evidence that they are unlikely to be marketed in the current season.

Although a number of GE plants have been granted approval for cultivation in Japan, Japan has never commercially produced any of these GE plants. This is a reflection of the nature of Japanese approval

for "Type I Use" which includes approval for both importation and cultivation. When developers of GE plants request approval for food use, they also receive approval for cultivation. However, prefecture-based regulations effectively discourage farmers from growing any of these approved GE crops. In Hokkaido, farmers must obtain approval from the Hokkaido Governor's Office. To gain such approval requires holding public meetings at the farmer's expense and the farmer is responsible to maintain confinement (GAIN JA2013, 2012).

Of the 47 GE crop events listed in Table 1, APHIS has at least some information on the genetics for all but three GE events. Should there be a need to conduct a safety or risk assessment relative to an unauthorized importation, genetic information about the GE event is essential. The three GE events for which APHIS lacks information are: (1) the insect-resistant cotton event (Ngwe Chi 6 Bt) developed in Burma; (2) the product quality tomato event (Da Dong No 9) developed in China; and (3) the product-quality petunia event (Petunia-CHS) developed in China. Through our bilateral discussions with China, USDA will attempt to obtain at least some basic genetic information about the Chinese GE plants.

PPQ Entry Requirements

For each GE plant listed in Table 1, the PPQ entry requirements under 7 CFR §319.37 and 7 CFR §319.56 are summarized by country/commodity in Appendix C. Relative to specific commodities, rice seed is prohibited from all countries (7 CFR §319.55), and corn seed is prohibited from all countries other than Canada (7 CFR §319.41). Cotton seed can only be imported into the United States with a valid PPQ 588 permit.

Crops with GE Events Approved for Cultivation in Other Countries but Still Subject to APHIS regulations found at 7 CFR part 340.

Canola: The five GE canola events are all Bayer events from the 1990's. These five events (Oxy-235, Phy14, Phy23, Phy35 and Phy 36) were never produced commercially. Therefore, the likelihood that seed or viable grain of these GE canola events could enter the United States as an import is extremely low.

Carnation: Fifteen GE carnation events have been approved for cultivation in one or more of the following countries: Australia, Colombia, the European Union and Japan. These GE carnations are produced commercially in Colombia and Ecuador and exported as cut flowers. In Ecuador, where the GE carnations have not been approved for cultivation, the commercial production is all done in contained greenhouses. Florigene developed all of the GE carnations. In 2008, APHIS informed Florigene that cut carnations are not subject to APHIS-BRS regulations found at 7 CFR part 340 because they are not capable of self-propagation (USDA-APHIS, 2008). While these cut flower products are widely sold in the United States, APHIS still considers the GE carnation plants to be regulated articles and any importation into the United States of living GE carnation plants that meet the definition of regulated article under 7 CFR part 340 requires authorization under those regulations.

Corn: The Dow AgroSciences GE corn event (DAS-40278-9) has received asynchronous cultivation approvals in Canada and Japan. APHIS has a petition pending for determination of nonregulated status. Dow AgroSciences has confirmed that seed of this GE corn event will not be marketed anywhere prior to receiving nonregulated status from APHIS-BRS. Therefore, the likelihood that seed or viable grain of this GE corn event might be imported into the United States is extremely low. The GE corn event BVLA430101 was developed by the Chinese Academy of Agricultural Science and then licensed to the Chinese biotechnology company Origin Agritech Ltd. In China, cultivation of GE crops requires a biosafety certificate from the Ministry of Agriculture. This GE corn event received a biosafety certificate in 2009; however the 2012 GAIN report states that variety registration may take up to five additional years. Chinese government scientists recently announced that the introduction of this GE corn has been delayed (Reuters, 2013). Therefore, no commercial production of the Chinese GE corn is anticipated in 2013. Additionally, APHIS-PPQ phytosanitary regulations found at 7 CFR §319.41 prohibits the importation of corn seed from China (See Appendix C), so the likelihood that seed or viable grain of this GE corn could be imported into the United States is extremely low.

Cotton: Of the seven GE cotton events, four were developed in India, two were developed in China and one was developed in Burma. All seven GE cotton events are insect resistant. Cotton Event 1 was developed in India and received full approval for cultivation in India in 2006; the ISAAA database reports that this GE cotton has also been approved for cultivation in Pakistan. Cotton event MLS9124 was also developed in India and received full approval for cultivation in 2009. Very little information is available for the additional five GE cotton events listed in Table 1. APHIS-PPQ phytosanitary regulations require permits for the importation of cotton, cotton products and seeds; therefore the likelihood of importation of seed of these GE cotton events into the United States is extremely low.

Dry Edible Bean: EMBRAPA, the Brazilian Agricultural Research Corporation, has developed and commercialized a virus-resistant dry edible bean (*Phaseolus vulgaris*). While Brazil is responsible for 20% of global dry edible bean production, this does not meet domestic demand and Brazil is a net importer of dry edible beans (GAIN BR0627, 2010). Although the GE dry edible bean was fully approved for cultivation in 2011, variety registration may take 2-3 additional years and no commercial production is anticipated prior to 2014. This GE bean event is not intended for production in the United States and APHIS-BRS has not received a petition for nonregulated status. The current likelihood that seed or viable grain of this GE bean might be imported into the United States is extremely low; however, this likelihood will increase when the GE bean is commercially launched.

Papaya: The one GE papaya event was developed in China. ISAAA reports that China produced this papaya on 5300 ha in 2011. Survey data indicates that this same GE papaya event is cultivated in Hong Kong (GAIN HK1220, 2012). Since APHIS has post-entry requirements for importation of papaya cuttings for planting and fresh papaya for consumption is not admissible from China (see Appendix C), the likelihood of importation of this GE papaya is extremely low.

Petunia: The one GE petunia event was developed in China. The 2012 GAIN report states that the biosafety certificate issued in 1996 for this GE petunia has expired and there is no commercial

production. The likelihood that this GE petunia would be imported into the United States is extremely low.

Poplar: The two GE poplar events were developed in China. Both of these GE poplar events are resistant to insects, and were approved for cultivation in 2001. According to the 2012 GAIN report from China, these GE trees have been planted on 333 ha (GAIN CH12046, 2012); the ISAAA annual report provides an estimate of 490 ha for 2011 (ISAAA, 2012). Poplar trees are propagated by cuttings and planting material typically moves internationally as cuttings. Since APHIS-PPQ regulations prohibit the importation of poplar cuttings from China, the likelihood that these GE poplar trees could enter the United States as imports is extremely low.

Potato: BASF's GE potato with modified starch is approved for placing on the market for cultivation in the EU. Because importation of potatoes from the EU is prohibited under APHIS-PPQ phytosanitary regulations (see Appendix C), import of this GE potato into the United States is extremely unlikely. Furthermore, BASF has discontinued all development activity for this GE potato (BASF, 2012) and no further production is expected.

Rice: Of the four GE rice events, two were developed in China, one was developed in Japan and one was developed in Iran. Both Chinese rice events (GM Shanyou 63 and Huahui-1/TT51-1) are insect resistant and received biosafety certificates in 2009; however commercial production requires variety registration which can take up to five additional years. Chinese government scientists recently announced that the introduction of these GE rice events has been delayed (Reuters, 2013). The Japanese GE rice (event 7Crp#10) received authorization for cultivation in 2007; however, as discussed above, there is currently no commercial production of any GE crops in Japan. The GE rice event from Iran is also insect resistant and was approved for cultivation in Iran in 2004. Nearly all rice grain shipped internationally has been de-hulled and is therefore no longer viable. Since APHIS-PPQ prohibits the importation of rice seed (7 CFR §319.55), the likelihood that seed or viable grain of these GE rice events could enter the United States as imports is extremely low.

Soybean: The three GE soybean events have received asynchronous cultivation approvals in Brazil, Canada and/or Japan; all three of these GE soybeans are the subject of pending petitions for nonregulated status with APHIS-BRS. The developers of these three events (BASF, Dow AgroSciences and Monsanto) have confirmed that none of these GE soybeans will be marketed prior to receiving nonregulated status from APHIS-BRS (BASF, 2012; Dow AgroSciences, 2013). Therefore, the likelihood of imports of these GE soybean events into the United States is extremely low.

Sweet Pepper: The one GE sweet pepper event was developed in China. The 2012 GAIN report states that the biosafety certificate for this GE sweet pepper issued in 1998 has expired and that there is no commercial production (GAIN CH12046, 2012). Although seed and other propagules of sweet pepper are admissible (see Appendix C), the likelihood that seed of this GE sweet pepper might be imported into the United States is extremely low because the biosafety certificate has expired.

Tobacco: The one GE tobacco event was developed in France and approved for placing on the market for cultivation in the EU in 1994. According to the ISAAA database, this authorization for cultivation has expired. Since France has not produced any GE crops since 2008 (GAIN FR9096, 2012), it is extremely unlikely that this GE tobacco event could be imported into the United States.

Tomato: All three GE tomato events were developed in China. The 2012 GAIN report states that the biosafety certificates for these GE tomatoes have expired and there is currently no commercial production. Although seed and other propagules of tomato are admissible (see Appendix C), the likelihood that seed or fruit of these GE tomato events could be imported into the United States is extremely low because the biosafety certificates have expired.

Current and Future Trends in GE Crop Development

The vast majority of global GE crop production consists of GE crop events that have received determinations of nonregulated status from APHIS-BRS. Of the 47 GE events listed in Table 1, four of them, one GE corn event, and three GE soybean events, are asynchronous approvals. That is, APHIS-BRS has petitions for determination of nonregulated status for each of the four. Through press releases and direct contacts with company personnel, APHIS-BRS was able to confirm that none of the developers intend to market these GE plants prior to receiving nonregulated status from APHIS-BRS.

In contrast to these four asynchronous approvals, the other 43 GE plant events in Table 1 are asymmetric approvals for which APHIS-BRS has not received petitions for determination of nonregulated status. If we disregard the five GE canola events that were never commercialized, as well as the 15 carnations events, there are 23 remaining asymmetric approvals for further analysis, 21 of which were developed by public institutions or regional seed companies. For purpose of discussion, we will refer to these as regionally developed GE crops. These regionally developed GE crops may be commercialized in multiple countries within the region, but the developers may or may not seek regulatory approval from APHIS-BRS.

Of the 23 regionally developed GE crops, 13 were developed in China and four were developed in India. The Chinese events represent several crop species; these are discussed in detail by crop above. All four GE events developed in India are insect resistant cotton events. The remaining regional GE plant events include: insect-resistant cotton developed in Burma, and insect-resistant rice developed in Iran. Regional GE crop development continues to expand in Brazil, China and India, and USDA will continue to track the development and deployment of regional GE events, including bilateral discussions with these key countries.

The one asymmetric approval that may achieve large-scale production in the next few years is the virus-resistant dry edible bean developed in Brazil. Although this GE bean was fully approved for commercial cultivation in Brazil in 2011, registration of the new varieties will take 2-3 years and no commercial production is anticipated prior to 2014. Exports of dry edible beans from Brazil are not significant (GAIN

BR0627, 2010); however, since bean seed intended for consumption is typically still viable, the possibility of unauthorized importation exists.

Because of the recent growth in regional GE crop development, the number of asymmetric approvals that would qualify for inclusion in Table 1 is expected to increase substantially in future years. Presently, none of these regional GE events are cultivated on a large scale; however as the list grows longer and these GE events are adopted by farmers, the likelihood of unauthorized imports will necessarily increase.

Regional GE Crop Development in Selected Foreign Countries

Regional development of GE crops has been rapidly increasing, particularly in Brazil, China and India; these countries have the scientific capacity and regulatory infrastructure to bring their own GE crops to the market. Of the 23 regionally developed GE crops discussed above, 13 were developed in China and four were developed in India. In the long term, the asymmetric commercialization of regionally developed GE crops for which APHIS-BRS may not receive petitions for nonregulated status will increase the likelihood of unauthorized GE imports into the United States.

The following is a brief summary of crop biotechnology research and production in these three key countries.

1. *Regional GE Crop Development in Brazil*

   After the United States, Brazil is currently the second largest producer of GE crops, with annual production of more than 30M ha of GE corn, cotton and soybean. BASF has recently developed a GE soybean specifically for the Brazilian market; that is, this GE soybean will not be marketed for production in the United States.

   EMPRAPA, the Brazilian Agricultural Research Corporation, has a strong internal capacity for GE crop development and recently achieved regulatory approval for a virus-resistant dry edible bean. This is first GE event that EMPRAPA has taken through the Brazilian regulatory system and many more are in the development pipeline. For example, EMBRAPA has a project to develop high-folate lettuce to combat certain birth defects. BASF's new soybean for Brazil was developed in partnership with EMBRAPA, and Monsanto is partnering with EMBRAPA to develop fungus-resistant soybeans.

2. *Regional GE Crop Development in China*

   China is a major producer of GE cotton and also has commercial production of GE poplar trees and GE papaya. Because of limited transparency, it is more difficult to get an accurate sense of GE crop development in China as compared to Brazil or India. We were unable to determine if

the unapproved tomato, sweet pepper and petunia events remain in production; we only know that the biosafety certificates for these crops have expired.

Phytase corn and insect-resistant rice received biosafety certificates in 2009, and appear to be on a commercialization track. They have the potential to become the first GE food crops to achieve wide-scale cultivation in China; however, China recently announced that the commercialization of these GE rice and corn events has been delayed (Reuters, 2013).

3. Regional GE Crop Development in India

Like many developing countries, India has embraced the production of GE cotton that provides economic benefits to millions of smallholder cotton producers. India also has the scientific capacity and regulatory infrastructure to bring domestic GE crop products to the market. While this has succeeded for GE cotton, where four of the six events on the market were developed in India, this success has not yet been duplicated for food crops.

Although the USAID-funded insect-resistant eggplant project is currently mired in political controversy, Indian scientists continue to develop a wide range of GE crops for India. Confined field trials of castor bean, corn, rice, mustard, peanut, potato, and sorghum are ongoing.

Aside from Brazil, China and India, regional GE crop development is occurring on a small scale in many other countries, too numerous to discuss in this report. Short summaries of GE crop activity in these countries are presented in Appendix D. For example, insect-resistant eggplant could be commercialized in the Philippines during 2013. A quick reference table of countries with GE crop production and/or development is presented in Appendix E.

Unauthorized Importation of GE Plants not Approved by Any Country

In addition to the 47 GE plants listed in Table 1, we must also recognize the possibility of the unauthorized importation of GE plants that remain regulated in the country of origin. The two sources of such unauthorized imports are: (1) illegal GE crop production; and (2) failure of confinement methods in CFTs.

The GAIN reports indicate that there is unauthorized production of GE corn and GE soybean in Poland and Ukraine; however, these are GE plants that are no longer regulated by APHIS-BRS. Unauthorized GE papaya is produced in Hong Kong; however, as discussed above, fresh papaya for consumption is not admissible from China. Therefore, the likelihood of an unauthorized importation of these GE plants is extremely low.

Due to the relatively small scale of most CFTs, failure of confinement methods is unlikely to result in a detectable unauthorized import of the GE plant. All countries with authorized CFTs are included in Appendix E.

CONCLUSIONS

From analysis of several global databases as well as the annual GAIN reports focused on biotechnology, APHIS generated a list of 47 GE events authorized for commercial cultivation in other countries but still subject to APHIS-BRS regulations found at 7 CFR part 340. Presently, the likelihood that any of these 47 events could enter the United States as imports is extremely low.

From the database analyses, APHIS has at least some information on the genetics for all but three of the 47 GE events. Should there be a need to conduct a safety or risk assessment relative to an unauthorized importation, genetic information about the GE event is essential. Through our bilateral discussions with China, USDA will attempt to obtain at least some basic genetic information about the Chinese GE plants.

While the current likelihood of importing any of the 47 GE events discussed in this report is extremely low, APHIS expects that the number of regionally developed GE crops will continue to grow and these asymmetric approvals may become the most likely sources of unauthorized imports in the future. Regional GE crop development continues to expand in Brazil, China and India, and a continued focus on tracking the development and deployment of these regional GE events will be required to guard against unauthorized imports.

APHIS and USDA's Foreign Agricultural Service (FAS) have agricultural attachés assigned to U.S. Embassies around the world that monitor GE crop development in country. We have ongoing mechanisms for information exchange with the countries that appear to be the most likely sources for unauthorized imports of GE crops. We will focus our efforts on obtaining genetic information for any asymmetric GE crop approvals during out annual bilateral meetings with Chinese regulators and pending bilateral meetings with Brazil. For India, we will necessarily rely more on our in country USDA personnel to obtain the genetic information required to facilitate an ERA.

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Appendices

Appendix A – OIG Audit Recommendations

Appendix B – Descriptions of the Databases Utilized to Generate Table 1

Appendix C – PPQ Admissibility of the 47 GE Events in Table 1 by Country and Commodity

Appendix D – Brief Country Summaries of GE Crop Development Activity

Appendix E – Summary of GE Crop Environmental Release Activity by Country

Appendix A
OIG Audit Recommendations

The USDA Office of Inspector General (OIG) conducted an audit of controls over the importation of transgenic plants and animals from October 1, 2007 through April 7, 2008 (50601-17-Te). The OIG found that USDA agencies' controls are appropriate for the current risk associated with transgenic biotechnology; however, OIG also found that USDA had 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 summary, USDA committed to a plan that includes the following actions:

- Coordinating among agencies
- Working with other international entities
- Engaging with other countries involved in biotechnology research through bilateral and multilateral efforts
- Performing an annual vulnerability assessment
- Analyzing input from non-governmental organizations

APHIS committed to follow through with these recommendations, including a commitment to perform the annual vulnerability assessment (VA) of the potential for unapproved transgenic plants to be imported into the United States and to draft potential import control policies to specifically respond to outstanding recommendation #1. The policy and primary strategy for control of transgenic imports will be based on information gathered from publicly available databases and advance intelligence gathered 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 USDA regulations will minimize the potential for unapproved transgenic plants to be imported into the United States.

Appendix B
Descriptions of the Databases Utilized to Generate Table 1

International Service for the Acquisition of Agri-biotech Applications (ISAAA) GM Approval Database

http://www.isaaa.org/gmapprovaldatabase/default.asp

- ISAAA is a not-for-profit international organization that shares the benefits of crop biotechnology to various stakeholders, particularly resource-poor farmers in developing countries, through knowledge sharing initiatives and the transfer and delivery of proprietary biotechnology applications.
- Search capabilities include: crops, events, genes, traits, phenotypes, developers, countries and method of transformation.
- The ISAAA database appears to be much more up-to-date than either CERA or BCH databases. For example, of the 23 regionally developed GE events identified in this analysis, all 23 can be found in the ISAAA database; however, only 1 and 3 of the 23 events can be found in the CERA and BCH databases, respectively. ISAAA also lists the virus-resistant dry edible bean from Brazil.

Center for Environmental Risk Assessment (CERA) GM Crop Database

http://cera-gmc.org/index.php?action=gm_crop_database

- CERA was established by the non-profit International Life Sciences Institute (ILSI) in March, 2009.
- The search capabilities of the CERA GM Crop Database include crop, trait, country, and type of approval.
- For purposes of this report, one major drawback of the CERA database is that it lists all of the non-GE approvals in Canada. Because of Canada's unique PNT regulatory system, the products of mutagenesis are also subject to the regulatory review and approval process. These products of mutagenesis are not considered LMOs, are not listed in either the ISAAA or BCH databases and are not considered GE plants by APHIS.
    - All of the wheat, sunflower and lentil listed in CERA are non-GE plants.
- The database includes tables that concisely summarize food, feed and release approvals by country.

Biosafety Clearing-House (BCH) Living Modified Organism (LMO) Registry

http://bch.cbd.int/database/lmo-registry/

- The BCH was established under the Cartagena Protocol on Biosafety as a mechanism for international communication regarding LMOs.
- For each LMO in the registry, the tab called "Decisions on the LMO" clearly distinguishes environmental release authorizations for commercialization from those for CFTs.

USAID Development Experience Database

https://dec.usaid.gov/dec/home/Default.aspx

- The USAID Development Experience Database provides details descriptions of USAID-funded GE crop development projects.
- The search term "biotechnology" yielded 21 documents.
- These include reports on the development of insect-resistant eggplant in India, insect-resistant cowpea in Nigeria, virus-resistant cassava in East Africa, fungus-resistant banana in Uganda and virus-resistant papaya in the Philippines.

Canadian Food Inspection Service (CFIA) Database of Plants Evaluated for Environmental and Feed Safety

http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp

- The CFIA database clearly distinguishes GE plants (LMO) from non-GE plants (non-LMO).
- The database also notes whether or not the GE plant has a current variety registration in Canada.

The USDA Foreign Agricultural Service (FAS) Global Agriculture Information Network (GAIN)

http://gain.fas.usda.gov/Pages/Default.aspx)

- GAIN has provided 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 FAS, which maintains the GAIN network.
- GAIN reports are documents that capture insight and intelligence garnered by FAS Ag Attachés in country, utilizing local sources of information.
- GAIN includes reports on biotechnology and other new technologies.

Appendix C

PPQ Admissibility of the 47 GE Events in Table 1 by Country and Commodity

Country	Crop	Events	Q37 Seed	Q37 Propagules Other than Seed	Q56
Australia	Carnation	4, 15, 16, 66, 11 (7442), 123.2.2 (40619), 123.2.38 (40644), 123.8.8 (40685), 1363A	Admissible	Admissible	Not Admissible
Brazil	Dry Edible Bean	EMB-PVØ51-1	Admissible	Prohibited	Not Admissible
Brazil	Soybean	BPS-CV127-9	Admissible	Admissible	Not Admissible
Burma	Cotton	Ngwe Chi 6 Bt	Admissible / PPQ 588 Permit	Prohibited	Not Admissible
Canada	Canola	Oxy-235, PHY14, PHY23, PHY35, PHY36	Admissible	Admissible	Not Admissible
Canada	Corn	DAS-40278-9	Admissible	Prohibited	Not Admissible
Canada	Soybean	BPS-CV127-9, DAS-68416-4, MON 87708	Admissible	Admissible	Not Admissible
China	Corn	BVLA430101	Prohibited	Prohibited	Not Admissible
China	Cotton	GK12, SGK321	Admissible / 588 PPQ Permit	Prohibited	Not Admissible
China	Papaya	Huanong No. 1	Admissible	Postentry	Not Admissible
China	Petunia	Petunia-CHS	Admissible	Admissible	Not Admissible
China	Poplar	Bt Poplar, Hybrid Poplar Clone 741	Admissible	Prohibited	Not Admissible
China	Rice	GM Shanyou 63, Huahui-1/TT51-1	Prohibited	Prohibited	Not Admissible
China	Sweet Pepper	PK-SP01	Admissible	Admissible	Not Admissible
China	Tomato	Da Dong No 9, Huafan No 1, PK-TM8805R	Admissible	Admissible	Not Admissible

Country	Crop	Events	Q37 Seed	Q37 Propagules Other than Seed	Q56
Colombia	Carnation	1351A (11351), 1400A (11400), 123.2.38 (40644), 959A (11959)	Admissible	Admissible	Not Admissible
European Union	Carnation	4, 15, 1226A, 11 (7442), 1363A, 959A (11959), 988A (11988)	Admissible	Admissible	Not Admissible
European Union	Potato	EH92-527-1	Prohibited	Prohibited	Not Admissible
European Union	Tobacco	C/F/93/08-02	Admissible	Prohibited	Not Admissible
India	Cotton	BNLA-601, Event 1, GFM Cry 1A, MLS 9124	Admissible / PPQ 588 Permit	Prohibited	Not Admissible
Iran	Rice	Tarom molaii + cry1Ab	Prohibited	Prohibited	Not Admissible
Japan	Canola	Oxy-235, PHY14, PHY23, PHY34, PHY36,	Admissible	Admissible	Not Admissible
Japan	Carnation	11 (7442), 123.2.2 (40619), 123.8.12, 123.2.38 (40644), 123.8.8 (40685), 1363A	Admissible	Admissible	Not Admissible
Japan	Corn	DAS-40278-9	Prohibited	Prohibited	Not Admissible
Japan	Rice	7Crp#10	Prohibited	Prohibited	Not Admissible
Japan	Soybean	DAS-68416-4 MON 87708	Admissible	Prohibited	Not Admissible
Pakistan	Cotton	GFM Cry1A	Admissible / PPQ 588 Permit	Prohibited	Not Admissible

Appendix D
Brief Country Summaries of GE Crop Development Activity

The summaries below represent a synthesis of information derived from multiple sources. These include: (1) the databases described in Appendix B; (2) the annual ISAAA report (ISAAA, 2012); (3) the GAIN reports; (4) conference calls to APHIS personnel in country; and (5) public news reports.

ARGENTINA: Argentina is the 3rd largest producer of GE crops with more than 24M ha of GE corn, GE soybean and GE cotton. Argentina intends to maintain a position of leadership in biotechnology and in 2012 announced a new regulatory framework for agricultural biotechnology, with a goal of reducing the approval time for new events to 24 months. Argentine scientists have developed GE sugarcane events with herbicide tolerance and insect tolerance; these events have been submitted for regulatory approval. GE potatoes are also in the regulatory review process. Argentina is exploring a joint venture with Brazil to develop GE sugarcane.

AUSTRALIA: Australia produces less than 1M ha GE cotton and GE canola. While Australia has been slow to approve GE food crops for cultivation, both public and private sector Australian researchers have active GE crop development programs and have been conducting CFTs in several crops including barley, banana, canola, clover, cotton, grapevines, Indian mustard, papaya, pineapple, ryegrass and wheat.

BANGLADESH: Bangladesh has yet to authorize commercial production of GE crops, but has recently conducted CFTs of Bt eggplant and late blight resistant potato. Through the Agricultural Biotechnology Support Project II (ABSP II), USAID has financially supported these field trials.

BELGIUM: No GE crops are commercially produced in Belgium, but CFTs of poplar and potato were conducted in 2011. A GE corn CFT was approved for 2012, and the poplar and potato trials are expected to continue.

BOLIVIA: Bolivia produces about 1M ha of GE soybean. No information was available on domestic GE crop development projects or CFTs of GE crops.

BRAZIL: After the United States, Brazil is the 2nd largest producer of GE crops with more than 35M ha of GE corn, GE soybean and GE cotton. Brazil has excellent capacity for GE crop development and recently approved a virus resistant dry-edible bean for commercialization. APHIS expects this is only the first of many GE plants that will be wholly developed in Brazil. Other GE crops in the regulatory approval pipeline include eucalyptus, papaya, potato and sugarcane.

BURKINA FASO: Burkina Faso produces about 0.3M ha of GE cotton. In 2012, GE cowpea was tested in CFTs and will be tested again in 2013.

BURMA (MYANMAR): Burma produces about 0.5M ha of GE cotton. The insect resistant cotton event Ngwe Chi 6 Bt appears to have been fully developed in Burma.

CANADA: Canada is now the 4th largest producer of GE crops, with more than 11M ha of GE crop production. GE canola accounts for about 70% of this production, with the remainder made up of GE corn, GE soybean and GE sugar beet. Canada also produces several herbicide tolerant crops developed by mutagenesis, which are therefore not GE; these include wheat, sunflower and lentil.

CHILE: Chile produces about 1M ha of GE corn, soybean and canola, all of which is seed for export. None of these crops has been approved for food or feed in Chile. Chile also permits CFTs; however, no information was available on the crops or numbers of trials that have been approved.

CHINA: China is the 6th largest producer of GE crops, primarily GE cotton. China also produces 300-400 ha of GE poplar and 5300 ha of GE papaya. Biosafety Certificates were issued for insect-resistant rice and phytase corn in 2009 and these crops continue to be developed. ISAAA includes tomato and sweet pepper among the commercial GE crops in China; however it is unclear if these crops are in commercial production.

COLOMBIA: Colombia has been producing GE cotton on a small scale for several years. GE corn and GE soybean have now received limited commercial authorizations; some GE corn is in production, but GE soybean has yet to be planted in Colombia. GE carnations and roses have been approved for commercial production but only for export; these flower crops are produced in confined greenhouses. The International Center for Tropical Agriculture (CIAT) has programs to develop GE rice and GE cassava, and several other institutes in Colombia have active GE crop development programs.

COSTA RICA: Costa Rica allows production of GE cotton and soybean seed for export only and recently granted similar authorization for production of GE corn seed for export only. Del Monte has been developing GE pineapple production in Costa Rica, but this GE event has not yet been commercialized. Costa Rica scientists are active in GE crop development and are developing GE rice with virus and herbicide resistance, GE banana with black Sigatoka resistance and GE pineapple with increased antioxidants. Authorized CFTs for these three GE crops are ongoing.

CZECH REPUBLIC: The Czech Republic produces GE corn on a small scale. GE potato was in production in 2010; however, this BASF project has since been cancelled. The Czech Republic is in a consortium with USDA-ARS seeking deregulation of the USDA's virus-resistant plum in the EU. CFTs of GE corn and GE sugar beet were conducted in 2012.

CUBA: Together with Sudan, Cuba is one of two countries to have adopted GE crops in 2012, and now produces GE corn on a small scale.

ECUADOR: No GE crops have been authorized for cultivation in Ecuador; however, Ecuador commercially produces GE carnation in confinement (greenhouses) and exports cut flowers globally, including to the United States.

EL SALVADOR: There is no commercial GE crop production in El Salvador and none is expected in the near future. Two GE corn events developed in the United States have been evaluated in CFTs.

EGYPT: Egypt produces GE corn on a small scale, less than 3000 ha. Egypt's Agricultural Genetic Engineering Resources Institute (AGERI) is the leading biotechnology institute in the Arab world with a wide range of GE crops in development. Drought tolerant GE wheat was field tested in 2011. Other GE crops in development include banana, barley, cotton, potato and tomato.

FRANCE: France produced 22,000 ha of GE corn in 2007; however, the cultivation of GE corn was banned in 2008. Despite this ban, France has several active GE crop development programs. France once led the EU in the number of CFTs, but there have been none since 2010.

GHANA: There is no commercial GE crop production in Ghana and none is expected in the near future. However, the Biosafety Act approved in 2011 should allow for CFTs of cassava, cowpea, rice and sweet potato in the next few years.

GUATEMALA: No GE crops are authorized for cultivation in Guatemala. CFTs of GE corn and GE cotton were conducted in 2004.

HONDURAS: With about 30,000 ha of GE corn, Honduras is the leading producer of GE crops in Central America. Honduras has authorized several CFTs, mostly of GE corn, but also a few for GE banana and GE rice.

HONG KONG: There is no authorized GE crop production in Hong Kong nor are there any confined field trials. However, because survey data indicated that 40% of the locally grown papaya is GE papaya, Hong Kong exempted GE papaya from the Genetically Modified Organisms Ordinance that became effective in 2011 (GAIN HK1220, 2012). GE rice projects are ongoing at the Chinese University of Hong Kong; however, the CFTs are conducted in China.

INDONESIA: Indonesia does not produce any commercial GE crops; however there are several GE crops under development. These include cassava, potato, rice, sugarcane and tomato. One GE sugarcane event has received an environmental safety recommendation, making it the GE crop closest to commercial cultivation in Indonesia.

INDIA: Although GE crop production is currently limited to GE cotton, India is the 5th largest producer of GE crops. The USAID-funded insect resistant eggplant was close to commercialization before it became mired in controversy. India has significant capacity for GE crop development and has many ongoing projects. CFTs conducted in 2011 include castor bean, cotton, corn, rice, mustard, peanut, potato, and sorghum.

KENYA: Although Kenya has allowed CFTs of GE crops for several years, no GE crops have yet been approved for commercial production. Currently authorized GE field trials include corn, cotton, cassava and sorghum.

KOREA, REPUBLIC OF: Although Korea has not authorized the cultivation of any GE crops, they do import GE commodities from the United States for use in food and feed. Korea has recently made significant investments in biotechnology research and development, and authorized more than 200 contained field trials in 2012. The most advanced GE crops in development are high resveratrol rice and virus resistant pepper; however it will take at least 5 years for either of these GE plants to complete the regulatory review process.

MALAYSIA: Malaysia has yet to authorize cultivation of any GE crops; however they have several GE crop development projects including GE papaya, GE passion fruit and GE oil palm. No information was found to confirm whether or not any of these GE crops have been field tested in Malaysia.

MEXICO: Mexico produces about 200,000 ha of GE cotton, and has minor production of GE soybean. GE corn and GE wheat are being produced in confinement. The 2012 GAIN report states that Mexico only allows CFTs for events approved in the United States; however, the United States has yet to grant nonregulated status to any GE wheat events.

NEW ZEALAND: While no GE crops have been approved for commercial cultivation, New Zealand has authorized 13 CFTs of GE plants including corn, onion, pine, potato, and sugar beet.

NIGERIA: There are no commercial GE crops grown in Nigeria, but Nigeria has been increasingly active in GE crop development. GE cassava, GE cowpea and GE sorghum have been evaluated in CFTs. The cowpea project is funded by USAID and the Gates Foundation funds both the cassava project and the sorghum project.

PAKISTAN: Pakistan now produces nearly 3M ha of GE cotton. This is presently all insect-resistant cotton; however, Pakistan has recently developed a virus-resistant cotton event that they hope to commercialize by 2016. Pakistan has also been conducting CFTs of herbicide tolerant and insect resistance in corn and cotton. GE wheat development is also ongoing.

PANAMA: Panama does not produce any GE crops, but has conducted 2 years of CFTs with GE corn.

PARAGUAY: Paraguay produces nearly 3M ha of GE soybean and recently approved the commercial production of GE cotton. Varieties of GE corn are currently in the final stages before commercial approval.

PHILIPPINES: The Philippines produces nearly 1M ha of GE corn. CFTs have been authorized for GE corn, GE cotton, GE eggplant GE papaya, and GE rice. Insect-resistant GE eggplant could be commercialized as early as 2013.

POLAND: Poland officially banned GMO crops in 2006. However, unofficial estimates place GE corn production at 3900 ha (GAIN PL1212, 2012).

PORTUGAL: Portugal produces GE corn on a small scale, less than 10,000 ha.

ROMANIA: Romania produces GE corn on a very small scale (300 ha). Romanian farmers have a high interest in the approval of GE soybean which they were able to produce before Romania joined the EU. CFTs of GE crops authorized in 2011 include corn, sugar beet and plum trees.

RUSSIAN FEDERATION: Russia has yet to develop the legal mechanism to authorize the cultivation of GE crops. No information was found to confirm whether or not any of these GE crops have been field tested in Russia.

SLOVAKIA: Slovakia produces GE corn on a small scale, less than 400 ha in 2012. CFTs have been authorized for one GE sugar beet event and for several GE corn events.

SPAIN: With only about 100,000 Ha of GE corn, Spain is the largest producer of GE crops in the EU. About 26 CFTs were authorized for 2011, mostly for GE corn, but also for sugar beet, cotton, tobacco and poplar trees.

SOUTH AFRICA: With nearly 3M ha of GE crops, South Africa is the leading producer of GE crops in Africa. This production consists entirely of GE corn, soybean and cotton events developed in the United States. In 2011, South Africa authorized 32 CFTs of GE crops or clinical trials of GE vaccines. The CFTs include corn, soybean, cotton and sugarcane. The South African Sugarcane Research Institute (SASRI) has received authorization to CFTs of four GE sugarcane events with modified carbohydrate metabolism. GE grapevines are also being evaluated in greenhouses.

SUDAN: One of the two countries to have adopted GE crops in 2012, Sudan has initiated production of GE cotton. No other information was available on GE crop development in Sudan.

SWEDEN: Starting in 2010, Sweden allowed cultivation of the BASF's GE potato with modified starch; however, this GE potato was only cultivated for 2 years. Since BASF has canceled this project, no further cultivation of this GE potato is expected. Sweden does allow CFTs and has authorized 130 field trials since 1989. In 2012, there were CFTs of GE aspen, GE apple and pear rootstocks, GE sugar beet and GE potato.

TAIWAN: No GE crops are commercially produced and none are expected to be authorized in the near future. Taiwan has 5 accredited field trial facilitates and has authorized field trials of GE broccoli, eucalyptus, papaya, potato, rice and tomato.

THAILAND: Thailand had allowed CFTs of tomato as early as 1994, and subsequently authorized CFTs of GE corn, cotton, papaya and tomato. No GE crops are commercially produced and CFTs have been banned since 2003.

UGANDA: No GE crops are commercially produced in Uganda; however the country has made great strides to increase their capacity for GE crop development. GE banana, GE cotton, GE cassava, and GE corn have all been evaluated in CFTs. Ugandan scientists are now producing all of the GE banana events in Uganda.

UKRAINE: Although no GE crops have been approved for commercial production, Ukrainian farmers have been growing unauthorized GE crops for several years. Experts estimate that the GE share is 60% for soybean and 30% of corn.

URUGUAY: Uruguay produces 1.4M ha of GE corn and GE soybean. CFTs are permitted; however no information was available on the crops or numbers of field trials.

Appendix E

Global GE Crop Commercial Cultivation and CFT Activity by Country

The table below represents a synthesis of information derived from multiple sources. These include: (1) the databases described in Appendix B; (2) the annual ISAAA report (ISAAA, 2012); (3) the GAIN reports; (4) conference calls to APHIS personnel in country; and (5) public news reports.

Country	Commercial Cultivation	GE Crops	CFTs	GE Crops	Comments
Argentina	YES	corn, cotton, soybean	YES	corn, potato, soybean, sugarcane, wheat	Significant R&D
Australia	YES	cotton, canola	YES	barley, banana, canola, clover, cotton, grapevines, Indian mustard, papaya, pineapple, ryegrass and wheat	Significant R&D
Bangladesh	NO		YES	eggplant, potato	ABSPII
Belgium	NO		YES	corn, poplar, potato	
Bolivia	YES	soybean	NA		
Brazil	YES	corn, cotton, soybean, dry edible bean	YES	eucalyptus, papaya, potato and sugarcane	Significant R&D
Burkina Faso	YES	cotton	YES	cowpea	
Burma	YES	cotton	YES	cotton	
Canada	YES	canola, corn, soybean, sugar beet	YES	many crops	Canada regulates mutants
Chile	YES	corn, soybean, canola	YES	NA	Seed production for export only
China	YES	cotton, papaya, poplar	YES	corn, rice	Significant R&D
Colombia	YES	cotton, corn, soybean	YES	NA	GE roses and GE carnations produced in containment
Costa Rica	YES	cotton, soybean, corn (new)	YES	rice, pineapple, banana	Seed production for export only

Country	Commercial Cultivation	GE Crops	CFTs	GE Crops	Comments
Czech Republic	YES	corn	Yes	corn, sugar beet	
Cuba	YES	corn	NA	NA	
Ecuador	NO		NO		GE carnations produced in confinement
Egypt	YES	corn	YES	wheat	
El Salvador	NO		YES	corn	
France	NO		YES	none	None since 2010
Ghana	NO		YES	none	New Biosafety Act (2011)
Guatemala	NO		YES	corn	None since 2004
Honduras	YES	corn	YES	banana, corn, rice	
Hong Kong	NO	papaya	NO		Exemption for GE papaya
India	YES	cotton	YES	castor bean, corn, eggplant, rice, mustard, peanut, potato, sorghum	Significant R&D ABSPII
Indonesia	NO		YES	cassava, rice, potato, sugarcane, tomato	ABSPII
Kenya	NO		YES	corn, cotton, cassava, sorghum	
Korea, Republic of	NO		NO	rice, pepper, bean	Significant R&D
Malaysia	NO		NA		ABSPII
Mexico	YES	cotton, soybean	YES	corn, wheat	
New Zealand	NO		YES	corn, onion, pine, potato, sugar beet	
Nigeria	NO		YES	cassava, cowpea, sorghum	
Pakistan	YES	cotton	YES	corn, cotton	GE wheat?
Panama	NO		YES	corn	
Paraguay	YES	corn, cotton, soybean	YES	corn, cotton, soybean	

Country	Commercial Cultivation	GE Crops	CFTs	GE Crops	Comments
Philippines	YES	corn	YES	corn, cotton, eggplant, papaya, rice	ABSPII
Poland	NO	corn	NO		Unauthorized GE production
Portugal	YES	corn	YES	none	None since 2010
Romania	YES	corn	YES	corn, sugar beet, plums	
Russian Federation	NO		NA		
Slovakia	YES	corn	YES	corn, sugar beet	
Spain	YES	corn	YES	corn, cotton, poplar, sugar beet, poplar	
South Africa	YES	corn, soybean, cotton	YES	corn, soybean, cotton, sugarcane	Regional GE sugarcane
Sudan	YES	cotton	NA		
Sweden	NO		YES	apple, aspen, pear, potato, sugar beet	
Taiwan	NO		YES	broccoli, eucalyptus, papaya, potato, rice, tomato	CFTs only at accredited sites
Thailand	NO		YES	none	None since 2003
Uganda	NO		YES	banana, corn, cotton, cassava	ABSPII
Ukraine	NO	corn, soybean	NO		Unauthorized GE production
Uruguay	YES	corn, soybean	YES	NA	