HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

ISAAA
INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS

EXECUTIVE SUMMARY

BRIEF 51

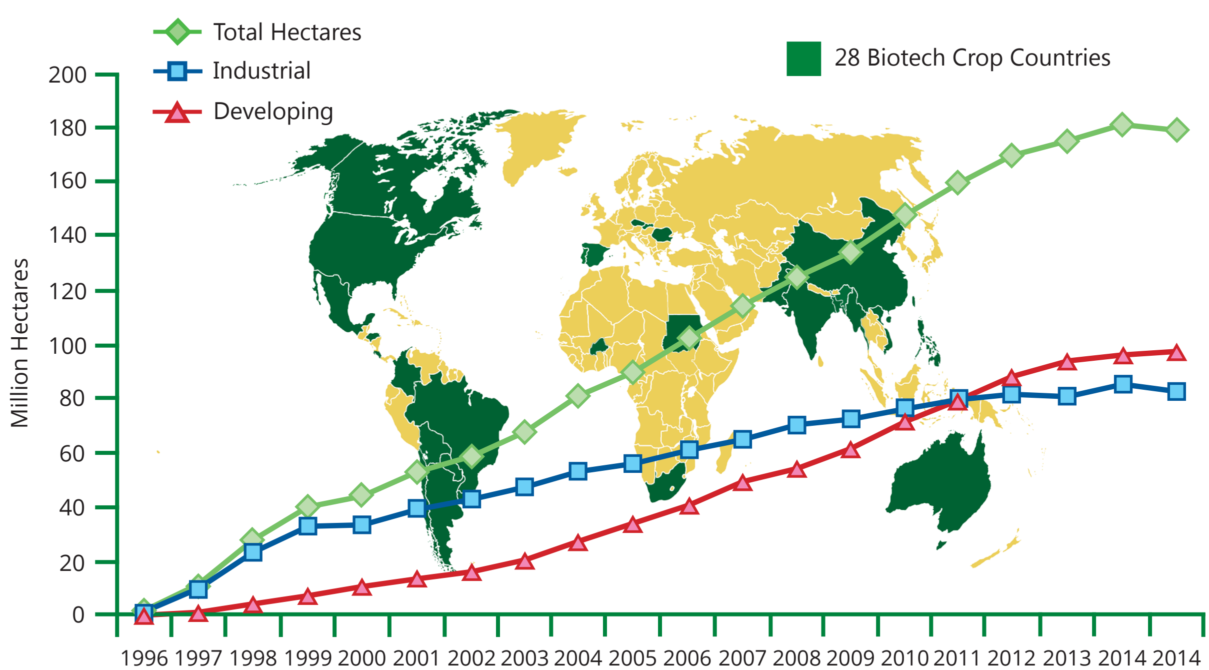
20th Anniversary of the Global Commercialization of Biotech Crops (1996 to 2015) and Biotech Crop Highlights in 2015

By

Clive James
Founder and Emeritus Chair of ISAAA

The author has dedicated Brief 51-2015, to his mentor and colleague, the late Nobel Peace Laureate, Norman Borlaug, who was also the founding patron of ISAAA

GLOBAL AREA OF BIOTECH CROPS
Million Hectares (1996-2015)



Up to ~18 million farmers, in 28 countries planted 179.7 million hectares (444 million acres) in 2015, a marginal decrease of 1% or 1.8 million hectares (4.4 million acres) from 2014.

Source: Clive James, 2015.

No. 51 - 2015

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

AUTHOR'S NOTE:

Global totals and subtotals of millions of hectares planted with biotech crops have been rounded off 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 hectarage in the year stated. Thus, for example, the 2015 information for Argentina, Brazil, Australia, South Africa, and Uruguay is hectares usually planted in the last quarter of 2015 and harvested early in 2016 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 2015 and more intensively through January and February 2016 is classified as a 2015 crop in this Brief consistent with a policy which uses the first date of planting to determine the crop year. In the interest of uniformity, continuity, and comparability, wherever possible ISAAA utilizes the same published data source annually; for example, for Brazil the August biotech reports of Celeres are used; similarly, for the US, the USDA/NASS crop acreage reports published on 30 June annually are used. 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, the estimates of economic benefits, productivity, land-saving, carbon data and pesticide data were for 1996-2014 (Brookes and Barfoot, 2016), and thus, are under estimates for the 20 year period 1996-2015. Details of the references listed in the Executive Summary are found in the full Brief 51.

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

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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.

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HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

EXECUTIVE SUMMARY

Global Status of Commercialized Biotech/GM Crops: 2015

Table of Contents

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

Page Number

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

EXECUTIVE SUMMARY

20th Anniversary of the Global Commercialization of Biotech Crops (1996 to 2015) and Biotech Crop Highlights in 2015

By

Clive James, Founder and Emeritus Chair of ISAAA

Introduction

This Brief focuses on the 20th Anniversary of the global commercialization of biotech crops (1996 to 2015) and biotech crop highlights in 2015. The author of this Brief, Dr. Clive James, has dedicated this Brief to his mentor and colleague, the late Nobel Peace Laureate Norman Borlaug, who was the founding patron of ISAAA. Borlaug was also the greatest advocate for biotechnology/GM crops, credited with saving 1 billion poor people from hunger during the 1960s green revolution that he created and pioneered.

20th anniversary (1996-2015) of the commercialization of biotech crops

2015 marked the 20th anniversary (1996-2015) of the commercialization of biotech crops, also known as genetically modified (GM) or transgenic crops, now more often called "biotech crops", as referred to in this Brief. An unprecedented cumulative hectarage of 2 billion hectares of biotech crops, equivalent to twice the total land mass of China (956 million hectares) or the United States (937 million hectares), were successfully cultivated globally in the 20 year period 1996 to 2015; farmer benefits for the period 1996 to 2015 were estimated at over US$150 billion. The 2 billion accumulated hectares comprise 1.0 billion hectares of biotech soybean, 0.6 billion hectares of biotech maize, 0.3 billion hectares of biotech cotton and 0.1 billion hectares of biotech canola.

The experience of the first 20 years of commercialization, 1996 to 2015, has confirmed that the early promise of crop biotechnology has been fulfilled. Biotech crops have delivered substantial agronomic, environmental, economic, health and social benefits to farmers and, increasingly, to society at large. The rapid adoption of biotech crops, during the initial 20 years of commercialization, 1996 to 2015, reflects the substantial multiple benefits realized by both large and small farmers in industrial and developing countries, which have grown biotech crops commercially.

Global Status of biotech crops in 2015

In general, the status of biotech crops in 2015 was variable with several countries, led by Brazil with increasing hectarage, others led by the US with decreasing hectarage, and the balance of countries registering no or negligible year-to-year change, which was relatively low in 2015 and detailed in Table 1 and Figure 1.

Progress with adoption of biotech crops during the first 20 years

Following a remarkable run of 19 years of consecutive yearly growth from 1996 to 2014, the annual global hectarage of biotech crops peaked at 181.5 million in 2014, (see graph on cover page) compared

Table 1. Global Area of Biotech Crops in 2015: by Country (Million Hectares)**

Rank	Country	Area (million hectares)	Biotech Crops
1	USA*	70.9	Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash, potato
2	Brazil*	44.2	Soybean, maize, cotton
3	Argentina*	24.5	Soybean, maize, cotton
4	India*	11.6	Cotton
5	Canada*	11.0	Canola, maize, soybean, sugar beet
6	China*	3.7	Cotton, papaya, poplar
7	Paraguay*	3.6	Soybean, maize, cotton
8	Pakistan*	2.9	Cotton
9	South Africa*	2.3	Maize, soybean, cotton
10	Uruguay*	1.4	Soybean, maize
11	Bolivia*	1.1	Soybean
12	Philippines*	0.7	Maize
13	Australia*	0.7	Cotton, canola
14	Burkina Faso*	0.4	Cotton
15	Myanmar*	0.3	Cotton
16	Mexico*	0.1	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	Vietnam	<0.1	Maize
24	Czech Republic	<0.1	Maize
25	Slovakia	<0.1	Maize
26	Costa Rica	<0.1	Cotton, soybean
27	Bangladesh	<0.1	Brinjal/Eggplant
28	Romania	<0.1	Maize
	Total	**179.7**	

* 19 biotech mega-countries growing 50,000 hectares, or more, of biotech crops
** Rounded off to the nearest hundred thousand

Source: Clive James, 2015.

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

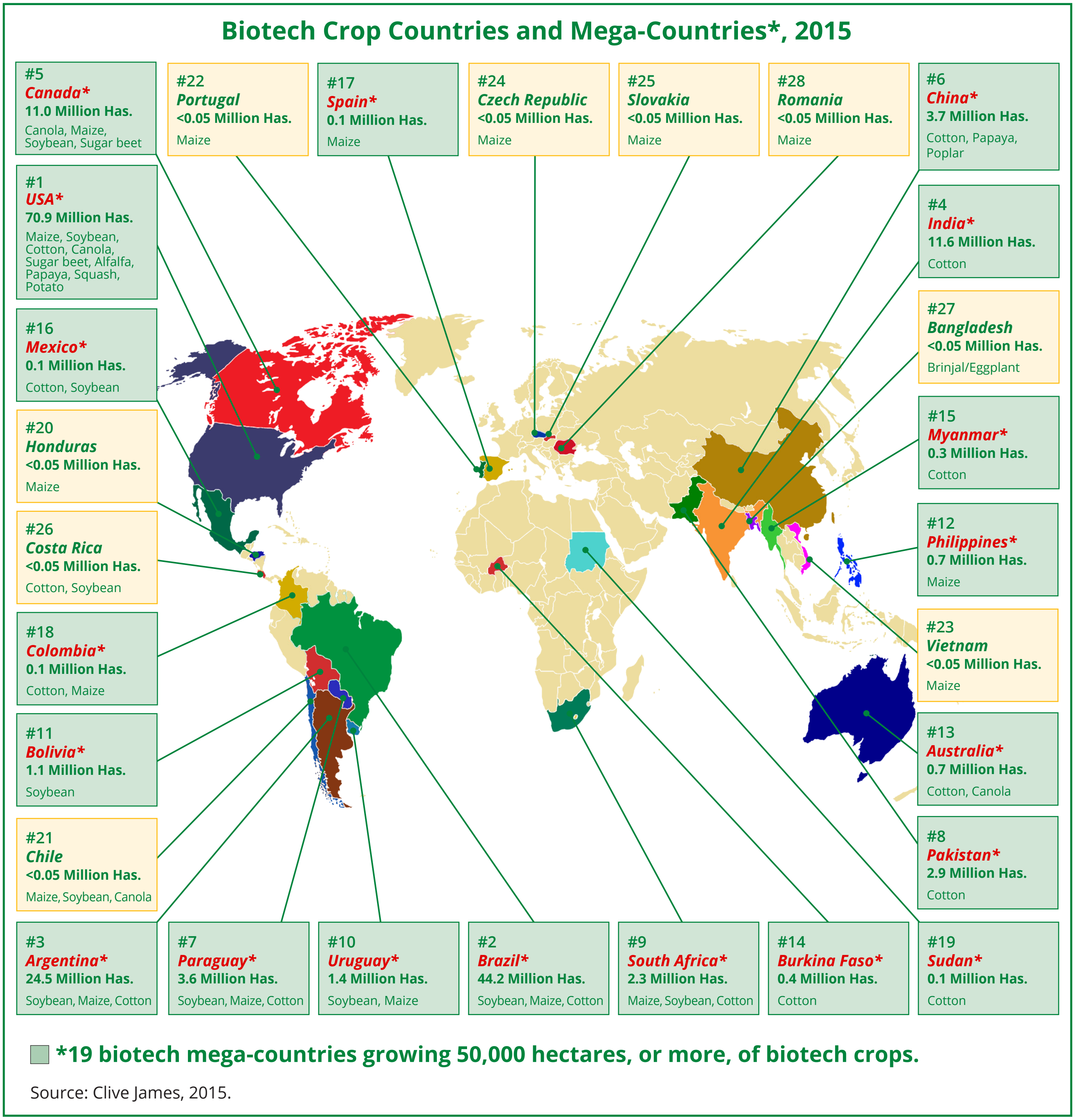

Figure 1. Global Map of Biotech Crop Countries and Mega-Countries in 2015

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

with 179.7 million hectares in 2015; this change is equivalent to a net marginal year-to-year change of minus 1% between 2014 and 2015. Annual fluctuations in biotech crop hectarage (both increases and decreases) are influenced by several factors. In 2015, a principal factor leading to decreased biotech hectarage in some countries was decreased total crop plantings; for example, for maize it was minus 4% and for cotton minus 5%, driven by low prices, with some farmers switching from maize, cotton and canola to a more easily managed crop such as biotech soybean, and also to other less demanding crops like pulses, sunflower, and sorghum. Year-to-year biotech crop hectarage decreases, driven by low prices in 2015, are likely to reverse when crop prices revert to higher levels in the future.

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

The global hectarage of biotech crops has increased 100-fold from 1.7 million hectares in 1996 to 179.7 million hectares in 2015 by up to 17 to 18 million farmers – 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.

Major developments in the US in 2015

Overall, significant progress was made on many fronts in the US in 2015 ranging from: new approvals; new commercialized biotech crops: first time approval of a GM animal food product for human consumption; widespread use of breakthrough new and powerful genome-editing technology, named CRISPR; and some success on labeling.

For GM crop products, Innate™ generation 1, an improved multi-trait potato, developed by Simplot, was first commercialized on 160 hectares in 2015; an improved version, Innate™ 2 was approved in 2015, and has added resistance to the fungal disease, potato late blight, the cause of the Irish famine of 1845, when 1 million people died of hunger. Remarkably, it is still the most important disease of potatoes 150 years after the famine, with annual global losses of US$7.5 billion. Another global first was the commercialization of the first non-transgenic genome-edited crop, SU Canola™, developed by Cibus and grown on 4,000 hectares. Two varieties of Arctic® apples, with less bruising and less browning when sliced were approved for planting in the USA and Canada, with 6 hectares planted in the USA alone in 2015. The first delivery to consumers is planned for next year. The company that developed Arctic® apple, Okanagan Specialty Fruits, from Canada, is applying the same technology to other perishable fruits including peaches, pears and cherries. Okanagan Specialty Fruits was acquired by Intrexon, a US-based synthetic biology company, in 2015. A low lignin alfalfa event, KK179 (HarvXtra™) with higher digestibility and yield (alfalfa is #1 forage crop in the world) was already approved in November 2014 and is a candidate for commercialization in the US in 2016. Hectarage of biotech DroughtGard™ tolerant maize, first planted in the US in 2013, soared more than 15-fold from 50,000 hectares in 2013 to 275,000 hectares in 2014 and 810,000 hectares in 2015 reflecting high farmer acceptance. In December 2015, Dow and DuPont agreed to merge to form DowDuPont, with a view to splitting the new company into three companies focusing on Agriculture, Materials and Specialty Products.

For GM animals, after 20 years of review, in a landmark decision in November 2015, the FDA approved the first GM animal for commercial food production and human consumption– a faster growing GM salmon, which is expected to enter the food chain in the US before 2018; Atlantic salmon normally takes

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

three years to harvest in fish farms, compared with only 18 months, or half the time, for GM salmon. The GM AquAdvantage salmon was developed by AquaBounty Technologies, which was acquired by the US company Intrexon in 2015. FDA approved a new GM chicken whose eggs will be used to treat a rare but fatal human disease called lysosomal acid lipase deficiency.

The award-winning CRISPR genome-editing technology was selected by Science magazine as the breakthrough technology of 2015. It is being used in many laboratories to develop improved crops and animals. For example, improved soybeans and maize are already being evaluated in greenhouses and, subject to regulation, approval could be commercialized as early as five years from now. Pigs are being developed that are resistant to a deadly viral disease which costs the US pork industry US$600 million a year.

On labeling, whereas a herculean costly effort has been made by both proponents and opponents of GM crops, with mixed results, significant success was achieved by proponents in 2015. Ballots that would require state level labeling in Oregon and Colorado failed in 2014 and similarly ballots in 2015 in California and Washington failed. Perhaps, more importantly, a bill was passed in the House of Representatives in July 2015 that would pre-empt state and local non-GM laws; a similar bill is slated for an imminent hearing in the Senate. In November 2015, FDA rejected a "citizen petition" to require mandatory labelling of GM products. Finally, the food company Chipotle, after announcing that it would eliminate GM products from its menu, and focus solely on non- GM vegetable products sourced locally, is now re-centralizing its vegetable supply after up to 300 people in the US claim they have suffered sickness after consuming Chipotle non-GM locally sourced vegetables.

The top 5 countries planting biotech crops

The US continued to be the lead country with 70.9 million hectares (39% of global) with over 90% adoption for the principal crops of maize (92% adoption), soybean (94%), and cotton (94%).

Brazil, the second largest grower globally with 44.2 million hectares (reached 25% of global, for the first time in 2015), resumed its important role as the engine of biotech crop growth globally with 2 million hectares more in 2015 than 2014; this compares to minus 2.2 million hectares for the US. This decrease in the US is mainly due to a temporary reduction in total plantings of maize, cotton and canola which are expected to recover when prices of these crops strengthen and total hectarage increases. Notably, Brazil planted the stacked HT/IR soybean on a record 11.9 million hectares (up from 5.2 in 2014) in its third year after the launch. Argentina with 24.5 million hectares retained third place, and was up modestly from 24.3 million hectares in 2014. India ranked fourth, had 11.6 million hectares of Bt cotton (same as 2014), and a resilient 95% adoption rate. Canada was fifth at 11.0 million hectares, with 0.4 million hectares less total canola grown in 2015, but with a continued high rate of biotech adoption at 93%. In 2015, each of the top 5 countries planted more than 10 million hectares providing a broad, solid foundation for future sustained growth.

Up to 28 countries/annum grew biotech crops, in the period 1996 to 2015; Vietnam grew a biotech crop for the first time in 2015.

A global total of 17 to 18 million farmers, ~ 90% of which were small farmers, planted biotech crops in 28 countries in 2015 (Table 1 and Figure 1), 20 were developing and only 8 were industrial countries.

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

The 28 countries include Vietnam which commercialized stacked biotech maize in 2015 for the first time. Cuba, which has planted biotech maize for the last two years will resume planting of biotech maize in two years' time when their improved maize hybrids are ready for deployment.

Of the top ten biotech crop countries, listed by hectarage, 8 were developing.

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 which planted biotech crops in 2015.

Bangladesh, one of the smaller and poorest countries in the world, is an exemplary model of the importance of political will in the adoption of biotech crops.

Bangladesh, a small poor country with 150 million people, doubled the commercial hectarage of the prized vegetable Bt brinjal/eggplant; it was grown by 250 small farmers on 25 hectares in 2015 compared with 120 farmers on 12 hectares in 2014. Importantly, seed is now being multiplied to meet the growing needs of substantially more farmers in 2016. Success with Bt brinjal has led Bangladesh to prioritize the field testing of a new late blight resistant potato (an important crop occupying ~0.5 million hectares in Bangladesh) which could be approved as early as 2017; potato is the fourth most important food staple globally and can contribute to food security in countries like China (6 million hectares of potato), India (2 million) and the EU (~2 million). Given the importance of the large cotton/textile industry in Bangladesh, Bt cotton is being evaluated in field trials as well as Golden Rice, which could address the prevalent Vitamin A deficiency in the country. This feat of promoting home-grown biotech crops through public/private partnerships, PPP, is very effective but could not have been achieved without strong Government support and **political will**, particularly from the Minister of Agriculture, the Honorable Matia Chowdhury – the experience of Bangladesh is exemplary for small poor countries.

Up to ~18 million farmers benefit from biotech crops in the 20 year period 1996 to 2015 – ~90% were small resource-poor farmers.

In the period 1996 to 2015, up to approximately 18 million farmers, grew biotech crops annually – remarkably, about 90%, or 16.5 million, were risk-averse small, poor farmers in developing countries. The latest economic data available for the period 1996 to 2014 indicates that farmers in China gained US$17.5 billion and in India US$18.3 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 fourth consecutive year, developing countries planted more biotech crops than industrial countries in 2015.

In 2015, Latin American, Asian and African farmers collectively grew 97.1 million hectares or 54% of the global 179.7 million biotech hectares (versus 53% in 2014) compared with industrial countries at 82.6 million hectares or 46% (versus 47% in 2014), equivalent to a gap of 14.5 million hectares in favor

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

of developing countries. The higher hectarage 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 1996-2014, total cumulative economic benefits were US$150 billion: industrial countries at US$74.1 billion compared to US$76.2 billion generated by developing countries. In 2014, developing countries had 46.5% equivalent to US$8.3 billion of the total US$17.8 billion gain, with industrial countries at US$9.5 billion (Brookes and Barfoot, 2016).

Increased adoption of biotech drought tolerant maize in the US

Biotech DroughtGard™ tolerant maize, first planted in the US in 2013, increased more than 15-fold from 50,000 hectares in 2013 to 275,000 hectares in 2014 and 810,000 hectares in 2015, reflecting high farmer acceptance at 3-fold year-to year-between 2014 and 2015. The same event, MON 87460, was donated by Monsanto to the public-private partnership, Water Efficient Maize for Africa (WEMA) aimed at delivering biotech drought tolerant maize to selected countries in Africa by 2017. Biotech drought tolerance is an extremely important goal given that droughts will likely become more severe and more frequent, as climate change impacts crop productivity, agriculture and society. Notably, the conventional drought tolerant maize has been distributed in South Africa in 2014 which is hoped to facilitate acceptance of the biotech drought tolerant maize DroughtGard™ (MON 87460) which was approved for commercialization in June 2015, and expected to be available to farmers in 2017.

A selection of "new" biotech crops, several home-grown, were approved in 2015 and planned for commercialization in 2016 and beyond, in countries other than the US, which is covered earlier in this Executive Summary.

In Argentina, two home- grown products were approved – a drought tolerant soybean and a virus-resistant potato. In Brazil, approval was gained for cultivation of a 20% higher yielding home-grown eucalyptus, developed by FuturaGene/Suzano, plus commercialization of two home-grown crop products in 2016 – a virus resistant bean and a new herbicide tolerant soybean. In Myanmar, a new Bt cotton variety Ngwe-chi-9 was commercialized in 2015. In Canada, there was approval of a higher quality non-browning apple. Note, the important shift towards more food crops – current biotech food crops include white maize in South Africa, sugar beet and sweet corn in the US and Canada; papaya, squash, potato and apple in the US; papaya in China; and Bt eggplant in Bangladesh.

Stacked traits occupied 33% of the global 179.7 million hectares, up from 28% in 2014.

Stacked traits are favored by farmers in all countries for all crops. Stacked traits increased from 51.4 million hectares in 2014 to 58.5 million hectares in 2015 – an increase of 7.1 million hectares equivalent to a 14% increase. The substantial shift to stacked traits was largely due to an increase in Bt/HT soybean with 12.9 million hectares principally planted in Brazil, and to a lesser extent by its neighbors, Argentina, Paraguay and Uruguay. Stacked traits continued to be an important and growing feature of biotech crops – 14 countries planted biotech crops with two or more traits in 2015, of which 11 were developing countries. Vietnam planted a stacked biotech Bt/HT maize as its first biotech crop in 2015.

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 almost half (48%) 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 India and China in Asia, Brazil and Argentina in Latin America, and South Africa on the continent of Africa. They collectively grew 86.3 million hectares (48% of global) and together represent ~41% of the global population of 7.3 billion, which could reach ~11.0 billion, or more, by the turn of the century in 2100. Remarkably, the population in Africa alone could escalate from ~1.2 billion today (~16% of global) to a possible high of 4.4 billion (~39% of global) by the end of this century in 2100. On a hectarage basis, of the 28 countries that planted biotech crops in 2015, 87% of the hectarage was in the Americas, 11% in Asia, 2% in Africa and <1% in Europe.

Ten Latin American countries benefit from biotech crops.

It is noteworthy, that there are now 10 countries in Latin America which benefit from the extensive adoption of biotech crops. Listed in descending order of hectarage, they are Brazil, Argentina, Paraguay, Uruguay, Bolivia, Mexico, Colombia, Honduras, Chile, and Costa Rica, with Cuba planning to resume planting in two years pending availability of their home-grown maize hybrids.

Brazil, the global engine of growth for biotech crops is second only to the US in biotech crop hectarage.

In 2015, Brazil ranked second only to the USA in biotech crop hectarage in the world with 44.2 million hectares (up from 42.2 million in 2014); the increase in 2015 was 2 million hectares equivalent to a growth rate of 5%. For the last six years, Brazil was the engine of growth globally. In 2015, Brazil grew 25% (2% more than in 2014) of the global hectarage of 179.7 million hectares. In the long term, Brazil is expected to close the gap with the US which has an efficient and science-based approval system that facilitates fast adoption. In 2015, Brazil commercially planted, for the third year, the stacked soybean with insect resistance and herbicide tolerance on 11.9 million hectares, up substantially (five-fold increase) from 2.3 million hectares in 2013 and 5.2 million hectares in 2014. In Brazil, approval was gained by FuturaGene /Suzano for cultivation of a 20% higher-yielding home-grown biotech eucalyptus, plus commercialization of two home-grown crop products in 2016 – a virus resistant bean and a new herbicide tolerant soybean.

Canada decreased hectarage of biotech canola, whereas biotech national hectares in Australia increased due to biotech canola.

Canada retained its fifth place in world ranking of biotech crops with biotech crop hectarage of 11.0 million hectares compared with 11.6 million hectares in 2014 – a ~ 5% decrease, largely due to a decrease in hectarage of total canola and driven by low canola prices. The decrease in canola hectares in 2015 is expected to reverse when prices of canola increase, and become more competitive versus other crops. Australia grew 658,000 hectares of biotech crops in 2015 compared to 542,000 hectares in 2014, a 21% increase. This comprises 214,000 hectares cotton, a 7% increase from 200,000 hectares in 2014; and 444,000 hectares biotech canola, a 30% increase from 342,000 hectares in 2014. Notably, biotech cotton adoption remains at ~100% of all cotton grown in Australia and ~99% of it featured

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

the stacked traits (insect resistance and herbicide tolerance). Australia is providing global leadership in deployment of biotech cotton and insect resistance management with Bolgard™ lll already field-tested in 2015 on ~30,000 hectares.

India sustains its biotech cotton hectarage and becomes #1 cotton producer in the world.

In a landmark development, India became the #1 cotton producer in the world, with much of the success attributed to Bt cotton. India continued to be the largest biotech cotton country in the world with 11.6 million hectares planted by 7.7 million small farmers with an adoption rate of 95%, similar to 2014. Brookes and Barfoot's latest estimate indicated that India had enhanced farm income from Bt cotton by US$18.3 billion in the twelve year period 2002 to 2014 and US1.6 billion in 2014 alone.

Status of Bt cotton and virus resistant papaya in China

In 2015, China successfully planted ~3.7 million hectares of biotech cotton at an adoption rate of 96%, (up from 93% in 2014) of its 3.8 million total cotton hectarage. In addition, ~7,000 hectares of virus resistant papaya were planted in Guangdong, Hunan Island and Guangxi; plus ~543 hectares of Bt poplar. Despite China's decreased total cotton hectarage, from 4.2 million hectares in 2014 to 3.8 million hectares, mainly due to lower prices and high stockpiles of cotton in China, biotech cotton adoption rate has increased from 93% in 2014 to 96% in 2015, and planted by an estimated ~6.6 million or more farmers. Virus resistant papaya plantings decreased from 8,475 hectares in 2014 to 7,000 hectares in 2015, due to over supply in 2014, but the adoption rate remained high at ~90%. In addition to farmers benefiting directly from biotech Bt cotton there may be an additional 10 million secondary beneficiary farmers cultivating 22 million hectares of crops which are alternate hosts for cotton bollworm and benefit from decreased pest infestation due to the planting of Bt cotton. Thus, the actual total number of beneficiary farmers of biotech Bt cotton in China alone may well exceed 17 million. Economic gains at the farmer level from Bt cotton for the period 1997 to 2014 was US$17.5 billion and US$1.3 billion for 2014 alone.

Bt maize and Bt rice, offer significant potential benefits and have enormous implications for China, Asia, and the rest of the world in the near, mid and long term, because rice is the most important food crop 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 Bt rice, will be very important potential contributions to China and the global food and feed needs. Whereas, President Xi Jinping has endorsed the GM technology that is used in biotech soybean and maize imported by China in very large quantities (77 million tons of soybean and 3.3 million tons of maize in 2015), domestic production of these biotech crops has not been implemented to-date. It is noteworthy that at the same time that the US approved biotech potato in 2015, China, the largest producer of potatoes in the world (6 million hectares), announced its intention to double its potato hectarage and designated potato as its fourth food staple following rice, maize, and wheat.

The Chinese government has disbursed at least US$3 billion to research institutes and domestic companies to develop home-grown biotech seeds and discussions are underway to expedite approvals of pending biotech crops for cultivation. Domestic production of biotech maize would increase productivity and reduce China's dependency on imports of increasing quantities of maize, most of which (more than 90%) are biotech. China consumes one-third of global soybean production and

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

imports 65% of global soybean imports, over 90% of which is biotech. Some observers speculate that home-grown biotech maize (Bt or phytase maize) will be commercialized in the next three years opening up an enormous potential market of 35 million hectares of maize. Thus, biotech crops could help China become less dependent on increasing imports of soybean and maize, over 90% of which are biotech. Bloomberg (November 2015) reported that President Xi Jinping has been urging China to support "strong research and innovation" on GM crops. His urging is consistent with the US$43 billion bid from ChemChina for Syngenta, which could have high potential impact on the timely adoption of biotech maize on up to 35 million hectares in China in the near-term. A successful bid would provide ChemChina with immediate access to a large portfolio of ready- made safety- tested commercial GM crop products that have been grown globally for many years.

Status in Africa

Despite some significant challenges, the African continent continued to make general progress on several fronts. A devastating drought in South Africa resulted in the country decreasing its intended biotech crop hectarage in 2015 by approximately 700,000 hectares from 3 million hectares to 2.3 million hectares – a massive 23% decrease. This underscores yet again the critical nature, and potentially life-threatening importance of drought in Africa and the impending new drought challenges exacerbated by climate change. Importantly, the drought tolerant maize (DroughtGard®) under the WEMA project has been approved for general release in South Africa, while the (DT) maize with insect control (Bt) will be launched as scheduled in 2017. Sudan increased Bt cotton hectarage by 30% to 120,000 hectares whilst political transition changes and fiber quality precluded a potentially higher hectarage than ~0.4 million hectares in Burkina Faso. An additional eight countries (Cameroon, Egypt, Ghana, Kenya, Malawi, Nigeria, Swaziland and Uganda) conducted field trials on priority African crops, the penultimate step prior to approval. The on-going trials focus on traits of high relevance to challenges facing Africa, including drought, nitrogen use efficiency, salt tolerance, nutritional enhancement, as well as resistance to tropical pests and diseases. Slow implementation of science-based and cost/time-effective regulatory systems is the major constraint to adoption. Responsible, rigorous but not onerous regulation is urgently needed to suit the needs of both public and private sector technology developers in ensuring smooth delivery of the much needed tool into the hands of African famers. Ultimately, sustained political goodwill and intense engagement with all sector players will be keys in unlocking the regulatory stalemate.

Five EU countries planted 116,870 hectares of biotech Bt maize. Spain was by far the largest adopter, planting 92% of the total Bt maize hectarage in the EU.

The same five EU countries (Spain, Portugal, Czechia, Slovakia and Romania) continued to plant 116,870 hectares of Bt maize, down 18% from the 143,016 hectares planted in 2014. Spain, which grew 92% of all biotech maize, led the EU with 107,749 hectares of Bt maize, down 18% from the 131,538 in 2014, with a 28% adoption rate compared with a 31% adoption in 2014. Bt maize hectarage declined in all five EU countries. The decreases in Bt maize were associated with several factors, including less total hectares of maize planted in 2015, but also due to significant disincentives for farmers confronted with bureaucratic and onerous reporting of intended plantings of Bt maize. In October 2015, 19 of the 28 EU countries voted to opt out of growing biotech crops but importantly all five countries currently growing Bt maize voted to continue planting so that they can benefit from the significant advantages that biotech crops offer.

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

Status of approved events for biotech crops

As of November 15, 2015, a total of 40 countries (39 + EU - 28) have granted regulatory approvals to genetically modified crops for use as food and/or feed use or for environmental release since 1994. From these countries, 3,418 regulatory approvals have been issued by regulatory authorities across 26 GM crops (not including carnation, rose and petunia) and 363 GM events. The top five countries with the most number of regulatory approvals include Japan (214 approvals), U.S.A. (187 not including stacked events), Canada (161), Mexico (158), and South Korea (136). Maize still has the most number of approved events (142 in 29 countries), followed by cotton (56 events in 22 countries), potato (44 events in 11 countries), canola (32 events in 13 countries), and soybean (31 events in 28 countries). The herbicide-tolerant maize event NK603 (54 approvals in 26 countries + EU-28) has the most number of approvals followed by the herbicide-tolerant soybean event GTS 40-3-2 (52 approvals in 26 countries + EU-28), the insect-resistant maize MON810 (50 approvals in 25 countries + EU-28), and the insect-resistant maize Bt11 (50 approvals in 24 countries + EU-28). In December 8, 2015, the Supreme Court of the Philippines decided that the conduct of Bt eggplant field testing is permanently enjoined; the Department of Agriculture Administrative Order No. 08, series of 2002 is declared null and void; and, consequently, any application of contained use, field testing, propagation, and commercialization, and importation of genetically modified organisms is temporarily enjoined until a new administrative order is promulgated in accordance with the law.

Global value of biotech seed alone was ~US$15.3 billion in 2015

In 2015, the global market value of biotech crops, estimated by Cropnosis, was US$15.3 billion, (down marginally from US$15.7 billion in 2014); this represents 20% of the US$76.2 billion global crop protection market in 2014, and 34% of the ~US$45 billion global 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. A 2011 study estimated that the cost of discovery, development and authorization of a new biotech crop/trait was ~US$135 million. A report by Transparency Market Research for the period 2013-2019 indicated that, global agricultural biotechnology which was worth US$15.3 billion in 2012 is expected to be worth US$28.7 billion by 2019. The value is estimated to expand at a rate of 9.5% compounded annual growth rate (CAGR) from 2013 to 2019 due to the rising demand for higher crop yield, combined with diminishing amounts of arable land that will drive the transgenic application segment of the market.

THE CHALLENGE

The enormous challenge of feeding 9.7 billion in 2050

Feeding 9.7 billion people in 2050, and ~11.0 billion in 2100, is one of, if not THE most daunting challenges facing mankind during the remaining years of this century. Global population, which was only 1.7 billion at the turn of the century in 1900, is now 7.3 billion (July 2015) – the world has added approximately 1 billion people in the span of the last 12 years. It is expected to climb to 9.7 billion by 2050, and to 11 billion at the end of this century in 2100. Globally, 870 million people are currently chronically hungry and 2 billion are malnourished. The world may consume more grain than it produced in 2015. Rates of growth in crop productivity have declined subsequent to the significant contribution of

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

the green revolutions of the 1960s for 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 on small resource-poor farmers and the rural landless dependent on agriculture, who represent the majority of the world's poorest people.

Climate Change: Papal Encyclical and COP 21 in Paris

Pope Francis in his 2015 papal encyclical, 'Laudato Si', **underscored the importance for everyone, in a coordinated effort, to implement the necessary strategies to address climate change and environmental destruction which will affect everyone, especially the vulnerable members of global society** – the poor and the hungry. Efforts in the past by rich countries to help poor countries were determined not to be sufficient, hence there is an urgent global need to double and unify efforts.

The Pope's concern was also appropriately addressed **in a clarion call for action (not promises)** during the 21st Session of the Conference of the Parties (COP21) to the UN Framework Convention on Climate Change (UNFCCC) held in Paris, France in December 2015. Importantly, for the first time ever, a legally binding agreement was signed by 195 countries to limit global warming to below 2^{o}C, above which, global crop production will decline substantially, particularly the developing countries, which can least afford the losses due to abiotic-stresses (higher temperatures and droughts) and biotic-stresses (pests, weeds and diseases). It is very important to acknowledge that **GM/biotech crops are already making a contribution to reduce the effects of increased stresses associated with climate change, as detailed in the next paragraph. Moreover, the potential of GM and the new biotech applications, such as CRISPR, is enormous for the future, when global population will reach 11 billion in 2100.** The challenge for society is to adopt harmonized, science-based appropriate/ proportionate regulation, which is practical and not overly onerous, that will ensure timely deployment to farmers of improved crops that can increase productivity, and double food production.

Biotech crops contribution to Food Security, Sustainability, the Environment and Climate Change

The latest data for 1996 to 2014 showed that biotech crops contributed to Food Security, Sustainability and Climate Change by: increasing crop production valued at US$150 billion; providing a better environment, by saving 583.5 million kg a.i. of pesticides in 1996-2014; in 2014 alone reducing CO2 emissions by 27 billion kg, equivalent to taking 12 million cars off the road for one year; conserving biodiversity in the period 1996-2014 by saving 152 million hectares of land (Brookes and Barfoot, 2016); and helped alleviate poverty by helping up to 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 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. Biotech crops can contribute to a **"sustainable intensification"** strategy favored by many Academies of Science 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 for

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

insects, pathogens and weeds, are a must for biotech crops as they are for conventional crops.

Regulation of biotech crops

Onerous regulation for transgenic biotech crops remains the principal constraint to adoption, which is particularly important for many developing countries, denied the opportunity of using biotech crops to address food, feed and fiber security. Unlike the onerous regulation that currently applies to transgenics, genome-edited products logically lend themselves for science-based, fit-for-purpose, proportionate and appropriate regulation. Opponents of GM crops and the new genome-editing technologies such as CRISPR are opposed to science/evidence- based regulation and are demanding onerous regulation that is denying poor farmers in the developing countries, as well as Europe's access to the technologies. By using these technologies, small poor farmers will be able to survive and contribute to the doubling of food production to meet the needs of a growing population which will reach 11 billion in 2100. Moreover, the opponents of GM crops and the biotech applications such as CRISPR are estimated to have a massive global budget which doubled from an estimated US$10 billion in 2011 to US$20 billion in 2014.

The encouraging outlook is that technology, in conjunction with conducive policies can double food production. However, the doubling of food production cannot be realized by society unless it ensures that regulation of GM and genome-edited derived crops is science/evidence-based, fit-for- purpose, and to the extent possible harmonized globally. Failure by global society to ensure timely and appropriate regulation on food production will have dire consequences. On the one hand the world will suffer because of inadequate food supplies, whilst on the other hand the power of science and technology to produce a safe, adequate and assured supply of food for all of mankind will be rejected because of the dominant ideological voices of the opponents of the new biotech technologies.

Global meta-analysis, confirms significant and multiple benefits

The meta-analysis conducted by Klumper and Qaim (2014) on 147 published biotech crop studies during the last 20 years, 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."*** These findings corroborate the findings of the annual global impact study by Brookes and Barfoot of PG Economics, annually referenced in the Annual ISAAA Briefs. Qaim (2015) presented a more thorough description of the impacts of current and possible future GM crop applications, and their substantial contribution to sustainable agricultural development and food security, in his recent book, *Genetically Modified Crops and Agricultural Development*. He concluded that continued opposition to technologies that were shown to be beneficial and safe entails unnecessary human suffering and environmental degradation.

Status of Golden Rice

WHO concluded that 190 to 250 million preschool children worldwide are affected by VAD annually. Golden Rice could prevent 1.3 to 2.5 million child deaths annually. At IRRI, the Golden Rice trait event E, has been bred into mega varieties, and confined field tests are in progress in the Philippines

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

and a field trial has been approved in Bangladesh. The important mission of the Golden Rice project is to contribute to improving the health of millions of people suffering from micronutrient deficiency. Rice is the staple of 4 billion people in the South who collectively consume only 2,006,869 calories per day. This consumption is broken down by region, per day in: South Asia (1,130,648 calories), Southeast Asia (660,979 calories), Africa (125,124), Latin America (75,238), and Central Asia (14,880) for a total of 2,006,869 calories per day (HarvestPlus, Personal Communications). These are the regions where most Vitamin A Deficiency (VAD) and associated illnesses occur – these can be reduced if people are provided with Golden Rice, a biotech rice with beta carotene. Around 100 to 150 grams per day of the improved Golden Rice will provide more than half the needs of people suffering from vitamin A deficiency.

New Breeding Technologies (NBT): The critical role of utilizing evolving and promising new biotechnology applications, such as CRISPR, in crop improvement

Twenty years after the commercialization of biotech/GM crops developed through the use of *Agrobacterium* or particle bombardment, the scientific global community are again enthusiastic about the potential of a new crop biotechnology called "genome- or gene-editing". There are different types of genome editing technologies, the most recent named CRISPR (Clustered regularly interspaced short palindromic repeat) is judged to be promising by many stakeholders. These new technologies 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. Readers are referred to two essays on new breeding technologies and genome-edited applications in the collection of invitational essays in the companion document to the Brief on the ISAAA website. Experts in the field believe that potentially the "real power" of these new technologies is their ability to "edit" and modify single or multiple native plant genes (non-GM), coding for important traits such as drought and, generating useful improved crops that are not transgenic. Products already under development include all the major food and feed crops: canola (herbicide tolerance), maize (drought tolerance), wheat (disease resistance and hybrid technology), soybean (oil quality), rice (disease resistance), potato (improved storage qualities), tomato (fruit ripening), and peanuts (allergen-free). More complex traits, coded by multiple genes, like improved photosynthesis, are planned for the future, which may be closer than some people think. CRISPR earned *Science's* 2015 "Breakthrough of the Year Laurels". A runner-up in 2012 and 2013, the technology now revolutionizing genetic research and gene therapy "broke away from the pack, revealing its true power in a series of spectacular achievements," opined Science correspondent John Travis in the December 18 issue.

Acknowledging that no technology, including genome-editing, is a panacea or a silver bullet, many well-informed observers in the scientific community (gene therapy in medicine, where the technology was first developed, and crop improvement in agriculture) are of the view that genome-editing offers a timely and unique set of significant comparative advantages over conventional and GM crops in four domains: **precision** – due to its ability to precisely control single or multiple genes resulting in products that do not differ from natural mutations; **regulation** – unlike the onerous regulation that currently applies to transgenics, genome-edited products logically lend themselves for science-based, fit-for-purpose, proportionate regulation; **speed** – some products, for example, genome-edited derived potato, have been developed in only one year, compared with up to 10 years using conventional or GM technology; and **cost** – higher speed in improving crops and reduced regulation translates into significant overall savings. The average cost for developing a GM crop is US$135 million of which

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

US$35 million is onerous regulation costs. The hope is that regulatory bodies worldwide will not require stringent regulation for genome edited crops and to the extent possible facilitate harmonization of regulations internationally. This augers well for the new genome-edited technologies which will allow more affordable, superior, state-of-the-art crops to be offered to producers and consumers.

To ISAAA's knowledge, the first non-GM, genome-edited product, to be approved and commercialized is SU Canola™ developed by Cibus and grown on 10,000 acres (4,000 hectares) in the USA in 2015. Canada has also approved SU Canola™ for planting. Similar non-GM products are under development in many laboratories globally with a view to commercialization by farmers as early as five years from now in 2020. For example, DuPont has indicated that it already has CRISPR-derived maize and wheat plants growing in the greenhouse and is hoping to conduct the first field tests in 2016. Several countries – USA, Canada, Sweden and Argentina, have already considered regulation of simply mutated products through CRISPR and similar technologies, and concluded that they do not require to be deregulated under their respective national GM regulations. Dr. Jansson from Sweden has opined that **"the decision of the Swedish Board of Agriculture is the only logical one"** for their particular genome-edited products. Importantly, the determination of the need to regulate should be focused on the specific product and not the process.

Leading scientists from the global scientific community are of the view that international harmonization of science-based regulation of genome-edited crops is absolutely critical for plant breeding programs. This is because these programs are required to urgently increase global crop productivity, in order to achieve food security for 11 billion people in 2100, as well as mitigating the additional and formidable challenges, such as more frequent and more severe droughts posed by climate change. **The EU and many other countries are expected to report their findings, positions and decisions on regulation of genome-edited technologies in the near term – these will be critical game-changing decisions with global implications for the role of science in food security, climate change, and the alleviation of hunger and poverty for almost one billion people in the developing countries.**

To summarize, the unusual degree of interest and enthusiasm in genome-editing is that, relative to other conventional and GM technologies, it is simple, swift, precise and affordable – features that make it a universally attractive development for most stakeholders. Genome-editing can help solve the misery of the ~ 850 million poor people who are suffering from food insecurity in the developing countries, where one thousand people an hour die from hunger and malnutrition – a situation that is unacceptable in a just society. Norman Borlaug opined that you cannot build peace on empty stomachs, and that **technology can contribute to food security** and a better quality of life for millions of poor people – he was right – the right to adequate food is imperative, and **biotechnology** can help make it happen.

FUTURE PROSPECTS

There are three domains that merit considerations:

Firstly, the high rates of adoption (90% to 100%) of current major biotech crops **leave little room for expansion in mature markets in principal biotech crop countries.** However, there is a significant potential for selected products such as biotech maize. For example, in Asia, there are about 60 million hectares of potential biotech maize, with 35 million hectares in China alone; there is a similar potential

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

in Africa for up to 35 million hectares of biotech maize and for biotech cotton, in up to 10 African countries growing 100,000 hectares, or more, of cotton.

Secondly, the pipeline is full of new biotech crop products which could (subject to regulatory approval for planting and import) be available during the next 5 years or so – a portfolio of over 85 potential products are listed in the full Brief. They include, the WEMA-derived biotech drought tolerant maize expected to be released in Africa in 2017, a broad range of new crops and traits including products with multiple modes of resistance to pests/diseases and tolerance to herbicides, as well as resistance to nematodes. Golden Rice is progressing with field testing in Asia. Crops for the poor, particularly in Africa, such as fortified bananas and pest resistant cowpea, look promising and **institutionally, public-private partnerships (PPP) have been relatively successful in developing and delivering approved products to farmers** – four PPP case studies, featuring a broad range of different biotech crops and traits in all three continents of the South, are presented in the Appendix of the full Brief.

Thirdly, the advent of genome-edited crops may be, by far, the most important development identified by today's scientific community. A recent and promising application is the powerful technology named **CRISPR**. Many well-informed observers in the scientific community are of the view that genome-editing offers a timely and powerful unique set of significant advantages over conventional and GM crops in four domains: **precision, speed, cost and regulation** – unlike the onerous regulation that currently applies to transgenics, genome-edited products logically lend themselves for science-based, fit-for-purpose, proportionate regulation. Progress with the latter would be an enormous advantage. For more details the reader is referred to two essays in the companion document to Brief 51 on the ISAAA website (to celebrate the 20th anniversary of the commercialization of biotech crops) which describe the evolution of crop improvement technology, particularly the role of the new breeding technologies (NBT). It includes **a proposed forward-looking strategy of using the troika of transgenes, genome-editing and microbes** (the use of plant microbiomes as a new source of additional genes to modify plant traits) to increase crop productivity which in turn can contribute to the noble goal of food security and the alleviation of hunger and poverty.

CLOSING COMMENTS

The Way Forward

The way forward is to work together – <u>collaboration</u> – between the North and the South, East and West, Public and Private Partnerships (PPP), using both conventional (well-adapted germplasm) and biotechnology applications (enhanced beneficial traits). In reviewing crop technology transfer projects over the last two decades, the progress and promise of public-private sector partnerships (PPP) is striking. PPP projects offer flexibility and have been successful under a very broad range of circumstances. **Importantly, PPP offer advantages that increase the probability of <u>delivering</u> an approved biotech crop product at the farmer level <u>within a reasonable time frame</u>.** Four PPP case studies/projects, selected and reviewed by ISAAA illustrate the range of diversity in the four model PPP projects: Bt brinjal (eggplant) 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 updated descriptions of each of the four case studies, are summarized in the Appendix of Brief 51-2015.

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

Norman Borlaug's Legacy and Advocacy of Crop Biotechnology

It is fitting and timely to close this celebratory 20th Anniversary ISAAA Brief for 2015, by chronicling the counsel of the late 1970 Nobel Peace Laureate, Norman Borlaug, on biotechnology including GM crops. 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 and poverty. Norman Borlaug was also the founding patron of ISAAA, and the greatest advocate for biotechnology and biotech/GM crops worldwide.

Below is a memorable Norman Borlaug quote, in which he calls for **courage** from our leaders, (both scientific and political) to support crop biotechnology which can contribute to global food security and a more peaceful world. It is noteworthy that the quote is from the man who knew more than anyone about feeding the world because he had **"done it"** during the green revolution of the 1960s and understood the essence of the proverb – **reading is learning, seeing is believing, but <u>doing is knowing</u> – knowledge.** This Brief seeks to share knowledge freely about all aspects of biotech crops whilst respecting the rights of readers to make their own informed-decisions about crop biotechnology.

Norman Borlaug Quote:

"What we need is <u>courage by the leaders</u> 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).

ISAAA is a not-for-profit organization, sponsored by public and private sector organizations. More detailed information to complement the content of this Executive Summary is provided in the full xxx-page ISAAA Brief 51, **"20th Anniversary of the Commercialization of Biotech Crops (1996 to 2015), and Highlights for 2015**. authored by Clive James. For further information, please visit http://www.isaaa.org or contact ISAAA SEAsiaCenter at +63 49 536 7216, or email to info@isaaa.org.

HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT

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HOLD EMBARGO UNTIL APRIL 13, 2016, 1:00 A.M. EDT