Global Analysis of GE Crop Production
FY2016 / FY2017

Executive Summary

This is the fifth report produced by USDA 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 title of the first four reports, which covered single years, was "Report on Genetically Engineered (GE) Plant Imports: Current and Future". For this fifth report, which covers two years, FY2016 and FY2017, we have revised the title to "Global Analysis of GE Crop Production" (GAP).

The purpose of this report is to identify the development and commercialization of GE plant events in foreign nations, and to analyze the likelihood of unauthorized importation into the United States of those GE plant events that are subject to the Animal and Plant Health Inspection Service (APHIS) regulations found at 7 CFR part 340.

The key findings are as follows:

- We identified 57 GE plant events authorized for commercial cultivation in other countries that would be subject to the APHIS regulations found at 7 CFR part 340 if they were imported, moved interstate or released into the environment in the United States. The likelihood of viable material of any of these 57 GE plant events entering the United States as imports is estimated to be either very low or extremely low.

- In the fourth annual report, FY2015, there were 56 GE plant events authorized for cultivation in other countries, but not in the United States, with the potential to enter the United States. In this fifth report, only one GE plant event was added to the list for FY2016/FY2017. In the long term, the asymmetric commercialization of regionally developed GE crops for which USDA may not receive petitions for nonregulated status under 7 CFR part 340 will increase the likelihood of unauthorized GE imports into the United States. Additionally, reduced regulatory harmonization due to divergent polices on genome editing has the potential to further complicate future analyses.

- Presently, with the exception of several GE cotton events, all of the regional GE plant events are cultivated on a relatively small scale; however as the list grows or the current list of these GE plant events are adopted by more farmers, the likelihood of unauthorized imports may increase.

- Unauthorized production of GE rice and GE papaya, initially in China and Thailand, respectively, appears to be spreading across Southeast Asia. Should this trend continue, the likelihood of viable material of these GE plant events entering the United States as imports will continue to increase.

TABLE OF CONTENTS

INTRODUCTION

Global production of GE crops has increased steadily during the past 22 years; in 2017, farmers in 24 countries grew more than 189M hectares (ha) of GE crops (ISAAA, 2017). Nearly all of the global GE crop production consists of corn, cotton, canola and soybean derived from GE plants that were first developed in the United States and for which USDA-APHIS has determined nonregulated status under APHIS regulations found at 7 CFR part 340 (hereinafter "APHIS GE Regulations"). However, GE crop development has been ongoing in many countries and some of these GE crops have been authorized for cultivation, yet might fall under the APHIS GE Regulations if imported into the United States.

Under the APHIS GE Regulations, APHIS-Biotechnology Regulatory Services (BRS) regulates the importation, interstate movement, and release into the environment of GE organisms which meet the definition of regulated article as defined in 7 CFR Part 340. These regulations include provisions for a petition procedure whereby USDA may determine nonregulated status for GE organisms. GE organisms with nonregulated status are no longer subject to these regulations. As of January 1, 2018, USDA has made determinations of nonregulated status in response to 127 petitions, representing 18 plant species. A USDA 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 USDA has previously determined nonregulated status.

In addition to the APHIS GE Regulations, APHIS-Plant Protection and Quarantine (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 APHIS-PPQ regulations found at 7 CFR 319 Subpart-Plants for Planting ("Q37") and 7 CFR §319.56 ("Q56") cover the importation of propagative plant material and fruits and vegetables for consumption, respectively (USDA-APHIS, 2018a; USDA-APHIS, 2018b).

In assessing the likelihood of unauthorized imports of GE plants subject to the APHIS GE Regulations, 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 Q37 and Q56. USDA also considered the APHIS-PPQ regulations specific to the importation of corn material for consumption (7 CFR §319.24 and 7 CFR §319.41), cotton (7 CFR § 319.8), rice (7 CFR § 319.55), and sugarcane (7 CFR § 319.15).

In FY2012, USDA developed the first report in this series as an initial baseline of the likelihood of unauthorized importation of GE plants; we referred to that report as a Vulnerability Assessment (VA). The FY2013, FY2014 and FY2015 reports were also referred to as VAs. Consistent with the scope of the APHIS GE Regulations cited above, the assessment included plants, seed, viable grain, whole plants, or other viable plant products (USDA, 2012). The FY2013, FY2014 and FY2015 VAs included new sections on regional GE crop development and unauthorized GE crop production (USDA, 2013; USDA, 2014; USDA, 2015). This FY2016-FY2017 report, now referred to as the Global Analysis of GE Crop Production (GAP) builds upon the previous four reports and includes a new section on plant breeding innovation.

USDA has been producing the annual GAP report in response to the USDA Office of Inspector General (OIG) audit of controls over the importation of transgenic plants and animals[1] 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 GAP (aka VA)

[1] GE animals are not covered in this report or the previously issued reports in this series. Because no GE animals are currently produced in open environments, the scope of this report has been limited to GE plants.

reports all use the term GE rather than transgenic because GE is the term used in the APHIS GE Regulations. Additional information about the OIG audit recommendations can be found in Appendix A.

Purpose

The purpose of this FY2016-2017 GAP report is to identify the development and commercialization of GE plants in foreign nations, and to analyze the likelihood for the unauthorized importation of those GE plants that are subject to the APHIS GE Regulations.

TERMINOLOGY

Several terms used in this analysis warrant some explanation. For the purpose of this report, these are defined as follows[2]:

Asynchronous Approval – An asynchronous approval is an approval for commercial cultivation in another country in cases where USDA has received a petition for a determination of nonregulated status. In these cases, USDA has the full data package required to conduct a plant pest risk assessment (PPRA) and Environmental Assessment (EA) of the GE plant. If USDA grants a determination of nonregulated status, the approval in the other country is no longer asynchronous: therefore, asynchronous approvals are transient by definition.

Asymmetric Approval – An asymmetric approval is an approval for commercial cultivation in another country in cases where USDA has not received a petition for a determination of nonregulated status. If the GE plant was developed for regional production and consumption, with no exports of viable material intended for the United States, USDA is unlikely to receive such a petition. In these cases, USDA does not have the full data package required to generate the PPRA and EA of the GE plant.

Biosafety Certificate – A biosafety certificate is a regulatory document 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). A biosafety certificate is not an authorization for commercial cultivation. GE plant events receiving a biosafety certificate are eligible for variety registration, which is the final step in commercialization; however, the Chinese government has yet to establish a variety registration process for GE crops. Vietnam also requires a biosafety certificate prior to commercialization; however, the above definition only applies to China.

Confined Field Trial (CFT) – A confined field trial is one that is conducted in a manner that minimizes persistence in the environment. A regulated field trial (environmental release) of a GE plant is commonly referred to as a CFT.

Variety Registration – Variety registration is the formal process of registering specific varieties for cultivation in a country. In many countries, but not in the United States, variety registration is

[2] 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.

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 derived from the GE plant. Lack of variety registration may indicate 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

The data collection phase had three distinct goals: (1) to identify all GE plants approved for commercial cultivation in other countries but subject to the APHIS GE Regulations; (2) to compile brief synopses of GE crop development by country; and (3) to identify countries with reported 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 the APHIS GE Regulations. 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 and subject to the APHIS GE Regulations:

- The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) Genetically Modified (GM) Approval Database
- The Center for Environmental Risk Assessment (CERA) GM Crop Database
    - Note: This database is currently offline due to funding constraints.
- The Biosafety Clearing-House (BCH) 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 subject to the APHIS GE Regulations. Each of the databases provided useful information, and analyzing multiple databases allowed discrepancies to be detected. A detailed description of each database is presented in Appendix B.

When USDA makes a determination of nonregulated status the determination applies to all of the progeny of the GE plant. Developers are then free to use traditional 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 USDA, 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 USDA. Similarly, products of mutagenesis are not regulated by USDA under the APHIS GE Regulations; 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 (FAS) Global Agriculture Information Network (GAIN)
- The European Commission's Joint Research Centre's Deliberate Release and Placing on the EU Market of GMOs – GMO Register (GMOINFO)

The annual ISAAA report (ISAAA, 2017) provides commercial production details of GE crops by country. In some cases, the GAIN reports provided more accurate information on the extent of commercial production. The GAIN reports were used to assess the extent of GE crop research and development in each country, with emphasis on authorized CFTs.

In addition to the regulatory approval of the GE crop, many 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 is 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 three potential sources of such unauthorized imports are: (1) unauthorized GE crop production; (2) failure of confinement methods in CFTs; and (3) mislabeled planting material. While it was not possible to fully analyze the likelihood of such imports, available information derived from GAIN reports and from the press is summarized below. The European Commission's Rapid Alert System for Food and Feed (RASFF) provides some information on global trade in food and feed derived from GE crop products not approved for food or feed use in the European Union (European Commission, 2017).

Analysis Process

The primary goal of the analysis phase was to evaluate the likelihood that viable material of 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 Q37 and Q56 were reviewed to determine the entry requirements (admissibility) of imports for each crop/country combination. Under Q37, certain

agricultural commodities imported into the United States and intended for planting must meet entry requirements, while others are prohibited (Not Authorized Pending Pest Risk Analysis (NAPPRA)). Under Q56, 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, 2018a), and the entry requirements for fruits and vegetables were obtained from the Fruits and Vegetables Import Requirements (FAVIR) Online Database (USDA-APHIS, 2018b). Since nonviable products are outside the scope of the APHIS GE Regulations, the analysis of entry requirements did not include processed products such as oils, corn meal, de-hulled (white) rice, 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 analysis phase of the methodology. This was supplemented with information obtained through direct communication with USDA personnel in key countries, and in some cases by direct communication with the developers of the GE plant. When available, press releases and news reports were obtained to analyze commercialization plans.

RESULTS and ANALYSIS

Our analysis identified 57 GE plant events that are authorized for commercial cultivation in other countries and would be subject to APHIS GE Regulations if imported into the United States (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 currently regulate at the level of the transformation event. Note that details about the 19 GE carnation events have been extracted from Table 1 and moved to Appendix C.

The 57 GE plant events in Table 1 represents an increase of one GE plant event (1 addition and 0 deletions) relative to the FY2015 report. The one newly added GE plant event is an insect resistant GE sugarcane event and is denoted in bold in Table 1.

Not all of the 57 GE plant events 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 plant events is evidence that seed of those GE plant events is no longer sold, while lack of variety registration for newly developed GE plant events is partial evidence that they are unlikely to be marketed in the current growing season.

Although 133 GE plant events have been approved for commercial cultivation in Japan, GE rose is the only GE crop that has ever been commercially produced in Japan (GAIN JA7138, 2017). 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 and feed use, they are required to conduct a CFT for the environmental safety review. However, prefecture-based regulations effectively discourage farmers from growing any of these approved GE crops. In Hokkaido,

Table 1. Complete list of GE plant events approved for commercial cultivation in other countries and subject to the APHIS GE Regulations.

Crop	Applicant	OECD Unique ID	Event	Trait[1]	Release Approvals	Likelihood for Unauthorized Importation[2]
Canola	Bayer	ACS-BNØ11-5	Oxy-235	HR	Canada, Japan	Extremely Low
Canola	Bayer	NONE	PHY14	HR	Japan	Extremely Low
Canola	Bayer	NONE	PHY23	HR	Japan	Extremely Low
Canola	Bayer	NONE	PHY35	HR	Japan	Extremely Low
Canola	Bayer	NONE	PHY36	HR	Japan	Extremely Low
Carnation[3]	Florigene / Suntory	Various	19 Events	PQ	Various	Very Low
Corn	Pioneer	DP-Ø33121-3	33121	IR/HR	Japan	Very Low
Corn	Origin Agritech (China)	NONE	BVLA430101	PQ	China	Very Low
Corn	CIGB	NONE	FR-Bt1	IR	Cuba	Very Low
Cotton	Chinese Acad Ag Sci	NONE	SGK321	IR	China	Extremely Low
Cotton	Chinese Acad Ag Sci (China)	NONE	GK12	IR	China	Extremely Low
Cotton	CICR (India)	NONE	BNLA-601	IR	India	Extremely Low
Cotton	Cotton and Sericulture Dept (Myanmar)	NONE	Ngwe China 6 Bt	IR	Burma	Extremely Low
Cotton	JK Agri Genetics Ltd (India)	NONE	Event 1	IR	India	Extremely Low
Cotton	Metahelix Pvt Ltd (India)	NONE	MLS 9124	IR	India	Extremely Low
Cotton	Nath Seeds (India)	GTL-GFM311-7	GFM Cry1A	IR	India, Pakistan	Extremely Low
Dry Edible Bean	EMBRAPA	EMB-PVØ51-1	EMBRAPA 5.1	VR	Brazil	Extremely Low
Eggplant	BARI	NONE	EE-1	IR	Bangladesh	Very Low

Crop	Applicant	OECD Unique ID	Event	Trait[1]	Release Approvals	Likelihood for Unauthorized Importation[2]
Eucalyptus	FuturaGene (Brazil)	NONE	H421	AP	Brazil	Very Low
Papaya	South China Ag U (China)	NONE	Huanong No. 1	VR	China	Very Low
Petunia	Beijing U (China)	NONE	Petunia-CHS	PQ	China	Extremely Low
Poplar	Res Inst of Forestry (China)	NONE	Bt Poplar, poplar 12	IR	China	Extremely Low
Poplar	Res Inst of Forestry (China)	NONE	Hybrid Poplar Clone 741	IR	China	Extremely Low
Potato[4]	BASF Plant Science	BPS-25271-9	EH92-527-1	PQ	EU	Extremely Low
Potato	Tecnoplant S.A. (Argentina)	TIC-AR233-5	TIC-AR233-5	VR	Argentina	Extremely Low
Rice	Ag Biotech Res Inst (Iran)	NONE	Tarom molaii + cry1Ab	IR	Iran	Extremely Low
Rice	Huazhong Ag U (China)	NONE	GM Shanyou 63	IR	China	Extremely Low
Rice	Huazhong Ag U (China)	NONE	Huahui-1/TT51-1	IR	China	Extremely Low
Rice	Nat Inst Ag Sci (Japan)	NONE	7Crp#10	PQ	Japan	Extremely Low
Soybean	Verdeca Inc.	IND-ØØ41Ø-5	IND-ØØ41Ø-5	AP	Argentina	Extremely Low
Sugarcane[5]	**Centro de Tecnologia Canavieira (Brazil)**	**CTC-14117-4**	**CTB141175/01-A**	**IR**	**Brazil**	**Extremely Low**
Sugarcane	PT Perkebunan XI	NONE	NXI-1T	AP	Indonesia	Extremely Low
Sugarcane	PT Perkebunan XI	NONE	NXI-4T	AP	Indonesia	Extremely Low
Sugarcane	PT Perkebunan XI	NONE	NXI-6T	AP	Indonesia	Extremely Low
Sweet Pepper	Beijing U (China)	NONE	PK-SP01	VR	China	Extremely Low
Tobacco	SNETA (France)	NONE	C/F/93/08-02	HR	EU	Extremely Low
Tomato	Beijing U (China)	NONE	PK-TM8805R	VR	China	Extremely Low

Crop	Applicant	OECD Unique ID	Event	Trait[1]	Release Approvals	Likelihood for Unauthorized Importation[2]
Tomato	Huazhong Ag U (China)	NONE	Huafan No 1	PQ	China	Extremely Low
Tomato	Inst Microbiology, CAS (China)	NONE	Da Dong No 9	PQ	China	Extremely Low

[1] – Phenotypic categories used by APHIS-BRS and defined as follows: AP – agronomic properties, HR – herbicide resistant, IR – insect resistant, PQ – product quality; VR – virus resistant.
[2] – Likelihood of Unauthorized Importation is estimated at the commodity level; no estimates were made for individual events.
[3] – Further details about the 19 GE carnation events can be found in Appendix C.
[4] – The cultivation approval for the BASF potato was annulled in 2013; however, it is included here because there had been significant production in prior years.
[5] – The one GE event new to Table 1 is denoted in bold.

for example, farmers must complete a series of steps to obtain approval from the Hokkaido Governor's Office. These steps include holding public meetings at the farmer's expense, and covering the $3000 cost of the application review (GAIN JA6050, 2016).

Of the 57 GE crop events listed in Table 1, USDA has at least some information on the genetics for all but four GE events. Should there be a need to generate a plant pest risk assessment (PPRA) and an Environmental Assessment (EA) relative to an unauthorized importation into the United States, genetic information about the GE event is essential. The four GE events for which USDA lacks information are: (1) the insect-resistant cotton event (Ngwe Chi 6 Bt) developed in Burma; (2) the insect-resistant corn (FR-Bt1) developed in Cuba; (3) the tomato event (Da Dong No 9) developed in China; and (4) the product-quality petunia event (Petunia-CHS) developed in China.

USDA Entry Requirements

For each GE plant event listed in Table 1, the USDA entry requirements under Q37 and Q56 are summarized by country/commodity in Appendix D. 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). For sugarcane, both seed and propagules are prohibited from all countries (7 CFR §319.15). Cotton seed can only be imported into the United States with a permit (7 CFR §319.8).

Crops with GE Events Approved for Cultivation in Other Countries and Subject to the APHIS GE Regulations.

At the end of each crop summary, there is an estimate of the "Likelihood for Unauthorized Importation" of viable plant material. The estimates are based on consideration of the extent of authorized commercial production, whether or not this authorization is current and the USDA entry requirements. The five categories used to describe these likelihoods are as follows:

- High – Such as events in large-scale production, of which some is routinely exported to the United States
- Moderate – Such as events in large-scale production in crops not typically or only occasionally exported to the United States, but for which importation is not prohibited by APHIS-PPQ.
- Low – Such as events in small-scale production, if importation is not prohibited by APHIS-PPQ.
- Very Low – Such as events no longer in commercial production, or when importation is prohibited by APHIS-PPQ.
- Extremely Low – Such as events that were never commercialized.

Note that all of the GE crops summarized below were estimated to fall into the very low or extremely low categories.

Canola: The five GE canola events are all older Bayer CropScience events developed in the 1990's. The four glufosinate resistant events (PHY14, PHY23, PHY35 and PHY36) were never produced commercially. The only cultivation approval for these events is the Type I approval from Japan; they were never authorized for production in Canada. The bromoxynil resistant event Oxy-235 was grown commercially in Canada in 2000 and 2001; the bromoxynil resistant cultivars were deregistered by CFIA in 2004 (Beckie and Warwick, 2010). No registered varieties for any of these five events can be found in the CFIA database.
Likelihood of Unauthorized Importation: Extremely Low.

Carnation: Nineteen GE carnation events, all developed by Florigene or Suntory, have been approved for cultivation in one or more of the following countries/regions: Australia, Colombia, the European Union, Japan, Malaysia and Norway. These GE carnations are commercially produced in greenhouses in Colombia and exported as cut flowers (GAIN CO1717, 2017). In 2008, APHIS informed Florigene that cut carnations are not subject to the APHIS GE Regulations 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 the APHIS GE Regulations requires authorization. Malaysia has authorized the importation of cut flowers of 8 GE carnation events. The ISAAA database lists these as cultivation approvals; however the authorizations prohibit use as planting material. Under USDA phytosanitary regulations found at Q37, carnation seed is admissible, but other propagules are restricted and subject to post-entry quarantine requirements. A USDA database search covering 2014-2018 did not reveal any importations of carnation seed from Colombia.

These post-entry requirements do not apply to the Netherlands and the United Kingdom; therefore, the likelihood of unauthorized importation may increase if these countries initiated production of GE carnation.
Likelihood of Unauthorized Importation: Very Low

Corn: Of the three GE corn events, one was developed in the United States, one was developed in China and one was developed in Cuba. The DuPont/Pioneer event (DP-Ø33121-3) received a cultivation approval from Japan; however, this is an asymmetric approval since USDA has not received a petition for this product. In this case, DuPont/Pioneer made a business decision to seek approval in Japan prior to making the final commercialization decision on this product for North America (A. Gutsche, personal communication). Regardless, since no GE crops are commercially cultivated in Japan, the likelihood that seed or viable grain of this GE corn event might be imported into the United States without an authorization is extremely low. The GE corn event BVLA430101, developed by the Chinese Academy of Agricultural Science and then licensed to the Chinese biotechnology company Origin Agritech Ltd., received a biosafety certificate in 2009 from the Ministry of Agriculture. This biosafety certificates expired in August 2014, but was renewed in December 2014. USDA phytosanitary regulations found at 7 CFR §319.41 prohibit the importation of corn seed from China (See Appendix D), so the likelihood for seed or viable grain of this GE corn to be imported into the United States is very low. The GE corn event FR-Bt1 developed in Cuba was a new addition to Table 1 in the FY2014 report. Although this event is not listed in the BCH, CERA or ISAAA databases, the annual ISAAA publication reported that Cuba produced 3000 ha of this event in 2014 under a system of "regulated commercialization" (ISAAA, 2014). In 2015, ISAAA reported that Cuba had not planted GE corn, but would resume planting in two years (ISAAA, 2015a); however, the 2016 ISAAA report made no mention of Cuba (ISAAA, 2016). Recent reports suggest that Bt corn production may have been reinitiated in 2017 (Action Institute, 2017; Granma, 2017). USDA regulations prohibit importation (NAPPRA) of corn seed from Cuba. While trade with Cuba has been curtailed for many years due to the U. S. embargo, the recent establishment of diplomatic relations raises the theoretical possibility of potential future trade.
Likelihood of Unauthorized Importation: Very 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. 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. USDA phytosanitary regulations require permits for the importation of cotton, cotton products and seeds. All propagules of cotton except seed are NAPPRA from all countries. Cotton seed is prohibited from all countries when not meeting conditions of entry; treatment is required if seeds are fuzzy and have lint. During the period 2014-2018, the United States imported two shipments of cottonseed from China with a total weight of 8 kg, and two shipment of cottonseed from India with a total weight of 150 gm; no cottonseed was imported from Burma in this same timeframe. All of the cottonseed was imported with USDA permits.
Likelihood of Unauthorized Importation: Extremely Low

Dry Edible Bean: EMBRAPA, the Brazilian Agricultural Research Corporation, has received regulatory approvals for a virus-resistant GE dry edible bean (*Phaseolus vulgaris*); however, GE bean varieties are not yet in commercial production. 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 this GE dry edible bean was fully approved for cultivation in 2011, no GE varieties have been registered. The discovery that the GE dry edible bean is susceptible to a second virus has significantly delayed the commercial timelines; incorporating resistance to the second virus requires an additional 2-5 years (Jim Kelly, personal communication). Although the event was created in a pinto bean background, it was backcrossed into the carioca seed type, which represents 70% of the beans consumed in Brazil, and will not be incorporated into black beans or other beans that might be exported (Jim Kelly, personal communication). Yield trials of 10 elite GE bean lines have shown encouraging results (Souza et al, 2018). FAS reports that the GE bean will not be launched until 2019/2020 (GAIN BR1720, 2017). The GE dry edible beans are not intended for production in the United States and USDA has not received a petition for nonregulated status. Since seed of dry edible bean from Brazil is admissible under Q37, the likelihood of unauthorized importation may increase when the varieties are commercially launched.
Likelihood of Unauthorized Importation: Extremely Low.

Eggplant: Bangladesh made global headlines in 2013 with the commercial approval of Bt eggplant, the same USAID-supported project that has been entangled in politics in India. Four varieties of the GE eggplant were approved and seed was distributed to 20 farmers for planting in 2014 (GAIN BG5006, 2015). Since 2014, news reports have suggested that some of this seed had been smuggled into India (Business Standard, 2014), and reports of unauthorized GE eggplant production in India have continued into 2017 (GAIN IN7135, 2017). USDA permits importation of eggplant seed, subject to sampling, but eggplant fruit from Bangladesh or India is not admissible. Due to the small scale of cultivation to date, the likelihood of importation of seed of these GE eggplants is very low; however, this likelihood will increase as the scale of cultivation increases.
Likelihood of Unauthorized Importation: Very Low.

Eucalyptus: In April 2015, the Brazilian National Technical Committee on Biosafety (CTNBio) approved the high yielding GE Eucalyptus (event H421) developed by FuturaGene, a wholly owned subsidiary of Suzano Pulp and Paper (São Paulo, Brazil). This represents the first approval of a GE Eucalyptus by any country (FuturaGene, 2015). The GE Eucalyptus expresses the cel1 protein, an endoglucanase derived from *Arabidopsis thaliana*. These GE Eucalyptus trees will not be available until 2019/2020 (GAIN BR1720, 2017). Regardless of whether the trees are initiated from seed or from cuttings, Eucalyptus plantations are planted with containerized seedlings (Arborgen, 2014). Eucalyptus seed imported from Brazil requires a USDA permit, and Eucalyptus cuttings imported from Brazil are subject to post-entry quarantine.
Likelihood of Unauthorized Importation: Very Low.

Papaya: The one GE papaya event in Table 1 was developed in China. ISAAA reports that China produced this papaya on 7130 ha in 2017 (ISAAA, 2017). Survey data indicates that this same GE papaya

event is widely cultivated in Hong Kong (GAIN HK1220, 2012). Because these GE papaya trees were widespread in Hong Kong, they were exempted from its GMO Ordinance which became effective in 2011. Since USDA has post-entry quarantine requirements for importation of papaya cuttings for planting and fresh papaya for consumption is not admissible from China or Hong Kong (see Appendix D), the likelihood of unauthorized importation of this GE papaya is extremely low. In 2010, another GE papaya event known as Tainung No. 1 and developed in Taiwan was detected in papaya seedlings for sale in a local garden store in Japan (GAIN JA5024, 2015). Since there are no cultivation approvals for this GE papaya, it is not included in Table 1; however, the unauthorized distribution of GE papaya plants in Japan suggests that there may have been mislabeling of planting material or breaches of confinement when these GE papayas were tested in CFTs in Taiwan. In 2011, the Japanese government cut down over 8000 farm-grown unapproved GE papaya plants. Since no GE papaya plants were detected in 2013 and 2014, monitoring was discontinued (GAIN JA5024, 2015). There are also anecdotal reports of unauthorized cultivation of GE papayas in Thailand, and continued RASFF notifications of GE papaya products exported from Thailand to Europe supports these reports (European Commission, 2017). Papaya from Thailand is not admissible to the United States under Q56. Japan routinely screens for GE content in all papaya imports from China, Vietnam and Thailand (Emi Nagata, personal communication).
Likelihood of Unauthorized Importation: Very Low.

Petunia: The one GE petunia event in Table 1 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 (GAIN CH12046, 2012). This petunia event is not the same event that was detected in global commerce in 2017; see below for a discussion of the second petunia event.
Likelihood of Unauthorized Importation: Extremely Low.

Poplar: The two GE poplar events were developed in China. Both of these GE poplar events are resistant to insects, and were first approved for cultivation in 2001. According to ISAAA, China grew these GE trees on 543 ha in 2016 (ISAAA, 2016); no update was provided for 2017 (ISAAA, 2017). Poplar trees are propagated by cuttings and planting material typically moves internationally as cuttings. USDA regulations prohibit the importation of poplar cuttings from China.
Likelihood of Unauthorized Importation: Extremely Low.

Potato: The two GE potatoes in Table 1 include one event from BASF that has since gone off the market, and one event from Technoplant S.A. (Buenos Aires, Argentina) just entering the market. BASF's GE potato with modified starch was approved for placing on the market for cultivation in the EU in 2010. BASF cancelled the project in 2012 and withdrew the product from the market (BASF, 2013). Subsequently, the authorization for placing on the market was annulled by a court decision. However, because the GE potato was commercially cultivated, for example on 147 ha in the Czech Republic in 2010, the possibility exists that it could inadvertently enter commerce. Importation of potatoes from the EU is prohibited (NAPPRA) under USDA phytosanitary regulations (see Appendix D). The virus resistant GE potato recently approved for cultivation in Argentina was not expected to reach the market for two years (FreshPlaza, 2015); however, no additional information is available. Fresh potatoes for consumption are not admissible to the United States.

Likelihood of Unauthorized Importation: Very Low.

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; these biosafety certificates expired in August 2014, but were renewed in December 2014. Variety registration is required before these two GE rice events can be produced commercially; however, the numerous notifications to RASFF suggest that unauthorized cultivation is widespread (European Commission, 2017). The Japanese anti-allergy 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. ISAAA does not include Iran on the list of countries growing GE crops (ISAAA, 2017) and information as to the extent of commercial production, if any, of this GE rice event is unavailable. Nearly all rice grain shipped internationally has been de-hulled and is therefore no longer viable. USDA prohibits the importation of rice seed (7 CFR 319.37.4, NAPPRA).
Likelihood of Unauthorized Importation: Extremely Low.

Soybean: The new drought tolerant HB4 soybean event (IND-ØØ41Ø-5) developed by Verdeca in Argentina represents the first GE soybean developed outside of the United States. The developers are now focused on gaining approval to export HB4 soybeans to China, the largest importer of South American soybeans, prior to commercial launch. The approval of this event, as well as another GE soybean approved earlier in 2015, includes a requirement that the event must be approved in China before it can be commercialized in Argentina (GAIN Argentina, 2015). In August 2017, Verdeca submitted a petition for a determination of nonregulated status to USDA. Therefore, this asymmetric approval is now an asynchronous approval. Soybean as grain for consumption is admissible to the United States, and is only subject to inspection upon arrival. While the short term likelihood that these GE soybeans may enter the United States as unauthorized imports is currently extremely low, this likelihood will decrease to zero if this event is granted a determination of nonregulated status by USDA.
Likelihood of Unauthorized Importation: Extremely Low.

Sugarcane: In 2013, Indonesia authorized the cultivation of 3 GE sugarcane events conferring drought tolerance. Once the food approvals are obtained, GE sugarcane will become the first GE crop produced commercially in Indonesia. A GE sugarcane event conferring herbicide resistance has completed the regulatory review in Argentina, and only awaits a pending decision by the Secretary of Agriculture (Andrea Yankelevich, personal communication). In 2017, Brazil approved insect resistant GE sugarcane for commercial cultivation. This new GE sugarcane event is the only new addition to Table 1 in this report, and is expected to be commercially available in 2019/2020 (GAIN BR1720, 2017). USDA prohibits the importation of sugarcane seed and propagules (7 CFR 319.37.4, NAPPRA).
Likelihood of Unauthorized Importation: 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). Sweet pepper seed is admissible, but other propagules are prohibited (except from Canada); fresh fruit is also not admissible (see Appendix D).
Likelihood of Unauthorized Importation: Extremely Low.

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 FR1714, 2017), it is extremely unlikely that this GE tobacco event could be imported into the United States. It also unclear if France ever authorized the cultivation of this GE tobacco in France; we only know that it was approved for placing on the market at the EU level. All propagules, except seed, of *Nicotiana* from all countries except Canada are not authorized entry into the United States as of May 20, 2013 when *Nicotiana* was added to the NAPPRA list. Small quantities of plants may be able to be imported for research and development purposes by applying for a Controlled Import Permit which would allow importation under conditions specified in the permit.
Likelihood of Unauthorized Importation: Extremely Low.

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 production (GAIN CH12046, 2012). Tomato seed is admissible, however other propagules are prohibited and tomato fruits are not admissible (see Appendix D).
Likelihood of Unauthorized Importation: Extremely Low.

In summary, for the 57 GE plant events listed in Table 1, the likelihood of unauthorized importation of viable material into the United States is estimated to be either very low or extremely low.

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 USDA. With the exception of the Verdeca soybean event, the 57 GE plant events listed in Table 1 are all asymmetric approvals for which USDA has not received petitions for determination of nonregulated status. The DuPont / Pioneer GE corn event represents a special case; a business decision was made to submit for regulatory approval in Japan first. However, the company subsequently decided to discontinue development of the product. The Verdeca soybean was an asymmetric approval prior to USDA receiving a petition in August 2017.

Because USDA chose to produce Environmental Impact Statements for the environmental reviews of several 2,4-D and dicamba resistant products, there was a transient increase in asynchronous approvals with Brazil, Canada and Japan in previous years while those reviews were being completed. However, UDSA has now completed all of those determinations and no new asynchronous approvals have been included in Table 1 since the FY2014 GAP report.

If we disregard the Pioneer GE corn event and the five GE canola events that were never commercialized, as well as the 19 carnation events, there are 32 remaining asymmetric approvals for further analysis, almost all of which were developed by public institutions or regional seed companies. For purpose of discussion, we 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 USDA.

Of the 32 regionally developed GE crops, 13 were developed in China, four were developed in India, three were developed in Brazil and two were developed in Argentina. 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 five events developed in Argentina and Brazil are discussed in further detail in the crop sections above and in Appendix E. The remaining regional GE plant events were developed in Bangladesh, Burma, Cuba, France, Indonesia, Iran and Japan. Regional GE crop development continues to expand, and USDA will continue to track the development and deployment of regional GE plant events, including through our bilateral discussions with key countries.

Two asymmetric approvals have the potential to achieve large-scale production in the near future: (1) the virus-resistant dry edible bean developed in Brazil; and (2) the drought tolerant soybean developed in Argentina. Although the GE dry edible bean was fully approved for commercial cultivation in Brazil in 2011, no GE bean varieties have been registered because the GE bean was found to be susceptible to a second virus (Jim Kelly, personal communication). Commercial production is not expected before 2019/2020 (GAIN BR1720, 2017). 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 will exist. Commercialization of the new GE soybean in Argentina will be delayed until the food use approval is obtained from China (GAIN Argentina, 2015). While the likelihood of unauthorized imports of these two products is currently extremely low, this likelihood will rise when these products enter the global market place.

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 plant events are cultivated on a large scale; however as this list grows or the current list of GE plant events are adopted by farmers, the likelihood for unauthorized imports will necessarily increase.

Regulatory Developments Related to Plant Breeding innovation

When countries developed regulations for GE crops, many developed a regulatory framework in which the use of recombinant DNA (rDNA) techniques is the regulatory trigger. However, since the introduction of GE crops more than 30 years ago, crop scientists have developed a wide variety of innovative techniques to genetically improve crops. These new techniques have been collectively

referred to as New Plant Breeding Techniques (NPBTs) (Lusser et al., 2012). The questions that regulators in some countries have been asking are:

1. Do these products fall under the GE regulatory framework in my country?
2. If not, should they be regulated?

When countries developed their frameworks for regulating agricultural biotechnology, there was a clear distinction between products developed with rDNA technology and products of traditional breeding. Today, with the development of NPBTs, in particular genome editing, this distinction is no longer clear. Lusser et al (2012) lists seven categories of NPBTs; however, some of these categories are not new at all. In the case of grafting, for example, the concern is how to regulate a tree with a GE rootstock and a non-GE scion. Rather than this being a new plant breeding technique, this is simply a new regulatory scenario.

In contrast to grafting, genome editing is clearly new and innovative. The first category on the original list of NPBTs was zinc finger nucleases (ZFNs). Since then, other nucleases (i.e. TALENs and CRIPSRs) have been developed and are being widely used for crop improvement. Therefore, this category would be better referred to as the Site-Directed Nuclease (SDN) category. Lusser et al (2012) also introduced three categories of ZFN products as ZFN-1, ZFN-2 and ZFN-3. These are now commonly referred to as SDN-1, SDN-2 and SDN-3. The distinction is that SDN-1 is delivered without a DNA repair template. That is, the SDN makes the directed cut which is then repaired by non-homologous end joining (NHEJ). During NHEJ, small deletions and/or insertions (indels) may result. However, these small indels are random and one could argue that all such indels would be possible with traditional plant breeding.

In contrast, SDN-2 and SDN-3 both involve the delivery of a DNA repair template along with the SDN. The distinction between SDN-2 and SDN-3 is the length of the DNA repair template, a short template with SDN-2 and a long template with SDN-3; however, there is not yet any accepted international definition that distinguishes these two categories. One proposal is that SDN-2 entails modifications of endogenous genes, whereas SDN-3 inserts whole new genes.

Australia's Office of the Gene Technology Regulator (OGTR) has unique regulatory authority because the OGTR is tasked with determining which gene technologies should be regulated. In 2016 OGTR initiated a Technical Review of the Gene Technology Regulations, which included consideration of whether genome editing should be considered a gene technology (OGTR, 2017). Under option 3, OGTR proposed that the products of SDN-1 would not be regulated as GE, while the products of SDN-2 and SDN-3 would be regulated as GE.

Israel was one of the first countries to announce regulatory policy for some genome edited products (GAIN Israel, 2017). Genome edited plants with deletions and no inserted foreign DNA will not be subjected to the GE Seed Regulation. Applicants must submit data showing that foreign DNA sequences were not incorporated into the final plant product. Genome edited plants where foreign DNA is incorporated will remain subject to the GE Seed Regulation.

With the passage of Resolution no. 173/15, Argentina also took a formal regulatory position relative to NPBTs. The policy debate revolved around the interpretation of "novel combination of genetic material" (GAIN Argentina, 2016). Case by case, applicants submit each product to determine whether or not it falls under the GE regulation. Inserted genetic material is always regarded as a new combination. Even when transgenes were used in the process, if the final product is free of transgenes it is considered to be non-GE. In other words, Argentina will not regulate the products of SDN-1 as long as none of the DNA from the initial construct remains in the final product.

Similar discussions are taking place around the globe. In January 2018, Brazil passed Normative Resolution No. 16, which includes an annex listing examples of products that may not be considered as GE. The Resolution establishes a consultation procedure to determine if a product can be exempt from the GE regulatory framework (Orozco, 2018).

In China, the Ministry of Agriculture has established a team of experts to determine whether or not genome editing is captured by the existing regulatory system (GAIN CH16065, 2016). In New Zealand, a 2014 court ruling established that genome edited products produced with ZFNs or TALENs would be regulated as new organisms (GAIN NZ1709, 2017). In France, the High Council for Biotechnology released a Scientific Report on Innovative Biotechnologies in 2016. They concluded that products of SDN-1, SDN-2 and ODM should not be regulated as GE under Directive 201/18/EC (GAIN FR1714, 2017). In the case of products of SDN-3, they would be regulated as GE only if the introduced DNA sequence was exogenous to the plant.

In the United States, USDA conducts an Am I Regulated (AIR) process to address some of these same issues (USDA-APHIS, 2018c). Developers send a letter to USDA describing their GE product and ask if it is subject to the APHIS GE Regulations. Many of these AIR inquiries have involved genome editing. Most of these are not subject to the APHIS GE Regulations because no inserted DNA remains in the final product. Aside from the plant pest consideration in the APHIS GE Regulations, these regulatory decisions are consistent with the policies in place in Israel, Argentina and Brazil.

If countries take different approaches to the regulation of the products of genome editing, the reduction in regulatory harmonization could lead to significant increases in asymmetric approvals in the coming years. For example, if some countries choose not to regulate some SDN-2 products, and those products contain inserted DNA derived from plant pests, they would be subject to the APHIS GE Regulations. If these product are not intended for the US market, they might remain on Table 1 indefinitely.

Unauthorized Importation of GE Plants not Approved by Any Country

In addition to the 57 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. There are three possible sources of such unauthorized imports: (1) unauthorized GE crop production; (2) failure of confinement methods in CFTs; and (3) mislabeled planting materials. Most examples of unauthorized

GE crop production are the result of GE seed smuggled from a neighboring country, for example, the large scale production of GE soybean in Brazil in the 1990's.

Of least concern is the unauthorized production of GE crops that are authorized for cultivation in the United States. Examples include unauthorized GE corn production in Ukraine, and unauthorized GE soybean production in India and Ukraine. The unauthorized production of GE crops not approved for cultivation in the United States is of much greater concern

The 2014 GAIN report from China mentions farmers planting unapproved GE rice and GE corn (GAIN 14032, 2014). More recent GAIN reports also mention this unauthorized production, but the extent of such plantings is not known (GAIN CH17054, 2017; GAIN CH16065, 2016; GAIN CH15032, 2015). A recent news report claims that Chinese farmers are illegally growing GE corn (Reuters, 2016). Testing identified the traits as belonging to Monsanto, Syngenta and DuPont Pioneer. Therefore, it is highly likely that these events being grown without authorization in China were developed in the United States and are no longer regulated by USDA. The 2016 GAIN Agricultural Biotechnology Annual report from Burma suggests that farmers may be growing GE crops with seeds smuggled from China (GAIN BM 6019, 2017).

The 2017 GAIN Agricultural Biotechnology Annual report from the Republic of Korea reported that an unapproved GE canola (event GT73) had been detected in seed imported from China (GAIN KS1739, 2017). More than 32 metric tons (MT) of canola seed, about 40% of the total canola seed imported, were found to have some GE content (The Hankyoreh, 2017). No information was encountered regarding whether or not this GE canola is in commercial production in China.

The 2017 GAIN Agricultural Biotechnology Annual report from India suggests that farmers may be growing unapproved GE cotton, soybean and eggplant (GAIN IN7135, 2017), and this unauthorized production is expected to increase substantially in future years. Unapproved cotton is currently estimated to be 5-8% of total cotton production (GAIN IN7135, 2017). News reports suggest that 15% of the cotton area in Andhra Pradesh has been planted to unauthorized GE cotton (Reuters, 2017a). The Bt eggplant seed is believed to be sourced from Bangladesh. There have also been news reports that GE eggplant seed is being smuggled into India from Pakistan (Business Standard, 2014), and that GE soybean seed is being illegally imported (Times of India, 2018).

The 2013 and 2014 GAIN reports from Nigeria suggests that smuggled GE seeds are being planted in that country, but there is no mention of what crops or from where these seeds may have been smuggled (GAIN Nigeria, 2013; GAIN Nigeria, 2014). More recent GAIN report from Nigeria do not mention the smuggled seeds (GAIN Nigeria, 2015; GAIN Nigeria, 2016; GAIN Nigeria, 2017).

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. However, GE papaya has been detected 24 times in exports from Thailand to the EU since 2006 (Bangkok Post, 2013; European Commission, 2017). More than 40 shipments of GE papaya were detected and rejected by the European Union from 2013-2017

(GAIN TH1761, 2017). Since GE papaya has not been authorized for cultivation in Thailand, a poorly confined CFT and/or mislabeled planting material are the most likely sources of the unauthorized GE papaya. All countries with authorized CFTs are included in Appendix F.

The RASFF database is a useful resource for information about unauthorized GE plant events that have entered global trade as food or feed. In the 24 month period covering FY2016 and FY2017, there continued to be notifications regarding food products imported from China derived from GE rice and food products imported from Thailand derived from GE papaya (European Commission, 2017). In addition to China, there were notifications to RASFF for products derived from GE rice from Burma, Cambodia, Hong Kong, Pakistan, the United States and Vietnam. These countries may be unknowingly importing GE rice from China; however, unauthorized GE rice production may also be spreading across Southeast Asia.

The notification for GE rice from the United States is quite curious; it concerned organic rice protein powder derived from GE rice (event Bt 63 from China). Since GE rice is not produced in the United States, this highlights the fact that the exporting country may not be the same country where the GE crop was produced. Another RASFF notification is the feed materials containing GE flax exported from the Czech Republic. The only approved GE flax event was produced in Canada in the 1990's but went out of production due to export markets. This suggests that this GE flax event which is no longer produced in North America may currently be in unauthorized production in the Czech Republic.

Similar to the GE rice situation, notifications have been increasing for countries exporting food products derived from GE papaya. In addition to Thailand, the list now includes Cambodia, India and China. The RASFF database provides limited information, so we don't know if the papaya from Cambodia and India are the same events as the authorized GE papaya being grown in China or the unauthorized papaya being grown in Thailand.

Japan routinely inspects imported rice and papaya products for unauthorized events. For rice, Japan screens for events Bt63, BtNN and CpTI from China and for event CpTI from Vietnam. For papaya from China, Vietnam and Thailand, Japan screens for events PRSV-YK, PRSV-HN and PRSV-SC, respectively (Emi Nagata, personal communication).

The GE Petunia Story

On May 2, 2017, Selecta Klemm GmbH & Co informed USDA that one of its petunia varieties – an orange petunia – was potentially genetically engineered and had been imported and moved interstate without the authorization required by USDA (USDA-APHIS, 2017). USDA tested numerous petunia varieties and confirmed that this particular variety, as well as several others, were indeed GE and met the definition of a regulated article under the APHIS GE Regulations. When USDA first confirmed the distribution of unauthorized GE petunia on May 16, 2017, there were 9 petunia varieties confirmed as GE. As of October 3, 2017, there were 124 GE petunia varieties on the USDA list. In addition to orange petunias,

there were various shades of red and purple among the 124 GE varieties. Since these petunias did not present any risks to human health or the environment, consumers were not asked to take any action. However, retailers chose to voluntarily remove them from distribution because they were not authorized.

During USDA's fact finding it was discovered that these GE petunias were identified near the train station in Helsinki, Finland (Servick K, 2017). The original GE petunias were first field tested in Germany in 1990 (Linn et al, 1990); these GE petunias were intended to be orange, but the flower color was described as an unattractive brick red (Oud et al, 1995) and the GE petunia research was discontinued.

A few years later, petunia breeders at S&G Seeds B.V. in the Netherlands began breeding the GE petunia with non-GE petunia to develop lines with desirable flower colors. Through traditional breeding with the original GE petunia, they succeeded in developing petunias with bright orange flower color that would be suitable for commercialization (Oud et al, 1995). These were field tested in Florida in 1995 under a USDA authorization. USDA learned that these GE petunias had moved freely in global commerce for many years despite not being granted authorization in any country.

CONCLUSIONS

From analysis of several global databases as well as the annual GAIN reports focused on biotechnology, a list of 57 GE plant events authorized for commercial cultivation in other countries but subject to the APHIS GE Regulations was generated. Presently, the likelihood that viable material of any of these 57 plant events could enter the United States as imports is estimated to be either very low or extremely low.

From the database analyses, APHIS has at least some information on the genetics for all but four of the 57 GE plant events. Should there be a need to conduct a PPRA relative to an unauthorized importation, genetic information about the GE plant event is essential.

The one GE plant newly added to the list is an asymmetric approval in Brazil. USDA expects that the number of regionally developed GE crops will continue to grow and these asymmetric approvals will become the most likely sources of unauthorized imports in the future. Regional GE crop development continues to expand globally, and a continued focus on tracking the development and deployment of these regional GE plant events will be required to guard against unauthorized imports.

APHIS-International Services and USDA-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.

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Appendices

Appendix A – OIG Audit Recommendations
Appendix B – Descriptions of the Databases Utilized to Generate Table 1
Appendix C – Descriptions of 19 GE Carnation Events Extracted from Table 1
Appendix D – USDA Admissibility of the 57 GE Events in Table 1 by Country and Commodity
Appendix E – Brief Country Summaries of GE Crop Development Activity
Appendix F – Global GE Crop Commercial Cultivation and CFT 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 likelihood of 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 likelihood of 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) Genetically Modified (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 use broader criteria for listing events than either the CERA or BCH databases. For example, of the 32 regionally developed GE events identified in this analysis, all but one can be found in the ISAAA database; however, only 5 of these 32 events can be found in the CERA database.

Center for Environmental Risk Assessment (CERA) GM Crop Database

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

- *2017 Note:* This database is currently offline due to funding constraints.
- 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 but one of the wheat lines listed in CERA are non-GE, and the listed sunflower and lentil are non-GE.
- 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" includes separate icons for each country for each type of approval: food, feed, processing, environmental release and contained use.

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.

The European Commission's Joint Research Centre Deliberate Release and Placing on the EU Market of GMOs – GMO Register (GMOINFO)

http://gmoinfo.jrc.ec.europa.eu/

- The GMOINFO portal provides a list of all CFTs approved by EU Member States since 2002.
- Links are provided to each notification, including details of the genetic modifications and associated risk assessments.

The European Commission's Rapid Alert System for Food and Feed (RASFF)

http://ec.europa.eu/food/safety/rasff/index_en.htm

- The RASFF Portal contains a searchable database of all notifications of violations of food safety standards submitted to the EU Commission.
- Includes "GMO/Novel Food" as a searchable hazard category.

Appendix C – Descriptions of 19 GE Carnation Events Extracted from Table 1

Crop	Applicant	OECD Unique ID	Event	Trait[1]	Release Approvals
Carnation	Florigene	FLO-ØØØØ4-9	4	PQ	Australia, Japan, Norway
Carnation	Florigene	FLO-ØØØ15-2	15	PQ	Australia, Norway
Carnation	Florigene	FLO-ØØØ16-3	16	PQ	Australia, Norway
Carnation	Florigene	FLO-ØØØ66-8	66	PQ	Australia, EU Norway
Carnation	Florigene	FLO-Ø7442-4	11 (7442)	PQ	Australia, EU, Japan, Norway
Carnation	Florigene	FLO-11226-8	1226A	PQ	Colombia, EU, Norway
Carnation	Florigene	FLO-4Ø619-7	123.2.2 (40619)	PQ	Australia, Japan, Malaysia
Carnation	Florigene	FLO-4Ø644-4	123.2.38 (40644)	PQ	Australia, EU, Japan, Malaysia
Carnation	Florigene	FLO-4Ø689-6	123.8.12	PQ	Japan, Malaysia
Carnation	Florigene	FLO-4Ø685-1	123.8.8 (40685)	PQ	Australia, Japan, Malaysia
Carnation	Florigene	FLO-11351-7	1351A (11351)	PQ	Colombia, EU, Norway
Carnation	Florigene	FLO-11363-1	1363A	PQ	Australia, EU, Japan, Norway
Carnation	Florigene	FLO-114ØØ-2	1400A (11400)	PQ	Colombia, Norway
Carnation	Florigene	FLO-11959-3	959A (11959)	PQ	Colombia, EU, Norway
Carnation	Florigene	FLO-11988-7	988A (11988)	PQ	Colombia, EU, Norway
Carnation	Suntory	IFD-199Ø7-9	19907	PQ	Colombia, Malaysia
Carnation	Suntory	IFD-25947-1	25947	PQ	Colombia, Malaysia
Carnation	Suntory	IFD-25958-3	25958	PQ	Colombia, Malaysia
Carnation	Suntory	IFD-264Ø7-2	264Ø7	PQ	Colombia, Malaysia

Appendix D – USDA Admissibility of the 57 GE Events in Table 1 by Country and Commodity

Country	Crop	Events	Q37 Seed[1]	Q37 Propagules Other than Seed	Q56[2]
Argentina	Potato	TIC-AR233-5	NAPPRA[3]	NAPPRA	Not Admissible
Argentina	Soybean	IND-ØØ41Ø-5	Admissible	NAPPRA	Admissible
Australia	Carnation	8 events	Admissible	Postentry Quarantine	Not Applicable
Bangladesh	Eggplant	EE-1	Admissible	NAPPRA	Not Admissible
Brazil	Dry Edible Bean	EMB-PVØ51-1	Admissible	NAPPRA	Not Applicable
Brazil	Eucalyptus	H421	Admissible	Postentry Quarantine	Not Applicable
Brazil	Sugarcane	CTB141175/01-A	NAPPRA	NAPPRA	Not Applicable
Burma	Cotton	Ngwe Chi 6 Bt	Needs Permit	NAPPRA	Not Applicable
Canada	Canola	Oxy-235, PHY14, PHY23, PHY35, PHY36	Admissible	Admissible	Not Applicable
China	Corn	BVLA430101	NAPPRA	NAPPRA	Not Applicable
China	Cotton	GK12, SGK321	Needs Permit	NAPPRA	Not Applicable
China	Papaya	Huanong No. 1	Admissible	Postentry Quarantine	Not Admissible
China	Petunia	Petunia-CHS	Admissible	Admissible	Not Applicable
China	Poplar	Bt Poplar, Hybrid Poplar Clone 741	Admissible	NAPPRA	Not Applicable
China	Rice	GM Shanyou 63, Huahui-1/TT51-1	NAPPRA	NAPPRA	Not Applicable
China	Sweet Pepper	PK-SP01	Admissible	NAPPRA	Not Admissible
China	Tomato	Da Dong No 9, Huafan No 1, PK-TM8805R	Admissible	NAPPRA	Not Admissible

Country	Crop	Events	Q37 Seed[1]	Q37 Propagules Other than Seed	Q56[2]
Colombia	Carnation	8 events	Admissible	Postentry Quarantine	Not Applicable
Cuba	Corn	FR-Bt1	NAPPRA	NAPPRA	Not Applicable
European Union	Carnation	8 events	Admissible	Postentry Quarantine – except UK and Netherlands	Not Applicable
European Union	Potato	EH92-527-1	NAPPRA	NAPPRA	Not Admissible
European Union	Tobacco	C/F/93/08-02	Admissible	NAPPRA	Not Applicable
India	Cotton	BNLA-601, Event 1, GFM Cry 1A, MLS 9124	Needs Permit	NAPPRA	Not Applicable
Indonesia	Sugarcane	NXI-1T, NXI-4T, NXI-6T	NAPPRA	NAPPRA	Not Applicable
Iran	Rice	Tarom molaii + cry1Ab	NAPPRA	NAPPRA	Not Applicable
Japan	Canola	Oxy-235, PHY14, PHY23, PHY34, PHY36,	Admissible	Admissible	Not Applicable
Japan	Carnation	8 events	Admissible	Postentry Quarantine	Not Applicable
Japan	Corn	DAS-40278-9	NAPPRA	NAPPRA	Not Applicable
Japan	Rice	7Crp#10	NAPPRA	NAPPRA	Not Applicable
Japan	Soybean	DAS-68416-4 MON 87708	Admissible	NAPPRA	Admissible
Malaysia	Carnation	8 events	Admissible	Postentry Quarantine	Not Applicable
Norway	Carnation	11 Events	Admissible	Postentry Quarantine	Not Applicable
Pakistan	Cotton	GFM Cry1A	Needs Permit	NAPPRA	Not Applicable

[1] – USDA-APHIS' Q37 regulations cover the importation of plants for planting.

[2] – USDA-APHIS' Q56 regulations cover the importation of fresh fruits and vegetable for consumption.

[3] – NAPPRA = Not Authorized Pending Pest Risk Assessment.

Appendix E – Brief Country Summaries of GE Crop Development Activity

This appendix includes all countries with commercial GE crop production and/or authorized CFTs of GE crops. 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, 2016); (3) the GAIN reports; (4) conference calls to APHIS personnel in country; and (5) public news reports.

ARGENTINA: Argentina continues to be the 3rd largest producer of GE crops with more nearly 25M ha of GE corn, GE soybean and GE cotton. Argentine scientists have been quite active in GE crop development; in 2015, Argentina approved a drought tolerant GE soybean and virus resistant GE potato. These were the first approved GE plant events that were developed in Argentina. They have also developed GE sugarcane events with herbicide resistance and insect resistance; the herbicide resistant event has successfully completed the regulatory reviews, and the final approval was expected during 2017. GE safflower and GE fescue, both herbicide resistant, are being tested in CFTs. Since 2012, Argentina has been collaborating with Brazil to develop drought tolerant GE sugarcane (GAIN Argentina, 2016). Argentina did not issue a GAIN Agricultural Biotechnology Annual report in 2017.

AUSTRALIA: In 2016, Australia produced 0.40M ha of GE cotton (98% adoption rate) and 0.45M ha of GE canola (23% adoption); GE carnation is also authorized for cultivation (ISAAA, 2016). While Australia has been slow to approve GE food crops for cultivation, both public and private sector Australian researchers are actively developing numerous GE crops. Currently authorized CFTs include banana, cotton, safflower, sorghum and sugarcane (GAIN AS1720, 2017); see the OGTR website for further details: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/map

BANGLADESH: In 2013, Bangladesh authorized commercial production of GE eggplant ("brinjal"). Enough seed has been distributed to cover one third of the winter brinjal area, and seed of three new varieties are in the approval process (BG7008, 2018). USAID is supporting the development of the GE brinjal as well as the late blight resistant Bt potato that has also been grown in CFTs. Bangladesh Agricultural Research Institute (BARI) scientists have applied for commercial release of the GE potato (The Daily Star, 2017). Field trials of Golden rice are also ongoing (GAIN BG6010, 2016; GAIN BG7008, 2018).

BELGIUM: No GE crops are commercially produced in Belgium, but Belgium has an active crop biotechnology sector. In recent years, CFTs of GE corn, GE poplar and GE potato have been conducted. Belgium has notified the Joint Research Centre that they intend to initiate new CFTs with corn in 2018 (Joint Research Centre, 2017). Belgium did not issue a GAIN Agricultural Biotechnology Annual report in 2017.

BOLIVIA: Bolivia produced about 1.2M ha of GE soybean in 2016 (ISAAA, 2016); however, the enactment of the Law of Mother Earth in 2012 has effectively banned future GE crop authorizations. No information was available on domestic GE crop development projects or CFTs of GE crops. There

are no biotechnology GAIN reports from Bolivia. CFTs of two GE cotton events were conducted in 2012 (Rüdelsheim and Smets, 2014).

BRAZIL: Brazil is the world's 2nd largest producer of GE crops with over 49M ha of GE corn, GE soybean and GE cotton (ISAAA, 2016). Brazil has a robust capacity for GE crop development and has now approved four home-grown GE crop events: (1) a virus resistant dry-edible bean approved in 2011; (2) an herbicide resistant soybean approved in 2015; (3) a GE eucalyptus with increased growth and yield approved in 2015; and (4) an insect resistant sugarcane approved in 2017 (GAIN BR1720, 2017). Other GE crops in the regulatory pipeline include drought resistant soybean, drought resistant sugarcane, citrus, papaya, potato and rice. GE sugarcane with insect resistance received commercial approval in 2017 (GAIN BR1720, 2017). Because Brazil exports sugar to about 150 countries, the developer will seek export approvals in those countries where they are required.

BURKINA FASO: In 2015, Burkina Faso produced about 0.35M ha of GE cotton; this significant production decline from the 0.5 M ha in 2014 was thought due to coups and government transitions (ISAAA, 2016). No GE cotton was planted in 2016 due to unresolved issues with Monsanto (GAIN Senegal, 2016). The GE cotton had significantly increased farmer's yields; however, the GE cotton variety produced shorter fibers, which produce lower quality fabric. Because trading companies were losing money, they insisted on a return to traditional varieties (Gakpo JO, 2017). Recent CFTs have included GE corn, GE cotton and GE cowpea. The African Agricultural Technology Foundation (AATF) is leading the project to develop the insect-resistant GE cowpea in Burkina Faso, Ghana and Nigeria. The Bt cowpea is expected to be commercialized in Burkina Faso in the next two years (GAIN Senegal, 2017). Several regional organizations have been meeting to discuss the development of a harmonized regional biosafety law. There are no biotechnology GAIN reports from Burkina Faso; see the GAIN reports from Senegal which cover all of Francophone West Africa (GAIN Senegal, 2017).

BURMA (MYANMAR): Burma produces about 0.3M ha of GE cotton, most of which is the Bt cotton variety "Ngwe Chi 6" (ISAAA, 2016). Two new varieties, "Ngwe Chi 9" and "Shwe Taung 8", both expressing the same Bt gene, have recently entered the market (GAIN BM7016, 2017). The insect resistant cotton event, known as Ngwe Chi 6 Bt, appears to have been fully developed in Burma. The 2016 GAIN Agricultural Biotechnology Annual report (GAIN BM6019, 2016) was the first one issued for Burma.

CANADA: Canada is the world's 5th largest producer of GE crops, with about 11.5M ha of GE crop production in 2016 (ISAAA, 2016). GE canola accounts for about 75% of this production, with the remainder mainly comprised of GE corn and GE soybean. Canada also produces about 8,000 ha of GE sugar beet in Alberta, and recently approved GE alfalfa, GE apple, and GE potato for unconfined release. With the 2012 changes to the Canadian Wheat Board, there appears to be increased opportunity for GE wheat in Canada. In 2017, Canada approved 50 Plant Novel Trait (PNT) submissions and 137 CFTs. GE crops authorized for CFTs included barley, Camelina, canola, mustard, poplar, potato, soybean and wheat (GAIN CA17042, 2017). See the CFIA website for further details:

http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/field-trials/spring-2016/eng/1471356206996/1471356272132

CHILE: Chile is the 5th largest producer of exported seeds, and the United States is the main destination for GE seeds from Chile (GAIN CI1730, 2017). In the 2016/2017 season, Chile produced about 10,000 ha of GE seed, primarily GE corn, soybean and canola, but also small amounts of GE cotton, tomato and grapevine. Chilean farmers are only authorized to produce GE seed for export, primarily to the United States and Canada; none of these crops has been approved for food or feed in Chile. Chile does permit CFTs, and these are regulated the same as the GE seed production. However, no specific information was available on the crops or numbers of trials that have been approved. While there is research and development of GE crops in Chile, none are expected to be commercialized in the near future.

CHINA: While they have yet to approve the cultivation of a major GE food crop, China continues to be one of the top producers of GE cotton (2.9M ha, 95% adoption rate). In 2016, the Ministry of Agriculture released a "roadmap" for the commercialization of GE crops, beginning with cash crops, followed by feed crops and eventually food crops (GAIN CH16065, 2016). China also produces about 543 ha of GE poplar and 7130 ha of GE papaya (ISAAA, 2017). The Biosafety Certificates for insect-resistant rice and phytase corn were renewed in 2014; however, there have been no final approvals for cultivation (GAIN CH17054, 2017). Recent RASFF notifications from EU member states suggest that GE rice remains in cultivation in China despite the lack of authorization for commercial cultivation (European Commission, 2017). ISAAA includes petunia, sweet pepper and tomato among the commercial GE crops in China; however, the biosafety certificates for these products expired more than 10 years ago and it appears that these crops were never produced commercially. China's biotechnology sector is focused on developing GE rice, GE wheat, GE corn and GE cotton; there are currently 585 new biotechnology breeding programs receiving grant funding (GAIN CH17054, 2017). Along with Japan, China is one of only two countries that require CFTs for food approvals. Cultivation of unauthorized GE corn events appears to be widespread in China; however, genetic tests suggest that the unauthorized events were all developed in the United States (GAIN CH15032, 2015; Reuters, 2016; GAIN CH16065, 2016). Japan routinely screens imports of rice and papaya from China for GE content (Emi Nagata, personal communication).

COLOMBIA: Colombia has been producing GE cotton since 2002 and GE corn production was authorized in 2007. In 2016, GE corn and GE cotton were planted on 100,109 ha and 9,814 ha, respectively (GAIN CO1717, 2017). GE soybean production was approved in 2010 but has not yet been commercially cultivated. GE carnations and GE roses are approved for commercial production but only for export; these flower crops are produced in containment in greenhouses. GE chrysanthemums have also been approved for commercial production in greenhouses; however, these GE chrysanthemums are not found in any of the GE crop databases. The International Center for Tropical Agriculture (CIAT) has programs to develop GE rice and GE cassava, and other Colombian scientists are developing GE coffee, GE potato, GE sugarcane, and GE tobacco. CFTs are permitted; recent authorizations have included cassava, corn, cotton, potato, and rice.

COSTA RICA: Since 1992, Costa Rica has allowed production of GE cotton and soybean seed for export only and in 2013 granted similar authorization for production of GE corn seed for export only. The total area of GE plantings was estimated at 300 ha in 2016, and a similar area was planted in 2017 (GAIN Costa Rica, 2017). Del Monte has been developing GE pineapple production in Costa Rica, and commercialization was expected soon after the FDA food safety review was completed in 2016. However, administrative issues at the National Technical Biosafety Commission (NTBC) resulted in a one year delay of product launch (GAIN Costa Rica, 2017). Costa Rican 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, but none are expected to be commercialized in 2018 (GAIN Costa Rica, 2017).

COTE D'IVOIRE: No GE crop production is authorized in Cote d'Ivoire. However, **n**otifications to RASFF in 2014 included GE cotton seeds imported to Italy from Cote d'Ivoire (European Commission, 2017), suggesting that unauthorized GE cotton is under production in Cote d'Ivoire. In all cases, the unauthorized GE cotton was event MON15985, which is the one event currently authorized for commercial production in Burkina Faso.

CZECH REPUBLIC: Until 2017. the Czech Republic remained as one of only five EU member countries (with Portugal, Romania, Slovakia and Spain) with commercial GE crop production; GE corn (MON 810) has been produced on a small scale since 2005, but none was planted in 2017 (GAIN EZ1707, 2017). GE corn was planted on 75 ha in 2016 (ISAAA, 2016), down from a peak of 5090 ha in 2011 (GAIN EZ1507, 2015). GE potato was in production in 2010; however, BASF has since withdrawn the product from the market. The Czech Republic is also one of the few EU member countries that continue to authorize CFTs; there were CFTs of barley, flax, plum and soybean in 2016. The Czech Republic is part of a consortium (which includes the French National Institute for Agricultural Research) with USDA-ARS seeking commercial approval of the USDA's virus-resistant GE plum in the EU. The consortium is seeking EU approval for Deliberate Release and Placing on the Market; however this process will take several years (GAIN EZ1707, 2017).

CUBA: During 2012-2014, Cuba produced about 3000 ha of GE corn under "regulated commercialization" (ISAAA, 2014). The event is referred to as FR-Bt1 (Guerrera, 2009); ISAAA (2014) says it "similar" to what is grown elsewhere. No additional information was found for this event; it is not listed in the BCH, CERA or ISAAA databases. Recent reports suggest that Bt corn production may have been reinitiated in 2017 (Action Institute, 2017; Granma, 2017), and that GE soybean are undergoing field trials. While diplomatic relations between the United States and Cuba were renewed in 2015, agricultural trade with Cuba cannot resume until congress rescinds the U.S. trade embargo; this is not expected in the near future. There are no biotechnology GAIN reports from Cuba.

ECUADOR: The 2008 Constitution prohibits the local development and cultivation of GE crops; however, a 2017 law now allows for CFTs of GE crops (GAIN Ecuador, 2017). No approval process for GE crops is in place. Ecuador's Ministry of Agriculture conducted a risk assessment for the introduction of GE carnations for greenhouse production, but there are no records of any actual production (GAIN EC13011, 2013). CFTs of GE corn could begin in 2018.

EGYPT: Egypt was the first North African country to approve cultivation of a GE crop, and until 2011 produced GE corn (MON 810) on a small scale. However, all GE corn plantings were suspended in early 2012, and the current draft Biosafety Bill would likely prevent GE crop development in Egypt. While Egyptian scientists continue to develop GE corn, GE potato, GE sorghum, GE tomato and GE wheat, no CFTs have been approved in the last three years (GAIN Egypt, 2017).

EL SALVADOR: Although El Salvador has completed the development of a biotechnology regulatory framework, there is no commercial GE crop production and none is expected in the near future. Two GE corn events developed in the United States were evaluated in CFTs in 2008-2009, but there has been no further progress since that time (GAIN ES1704, 2017).

ETHIOPIA: No GE crops are commercially produced in Ethiopia. However, Ethiopia has completed two years of Bt cotton field trials, and commercialization is expected in the next few years (GAIN ET1726, 2017).

FRANCE: France commercially produced of GE corn starting in 1998; however, cultivation of GE corn was banned in 2008 and a 2014 law authorizes destruction of any GE corn. France once led the EU in the number of CFTs, but none have been authorized since 2010. The multi-year permit for CFTs of GE poplar was not renewed and the trees were destroyed in 2013 (GAIN FR1714, 2017).

GHANA: There is no commercial GE crop production in Ghana; however, both GE cowpea and GE cotton approvals are anticipated within the next three years. CFTs for GE cowpea and GE rice are ongoing. GE cowpea with insect resistance is expected to be jointly commercialized with Burkina Faso and Nigeria as early as 2018 (GAIN Ghana, 2017).

GUATEMALA: Guatemala has a *de facto* moratorium in place; no GE crops have been authorized for cultivation. However, now that the Guatemalan-Honduras Customs Union is in place, and GE corn is produced in Honduras, producer groups are pressing for approval of GE corn in Guatemala (GAIN GT17007, 2017). Some CFTs of GE corn and GE cotton were conducted in the past; the most recent CFT of GE corn was conducted in 2012/2013 (GAIN 15007, 2015).

HONDURAS: With about 32,000 ha of GE corn in 2017, Honduras remains as the leading producer of GE crops in Central America. Honduras has authorized several CFTs, mostly of GE corn, and there have been one each for GE banana and GE rice (GAIN HO1703, 2017).

HONG KONG: There is no authorized GE crop production in Hong Kong nor are there any CFTs. However, because survey data indicated that 40% of the locally grown papaya is GE papaya, Hong Kong exempted GE papaya events from the Genetically Modified Organisms Ordinance that became effective in 2011 (GAIN HK1220, 2012). Two GE papaya events received the exemption (Event 55-1 from Cornell and event Huanong No.1 from China). GE rice projects are ongoing at the Chinese University of Hong Kong; however, the CFTs are conducted in China (GAIN HK1738, 2017).

INDONESIA: Indonesia does not currently produce any commercial GE crops; however, there is optimism that GE sugarcane and corn will soon be commercialized. Three GE sugarcane events developed by Indonesian scientists received environmental safety recommendations in 2013, but these still need feed approvals. One GE corn event (NK 603) has completed all regulatory approvals; however, there remains a requirement for a "monitoring and control" system per Government Regulation 21/2005 (GAIN ID1727, 2017). Indonesian scientists also have active GE crop development projects with potato, rice, sugarcane and tomato. USAID is funding the development of late blight resistant GE potato (GAIN ID1727, 2017).

INDIA: Although GE crop production is currently limited to GE cotton, India continues to be the world's 5th largest producer of GE crops (ISAAA, 2017). The USAID-funded insect resistant eggplant was recommended for commercial approval in 2009; however, this was followed by a moratorium and a final decision has yet to be made. India has significant capacity for GE crop development and has ongoing projects in more than 85 plant species (GAIN IN7135, 2017). In 2011, the GEAC introduced new procedures requiring developers to obtain a "No Objection Certificate" (NOC) from State governments prior to conducting field trials; this procedure has significantly reduced the pace of GE field testing. While the GEAC has recently approved CFTs of several GE crops, due to the NOC requirement, CFTs in the 2016/17 season were limited to chickpea and cotton (IN7135, 2017). In 2017, the GEAC recommended commercial approval for a GE mustard developed in India (GAIN IN7135, 2017; Reuters, 2017b); if approved, this would be the first GE food crop commercially produced in India. At least 2 or 3 additional GE crop events are at advanced stages of product development and could be approved in the next 2-3 years (GAIN IN7153, 2017).

IRAN: The ISAAA GMO Approval Database shows that Iran authorized cultivation of GE rice in 2004; no information was found to suggest that this event, which is included in Table 1, has actually ever been commercially cultivated. ISAAA does not list Iran among the countries with GE crop production (ISAAA, 2017). More recently, ISAAA (2015b) reported that Iran would initiate cultivation of Bt cotton in 2016. There are no GAIN biotechnology reports from Iran.

ISRAEL: While yet to approve any GE crops for commercial production, Israel is very active in agricultural biotechnology research and development (GAIN Israel, 2017). At least 10 organizations have authorizations from the National Committee for Transgenic Plants (NCTP) to conduct research on GE crops and many of these entities have been conducting CFTs. However, while numerous CFTs appear to be ongoing, details are kept confidential until the products are registered (GAIN Israel, 2017).

JAPAN: The only GE crop commercially cultivated in Japan is GE rose. Along with China, Japan is one of only two countries that require CFTs for food approvals; however, it is now possible to obtain an exemption from the "Stage 3 Field Trial" requirement for traits of "sufficient familiarity" (GAIN JA6050, 2016). Because of this regulatory nuance, 133 GE plant events in 9 crops are authorized for cultivation in Japan (GAIN JA7138, 2017); however, farmers wishing to plant GE crops face costly and burdensome prefecture-based administrative policies enacted to discourage cultivation of GE crops. In 2015, Japan authorized CFTs of GE "pollen free" Japanese cedar trees; this is the only CFT approved since 2009. GE strawberry is produced commercially in containment for treating gingivitis in dogs (GAIN JA7138, 2017). Japanese scientists are very active in plant biotechnology research; however, due to public perception, most of the research is focused on non-food uses (GAIN JA7138, 2017).

KAZAKHSTAN: No GE crops are produced in Kazakhstan. Drought resistant GE wheat was developed in collaboration with Australia and CFTs were conducted in 2014 (GAIN KZ-07, 2017)

KENYA: In November 2012, Kenya instituted a ban on all GE food imports, and has yet to authorize domestic production of any GE crops. The National Assembly's Agriculture Committee recently recommended that this ban stay in place until a new food safety law on GE products is approved (GAIN Kenya, 2016). The National Biosafety Authority is reviewing applications for cultivation of GE corn, GE cotton and GE gypsophila (baby's breath) flower (GAIN Kenya, 2016). Currently authorized GE field trials include banana, cassava, corn, cotton, sorghum and sweet potato. The first commercial GE crop approval is likely to be for GE gypsophila (GAIN Kenya, 2017). The GE gypsophila was developed by Danziger, an Israeli company. Danziger submitted an Am I Regulated request to BRS in 2011 for a GE Gypsophila with altered flower color; however, it is not clear if it was the same genetic event that is under development in Kenya.

KOREA, REPUBLIC OF: Although Korea is a major importer of GE commodities from the United States for use in food and feed, they have yet to authorize the cultivation of any GE crops. In 2017, the Rural Development Agency (RDA), bowing to pressure from activists, agreed to stop all efforts to commercialize GE crops in Korea (GAIN KS1739, 2017). Korea has a large biotechnology research and development sector, and the RDA authorized 471 "contained" field trials. While some of these CFTs are conducted in the open, they are fenced and covered with netting to exclude birds and insects (Korean visitor, personal communication). The most advanced GE crops in development are high resveratrol rice and virus resistant pepper; however, no commercial approvals for GE crops are expected within the next 5 years.

MALAWI: Malawi had been hesitant to initiate CFTs with GE crops, but now has three GE crops moving towards the market. Bt cotton has been tested in CFTs for three years and has reached the variety registration stage, Bt cowpea is in the second year of CFTs, and virus resistant banana is in first year CFTs (Chaweza, 2017). There are no biotechnology GAIN reports from Malawi.

MALAYSIA: Malaysia has yet to authorize cultivation of any GE crops; however, several GE corn and soybean events are approved for importation. Malaysia has authorized the importation of cut flowers of 8 GE carnation events. The ISAAA database lists these as cultivation approvals; however the authorizations prohibit use as planting material. The Malaysian GAIN reports do not mention these GE carnations. A CFT for GE papaya was approved in 2013, but it is unclear if any CFTs have been conducted (GAIN MY7008, 2017).

MEXICO: In 2017, Mexico produced just over 0.1 M ha of GE cotton (100% adoption). GE soybean production was suspended due to a court injunction; there had been 4,000 ha in 2016 (ISAAA, 2017). GE corn was legally banned in 2013; however this court decision was overturned in 2015. In 2016, a federal judge allowed cultivation of GE corn for research only. In 2016 and 2017, of 34 applications for field testing, only 11 have been approved; these were all for cotton and wheat (GAIN MX7053, 2017). Mexican scientists are actively developing GE kidney beans, GE corn, GE lemon trees and GE wheat. CIMMYT has been conducting GE wheat CFTs since 2008; they field tested two new events in 2016 (GAIN MX7053, 2017).

MOZAMBIQUE: In 2017, Mozambique planted its first CFT as part of the Water Efficient Maize for Africa (WEMA) program. GE corn was planted at a single site in the southern part of the country (GAIN Mozambique, 2017).

NEW ZEALAND: New Zealand has taken a cautious approach to GE crops and has yet to approve any for commercial cultivation. Since 1996, New Zealand has approved 13 CFTs, which they refer to as *contained* outdoor field trials. In fact, because they are conducted outside, these would be referred to as *confined* field trials in most other countries. Past CFT approvals have included brassicas, corn, onions, petunia, pine trees, potatoes and sugar beet. The most recent CFT approval came in 2011 for pine trees that will be field tested through 2035 (GAIN NZ1505, 2015). A 2014 court ruling established that genome edited products produced with ZFNs or TALENs would be regulated as new organisms (GAIN NZ1709, 2017)

NIGERIA: There are no commercial GE crops grown in Nigeria, but Nigeria has been increasingly active in GE crop development. Nigeria passed a biosafety bill in 2015 which established the National Biosafety Management Agency (NMBA), paving the way for GE crop commercialization. GE cotton, GE cowpea, GE rice and GE sorghum could all be commercialized in the next few years (GAIN Nigeria, 2017). GE cotton has been approved for "commercial release", the last stage before commercial approval (GAIN Nigeria, 2017). News reports suggest that GE cotton and GE cowpea could be commercialized during 2018 (Abuja, 2017). The cassava and sorghum projects are both funded by the Gates Foundation and the cowpea project is funded by USAID (GAIN Nigeria, 2017).

PAKISTAN: Pakistan has been growing GE cotton since 2010 and produced 3.0M ha in 2017, with an adoption rate above 96% (ISAAA, 2017). No new events have been approved since 2012; however, many GE crops have been moving through the approval process during the past two years. CFTs of

GE corn, GE cotton, and GE wheat are ongoing (GAIN PK1804, 2017). GE corn could be commercialized in the next 1-3 years.

PANAMA: In 2013, Panama authorized the cultivation of one GE corn event; however, no production has been possible because DuPont-Pioneer did not provide seed for planting. The company was concerned because the GE corn was approved for feed use but not for food use. In addition to the corn CFTs, Panama has authorized field tests of GE mosquitoes and GE salmon (GAIN Panama, 2016).

PARAGUAY: Following several years of unauthorized production, Paraguay approved GE soybean cultivation in 2004; in 2017, Paraguay produced about 2.7M ha of GE soybean (ISAAA, 2017). GE cotton was approved in 2012, and GE corn in 2014 (GAIN Paraguay, 2014). In 2017, Paraguay produced 0.27M ha of GE corn and 10,000 ha of GE cotton (ISAAA, 2017). Paraguay has not issued a GAIN biotechnology annual since 2012 (GAIN Paraguay, 2012).

PERU: In 2011, Peru enacted a 10 year moratorium on GE organisms. Despite the ban, public scientists have been developing GE papaya and scientists at the International Potato Center have been developing GE potato (GAIN Peru, 2017). In early 2015, adventitious GE presence was detected in a corn field (GAIN Peru, 2015).

PHILIPPINES: The Philippines has been producing GE corn since 2003; the area planted to GE corn in 2016/17 was 655,000 ha, representing about 46% of total corn production (GAIN RP1720, 2017); ISAAA, 2017). With wide-spread acceptance and science-based regulations, the Philippines has been the regional leader in agricultural biotechnology. Following a brief period of uncertainty after the Supreme Court struck down the 2002 regulations, the Joint Department Circular signed on March 7, 2016 was effective in lifting the temporary ban on field testing, commercialization and importation. Because there was no phase-in period, processing of applications has been delayed. The August 2016 Supreme Court decision also lifted the restrictions on the commercialization of Bt eggplant (GAIN RP1617, 2016). The USAID-funded GE eggplant has completed all required field trials and an application for commercialization could be submitted in 2018. CFTs with a new event of golden rice and with a delayed ripening papaya were expected in 2017 (GAIN RP1720, 2017).

POLAND: Poland officially banned GE crops in 2006, and prohibitions against planting GE crops entered into force in 2013. However, unofficial estimates placed GE corn production at 3900 ha in 2012 (GAIN PL1212, 2012); the GAIN reports since then have not mentioned this unauthorized production. The 2015 GAIN report states that the government conducted 9000 tests and confirmed that the GE crop ban had been successfully implemented (GAIN Poland, 2015). Despite the increased restrictions on GE crops, flax and poplar CFTs were conducted in Poland in 2015 (GAIN Poland 2017).

PORTUGAL: With only 7,000 ha of GE corn in 2017, Portugal remained as the second largest producer of GE crops in the European Union. Because MON810 is the only GE event approved for cultivation in

the European Union, it only has value to growers in areas where corn borer is a problem. GE corn production has been about 6% of total corn production for the past 5 years. CFTs are possible in Portugal and several were conducted in the past; however no CFTs have been conducted since 2010 (GAIN SP1732, 2017).

ROMANIA: Romania produced GE corn on a very small scale (<1000 ha) until 2015, but has not planted any the past two years. Romanian farmers also produced GE soybean prior to Romania's accession to the EU. Numerous CFTs have been authorized in the past; however, the only CFT in 2016 was an ongoing field trial of GE plum (GAIN RO1721, 2017).

RUSSIAN FEDERATION: Russia developed legislation for registering GE crops in 2013, but Resolution No. 770 passed in 2017 bans the cultivation and breeding of GE plants and animals within the territory of the Russian Federation (GAIN RS1760, 2017), formalizing the *de facto* ban on commercial cultivation that had been in place. No GE crops are expected to be commercialized before 2023. CFTs are theoretically possible, but no mechanism is currently in place to authorize CFTs (GAIN RS1545, 2015).

SENEGAL: Senegal has not commercialized any GE crops, nor has it authorized any CFTs. The annual GAIN biotechnology report from Senegal covers all of Francophone West Africa, including Burkina Faso, Cote d'Ivoire, Mali and Togo. A draft regional biosafety law is pending approval by the Economic Community of West African States; if approved, this would allow for regional approval of GE products (GAIN Senegal, 2017).

SLOVAKIA: Slovakia had been producing GE corn on a small scale since 2006, about 138 ha in 2016, but did not plant any GE corn in 2017 (ISAAA, 2017). CFTs have been authorized for one GE sugar beet event and for several GE corn events. Slovakia has not posted a GAIN biotechnology report since 2012 (GAIN LO1202, 2012).

SPAIN: GE corn has been continuously produced in Spain since 1998, and Spain continues to be the largest producer of GE crops in Europe. About 30% of the corn grown in Spain is Bt corn (MON 810), which is the only GE crop event currently approved for cultivation in the EU. The area planted to GE corn in 2017 was 124,000 ha (ISAAA, 2017). In 2016, CFTs were authorized for canola, corn, potato, tobacco and wheat (GAIN SP1737, 2017).

SOUTH AFRICA: With 2.7M ha of GE crops in 2017, 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, all with adoption rates exceeding 90%. Since 2013, South Africa authorized 37 CFTs of GE crops (mainly corn, cotton and soybean) or clinical trials of GE vaccines (GAIN South Africa, 2016). In 2013, the authorized CFTs also included GE sugarcane and GE cassava (GAIN South Africa, 2015); however, CFTs of these crops were not mentioned in this years' report (GAIN South Africa, 2017). The South African Sugarcane Research Institute (SASRI) has received authorization for CFTs of four GE sugarcane events with modified carbohydrate metabolism. The altered-starch GE cassava

project is funded by USAID. Prompted by an urgent need for corn imports, in December 2016 South Africa approved the six events that had been causing asynchrony, opening the door for importing corn from the United States (GAIN South Arica, 2017).

SUDAN: Sudan approved Bt cotton in 2012 and produced about 192,000 ha of GE cotton in 2017, with an adoption rate of 98% (ISAAA, 2017). No other information was available on GE crop development in Sudan. There are no biotechnology GAIN reports from Sudan.

SWEDEN: Starting in 2010, Sweden allowed cultivation of BASF's GE potato with modified starch; however, since BASF has canceled the project, cultivation of this GE potato is no longer authorized. Sweden does allow CFTs and has authorized over 130 field trials since 1989 (GAIN SW1202, 2012). In 2016 and 2017, Sweden notified the EU Commission of intentions for CFTs of Arabidopsis, aspen, Camelina, crambe, *Lepidium campestre* and potato (JRC, 2017). The most recent GAIN biotechnology report from Sweden was posted in 2012.

TAIWAN: No GE crops are commercially produced in Taiwan and none is expected to be authorized in the near future. Taiwan has five accredited field trial facilitates and has authorized 11 CFTs since 2005; these have included GE broccoli, GE cucumber, GE eucalyptus, GE papaya, GE potato, GE rice and GE tomato (GAIN TW17022, 2017).

TANZANIA: No GE crops are commercially produced in Tanzania. In 2016 the government relaxed the "strict Liability" biosafety regime, which had previously served as a barrier to conducting CFTs. A CFT of GE corn was conducted in 2017 and GE cassava research is also proceeding (GAIN Tanzania, 2017).

THAILAND: Thailand has a *de facto* ban on GE crop cultivation. Thailand 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 (GAIN TH7161, 2017). However, unauthorized GE papaya has routinely been detected in papaya products exported to Europe from Thailand (GAIN TH7161, 2017; European Commission, 2017), suggesting that the unauthorized cultivation of GE papaya is widespread. Japan routinely screens papaya imports for the GE papaya event (PRSV-SC) that was field tested in Thailand (Emi Nagata, personal communication).

UGANDA: No GE crops are commercially produced in Uganda. In 2017, the Ugandan Parliament passed the National Biotechnology and Biosafety Bill (Eyotaru O, 2017); however, President Museveni declined to sign the bill into law and it has been re-tabled (The Independent, 2018). Uganda has made great strides in recent years to increase their capacity for GE crop development. CFTs are in progress for GE banana, GE cassava, GE corn and GE cotton, GE potato, GE rice and GE sweet potato. USAID's Agricultural Biotechnology Support Project II (ABSPII) is supporting the local project to develop GE banana. Ugandan scientists are producing GE banana events with several traits, some of

which could be commercialized as soon as 2021. There are no biotechnology GAIN reports from Uganda.

UKRAINE: No GE crops are authorized for production in Ukraine, and no GE crops are under development. However, unauthorized production of GE corn and GE soybean appears to be widespread; estimates place the GE market share at 3-5% and 60-70% for GE corn and GE soybean, respectively. The share of GE corn has been going down due to lack of access to GE seeds, but the share of GE soybean has remained stable (GAIN UP1725, 2017).

UNITED KINGDOM: After the Brexit occurs, there may be more opportunity for GE crop production in the United Kingdom; however, no changes in policy are expected in the short term. Scotland, Wales and Northern Ireland have "opted out" of GE crop production, leaving England as a relatively small market for GE products. Many CFTs have been conducted, but they have frequently been vandalized. CFTs of GE Camelina, GE potato and GE wheat are ongoing (GAIN United Kingdom, 2017; JRC, 2017).

UNITED STATES: The United States has been the leading producer of GE crops since they first entered the market in the 1990's, and most of the GE crops produced globally were developed in the United States. In 2017, the United States produced nearly 75M ha of GE crops. These were mainly canola, corn, cotton, soybean and sugar beet, all of which have adoption rates above 90% (ISAAA, 2017). USDA has granted determinations of nonregulated status 127 times in 18 crop species. For further information, see the USD table of Petitions for Determination of Nonregulated Status: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

URUGUAY: In 2017, Uruguay produced about 1.1M ha of GE corn and GE soybean, both with adoption rates above 95% (ISAAA, 2016). Scientists in Uruguay have been developing GE potato and GE tomato (Dalla-Rizza, 2013); however, no further information was available on authorized CFTs. No GAIN biotechnology report has been posted for Uruguay since 2012.

VIETNAM: In August 2014, Vietnam approved the first GE corn event for commercial production, and approved three more GE corn events for commercial planting in 2015 (GAIN VM5042, 2015). In 2016, Vietnam produced about 35,000 ha of GE corn (GAIN VM70771, 2017; ISAAA, 2016). CFTs have been authorized for GE corn, GE cotton and GE soybean; however, only corn CFTs have been conducted. Japan routinely screens rice and papaya imports from Vietnam for GE content. For rice imports, they screen for event CpTI, suggesting either that this GE rice is now being grown in Vietnam, or that Chinese rice is passing through Vietnam on its way to Japan (Emi Nagata, personal communication).

Appendix F – 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, 2017); (3) the GAIN reports; (4) conference calls to APHIS personnel in country; and (5) public news reports.

Country	Commercial Cultivation		Confined Field Trials (CFTs)		Comments
	Authorized (Y/N)	GE Crops	Authorized (Y/N)	GE Crops	
Argentina	YES	corn, cotton, soybean	YES	fescue, corn, potato, safflower, soybean, sugarcane, wheat	Significant R&D
Australia	YES	canola, carnation, cotton	YES	banana, , cotton, safflower, sorghum, sugarcane	Significant R&D
Bangladesh	YES	eggplant	YES	cotton, eggplant, potato, rice	USAID – eggplant and potato
Belgium	NO		YES	corn, poplar	
Bolivia	YES	soybean	YES	cotton	None since 2012
Brazil	YES	corn, cotton, dry edible bean, eucalyptus, soybean,	YES	citrus, papaya, potato, rice, soybean, sugarcane	Significant R&D
Burkina Faso	YES	cotton	YES	corn, cotton, cowpea	
Burma	YES	cotton	YES	cotton	
Canada	YES	alfalfa, apple, canola, corn, potato, soybean, sugar beet	YES	many crops	Canada regulates products of mutagenesis
Cameroon	NO		YES	cotton	
Chile	NO		YES	canola, corn, soybean	GE seed production for *export only*

Country	Commercial Cultivation		Confined Field Trials (CFTs)		Comments
	Authorized (Y/N)	GE Crops	Authorized (Y/N)	GE Crops	
China	YES	cotton, papaya, poplar	YES	corn, cotton, rice, soybean, wheat	Significant R&D CFTs required for all food approvals
Colombia	YES	carnation, cotton, corn, rose, soybean	YES	cassava, corn, cotton, potato, rice, sugarcane	GE rose and GE carnation produced in containment for *export only*
Costa Rica	YES	cotton, soybean, corn	YES	rice, pineapple, banana	GE seed production for *export only*
Cote d'Ivoire	NO		NO		Unauthorized GE cotton production
Czech Republic	YES	corn	YES	barley, flax, plum, soybean	No GE Corn in 2017; GE potato in 2012
Cuba	NO	corn?	YES	corn, soybean	GE corn was produced from 2011-2014
Ecuador	NO		YES	corn	
Egypt	YES	corn	NO	none since 2011	GE Corn plantings suspended in 2012
El Salvador	NO		YES	corn	None since 2009
Ethiopia	NO		YES	cotton	
France	NO		YES	poplar	None since 2010
Ghana	NO		YES	cotton, cowpea, rice, sweet potato	
Guatemala	NO		YES	corn	No CFTs since 2013

Country	Commercial Cultivation		Confined Field Trials (CFTs)		Comments
	Authorized (Y/N)	GE Crops	Authorized (Y/N)	GE Crops	
Honduras	YES	corn	YES	banana, corn, rice	Only corn CFTs since 2011
Hong Kong	NO	papaya	NO	rice CFTs in China	Exemption for GE papaya
India	YES	cotton	YES	chickpea, corn, cotton, mustard and rice	Unauthorized Bt eggplant
Indonesia	NO		YES	rice, corn, sugarcane	USAID – potato
Iran	YES	rice	YES	cotton	
Israel	YES	tobacco	YES	Many crops but not public	GE Tobacco produced for cosmetics
Japan	YES	rose	YES	All crops seeking food approval	CFTs required for all food approvals
Kenya	NO		YES	banana, cassava, corn, cotton, gypsophila flower, sorghum, sweet potato	
Kazakhstan	NO		YES	wheat	No CFTs anticipated
Korea, Republic of	NO		NO	bean, bent grass, cabbage, flowers, rice, pepper	*Contained* Field Trials only
Malawi	NO		YES	banana, cotton, cowpea	
Malaysia	NO		YES	papaya	Unauthorized GE Papaya Cultivation
Mexico	YES	cotton, soybean	YES	common bean, cotton, corn, lemon tree, soybean, wheat	Advanced GE wheat R&D at CIMMYT
Malawi	NO		YES	cotton, cowpea	

Country	Commercial Cultivation		Confined Field Trials (CFTs)		Comments
	Authorized (Y/N)	GE Crops	Authorized (Y/N)	GE Crops	
Mozambique	NO		YES	corn	
New Zealand	NO		YES	brassicas, corn, onions, petunia, pine trees, potato, sugar beet	CFTs are referred to as "contained" outdoor field trials
Nigeria	NO		YES	cassava, cotton, cowpea, rice, sorghum	Unauthorized GE production
Pakistan	YES	cotton	YES	corn, cotton, wheat	
Panama	YES	corn	YES	corn	GE mosquito, GE salmon
Paraguay	YES	corn, cotton, soybean	YES	corn, cotton, soybean	
Peru	NO		NO		
Philippines	YES	corn	YES	corn, cotton, eggplant, papaya, rice	USAID – eggplant and papaya
Poland	NO	corn	YES	flax, poplar	Unauthorized GE production?
Portugal	YES	corn	YES	none	None since 2010
Romania	YES	corn	YES	plums	No GE corn since 2015
Russian Federation	NO		YES	none	
Senegal	NO		NO		
Slovakia	YES	corn	YES	corn, sugar beet	

Country	Commercial Cultivation		Confined Field Trials (CFTs)		Comments
	Authorized (Y/N)	GE Crops	Authorized (Y/N)	GE Crops	
Spain	YES	corn	YES	corn, canola, potato, tobacco, wheat	
South Africa	YES	corn, soybean, cotton	YES	corn, cotton, soybean	Developing GE sugarcane and GE cassava
Sudan	YES	cotton	NA		
Sweden	NO		YES	arabidopsis, aspen, Camelina, crambe, Lepidium campestre and potato	Cultivated GE potato from 2010 to 2012
Taiwan	NO		YES	broccoli, eucalyptus, papaya, potato, rice, tomato	CFTs only at accredited sites
Tanzania	NO		YES	corn	
Thailand	NO		YES	none	Unauthorized GE papaya
Uganda	NO		YES	banana, cassava, corn, cotton, potato, rice, sweet potato	USAID – banana
Ukraine	NO	corn, soybean	NO		Unauthorized GE production
United Kingdom	NO		YES	Camelina, potato, wheat	
United States	YES	canola, corn, cotton, soybean, sugar beet	YES	many crops	Determinations of Nonregulated Status for 18 crop species
Uruguay	YES	corn, soybean	YES	NA	
Vietnam	YES	corn	YES	corn, cotton and soybean	Only corn CFTs have been conducted