



EXECUTIVE SUMMARY

BRIEF 49

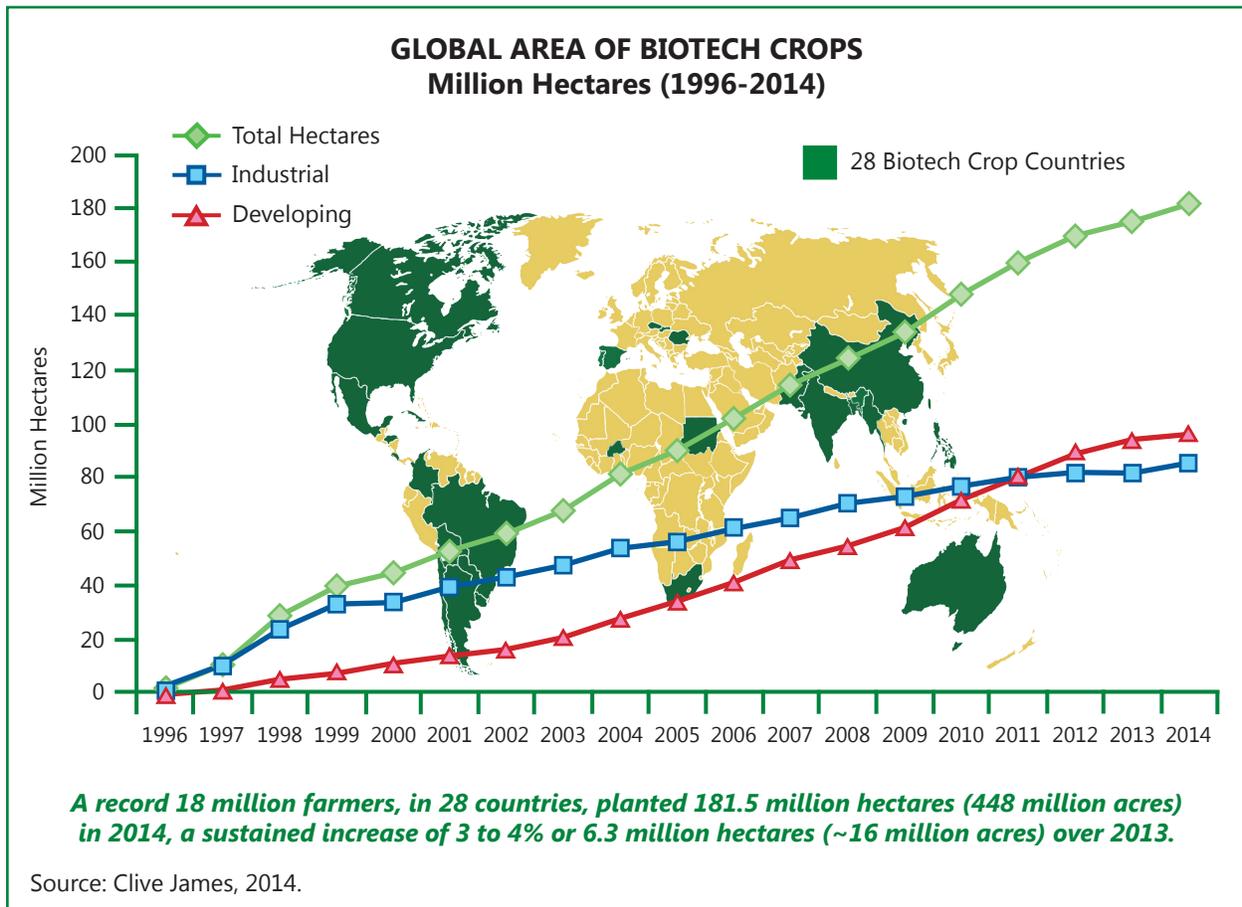
Global Status of Commercialized Biotech/GM Crops: 2014

By

Clive James

Founder and Emeritus Chair of ISAAA

Dedicated to the late Nobel Peace Laureate, Norman Borlaug, founding patron of ISAAA, on the centenary of his birth, 25 March 2014



AUTHOR'S NOTE:

Global totals of millions of hectares planted with biotech crops have been rounded off to the nearest million and similarly, subtotals to the nearest 100,000 hectares, using both < and > characters; hence in some cases this leads to insignificant approximations, and there may be minor variances in some figures, totals, and percentage estimates that do not always add up exactly to 100% because of rounding off. It is also important to note that countries in the Southern Hemisphere plant their crops in the last quarter of the calendar year. The biotech crop areas reported in this publication are planted, not necessarily harvested hectareage in the year stated. Thus, for example, the 2014 information for Argentina, Brazil, Australia, South Africa, and Uruguay is hectares usually planted in the last quarter of 2014 and harvested in the first quarter of 2015 with some countries like the Philippines having more than one season per year. Thus, for countries of the Southern hemisphere, such as Brazil, Argentina and South Africa the estimates are projections, and thus are always subject to change due to weather, which may increase or decrease actual planted hectares before the end of the planting season when this Brief has to go to press. For Brazil, the winter maize crop (safrinha) planted in the last week of December 2014 and more intensively through January and February 2015 is classified as a 2014 crop in this Brief consistent with a policy which uses the first date of planting to determine the crop year. ISAAA is a not-for-profit organization, sponsored by public and private sector organizations. All biotech crops hectare estimates reported in all ISAAA publications are only counted once, irrespective of how many traits are incorporated in the crops. Importantly, all reported biotech crop hectares are for officially approved and planted products, and do not include unofficial plantings of any biotech crops. At the time when this Brief went to press, estimates of economic benefits, productivity, landsaving, and carbon data were provisional for the period 1996-2013 (Brookes and Barfoot, 2015, Forthcoming); and pesticide data is for 1996-2012 (Brookes and Barfoot, 2014). Details of the references listed in the Executive Summary are found in the full Brief 49.

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ISAAA prepares this Brief and supports its free distribution to developing countries. The objective is to provide information and knowledge to the scientific community and society on biotech/GM crops to facilitate a more informed and transparent discussion regarding their potential role in contributing to global food, feed, fiber and fuel security, and a more sustainable agriculture. The author takes full responsibility for the views expressed in this publication and for any errors of omission or misinterpretation.

Published by: The International Service for the Acquisition of Agri-biotech Applications (ISAAA).

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Citation: James, Clive. 2014. Global Status of Commercialized Biotech/GM Crops: 2014. *ISAAA Brief* No. 49. ISAAA: Ithaca, NY.

ISBN: 978-1-892456-59-1

Publication Orders: Please contact the ISAAA *SEAsia*Center to acquire a hard copy of the full version of Brief 49. Access to the Executive Summary and the Top Ten Facts at <http://www.isaaa.org>. The publication is available free of charge to eligible nationals of developing countries.

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Remarkably, in 2014 global biotech crop hectareage continued to grow for the 19th consecutive year of commercialization; 18 million farmers in 28 countries planted more than 181 million hectares in 2014, up from 175 million in 27 countries in 2013. Notably, Bangladesh, a small poor country approved Bt brinjal/eggplant for the first time on 30 October 2013, and in record time – less than 100 days after approval – small farmers commercialized Bt brinjal on 22 January 2014. Innate™ potato, another food crop, was approved in the US in November 2014. It has lower levels of acrylamide, a potential carcinogen in humans, and suffers less wastage from bruising; potato is the fourth most important food staple in the world. A safer product and decreased wastage in a vegetatively propagated and perishable crop, can contribute to higher productivity and food security. Also in November 2014, a new biotech alfalfa (event KK179) with up to 22% less lignin, which leads to higher digestibility and productivity, was approved for planting in the US. The first biotech drought tolerant maize, planted in the US in 2013 on 50,000 hectares increased over 5 fold to 275,000 hectares in 2014 reflecting high acceptance by US farmers. Importantly, a new 2014 comprehensive global meta-analysis, on 147 published biotech crop studies over the last 20 years worldwide confirmed the significant and multiple benefits that biotech crops have generated over the past 20 years, 1995 to 2014; on average GM technology adoption has reduced chemical pesticide use by 37%, increased crop yields by 22%, and increased farmer profits by 68%. These findings corroborate earlier and consistent results from other annual global studies which estimated increases in crop productivity valued at US\$133.3 billion for the period 1996-2013.

Introduction

This Executive Summary focuses on the highlights of ISAAA Brief 49, details of which are presented and discussed in the full Brief, “Global Status of Commercialized Biotech/GM Crops: 2014”.

Biotech crop hectareage increases yet again in 2014, in their 19th consecutive year of commercialization.

A record 181.5 million hectares of biotech crops were grown globally in 2014, at an annual growth rate of between 3 and 4%, up 6.3 million hectares from 175.2 million hectares in 2013. This year, 2014, was the 19th year of commercialization, 1996-2014, when growth continued after a remarkable 18 consecutive years of increases every single year; notably 12 of the 18 years were double-digit growth rates.

Biotech crops are the fastest adopted crop technology in the world.

The global hectareage of biotech crops has increased more than 100-fold from 1.7 million hectares in 1996 to 181.5 million hectares in 2014 – this makes biotech crops the fastest adopted crop technology in recent times. This impressive adoption rate speaks for itself, in terms of its sustainability, resilience and the significant benefits it delivers to both small and large farmers as well as consumers.

A new and rigorous 2014 comprehensive global meta-analysis of 147 published biotech crop studies over the last 20 years, confirmed the significant and multiple benefits that biotech crops have generated over the past 20 years (1995 to 2014).

The meta-analysis was performed by Klumper and Qaim (2014) on 147 published biotech crop studies conducted during the last 20 years, using primary data from farm surveys or field trials world-wide and reporting impacts of GM soybean, maize, or cotton on crop yields, pesticide use, and/or farmer profits. The meta-analysis concluded that ***“on average GM technology adoption has reduced chemical pesticide use by 37%, increased crop yields by 22%, and increased farmer profits by 68%. Yield gains and pesticide reductions are larger for insect-resistant crops than for herbicide-tolerant crops. Yield and profit gains are higher in developing countries than in developed countries.”*** The authors concluded that ***“this meta-analysis confirms that in spite of impact heterogeneity, the average agronomic and economic benefits of GM crops are large and significant. Impacts vary especially by modified crop trait and geographic region. Yield gains and pesticide reductions are larger for IR crops than for HT crops. Yield and farmer profit gains are higher in developing countries than in developed countries. Recent impact studies used better data and methods than earlier studies, but these improvements in study design did not reduce the estimates of GM crop advantages. Rather, NGO reports and other publications without scientific peer review seem to bias the impact estimates downward. But even with such biased estimates included, mean effects remain sizeable.”*** The authors of the meta-analysis note that it reveals ***“robust evidence of GM crop benefits for farmers in developed and developing countries.”*** It is noteworthy that the findings of this meta-analysis corroborates results from previous peer reviewed studies including the annual global impact study on biotech crops conducted by Brookes and Barfoot of PG Economics and regularly referenced in the Annual ISAAA Briefs.

Millions of risk-averse farmers, both large and small, world-wide, have concluded that the returns from planting biotech crops are high, hence repeat planting is virtually 100%; good returns on their investment is the critical test applied by demanding farmers when judging the performance of any technology.

In the 19 year period 1996 to 2014, millions of farmers in almost 30 countries worldwide, adopted biotech crops at unprecedented rates. The most compelling and credible testimony for biotech crops is that during the 19 year period 1996 to 2014, millions of farmers in ~30 countries worldwide, elected to make more than 100 million independent decisions to plant and replant an accumulated hectareage of more than 1.8 billion hectares exceeding 4 billion acres for the first time in 2014. This is an area equivalent to >180% the size of the total land mass of the US or China which is an enormous area. There is one principal and overwhelming reason that underpins the trust and confidence of risk-averse farmers in biotechnology – biotech crops deliver substantial, and sustainable, socio-economic and environmental benefits. Comprehensive analytical studies by many organizations including a 2011 EU

study have confirmed that biotech crops are safe and deliver substantial agronomic and environmental benefits, and result in significant reductions in pesticide usage.

28 countries, up one from 27 in 2013, grew biotech crops in 2014.

Of the 28 countries which planted biotech crops in 2014 (Table 1 and Figure 1), 20 were developing (including the new biotech crop country Bangladesh) and only 8 were industrial countries. Each of the top 10 countries, of which 8 were developing, grew more than 1 million hectares providing a broad-based worldwide foundation for continued and diversified growth in the future. More than half the world's population, ~60% or ~4 billion people, live in the 28 countries planting biotech crops.

Bangladesh, one of the smaller and poorest countries in the world, approved and commercialized Bt brinjal in record time in 2014. Vietnam and Indonesia moved towards planting their first biotech crops in 2015, for a total of 9 biotech countries in Asia.

Bangladesh approved a biotech crop (Bt brinjal/eggplant) for planting for the first time on 30 October 2013, and in record time – less than 100 days after approval – commercialization was initiated on 22 January 2014 when 20 very small farmers planted their first crop of Bt brinjal; a total of 120 farmers planted 12 hectares of Bt brinjal in 2014. This feat, which is an excellent working model for other small poor countries, could not have been achieved without strong political will and support from the government, particularly from the Minister of Agriculture Matia Chowdhury. This approval by Bangladesh is important in that it serves as an exemplary model for other small poor countries. Also, very importantly, Bangladesh has broken the impasse experienced in trying to gain approval for commercialization of Bt brinjal in both India and the Philippines.

It is noteworthy that in Asia, two other developing countries, Vietnam and Indonesia also approved cultivation of biotech crops in 2014 for commercialization in 2015 (these hectares are not included in the data base for this Brief). Vietnam approved biotech maize and Indonesia approved a drought tolerant sugarcane for food, whilst approval for feed is pending; 50 hectares of biotech seed setts of sugarcane were planted in 2014 for planned commercialization in 2015. With the addition of Vietnam and Indonesia this would bring the total number of countries in Asia commercializing biotech crops to nine.

Increased adoption of biotech drought tolerant maize in the US

The estimated hectares of DroughtGard™ maize with event MON 87460 planted for the first time in the US in 2013 was 50,000 hectares and in 2014 was of the order of 275,000 hectares. This is equivalent to a large 5.5-fold year-to-year increase in planted hectares between 2013 and 2014, and reflects strong US farmer acceptance of the first biotech-derived drought-tolerant maize technology to be deployed globally. It is noteworthy that Event MON 87460 was donated by Monsanto to the Water Efficient Maize for Africa (WEMA), a public-private partnership (PPP) designed to deliver the first biotech drought tolerant maize to selected African countries starting 2017.

A selection of “new” biotech crops was recently approved and planned for commercialization in 2015 and beyond; they include two new food staples, potato and the vegetable brinjal (eggplant).

In 2014, the US approved the following two new biotech crops for cultivation starting in 2015; Innate™

Table 1. Global Area of Biotech Crops in 2014: by Country (Million Hectares)**

Rank	Country	Area (million hectares)	Biotech Crops
1	USA*	73.1	Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash
2	Brazil*	42.2	Soybean, maize, cotton
3	Argentina*	24.3	Soybean, maize, cotton
4	India*	11.6	Cotton
5	Canada*	11.6	Canola, maize, soybean, sugar beet
6	China*	3.9	Cotton, papaya, poplar, tomato, sweet pepper
7	Paraguay*	3.9	Soybean, maize cotton
8	Pakistan*	2.9	Cotton
9	South Africa*	2.7	Maize, soybean, cotton
10	Uruguay*	1.6	Soybean, maize
11	Bolivia*	1.0	Soybean
12	Philippines*	0.8	Maize
13	Australia*	0.5	Cotton, canola
14	Burkina Faso*	0.5	Cotton
15	Myanmar*	0.3	Cotton
16	Mexico*	0.2	Cotton, soybean
17	Spain*	0.1	Maize
18	Colombia*	0.1	Cotton, maize
19	Sudan*	0.1	Cotton
20	Honduras	<0.1	Maize
21	Chile	<0.1	Maize, soybean, canola
22	Portugal	<0.1	Maize
23	Cuba	<0.1	Maize
24	Czech Republic	<0.1	Maize
25	Romania	<0.1	Maize
26	Slovakia	<0.1	Maize
27	Costa Rica	<0.1	Cotton, soybean
28	Bangladesh	<0.1	Brinjal/Eggplant
Total		181.5	

* 19 biotech mega-countries growing 50,000 hectares, or more, of biotech crops

** Rounded off to the nearest hundred thousand

Source: Clive James, 2014.

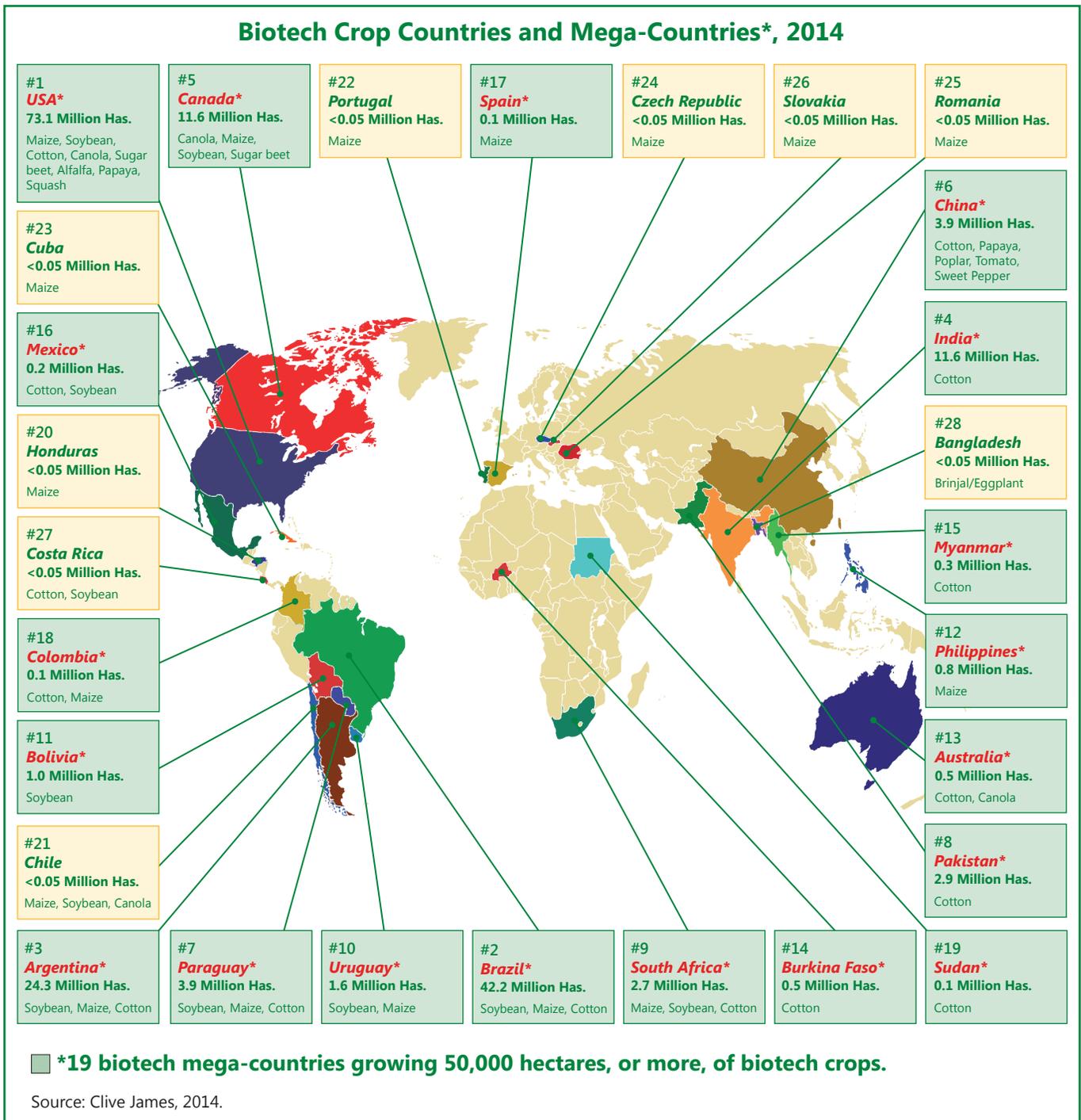


Figure 1. Global Map of Biotech Crop Countries and Mega-Countries in 2014

potato, a food staple with lower levels of acrylamide, a potential carcinogen, and less wastage due to bruising; and reduced lignin alfalfa with event KK179, to be marketed as HarvXtra™ with higher digestibility and higher yield. Another product Enlist™ Duo is a representative example of the second generation of HT products featuring dual-action/weed management systems for dealing with herbicide resistant weeds. Others in the same class include a dicamba/glyphosate soybean product, and event SYHTOH2 soybean tolerant to glufosinate, isoxaflutole and mesotrione. Enlist™ Duo has herbicide tolerance to both glyphosate and 2,4-D in soybean and maize. Indonesia has approved drought tolerant sugarcane with plans to plant in 2015 and Brazil has two products – Cultivance™, an HT soybean, and a home-grown virus resistant bean for commercialization in 2016. Finally, Vietnam has approved biotech maize (HT and IR) for the first time with commercialization planned for 2015. In summary, in addition to the current biotech food crops which directly benefit consumers (white maize in South Africa, sugar beet and sweet corn in the US and Canada, and papaya and squash in the US) new biotech food crops include the queen of the vegetables (brinjal) in Bangladesh and potato, the fourth most important food staple in the world.

- **Innate™ potato** developed by the private company, Simplot, in the US, was approved for commercialization in the US by APHIS/USDA in November 2014. Innate™ has 50 to 75% lower levels of acrylamide, a potential carcinogen in humans, produced when potatoes are cooked at high temperatures. Innate™ potato is also less susceptible to bruising. Given that potato is a perishable food product, quality can be significantly and negatively impacted by damage to the tubers during harvest, handling and processing. Innate™ potatoes are an excellent example of how biotech crops can enhance food safety, quality and provide benefits for all stakeholders, growers, processors and consumers. It is noteworthy that Innate™ potato was developed by transferring genes from one potato variety to another. Simplot claims that Innate™ potato is a safe and superior product that will confer the following benefits to farmers, processors and consumers: lower levels of asparagine, which in turn lowers the potential for production of undesirable acrylamide, a potential carcinogen, when potatoes are cooked at high temperatures; will not discolor when peeled; fewer spots due to bruising; they store better; reduce wastage and thus contribute to food security. Consumer surveys by Simplot indicate that 91% of those surveyed were comfortable with the Innate™ breeding method. RNA interference technology was used to silence four genes that lowered enzyme levels that in turn led to lower acrylamide level. The company plans to initiate commercialization on a modest hectareage in 2015, prioritizing the fresh potato market and the potato chip market whilst keeping Innate™ production separated from conventional potatoes for the export market. Simplot is planning on submitting applications to the major markets, Canada, Mexico and Japan.

Approval of Innate™ could open new windows of opportunity for biotech potatoes globally. Potato is the fourth most important food staple in the world after rice, wheat, and maize. Plant protection constraints are important in potato production because the potato is a vegetatively propagated crop, where the tubers and not the “true seed” are used to propagate the crop commercially. Thus, unlike crops propagated through the seed, potatoes do not benefit from the natural barrier provided by the seed for blocking transmission of many plant pathogens. Hence, like other tuber crops, the prevalence and importance of diseases is high in potatoes, compared with seed propagated crops. Global yield loss in potatoes due to fungal and bacterial pathogens is estimated at 22%, plus 8% for viruses for a total of 30% for all diseases. These disease losses are in addition to the estimated losses of 18% for insect pests and 23% for weeds. Without crop protection, up to 70% of attainable potato production could potentially be lost to pests such as Colorado beetle and virus vectors (aphids and leafhoppers),

diseases caused by fungi, bacteria and a complex of viruses, including potato virus Y (PVY) and potato leaf roll virus (PLRV) as well as nematodes, which cause devastating losses in localized areas. Seed certification programs, for field tubers grown for propagation, and plant tissue cultural systems, both requiring infrastructure and recurrent use of resources to produce clean potato stock annually, are used in industrial countries to provide effective control of some diseases particularly insect vectored viruses including PVY and PLRV. Certification is not very effective against the spread of destructive late blight and certification requires adequate infrastructure which is often not available in developing countries. Thus, potato suffers very high losses from pests and diseases, which biotech can effectively control.

Of the many pests that attack potatoes, late-blight (caused by the fungus *Phytophthora infestans*) is the single most important disease, accounting for up to 15% of potato yield losses due to plant pathogens – the disease that caused the Irish Famine of 1845. More than 150 years after the famine, conventional technology has still failed to confer resistance and late-blight is still the most important disease of potatoes world wide responsible for economic losses estimated at US\$7.5 billion annually. Potato is widely grown in many developing countries like Bangladesh, India, and Indonesia, where field trials are already underway for assessing biotech resistance to late-blight disease of potatoes. The approval of Innate™ potato in the US could have important implications globally particularly for developing countries, because it opens up new opportunities to apply biotech to a “new” crop by stacking several important traits already developed (late-blight resistance), approved (Innate™), or already commercialized (PVY, PLRV and Bt in the US in the late 1990s). It is noteworthy that recently, Simplot has pioneered this strategy by licensing biotech late blight resistant potato from the John Innes Institute in the UK and developed an enhanced Innate™ with late blight resistance potato, low acrylamide potential, reduced black spot bruising and lowered reducing sugars. The company has submitted an application for non regulated status of the enhanced Innate™ product to APHIS, which has already invited public comments on the application.

- **Reduced lignin alfalfa event KK179** (to be marketed as HarvXtra™) was recently deregulated by APHIS for cultivation in the US. Alfalfa is a perennial and the fourth largest crop by hectareage in the US after maize, soybean, and wheat, occupying up to 8 to 9 million hectares. It is the major forage crop in the US and globally, where it occupies approximately 30 million hectares. Biotech herbicide tolerant RR® alfalfa has already been grown since 2005 in the US. In November 2014, the US approved the planting of biotech alfalfa, event KK179, to be marketed as HarvXtra™, as a stack with RR® alfalfa with up to 22% reduction in lignin when compared to conventional alfalfa at the same stage of growth. This results in a reduced overall accumulation of total lignin in alfalfa forage. The amounts of lignin in event KK179 forage are generally similar to those found in conventional forage harvested several days earlier under similar production conditions. The reduced lignin alfalfa increases forage quality compared to conventional forage of the same age, maximizes forage yield by delaying harvest for several days, and gives farmers more flexibility in forage harvest timing. Thus, event KK179 maximizes forage quality with lower lignin levels; optimizes forage yields by allowing farmers to delay harvest for several days during which more forage biomass is accumulated; and allows more flexible harvest schedules to deal with adverse weather and varying labor schedules.

- **Enlist™ Duo** is a representative example of a second generation of herbicide tolerant products featuring dual-action/weed management systems for dealing with herbicide resistant weeds – others in the same class includes a dicamba/glyphosate soybean product and event SYHTOH2 soybean tolerant to the herbicides glufosinate, isoxaflutole and mesotrione. **Enlist™ Duo** products contain two pyramided

genes to confer tolerance to herbicide glyphosate and 2,4-D choline. The product was deregulated in the US to manage broad spectrum of weeds including hard-to-control and resistant weeds such as glyphosate-resistant Palmer amaranth, waterhemp and giant ragweed. Maize and soybean farmers can use the Enlist™ Duo seeds as a component in their stewardship of rotating various herbicide tolerant seeds and products on their farms – an important strategy to retain the value, effectiveness and durability of herbicide tolerant crops. A full launch of Enlist products is pending import approval in China which approved the last product in June 2013; asynchronous approval for cultivating and import of new products is a major challenge which needs urgent attention by all stakeholders.

18 million farmers benefit from biotech crops – 90% were small resource-poor farmers.

In 2014, approximately 18 million farmers, the same as 2013, grew biotech crops – remarkably, about 90%, or 16.5 million, were risk-averse small, poor farmers in developing countries. In China, 7.1 million small farmers benefited from biotech cotton and in India there were 7.7 million beneficiary farmers cultivating a total of more than 15 million hectares of Bt cotton. The latest provisional economic data available for the period 1996 to 2013 indicates that farmers in China gained US\$16.2 billion and in India US\$16.7 billion. In addition to economic gains, farmers benefited enormously from at least a 50% reduction in the number of insecticide applications, thereby reducing farmer exposure to insecticides, and importantly contributed to a more sustainable environment and better quality of life.

For the third consecutive year in 2014, developing countries planted more biotech crops than industrial countries.

Latin American, Asian and African farmers collectively grew 96 million hectares or 53% of the global 181 million biotech hectares (versus 54% in 2013) compared with industrial countries at 85 million hectares or 47% (versus 46% in 2013), equivalent to a gap of 11 million hectares in favor of developing countries. In the long term, this trend is expected to continue despite the fact that in 2014 the US had the highest increase (3.0 million hectares) whereas Brazil (with an increase of 1.9 million hectares in 2014) had the highest year-to-year increase for the last five years. The higher hectareage in developing countries is contrary to the prediction of critics who, prior to the commercialization of the technology in 1996, prematurely declared that biotech crops were only for industrial countries and would never be accepted and adopted by developing countries, particularly small poor farmers.

During the period 1996-2013 cumulative provisional economic benefits in industrial countries were at US\$65.2 billion compared to US\$68.1 billion generated by developing countries. In 2013, developing countries had 49.5% equivalent to US\$10.1 billion of the total US\$20.4 billion gain, with industrial countries at US\$10.3 billion (Brookes and Barfoot, 2015, Forthcoming).

Stacked traits occupied 28% of the global 181 million hectares.

Stacked traits continued to be an important and growing feature of biotech crops – 13 countries planted biotech crops with two or more traits in 2014, of which 10 were developing countries. About 51 million hectares equivalent to 28% of over 181 million hectares were stacked in 2014, up from 47 million hectares or 27% of the 175 million hectares in 2013; this steady and growing trend of more stacked traits is expected to continue. In 2014, 5.8 million hectares of HT/Bt soybean were grown in Brazil, Argentina, Paraguay and Uruguay in Latin America.

The 5 lead biotech developing countries in the three continents of the South: Brazil and Argentina in Latin America, India and China in Asia, and South Africa on the continent of Africa, grew 47% of global biotech crops and represent ~41% of world population.

The five lead developing countries in biotech crops in the three continents of the South are China and India in Asia, Brazil and Argentina in Latin America, and South Africa on the continent of Africa. They collectively grew 84.7 million hectares (47% of global) and together represent ~41% of the global population of 7 billion, which could reach 10.9 billion, or more, by the turn of the century in 2100. Remarkably, the population in Sub Saharan Africa alone could escalate from ~1 billion today (~13% of global) to a possible high of 3.8 billion (~38% of global) by the end of this century in 2100. Global food security, exacerbated by high and unaffordable food prices, is a formidable challenge to which biotech crops can contribute but are not a panacea.

USA maintains leadership role, and in 2014 its increase in year-to-year hectareage was higher than Brazil, which has recorded the highest increase of any country for the last five years.

The US continued to be the lead producer of biotech crops globally with 73.1 million hectares (40% of global), with an average adoption rate of over ~90% across its principal biotech crops; year-to-year growth in the US in 2014 was 4%. It is noteworthy that in 2014, the US increase in hectareage (3.0 million hectares) was higher than any country in the world including Brazil (1.9 million hectares) which had recorded the highest increase of all countries in the world for the last five years. The higher increase in the US in 2014 was principally due to an 11% increase in total planted hectareage to a record 34.3 million hectares of soybean planted. Despite very high levels of adoption in 2013, adoption in 2014 increased in all three principal crops – soybean adoption increased from 93% to 94%, maize from 90% to 93% and cotton from 90% to 96%.

Brazil continues to be second only to the US in biotech crop hectareage.

In 2014, Brazil ranked second only to the USA in biotech crop hectareage in the world with 42.2 million hectares (up from 40.3 million in 2013); the increase in 2014 was 1.9 million hectares equivalent to a growth rate of 5%. For the last five years, Brazil was the engine of growth globally. In 2013, it increased its hectareage by 3.7 million hectares of biotech crops, more than any other country in the world, however, in 2014, the highest year-over-year increase was in the US at 3.0 million hectares. In 2014, Brazil grew 23% (same as 2013) of the global hectareage of 181 million hectares. In the future, Brazil is expected to close the gap with the US. An efficient and science-based approval system in Brazil facilitates fast adoption. In 2014, Brazil commercially planted, for the second year, the stacked soybean with insect resistance and herbicide tolerance on 5.2 million hectares, up substantially from 2.2 million hectares in 2013. Notably, EMBRAPA, Brazil's agricultural R&D organization, with an annual budget of US\$1 billion, has gained approval to commercialize its home-grown biotech virus resistant bean, planned for 2016 and a herbicide tolerant soybean which it developed in a public-private partnership with BASF, which is waiting for an EU import approval prior to a planned commercialization in 2016.

Canada increases hectareage of biotech crops whereas area in Australia decreases because of continuing severe drought.

Canada grew 11.6 million hectares of biotech crops in 2014, up from 10.8 million hectares in 2013,

as farmers planted more biotech canola and soybean. Canada planted 8 million hectares of biotech canola (95% adoption) and over 2 million hectares of biotech soybean. Australia posted a decrease of ~200,000 hectares of biotech cotton (99% adoption) due to a severe drought. The decrease in cotton plantings was offset by an increase of ~50% for herbicide tolerant canola to 342,000 hectares.

India continues to benefit enormously from Bt cotton.

India cultivated a record 11.6 million hectares of Bt cotton planted by 7.7 million small farmers with an adoption rate of 95%, up from 11.0 million hectares in 2013. Notably, the increase from 50,000 hectares of Bt cotton in 2002 (when Bt cotton was first commercialized) to 11.6 million hectares in 2014, represents an unprecedented 230-fold increase in thirteen years. Brookes and Barfoot's latest provisional estimate indicated that India had enhanced farm income from Bt cotton by US\$16.7 billion in the twelve year period 2002 to 2013 and US\$2.1 billion in 2013 alone, similar to 2012.

Status of biotech crops in China

In 2014, 7.1 million small farmers (0.5 to 0.6 hectare/farm) successfully planted 3.9 million hectares of biotech cotton at an adoption rate of 93% of its 4.2 million total cotton hectareage. In addition ~8,500 hectares of virus resistant papaya were planted in Guangdong, Hunan Island and this year's new province of Guangxi; plus ~543 hectares of Bt poplar, the same as last year. Despite China's decreased total cotton hectareage from 4.6 million hectares in 2013 to 4.2 million hectares in 2014 (mainly due to low prices and high stockpiles of cotton in China), biotech cotton adoption has increased from 90% in 2013 to 93% in 2014. Impressively, virus resistant papaya plantings increased by ~50% from 5,800 hectares in 2013 to 8,475 hectares in 2014. In addition to the 7.1 million farmers benefiting directly from biotech cotton, there maybe an additional 10 million secondary beneficiary farmers cultivating 22 million hectares of crops which are alternate hosts of cotton bollworm that benefit from decreased pest infestation due to the extensive planting of Bt cotton. Thus, the actual total number of beneficiary farmers of biotech Bt cotton in China alone may well substantially exceed 7.1 million farmers. Latest provisional data shows that economic gains at the farmer level from Bt cotton for the period 1997 to 2013 was US\$16.2 billion and US\$1.6 billion for 2013 alone.

In the shorter term, biotech maize, and for the longer term Bt rice, offer significant benefits and have momentous implications for China, Asia, and the rest of the world, in the near, mid and long term; this is due to the fact that rice is the most important food staple, and maize the most important feed crop in the world. China's research and commercialization of Bt maize, herbicide tolerant maize and phytase maize as well as biotech rice, can make very important potential contributions to global food and feed needs as well as that of China. Whereas President Xi Jinping has endorsed the technology that is used in imported biotech soybean and maize in very large quantities by China (63 million tons of soybean and 3.3 million tons of maize in 2013), domestic production of staple food crops has not been implemented to-date, although biotech papaya, consumed as a fresh fruit/food is widely accepted with hectareage increasing by ~50% in 2014 to over 8,000 hectares. President Xi Jinping stated at the Communist Party Conference in December 2013 that, because the technology is new it's reasonable that society should hold controversial views and doubts. Importantly, now China, through the Ministry of Agriculture, has launched a large national public information media campaign to increase the awareness of the public regarding biotech crops including the benefits they offer China. Continuing high priority to R&D support for biotech crops in China (US\$4 billion for the period 2008 to 2020)

reflect the country's long term commitment to biotech crops. China imports increasing quantities of maize (~90% of which is biotech) and consumes one-third of global soybean production; China imports 65% of global soybean exports of which over 90% is biotech.

Status in Africa

Africa continued to make progress in 2014 with Sudan increasing its Bt cotton hectareage substantially to 90,000 hectares by ~46%, with South Africa and Burkina Faso marginally lower mainly because of uncertainty of planting conditions. Encouragingly, an additional seven African countries (listed alphabetically): Cameroon, Egypt, Ghana, Kenya, Malawi, Nigeria, and Uganda have conducted field trials on the following broad range of staple and orphan crops: rice, maize, wheat, sorghum, bananas, cassava, and sweet potato. The WEMA project is expected to deliver its first biotech stacked drought tolerant maize with insect control (Bt) in South Africa as early as 2017, followed by Kenya and Uganda, and then by Mozambique and Tanzania, subject to regulatory approval.

Five EU countries planted 143,016 hectares of biotech Bt maize. Spain was by far the largest adopter, planting 92% of the total Bt maize hectareage in the EU.

Five EU countries, same as last year, planted 143,016 hectares of Bt maize, down marginally by 3% from 2013, mainly due to lower total plantings of maize, particularly in Spain which reported a record adoption rate of 31.6% and grew 92% of all the Bt maize in the EU. Modest increases were reported in three countries: Portugal, Romania and Slovakia and marginal decreases in two countries: Spain and Czechia. Spain led the EU with 131,538 hectares of Bt maize, down 3% from 136,962 in 2014. Generally in the EU countries, there is a disincentive for farmers to plant Bt maize because of the negative effect of onerous and over-demanding EU farmer reporting procedures.

Status of approved events for biotech crops

As of the end of October 2014, a total of 38 countries (37 + EU - 28) have granted regulatory approvals to biotech crops for use as food, feed or for environmental release since 1994. From these countries, 3,083 regulatory approvals have been issued by competent authorities across 27 GM crops and 357 GM events. 1,458 are for food use (direct use or for processing), 958 for feed use (direct use or for processing) and 667 for environmental release or planting. Japan has the most number of approved events (201), followed by the U.S.A. (171 not including stacked events), Canada (155), Mexico (144), South Korea (121), Australia (100), New Zealand (88), Taiwan (79), Philippines (75), European Union (73 including approvals that have expired or under renewal), Colombia (73), South Africa (57) and China (55). Maize still has the most number of events (136 events in 29 countries), followed by cotton (52 events in 21 countries), canola (32 events in 13 countries), potato (31 events in 10 countries), and soybean (30 events in 28 countries).

Among the GM events, the herbicide-tolerant soybean event GTS-40-3-2 has the most number of approvals (52 approvals in 26 countries + EU-28). It is followed by the herbicide-tolerant maize event NK603 (52 approvals in 25 countries + EU-28), insect-resistant maize MON810 (50 approvals in 25 countries + EU-28), insect resistant maize Bt11 (50 approvals in 24 countries + EU-28), insect-resistant maize TC1507 (47 approvals in 22 countries + EU-28), herbicide-tolerant maize GA21 (41 approvals in 20 countries + EU-28), insect-resistant cotton MON531 (39 approvals in 19 countries + EU-28),

insect-resistant maize MON89034 (39 approvals in 22 countries + EU-28), herbicide-tolerant soybean A2704-12 (39 approvals in 22 countries + EU-28), insect-resistant maize MON88017 (37 approvals in 20 countries + EU-28), herbicide-tolerant maize T25 (37 approvals in 18 countries + EU-28) and insect-resistant cotton MON 1445 (37 approvals in 17 countries + EU-28).

Global value of biotech seed alone was ~US\$15.7 billion in 2014

Global value of biotech seed alone was ~US\$15.7 billion in 2014. A 2011 study estimated that the cost of discovery, development and authorization of a new biotech crop/trait is ~US\$135 million. In 2014, the global market value of biotech crops, estimated by Cropnosis, was US\$15.7 billion, (up slightly from US\$15.6 billion in 2013); this represents 22% of the US\$72.3 billion global crop protection market in 2013, and 35% of the ~US\$45 billion commercial seed market. The estimated global farm-gate revenues of the harvested commercial "end product" (the biotech grain and other harvested products) are more than ten times greater than the value of the biotech seed alone.

FUTURE PROSPECTS

Feeding the World of 2050

Feeding over 9 billion people in 2050 is one of, if not THE most daunting challenges facing mankind during the remaining years of this century. The fact that the majority of the world's population is not even aware of the magnitude of the challenge makes the task even more difficult. The following paragraphs chronicle some of the salient and critical facts in relation to the dimensions of feeding the world of 2050 and beyond.

- Global population, which was only 1.7 billion at the turn of the century in 1900, is now 7.2 billion, expected to climb to 9.6 billion by 2050, and will be close to 11 billion at the end of this century in 2100. Globally, 870 million people are currently chronically hungry and 2 billion are malnourished.
- Coincidentally, a change is occurring in favor of a less efficient higher protein diet, including significantly more meat in more prosperous developing countries led by China and India.
- Need to increase crop productivity, by at least 60% or more by 2050 and do so in an improved and sustainable use of less resources – less land, water, fertilizer and less pesticides.
- Increased demand for crop biomass to produce biofuels in response to more energy required for a more demanding and affluent growing world population.
- Respond to the additional new challenges associated with climate change, with more frequent and severe droughts with implications for availability and use of water – agriculture uses 70% of the fresh water in the world, a rate that is not sustainable by 2050 with 2 billion more people.

Rates of growth in crop productivity have declined subsequent to the significant contribution of the green revolutions of wheat and rice. It is now evident that conventional crop technology alone will not allow us to feed over 9 billion in 2050 and neither is biotechnology a panacea. An option being proposed by the global scientific community is a balanced, safe and sustainable approach, using the best of conventional crop technology (well adapted germplasm) and the best of biotechnology (appropriate GM and/non-GM traits) to achieve **sustainable intensification** of crop productivity on

the 1.5 billion hectares of cropland globally. The returns on investments in agriculture are high and furthermore they directly impact on poverty alleviation, particularly small resource-poor farmers and the rural landless dependent on agriculture, representing the majority of the world's poorest people.

Biotech crops contribution to Food Security, Sustainability and Climate Change

Provisional data for 1996 to 2013 showed that biotech crops contributed to Food Security, Sustainability and Climate Change by: increasing crop production valued at US\$133.3 billion; providing a better environment, by saving ~500 million kg a.i. of pesticides in 1996-2012; in 2013 alone reducing CO₂ emissions by 28 billion kg, equivalent to taking 12.4 million cars off the road for one year; conserving biodiversity in the period 1996-2013 by saving 132 million hectares of land; and helped alleviate poverty by helping 16.5 million small farmers, and their families totaling >65 million people, who are some of the poorest people in the world. Biotech crops can contribute to a **"sustainable intensification"** strategy favored by many science academies worldwide, which allows productivity/production to be increased only on the current 1.5 billion hectares of global crop land, thereby saving forests and biodiversity. Biotech crops are essential but are not a panacea and adherence to good farming practices, such as rotations and resistance management, are a must for biotech crops as they are for conventional crops.

Contribution of biotech crops to Sustainability

Biotech crops are contributing to sustainability in the following five ways:

- **Contributing to food, feed and fiber security and self sufficiency, including more affordable food, by increasing productivity and economic benefits sustainably at the farmer level**

Economic gains at the farm level of ~US\$133.3 billion were generated globally by biotech crops during the eighteen year period 1996 to 2013, of which 30% were due to reduced production costs (less ploughing, fewer pesticide sprays and less labor) and 70% due to substantial yield gains of 441.4 million tons. The corresponding figure for 2013 alone was 88% of the total US\$20.4 billion gain due to increased yield (equivalent to 64 million tons), and 12% due to lower cost of production (Brookes and Barfoot, 2015, Forthcoming).

- **Conserving biodiversity, biotech crops are a land saving technology**

Biotech crops are a land-saving technology, capable of higher productivity on the current 1.5 billion hectares of arable land, and thereby can help preclude deforestation and protect biodiversity in forests and in other in-situ biodiversity sanctuaries – a sustainable intensification strategy. Approximately 13 million hectares of biodiversity – rich tropical forests, are lost in developing countries annually. If the 441.4 million tons of additional food, feed and fiber produced by biotech crops during the period 1996 to 2013 had not been produced by biotech crops, an additional 132 million hectares (Brookes and Barfoot, 2015, Forthcoming) of conventional crops would have been required to produce the same tonnage. Some of the additional 132 million hectares would probably have required fragile marginal lands, not suitable for crop production, to be ploughed, and for tropical forest, rich in biodiversity, to be felled to make way for slash and burn agriculture in developing countries, thereby destroying biodiversity.

- **Contributing to the alleviation of poverty and hunger**

To-date, biotech cotton in developing countries such as China, India, Pakistan, Myanmar, Burkina Faso and South Africa have already made a significant contribution to the income of 16.5 million small resource-poor farmers in 2014. This can be enhanced in the remaining years of this decade 2011 to 2020 principally with biotech cotton and maize.

- **Reducing agriculture's environmental footprint**

Conventional agriculture has impacted significantly on the environment, and biotechnology can be used to reduce the environmental footprint of agriculture. Progress to-date includes: a significant reduction in pesticides; saving on fossil fuels; decreasing CO₂ emissions through no/less ploughing; and conserving soil and moisture by optimizing the practice of no till through application of herbicide tolerance. The accumulative reduction in pesticides, based on the latest information for the period 1996 to 2012, was estimated at ~500 million kilograms (kgs) of active ingredient (a.i.), a saving of 8.7% in pesticides, which is equivalent to an 18.5% reduction in the associated environmental impact of pesticide use on these crops, as measured by the Environmental Impact Quotient (EIQ). EIQ is a composite measure based on the various factors contributing to the net environmental impact of an individual active ingredient. The corresponding data for 2012 alone was a reduction of 36 million kgs a.i. (equivalent to a saving of 8% in pesticides) and a reduction of 23.6% in EIQ (Brookes and Barfoot, 2014).

Increasing efficiency of water usage will have a major impact on conservation and availability of water globally. Seventy percent of fresh water is currently used by agriculture globally, and this is obviously not sustainable in the future as the population increases by almost 30% to over 9.6 billion by 2050. The first biotech maize hybrids with a degree of drought tolerance were commercialized in 2013 in the USA, and the first tropical biotech drought tolerant maize is expected by ~2017 in sub-Saharan Africa. Drought tolerance is expected to have a major impact on more sustainable cropping systems worldwide, particularly in developing countries, where drought will likely be more prevalent and severe than industrial countries.

- **Helping mitigate climate change and reducing greenhouse gases**

The important and urgent concerns about the environment have implications for biotech crops, which contribute to a reduction of greenhouse gases and help mitigate climate change in two principal ways. First, permanent savings in carbon dioxide (CO₂) emissions through reduced use of fossil-based fuels, associated with fewer insecticide and herbicide sprays. Provisionally in 2013 alone, this was an estimated saving of 2.1 billion kg of CO₂, equivalent to reducing the number of cars on the roads by 0.93 million. Secondly, additional savings from conservation tillage (need for less or no ploughing facilitated by herbicide tolerant biotech crops) for biotech food, feed and fiber crops, led to an additional soil carbon sequestration equivalent in 2013 to 25.9 billion kg of CO₂, or removing 11.5 million cars off the road for one year. Thus in 2013, the combined permanent and additional savings through sequestration was equivalent to a saving of 28 billion kg of CO₂ or removing 12.4 million cars from the road up from 11.8 million in 2012 (Brookes and Barfoot, 2015, Forthcoming).

Droughts, floods, and temperature changes are predicted to become more prevalent and more severe as we face the new challenges associated with climate change, and hence, there will be a need for faster crop improvement programs to develop varieties and hybrids that are well adapted to more rapid changes in climatic conditions. Several biotech crop tools and techniques, including tissue culture, diagnostics, genomics, molecular marker-assisted selection (MAS) zinc fingers, and TALENS, and biotech crops can be used collectively for 'speeding the breeding' and help mitigate the effects of climate change. Biotech crops are already contributing to reducing CO₂ emissions by precluding the need for ploughing a significant portion of cropped land, conserving soil, particularly moisture, and reducing pesticide spraying as well as sequestering CO₂.

In summary, collectively the above five thrusts have already demonstrated the capacity of biotech crops to contribute to sustainability in a significant manner and for mitigating the formidable challenges associated with climate change – global warming, and the potential for the future is enormous. Biotech crops can increase productivity and income significantly, and hence, can serve as an engine of rural economic growth that can contribute to the alleviation of poverty for the world's small and resource-poor farmers.

Stewardship and Resistance Management of Biotech Crops

The two major biotech crop traits of insect resistance (IR) and herbicide tolerance (HT) have made an enormous contribution to global food, feed and fiber production since they were first approved for commercial cultivation in 1996, almost 20 years ago. In 2014, insect resistance and herbicide tolerance traits, were deployed singly or stacked in the four principal biotech crops of maize, soybean, cotton and canola, and were planted globally on 181 million hectares in 28 countries. Moreover, in the 19 year period, 1996 to 2014 the IR/HT biotech crops have gained the trust of millions of farmers world-wide and as a result have achieved a near-optimal adoption of 90% or more in virtually all the principal countries growing biotech crops. The IR/HT biotech crops have provided a successful complementary and alternative system to the conventional pesticide-based crop production systems and they are judged by farmers to be efficient, convenient and environment-friendly. These same two trait(s) have also been successfully incorporated in a range of other commercialized biotech crops including alfalfa, brinjal (eggplant), sugar beet and poplar; the two traits have also been successfully incorporated in the other two major staples of rice and wheat for future deployment as new commercial biotech crops.

Irrespective of whether the technology is conventional or biotech, the wide-spread adoption of insect resistance and herbicide tolerance leads, over time, to insect pest resistance and resistant weeds, thereby diminishing their benefits to farmers. **The issues of resistance management of IR/HT traits were anticipated and discussed by the scientific community, regulators and policy makers prior to the introduction of biotech crops in 1996.** Policy approaches were considered to manage development of resistance in IR/HT crops including the deployment of refugia, integration of IRM into general insect pest management (IPM) schemes using insect resistant management (IRM) strategies, and post release monitoring of biotech crops for early detection of resistance. Coincidentally, new scientific methods evolved around gene pyramiding, and stacking of traits to enable more effective management and stewardship of resistance in the new biotech crops. Thus, resistance management including IRM and stewardship, and good farming practices including rotation have played a significant role in the successful large scale adoption and acceptance of IR/HT biotech crops from the very beginning in 1996. These approaches are credited with prolonging the life of biotech crops, and making them more

durable than conventional technology thereby extending the benefits to farmers from planting IR/HT biotech crops season-after-season.

As anticipated, studies have confirmed that the first generation IR and HT traits are becoming susceptible to resistant targeted insect pests and weeds respectively. Single or stacked IR/HT GM crops involving single and multiple gene(s) in maize in the USA have led to field-evolved resistance of insect pests. Hence, approaches for managing Bt resistance must be assigned a high priority, particularly as more crops feature Bt genes (simple and stacked) and in 2014 already occupied 55 million hectares. Similarly, several studies indicate that a considerable number of weeds have shown resistance to the application of herbicides including the widely used glyphosate, thereby potentially limiting the future use of the product in its current form. Thus, the management of insect resistance and stewardship of IR/HT biotech crops have assumed greater importance and deserves priority and appropriate attention and implementation at the field level.

The two decades of experience and the trend in technological development suggest that the following 12 elements be considered to achieve effective and strict implementation of resistance management and stewardship:

- Planting of refugia and innovative methods for deploying them in simple but creative schemes such as refuge in the bag (RIB)
- Integration of IRM in integrated pest management (IPM) systems
- Stricter implementation of package of recommended practices
- Post release monitoring and timely reporting of detection of resistance
- Ensuring seed purity and adequate expression of traits
- Assurance of supply of high quality IR/HT seeds
- Gene pyramiding and stacking of insect resistance and herbicide tolerance traits
- Integrating multiple modes-of-action for IR/HT traits
- Development of innovative and more resilient new technologies capable of reversing resistance
- Timely replacement of current IR/HT products with improved versions
- Education, training and outreach to the farming community in managing IR/HT biotech crops and,
- Strengthen compliance of regulatory requirements

Early as possible approvals of the second generation of IR/HT crops such as Bollgard-III™ and Enlist™ products with dual and triple modes-of-action for insect and weed tolerant traits is important, and helps overcome the current challenges of managing the insect and weed resistance to IR/HT crops. The wide scale use of the refuge-in-bag (RIB) strategy and regulatory compliance needs to be strictly implemented. **Importantly, all stakeholders including the scientific community, farmers, policy makers and the private sector must be made aware of their collective responsibility and the fact that the overall system of managing resistance will NOT work if any single stakeholder is delinquent in its implementation.**

Status of Golden Rice

Women and children are the most vulnerable to vitamin A deficiency (VAD), the leading cause of childhood blindness and inability of the immune systems to combat disease. **WHO reports in 2009**

and 2012 that 190 to 250 million preschool children worldwide are still affected by VAD annually.

Studies showed that vitamin A supplementation could reduce all mortality in children younger than 5 years by 24-30%. This means that vitamin A availability for 8 million late infancy and pre-school age children in undernourished settings could prevent 1.3 to 2.5 million child deaths annually. Golden Rice (GR) is being developed by the Philippine Rice Research Institute (PhilRice) and the International Rice Research Institute (IRRI). IRRI reports that as of March 2014, the research, analysis and testing of beta carotene-enriched Golden Rice continues, in partnership with collaborating national research agencies in the Philippines, Indonesia, and Bangladesh. The Golden Rice event R (GR2-R) was introgressed into selected mega varieties, field tested for three seasons to evaluate the agronomic and product performance under Philippine field conditions.

Preliminary results of the conducted multi locational trials show that while the target level of beta-carotene in the grain was attained, yield was on an average lower than yields from comparable local varieties already preferred by farmers. Hence, the new objective of increasing yield became the focus of the current research to include other versions of GR2 such as GR2-E and others. At IRRI, the Golden Rice trait is being bred into mega varieties to get suitable advance lines, and once attained the series of confined field trials will resume. IRRI and its many research partners remain committed to developing a high-performing Golden Rice variety that benefits farmers and consumers. The important mission of the Golden Rice project – to contribute to improving the health of millions of people suffering from micronutrient deficiency – demands that every step and aspect of the scientific study of Golden Rice be carefully planned. IRRI and all participating organizations will continue to rigorously follow all biosafety and other regulatory protocols in continuing the research to develop and disseminate Golden Rice.

Once released, Golden Rice has the potential to provide beta carotene fortified carbohydrate staple, totaling an estimated 2,006,869 calories per day in the major countries of the South suffering from VAD. The following is the breakdown by region per day: people living in South Asia (1,130,648 calories), Southeast Asia (660,979), Africa (125,124), Latin America (75,238), and Central Asia (14,880) for a total of 2,006,869 calories per day – these are the regions where most VAD occurs (HarvestPlus, Personal Communications).

Potential New Biotech Crops in the next 5 to 10 years

One of the concerns often voiced by critics of biotech crops is the narrow focus on four principal crops (soybean, maize, cotton, and canola) and two traits, (herbicide tolerance and insect resistance). However, in the last five years there have been a significant broadening of the number of commercialized biotech crops to include a significant hectareage of sugar beet, and alfalfa along with continued small hectareages of squash, papaya, eggplant and poplar, for a total of 10 commercial biotech crops in 2014.

Global Information on biotech crops undergoing field trials is of interest to many but it is not always easy to access the information. Appendix 7 in the full Brief provides an incomplete listing of 71 selected new biotech crop/trait(s) that have, at a minimum, been field tested at the equivalent of contained field trials (CFT). The list provides the reader with a general global overview of the possible future scope of new biotech crops that may become available (subject to regulatory approval) during the next 5 to 10 years. The data base simply lists biotech crops by crop, trait(s), technology developer/facilitator, and countries where field tests have been conducted. Whereas the list of 71 entries is not exhaustive, in reviewing the data base of 71 entries, the following are some of the general features that maybe of interest:

- About half of the 71 entries involve products field tested in developing countries and the other half are in industrial countries; the general drift in favor of developing countries is both timely and appropriate given the greater need for food, feed, and fiber in the countries of the South, in Africa, Asia and Latin America.
- About one quarter is “new” crops that substantially diversify the current portfolio of 10 commercial biotech crops and they are by and large pro-poor orphan crops that can make an important contribution to food security for poor people. The new biotech crops include apple, banana, camelina, cassava, citrus, chickpea, cowpea, groundnut, mustard, pigeon pea, potato, rice, safflower, sugarcane and wheat.
- The range of traits include those for improved drought and salinity tolerance, yield enhancement, efficient nitrogen utilization, increased nutrition and food quality, resistance to pests and diseases, including resistance to viruses.
- About half of the listed entries represent technologies developed by public sector organizations or are crop biotech transfer projects involving public-private sector partnerships. This, combined with the fact that about half of the trials are being conducted in developing countries, with an increasing number in Africa which presents the greatest challenges, is encouraging news for the development community globally.

Non-transgenic Biotech Products

Up until now transgenic modification has been achieved using *Agrobacterium* or the gene gun. New advanced biotech applications such as **zinc finger nucleases (ZFN) technology, clustered regularly interspaced short palindromic repeat (CRISPR)-associated nuclease systems and transcription activator-like effector nucleases (TALENs)**, are being used to increase the efficiency and precision of the transformation process. These new techniques allow the cutting of the DNA at a pre-determined location and the precise insertion of the mutation, or single nucleotide changes at an optimal location in the genome for maximum expression. These techniques are well advanced – ZFN has already been used to successfully introduce herbicide tolerance and TALENs has been used to delete or “snip out” the gene in rice that confers susceptibility to the important bacterial blight disease of rice. **However, experts in the field believe that potentially the “real power” of these new technologies is their ability to “edit” and modify multiple native plant genes (non GM), coding for important traits such as drought and, generating improved crops that are not transgenic.** Regulators in the US have initially opined that changes not involving transgenics will be treated differently; this could have a very significant impact on the efficiency and timing of the current resource-intensive regulation/ approval process and the acceptance of the products by the public.

Powdery mildew-resistant wheat was developed by researchers from the Chinese Academy of Sciences through advanced gene editing methods. Researchers deleted genes encoding for proteins that repress defenses against the mildew using TALENs and CRISPR genome editing tools. Wheat is a hexaploid and thus required deletion of multiple copies of the genes. This also represents a significant achievement in modifying food crops without inserting foreign genes, hence considering it as a non GM technique.

Another class of new applications, still at the early stages of development, are **plant membrane transporters** that are being researched to overcome a range of crop constraints from abiotic and biotic stresses to enhancement of micronutrients. It is noteworthy that of the current 7 billion global population, almost one billion is undernourished but another one billion is malnourished, **lacking**

critical micro nutrients: iron (anemia), zinc and vitamin A. Adequate supply of nutritious foods with enhanced levels of important micronutrients is critical for human health. Recent advances show that specialized plant membrane transporters can be used to enhance yields of staple crops, increase micronutrient content and increase resistance to key stresses, including salinity, pathogens and aluminum toxicity, which in turn could expand available arable land. Acid soils are estimated to occupy 30% of land globally.

CLOSING COMMENTS

The Way Forward – The Role of Public-Private Partnerships (PPP)

In reviewing crop biotech transfer projects over the last decade the progress and promise of public-private sector partnerships (PPP) is striking. The first PPP biotech crop transfer project was facilitated by ISAAA in the early 1990s. The tripartite project involved three partners: the developing country partner was Mexico (more specifically the biotech lab CINVESTAV) which in conjunction with Ministry of Agriculture had identified resistance to virus diseases in potatoes, grown by small farmers as a top priority because conventional technology did not offer a solution; the private sector partner was Monsanto which agreed to donate the coat protein events that confer virus resistance to PVX and PVY in potatoes. Importantly, Monsanto also agreed to train scientists from CINVESTAV in the use of the new technology. The third partner was the Rockefeller Foundation which provided the entire funding for the 3 year project, because of its innovative nature and was consistent with the Foundation's program in crop biotechnology.

Following the implementation of the Mexican project, ISAAA further explored the possibility of building a biotech transfer project in which more than one country would share the same donated technology, thus providing a multiplier effect for technology transfer. The project that evolved featured the donation of an event for conferring resistance to the lethal papaya ringspot virus (PRSV) of papaya. The developing county partners were five countries in South East Asia all of whom had identified PRSV as a common need and top priority because conventional technology did not offer a solution. The five developing country partners in South East Asia (where lead public sector laboratories in crop biotechnology were involved) were, in alphabetic order: Indonesia, Malaysia, Philippines, Thailand and Vietnam. The private sector partner was Monsanto which agreed to donate the event(s) for virus resistance to PRSV in papaya for use by small farmers in the five respective partner countries. As in the Mexican project, Monsanto also agreed to train scientists from the five countries in South East Asia in the use of the new technology; the funding was provided by different donor agencies for a three year period. Subsequent to the establishment of the PRSV project, ISAAA facilitated a network of the five countries to share experiences and expedite progress with the technology. The network also provided an appropriate cost-effective mechanism for exchange of information and reciprocal training of project scientists among the five labs. Following interaction of the countries in the network, the five countries collectively identified a second papaya trait deemed important by all parties – delayed ripening. It is an important trait for a perishable fruit such as papaya which suffers significant post-harvest losses in the tropics – the technology for delayed ripening was donated by Zeneca.

In the last decade or so, several aid agencies and foundations have established projects to facilitate donation and transfer of biotech crop applications from both the private and public sector for the

benefit of developing countries particularly for small resource-poor farmers. Examples include, AATF based in Nairobi serving the needs of African countries, and Agricultural Biotechnology Support Project (ABSPII) which is a United States Agency for International Development (USAID) bilateral program, with global activities and operated by Cornell University.

A preliminary review of the initiatives involved in biotech crop transfer projects from both the public and private sector, suggests that public-private partnerships (PPP) projects have been encouragingly successful and offer advantages that increases the probability of delivering an approved biotech crop product at the farmer level within a reasonable time frame. Four PPP case studies have been selected to review and illustrate the diversity in characteristics of the four model projects: Bt brinjal in Bangladesh, herbicide tolerant soybean in Brazil, drought tolerant sugarcane in Indonesia, and the WEMA project for drought tolerance in maize in selected countries in Africa. For the convenience of readers, short descriptions of each of the four case studies, with more specific details are summarized in four boxes at the end of this closing chapter.

Norman Borlaug's Legacy and Advocacy of Biotech Crops

It is fitting to close this ISAAA Brief for 2014, by chronicling the counsel of the late 1970 Nobel Peace Laureate, Norman Borlaug, on biotech/GM crops, whose birth centenary was honored on 25 March 2014. Norman Borlaug, who saved a billion people from hunger, was awarded the Nobel Peace Prize for the impact of his semi-dwarf wheat technology on the alleviation of hunger. Norman Borlaug was the founding patron of ISAAA, and also the greatest advocate for biotechnology and biotech/GM crops worldwide, because he knew, better than anyone else their critical and paramount importance in feeding the world of tomorrow.

The following are two memorable and historical self-explanatory quotes from the man who knew more than anyone about feeding the world of tomorrow, because he had achieved it in the green revolution and understood the profundity of the proverb – **reading is learning, seeing is believing, but doing is knowing – knowledge**. This Brief seeks to share knowledge about biotech crops whilst respecting the rights of readers to make their own decisions about biotech/GM crops.

Borlaug Quotes:

“Over the past decade, we have been witnessing the success of plant biotechnology. This technology is helping farmers throughout the world produce higher yield, while reducing pesticide use and soil erosion. The benefits and safety of biotechnology has been proven over the past decade in countries with more than half of the world's population.”

“What we need is courage by the leaders of those countries where farmers still have no choice but to use older and less effective methods. The Green Revolution and now plant biotechnology are helping meet the growing demand for food production, while preserving our environment for future generations” (ISAAA, 2009).

Case Study 1 – Insect Resistant (IR) Bt Brinjal in Bangladesh

Brief Description: The Bt brinjal project in Bangladesh may lay claim to be the first crop biotechnology transfer project to deliver a product that has already been commercialized by farmers. Bt brinjal was developed as an international public private partnership, between an Indian seed company Mahyco generously donating technology to the Bangladesh public sector R&D institute Bangladesh Agricultural Research Institute (BARI) facilitated by the Cornell University led project, ABSP-II, and funded by USAID. Bangladesh approved Bt brinjal for commercial cultivation on 30 Oct 2013 and in record time – less than 100 days – on 22 January 2014 a group of small farmers planted the first commercial product in their own fields. In 2014, a total of 12 hectares of Bt brinjal were planted by 120 farmers and the area is expected to increase substantially in 2015. This feat would not have been possible without strong support for the project from the Government of Bangladesh and in particular the political will and support of the Minister of Agriculture, the Honorable Matia Chowdhury. Bt brinjal drastically reduces pesticide application, increases marketable yield and improves fruit quality. Farmers have successfully sold Bt brinjal fruits in the open market labelled as “BARI Bt Begun #, no pesticide used”. More specific details are provided below.

Country: Bangladesh

Crop: Brinjal/Eggplant

Area: ~50,000 hectares farmed by ~150,000 smallholder farmers (0.3 ha average farm size)

Importance: The poor man’s vegetable crop, known as “the queen of the vegetables”

Gene: *cry1Ac* gene from *Bacillus thuringiensis* (Bt)

Trait(s): Insect resistance (IR); imparts protection against the lethal insect pest “fruit and shoot borer” (*Leucinodes orbonalis*) which often requires small farmers to apply a polluting insecticide spray every other day and even then adequate control is not possible

Event: Elite Event EE-1

Technology Donor: The private sector company Mahyco, from India

Technology Recipient: Bangladesh Agricultural Research Institute (BARI)

Donor Funding Agency: USAID

Facilitator: Agricultural Biotechnology Support Program II (ABSPII) managed by Cornell University

Status of Approval: Approved for food, feed and environmental release on 30 Oct 2013 and commercialized in less than 100 days later on 22 January 2014

Varieties Approved: Brinjal-1 (Uttara), Bt Brinjal-2 (Kajla), Bt Brinjal-3 (Nayantara) and Bt Brinjal-4 (Iswardi/ISD 006)

Commercialization: 120 farmers planted Bt brinjal on 12 hectares in 2014

Number of Potential Beneficiary Farmers: 150,000 of the poorest and smallest farmers in Bangladesh which has a per capita of less than US\$1,000 per annum

Socio-Economic Impact: Increases marketable yield by at least 30% and reduces the number of insecticide applications by 70-90%, resulting in a net economic benefit of US\$1,868 per hectare; this is equivalent to a gain of up to US\$200 million per annum nationally

Case Study 2 – Herbicide Tolerant (HT) Soybean in Brazil

Brief Description: In 2010, the Brazilian regulator authority CTNBio approved the commercial cultivation of a new herbicide tolerant soybean variety developed through a public-private partnership jointly executed by the private sector company BASF Germany and the public sector R&D institute EMBRAPA, the Brazilian Agricultural Research Cooperation. In this collaborative project, BASF provided EMBRAPA with *csr1-2* gene which confers tolerance to the herbicide imidazolinone, whilst the Brazilian institution also provided an additional gene and was responsible for the insertion of the trait into well adapted soybean germplasm. EMBRAPA and BASF share the patent for the new varieties, which represent the first home-grown biotech crop developed through PPP and approved in Brazil. Commercialization in Brazil is waiting on final import approval from the EU. It is expected that the new HT varieties will be commercialized in Brazil by 2016, increasing the choice of weed management options for Brazilian growers. More specific information is provided below.

Country: Brazil

Crop: Soybean

Area: ~31 million hectares

Importance: Most important export crop of Brazil

Gene: *csr1-2* from *Arabidopsis thaliana* conferring tolerance to imidazolinone herbicides

Trait(s): Herbicide tolerance

Event: BPS-CV127-9

Technology Provider: BASF, Germany/EMBRAPA, Brazil (there are 2 main patents supporting the product development, one gene from BASF and another from EMBRAPA, 4 soy gene transfers)

Technology Recipient: BASF, Germany/EMBRAPA, Brazil

Donor Funding Agency: BASF, Germany/EMBRAPA, Brazil

Facilitator/Collaborator: BASF, Germany/EMBRAPA, Brazil

Status of Approval: Approved for commercial cultivation in 2009 (December), but pending EU final Import approval

Variety Approved: Varieties to be sold under the brand name Cultivance™

Commercialization: Expected planting as commercial crop in 2016

Potential Beneficiaries: Include farmers, seed growers and consumers

Socio-Economic Impact: Cultivance™ expected to reach up to 20% of market share on 31 million hectares of soybean with an export value of US\$17 billion

Case Study 3 – Drought Tolerant (DT) Sugarcane in Indonesia

Brief Description: In May 2013, Indonesia – the second largest (2.4 million tonnes, valued at US\$1.6 billion) raw sugar importing country in the world, issued food and environmental safety certificates for the country's first home-grown genetically modified drought tolerant sugarcane. The biotech sugarcane variety "Cane PRG Drought Tolerant NX1-4T" was developed under a public-private partnership between the Indonesian State-owned sugar company, PT. Perkebunan Nusantara XI (PTPN-11) and Ajinomoto Company, Japan in collaboration with Jember University in East Java, Indonesia. The drought tolerant sugarcane varieties can withstand water stress up to 36 days and under drought stress can yield substantially higher than the control variety BL-19; yield increases from 2 to 75% in the first planting, 14 to 57% in the first ratoon, and from 11 to 44% in the second ratoon. It is expected that the first home-grown drought tolerant sugarcane will be officially planted in Indonesia in 2015, pending approval of the product for feed. More specific information is provided below.

Country: Indonesia

Crop: Sugarcane

Area: 450,000 hectares

Importance: Indonesia is the second largest sugar importing country in the world

Gene: *betA* from *Rhizobium meliloti*

Trait(s): Drought tolerance

Event: NX1-4T

Technology Provider: Ajinomoto, Japan

Technology Recipient: PT. Perkebunan Nusantara XI (PTPN-11), Indonesia

Donor Agency: Govt of Indonesia

Facilitator/Collaborator: Jember University, East Java, Indonesia

Status of Approval: Approved for food and environmental release in 2013, pending feed approval

Variety Approved: Cane PRT Drought Tolerant NX1-4T

Commercialization: Expected first commercial planting in 2015

Case Study 4 – Drought Tolerant (DT) Maize for Africa WEMA (South Africa, Kenya, Uganda, Mozambique, and Tanzania)

Brief Description: Monsanto donated the biotech drought tolerant (DT) maize technology (MON 87460), DroughtGard™ to the public sector agriculture R&D institutions in five countries in Sub Saharan Africa including South Africa, Kenya, Uganda, Mozambique, and Tanzania through a public-private partnership project entitled “Water Efficient Maize for Africa (WEMA)”. WEMA is coordinated by the African Agricultural Technology Foundation (AATF) based in Nairobi in collaboration with Monsanto and CIMMYT for further technology development. The project is funded jointly by the Gates Foundation, the Howard G. Buffett Foundation and USAID. The first stacked biotech insect resistant/drought tolerant (Bt/DT) maize hybrids are expected to be available to farmers (subject to regulatory approval) as early as 2017. South Africa is expected to be the first country to deploy the technology in 2017, followed by Kenya and Uganda which are expected to conduct confined field trials (CFT) in 2015. The three countries have conducted CFTs with the DT maize for at least 5 seasons (Uganda 5th, Kenya 6th, and South Africa 7th season) with very encouraging results. Kenya is in its 3rd season CFT for Bt maize (MON 810 also donated by Monsanto subsequent to the initiation of the project) and Uganda is in the 2nd season of field testing. In Mozambique, a revised Biosafety decree and implementing regulations received approval by the Council of Ministers in October 2014, and the country is due to initiate WEMA CFTs in 2015. Tanzania has made substantive progress towards amendment of the 2009 Biosafety regulations for the CFTs. It is projected that the WEMA stacked DT/Bt maize hybrids may yield up to 20 to 35% more grain than other commercial hybrids under moderate drought, resulting in an additional 2 to 5 million metric tons of maize to feed about 14 to 21 million people in Africa. More specific information is provided below.

Countries: South Africa, Kenya, Uganda, Tanzania and Mozambique

Crop: Maize

Area: ~8 million hectares in the five countries

Importance: Africa grows 90% of its maize under rainfed conditions and up to 25% of the area suffers from frequent droughts

Gene: Cold shock protein gene (*CspB*) from *Bacillus subtilis*

Trait(s): Drought tolerance

Event: Event MON87460, to be deployed as a stacked hybrid maize, also featuring a Bt gene (MON 810) for insect control also donated by Monsanto subsequent to the initiation of the project. The DT event is the same as that deployed in the 50,000 hectares of biotech drought tolerant maize in the US in 2013, which increased 5.5-fold to 275,000 hectares in the US in 2014.

Technology Donor: Monsanto, USA

Technology Recipients: South Africa, Kenya, Uganda, Mozambique and Tanzania

Donor Agencies: The Gates Foundation, the Howard G. Buffet Foundation and USAID

Facilitator Agencies: African Agricultural Technology Foundation (AATF), NARIs in the 5 WEMA countries, CIMMYT

Status of Approval: First deployment of stacked DT/Bt expected in South Africa in 2017, followed by Kenya and Uganda who are expected to conduct confined field trials (CFT) of the stacked product next year, 2015. Revised Biosafety decree and implementing regulations endorsed in Mozambique which paves the way for CFTs to be conducted in 2015, and positive discussion on amendment of biosafety regulations proceeding in Tanzania.

Commercialization: To begin (subject to regulatory approval) in South Africa in 2017

Socio-Economic Impact: Could increase maize production by up to 2 to 5 million metric tons under moderate drought, to feed about 14 to 21 million people in Africa.



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