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Global Review of Commercialized Transgenic Crops: 2002
Feature: Bt Maize

by

Clive James
Chair, ISAAA Board of Directors

First Harvest of Commercial Bt Maize, Mindanao, Philippines, 2003

Conventional Maize | Bt Maize

Control of Asian Corn Borer in Bt Maize

No. 29 - 2003

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Global GM Crops in 2002

Growth in GM Crop Area

- In 2002, the global area of GM crops was 58.7 million hectares or 145 million acres, grown in sixteen countries by 6 million farmers, of whom 5 million were small resource-poor farmers in developing countries. GM crop area has grown 35 fold between 1996 and 2002 – one of the highest rates of adoption of any technology in agriculture. The US was the largest grower of GM crops (68%), followed by Argentina (23%) Canada (6%) and China (4%) with the balance grown by the other 12 countries. Three countries India, Colombia, and Honduras grew GM crops for the first time in 2002.

- The principal GM crops continued to be soybean, maize, cotton and canola. On a global basis 51% of the 72 million hectares of soybean was GM, 20% of the 34 million hectares of cotton, 9% of the 140 million hectares of maize and 12% of the 25 million hectares of canola. Herbicide tolerance continued to be the most dominant trait occupying 75% of the GM global area in 2002, followed by insect resistance (17%) and the stacked genes of herbicide tolerance and insect resistance, occupying 8%.

- In the first seven years of GM crop commercialization, 1996 to 2002, a cumulative total of over 235 million hectares of GM crops were planted globally which met the expectations of millions of small and large farmers in both industrial and developing countries. GM crops delivered significant agronomic, environmental health and social benefits to farmers and to global society, and contributed to a more sustainable agriculture.

- Global GM crop area is expected to continue to grow in 2003.

Value of the Global Transgenic Seed Market in 2002

- The value of the global transgenic seed market is based on the sale price of transgenic seed plus any technology fees that apply. The value in 2002 was $4.0 billion, up from $3.7 billion in 2001.

Global R&D Expenditures in Crop Biotechnology

- Global R&D expenditure in the private and public sectors is $4.4 billion with over 95% of the total in the industrial countries, led by the US. China is the leading investor in R&D crop biotechnology in the developing countries, followed by India.

GM Crops and the Commercial Seed Industry

- GM crops represent approximately 13% of the $30 billion global commercial seed market in 2001.

Feature: Bt Maize

The feature on Bt maize is devoted to:

- assessing the performance to-date of the first generation of Bt maize with the *cry1Ab* gene on a global basis over the last seven years
- evaluating the future potential of *cry1Ab* and other Bt or novel genes that confer resistance to the major caterpillar/moths (Lepidoptera), particularly the economically important stem borer complex
- a preliminary assessment of new genes for the control of the corn rootworm complex (Coleoptera/ beetles), an important pest in the Americas which has also been detected in 13 countries in Europe

The principal aim is to present a consolidated set of data that will facilitate a knowledge-based discussion of the potential benefits and risks that Bt maize offers global society. The topics presented include:

- the maize crop and its origins;
- global distribution of maize in developing and industrial countries, by area, production, consumption, imports, and exports as well as projections of future maize demand in 2020;
- definition of the areas sown to hybrids, open pollinated varieties and farmer-saved seed;
- estimates of the number of maize farmers worldwide, by principal country, and average size of maize holdings;
- maize production systems, germplasm development and maize utilization;
- an overview of the insect pests of maize as well as the crop losses they cause, including the cost of control, and an analysis of the $550 million global maize insecticide market and a gains from Bt maize;

- deployment of the *cry1Ab* gene in Bt maize, its global adoption and assessment of benefits;
- a preview of the second generation genes which include the genes *cry3Bb1* and *cry1Fa2,* first commercialized in the US in 2003, and five other gene products that are in development and expected to be launched within the next three years;
- a review of Insect Resistance Management, the potential effect of Bt maize on the environment and the food and safety aspects of Bt maize, including the important topic of mycotoxins and the advantage that Bt maize offers with lower levels of the mycotoxin fumonisin in terms of food and feed safety, particularly in developing countries;
- a brief overview of trade issues as they relate to Bt maize in the USA and the EU;
- concluding with an assessment of the global potential of Bt maize, as a safe and sustainable technology that has the capacity to make a critical contribution to global food and feed security, more specifically to the unprecedented demand for approximately 850 million tons of maize in 2020, 60% of which will be consumed in developing countries which will have the formidable challenge of having to produce most of their maize demands in their own countries with imports supplying only around 10% or less.

The Maize Crop

Approximately 75 countries in both the industrial and developing world, each grow at least 100,000 hectares of maize; the total of 140 million hectares produces 600 million MT of maize grain per year, valued at $65 billion annually, based on the 2003 international price of $108/MT. Developing countries plant two-thirds of the global maize area, and industrial countries one-third. The top five producers of maize are the US 229 million MT, China 124 m MT, Brazil 35.5 m MT, Mexico 19 m MT and France 16 m MT. Of the top 25 maize countries in the world 8 are industrial and 17 are developing countries including 9 from Africa, 5 from Asia and 3 from Latin America. There are approx. 200 million maize farmers worldwide, 98% of whom farm in developing countries; 75% of maize farmers are in Asia (105 million in China alone), between 15 and 20% in Africa and 5% in Latin America. Two thirds of the maize seed sold globally is hybrid and only 20 % is farmer-saved seed. In fact, hybrids are the predominant seed type in many of the principal developing countries which have a seed distribution system already in place for providing Bt maize to farmers; for example 84% of the 105 million Chinese maize farmers buy hybrid seed, and 81% of all maize seed used in Eastern and Southern Africa is hybrid.

Maize insect pests and the value of crop losses

The lepidopteran pests, particularly the stem borer complex, are a major constraint to increased productivity, and are of economic importance in most maize-growing countries throughout the world. Just under half (46%) of the maize area in the 25 key maize-growing countries have medium (40% area infested in temperate areas) to high levels (60% area infested in tropics/subtropics) of infestation with lepidopteran pests. Corn rootworm infests 20 million hectares in the Americas, requiring more insecticide than any other pest in the US, with losses and control measures in the US costing $1 billion per annum. The global losses due to all insect pests is 9%, equivalent to 52 million MT of maize, valued at $5.7 billion annually and consuming insecticide valued at $550 million. Losses associated with lepidopteran pests, that can be controlled by *cry1Ab*, are estimated to cause losses of 4.5%, equivalent to half the total losses from insect pests of maize.

Potential global benefits of Bt maize

Bt maize has proved to be a safe and effective product. Having undergone rigorous testing for food and feed safety, it has provided environmentally friendly and effective control of targeted pests, and the resistance is still durable after seven years of deployment on 43 million hectares. It is the first Bt maize product widely commercialized with proactively implemented, science-based insect resistant management strategies featuring refugia (areas planted to non-Bt maize) combined with high dose technology. Global deployment of the *cry1Ab* gene in Bt maize has the potential to increase maize production by up to 35 million MT valued at $3.7 billion per year; yield gains due to Bt maize are estimated at 5% in the temperate maize growing areas and 10% in the tropical areas, where there are more and overlapping generations of pests leading to higher infestations and losses. From a global perspective the potential for Bt maize in the near to mid-term is substantial. There are several reasons for this:

- Firstly, the *cry1Ab* gene has provided effective control of several of the primary pests of maize, principally the stem borers, and intermediate control for other caterpillar pests including armyworm and earworm. The successful performance of Bt maize *(cry1Ab)* has resulted in its rapid adoption on 43 million hectares in seven countries, since its introduction in 1996.

- Secondly, new Bt products are already being launched including the *cry3Bb1* gene for corn rootworm control in the US in 2003 and the *cry1Fa2* gene that provides effective control of pests controlled by *cry1Ab* with enhanced control of fall armyworm and black cutworm. In addition there are five new Bt and novel gene products that are anticipated for launch in the next three years that will provide the necessary diversity in modes of action to allow even more effective control of a broader range of the principal insect pests of maize.

- Thirdly, in addition to the significant advantages that Bt maize offers as a pest management tool, the product offers safer feed and food products than conventional maize with lower levels of harmful mycotoxins, an increasingly important attribute as food and feed safety is assigned higher priority. Of the three major staples, maize, wheat and rice, to-date maize is the only one that offers the significant benefits of commercialized biotechnology. Bt maize now offers an increasing range of options to meet the very diverse needs of the environments in which maize is grown.

Farmers assign Bt maize high value because it is a convenient and cost effective technology that allows them to manage risk in an uncertain environment and offers insurance against devastating crop losses in years when pest infestations are unusually high. For example, benefits from using Bt to control corn rootworm in the US alone, where it infests 13 million hectares, are projected at $460 million annually of which farmers would gain two-thirds and technology developers one-third. Producer gains of $289 million would be associated with increased yields, lower production costs and a significant decrease (2,300 MT a.i, or more) in insecticide use, which is currently the highest for any pest in the US. Global deployment of Bt or novel genes to control the principal lepidopteran pests of maize as well as corn rootworm has the potential to substitute up to 40 to 50% of the current 10,700 MT (a.i) of insecticides applied to maize globally, valued at approximately $550 million annually; this has significant environmental implications.

Challenges and Opportunities

The potential yield gains of up to 35 million MT, attainable from the first generation of Bt maize *(cry1Ab)*, with more gains to come from the second generation of Bt maize and novel gene technology, represent a challenge and an opportunity to contribute to feed and food security in 2020, when, for the first time ever, maize demand will exceed the demands for wheat and rice. The challenge is to produce an additional 266 million MT globally to meet an unprecedented global demand totaling approximately 850 million MT of maize by 2020, fuelled by more demand for meat by a more affluent global society. The 35 million MT potential gain from Bt maize amounts to almost a 15% contribution to the additional 266 million MT needed by 2020. Of the additional 266 million tons required globally in 2020, 80%, or 213 million MT, will be required by developing countries and the formidable challenge for them is to optimize domestic production to meet most of their own additional needs, with imports expected to continue to provide only around 10%. It is projected that Bt maize has the technological potential to deliver benefits on 40 to 45 million hectares in the near to mid term compared with the 10 million hectares it occupies today. This should be an incentive for major maize consuming developing countries, such as China and Brazil, to approve and adopt Bt maize because of the significant and multiple benefits it offers, including less risks associated with food and feed security. The major constraints are the lack of regulatory capacity in many developing countries, with acceptance, and trade issues being equally important, especially relative to the market influence of the European Union. Bt maize is likely to continue to experience high growth rates in the near-term in the traditional markets of the US, Canada, Argentina, South Africa, Spain, Philippines and Honduras. Subject to regulatory approval and acceptance, Asia offers significant new opportunities particularly in China and in India, Indonesia, and Thailand. Other important markets include Brazil and Mexico in Latin America and Egypt, Kenya, and Nigeria on the African continent.

Acceptance will be the major factor governing approval and adoption in Eastern European countries such as Romania and Hungary, which are EU accession countries. In Western Europe, France, Italy and Germany have much to gain from the technology, but political considerations related to acceptance have continued to result in rejection of the technology except in Spain where Bt maize has been a success, occupying 10% of the national maize area in 2003, having doubled from 5% in 2002.

Bt maize is a proven safe and effective technology that has the potential to deliver benefits on 25 million hectares through hybrid systems in temperate mega-environments, amongst which China offers the most important opportunity. In the tropical environments with a potential of 18 million hectares of Bt maize through hybrid systems, the most important opportunity is in Brazil. Bt maize offers a unique opportunity and an incentive for major maize consuming developing countries to approve and adopt Bt maize and benefit from the multiple and significant benefits it offers in terms of a safer and more affordable food and feed, which can coincidentally make a major contribution to food and feed security and to the alleviation of hunger and malnutrition which claims 24,000 lives a day in the developing countries of Asia, Africa and Latin America.

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1. INTRODUCTION

The rapid adoption of transgenic crops during the initial six-year period, 1996 to 2001 reflects the substantial multiple benefits realized by both large and small farmers in industrial and developing countries that have grown transgenic crops commercially. Between 1996 and 2001, a total of sixteen countries, 10 industrial and 6 developing, contributed to more than a thirty fold increase in the global area of transgenic crops from 1.7 million hectares in 1996 to 52.6 million hectares in 2001. The cumulative area of transgenic crops planted during the five-year period 1996 to 2001 total 175 million hectares, equivalent to more than 430 million acres.

Adoption rates for transgenic crops during the period 1996 to 2001 are unprecedented and are the highest for any new technologies by agricultural industry standards. High adoption rates reflect farmer satisfaction with the products that offer substantial benefits ranging from more convenient and flexible crop management, higher productivity and/or net returns per hectare, and social benefits, and a cleaner environment through decreased use of conventional pesticides, which collectively contribute to a more sustainable agriculture. There is a growing body of compelling evidence that clearly demonstrates the improved weed and insect pest control attainable with transgenic herbicide tolerant and insect resistant Bt crops, that also benefit from lower input and production costs; genetically modified (GM) crops offer substantial economic advantages to farmers compared with corresponding conventional crops. The severity of weed and insect pests varies from year to year and hence this will directly impact on pest control costs and economic advantage of GM crops.

Despite the on-going debate on GM crops, particularly in countries of the European Union, millions of large and small farmers in both industrial and developing countries continue to increase their plantings of GM crops in consecutive years because of the significant multiple benefits they offer. This high adoption rate is a strong vote of confidence in GM crops, reflecting farmer satisfaction. Several recent studies in both industrial and developing countries have again confirmed that farmers planting herbicide tolerant and insect resistant Bt crops are more efficient in managing their weed and insect pests. About 5 million farmers grew transgenic crops in 2001 and derived multiple benefits that included significant agronomic, environmental, social and economic advantages. ISAAA's 2001 Global Review predicted that the number of farmers planting GM crops, as well as the global area of GM crops, would continue to grow in 2002, and contribute to a more sustainable global production of food, feed and fiber. Global population exceeded 6 billion in 2000 and is expected to reach approximately 9 billion by 2050, when approximately 90% of the global population will reside in Asia, Africa and Latin America. Today, 815 million people in the developing countries suffer from malnutrition and 1.3 billion are afflicted by poverty. Transgenic crops, often referred to as genetically modified crops (GM), represent promising technologies that can make a vital contribution to global food, feed and fiber security and also make a contribution to the alleviation of poverty.

The activities of ISAAA, the International Service for the Acquisition of Agri-biotech Applications in crop biotechnology transfer and the dissemination of information and knowledge is described by James (2001c). Global reviews of transgenic crops have been published by the author as ISAAA *Briefs* annually since 1996. This publication is the seventh by the author in the annual review series, to characterize and monitor the global status of commercialized transgenic crops. The first, reviewed transgenic crops planted globally in 1996 (James and Krattiger 1996), the second for 1997 (James 1997a), the third for 1998 (James 1998); the fourth for 1999 comprised an early Preview (James 1999) followed by the annual Review for 1999 crops (James 2000a). The fifth for 2000 included a Preview (James 2000b) followed by the full annual Review for 2000 crops (James 2001a). The sixth for 2001 included a Preview (James 2001b) followed by the full annual Review for 2001 crops (James 2001a). The current publication presents the full annual global review of transgenic crops for 2002; a Preview (James 2002a) of this publication was published previously. This publication provides the latest information on the global status of commercialized transgenic crops for 2002. A detailed global data set on the adoption of commercialized transgenic crops is presented for the year 2002 and the changes that have occurred between 2001 and 2002 are highlighted. The global adoption trends during the last seven years from 1996 to 2002 are also illustrated. This publication also presents a feature on Bt maize in Chapter 8. The feature on Bt maize provides: a comprehensive global overview of the experience with Bt maize since its introduction in 1996; an assessment of the agronomic, environmental and economic and social benefits that it has delivered to-date and its global potential for the future.

Note that the words maize and corn, rapeseed and canola, as well as transgenic and GM crops, are used synonymously in the text, reflecting the usage of these words in different regions of the world. Global figures and hectares planted commercially with transgenic crops have been rounded off to the nearest 100,000 hectares and in some cases this leads to insignificant approximations, and there may be slight variances in some figures, totals, and percentage estimates. It is also important to note that countries in the Southern Hemisphere plant their crops in the last quarter of the calendar year. The transgenic crop areas reported in this publication are planted, not harvested, hectarage in the year stated. Thus, the 2002 information for Argentina, Australia, South Africa and Uruguay is hectares planted in the last quarter of 2002 and harvested in the first quarter of 2003.

2. OVERVIEW OF GLOBAL STATUS AND DISTRIBUTION OF COMMERCIAL TRANSGENIC CROPS

In 2002, the global area of transgenic crops continued to grow for the sixth consecutive year at a sustained rate of growth of more than 10% per year. The estimated global area of transgenic crops for 2002 is 58.7 million hectares or 145 million acres (Table 1). It is noteworthy that 2002 is the first year when the global area of transgenic crops has almost reached the milestone of 150 million acres equivalent to almost 60 million hectares. To put this global area of transgenic crops into context, 58.7 million hectares is equivalent to more than 5% of the total land area of China (956 million hectares) or the US (981 million hectares) and almost two and a half times the land area of the United Kingdom (24.4 million hectares). The increase in area of transgenic crops between 2001 and 2002 is 12%, equivalent to 6.1 million hectares or 15 million acres.

During the seven-year period 1996 to 2002, the global area of transgenic crops increased by 35 fold, from 1.7 million hectares in 1996 to 58.7 million hectares in 2002 (Figure 1). This high rate of adoption reflects the growing acceptance of transgenic crops by farmers using the technology in both industrial and developing countries. During the seven-year period 1996 – 2002 the number of countries growing transgenic crops more than doubled, increasing from 6 in 1996 to 9 in 1998, to 12 countries in 1999 and to 16 in 2002.

Table 1. Global Area of Transgenic Crops, 1996 to 2002

	Hectares (million)	Acres (million)
1996	1.7	4.3
1997	11.0	27.5
1998	27.8	69.5
1999	39.9	98.6
2000	44.2	109.2
2001	52.6	130.0
2002	58.7	145.0

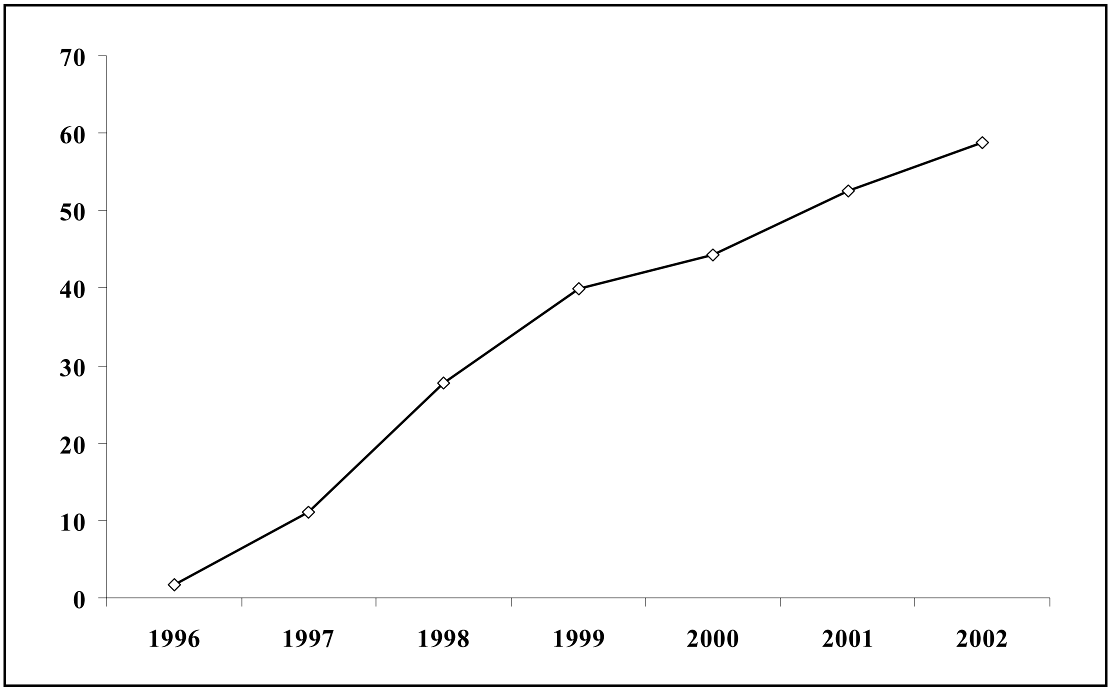
Increase of 12%, 6.1 million hectares or 15.0 million acres between 2001 and 2002

Source: Clive James, 2002.

2.1 Distribution of Transgenic Crops in Industrial and Developing Countries

Figure 2 shows the relative hectarage of transgenic crops in industrial and developing countries during the period 1996 to 2002. It clearly illustrates that whereas the substantial share of GM crops have been grown in industrial countries, the proportion of transgenic crops grown in developing countries has increased consistently from 14% in 1997, to 16% in 1998, to 18% in 1999, 24% in 2000, 26% in 2001 and 27% in 2002. Thus, in 2002, more than one quarter, 27%, (Table 2) of the global transgenic crop area of 58.7 million hectares, equivalent to 16.0 million hectares, was grown in developing countries where growth continued to be strong between 2001 and 2002, particularly in Argentina, China and

Figure 1. Global Area of Transgenic Crops, 1996 to 2002 (Million Hectares).



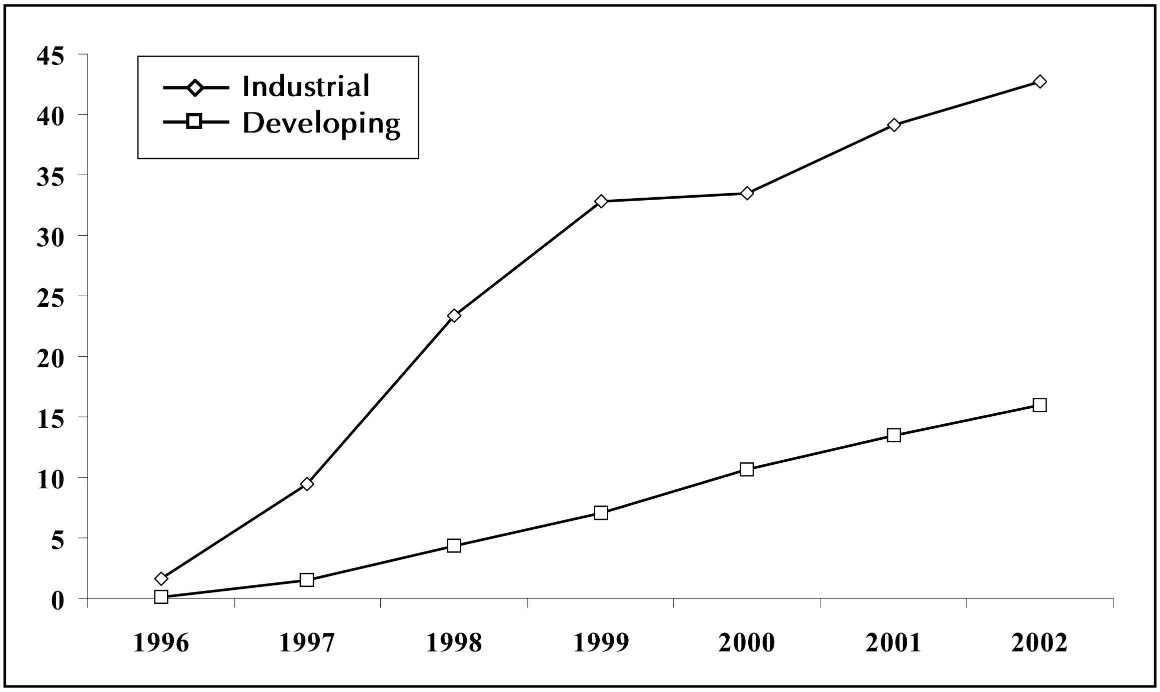
Source: Clive James, 2002.

South Africa, with India planting 45,000 hectares of Bt cotton for the first time in 2002. Whereas the absolute growth in GM crop area between 2001 and 2002 was higher in industrial countries (3.6 million hectares), compared with developing countries (2.5 million hectares), the percentage growth was more than twice as high in the developing countries of the South (19%) than in the industrial countries of the North (9%).

2.2 Distribution of Transgenic Crops, by Country

In 2002, four countries grew 99% of the global transgenic crop area (Table 3), and all four countries reported growth of GM crops between 2001 and 2002 (Figure 3). It is noteworthy that the top four countries include two industrial countries, USA and Canada, and two developing countries, Argentina and China. Consistent with the pattern since 1996, the USA grew the largest transgenic crop hectarage (66%) in 2002. The USA grew 39.0 million hectares, followed by Argentina with 13.5 million hectares (23%), Canada 3.5 million hectares (6%) and China 2.1 million hectares (4%); China displayed the highest percentage year-on-year growth with a 40% increase in its GM crop area of Bt cotton between 2001 and 2002. China's Bt cotton hectarage of 2.1 million hectares in 2002, equivalent to 51% of the total cotton area of

Figure 2. Global Area of Transgenic Crops, 1996 to 2002: Industrial and Developing Countries (Million Hectares)



Source: Clive James, 2002.

Table 2. Global Area of Transgenic Crops in 2001 and 2002: Industrial and Developing Countries (Million Hectares)

	2001	%	2002	%	+/-	%
Industrial Countries	39.1	74	42.7	73	+ 3.6	+ 9
Developing Countries	13.5	26	16.0	27	+ 2.5	+ 19
Total	**52.6**	**100**	**58.7**	**100**	**+ 61**	**+ 12**

Source: Clive James, 2002.

4.1 million hectares is the first time for the Bt cotton area in China to exceed more than half of the national cotton area. Despite the economic crisis in Argentina the growth rate of GM crops continued to be high (14%) in 2002, equivalent to 1.7 million hectares. Year-on-year growth was the same (9%) for the USA and Canada. In 2002, transgenic crop hectarage also increased in South Africa by over 20% from 0.22 million hectares in 2001 to 0.27 million hectares in 2002. A very severe drought, the worst for decades, decreased all cotton plantings by 50% in Australia and consequently GM cotton hectarage was also down by 50% from 0.2 million hectares in 2001 to 0.1 million hectares in 2002. Similarly, because of historically low international prices for cotton, total plantings were down by approximately 10% in the US, leading to a decrease in GM cotton hectarage.

The 16 countries that grew transgenic crops in 2002 are listed in descending order of their transgenic crop areas (Table 3). There are 9 developing countries and 5 industrial countries and two from Eastern Europe. In 2002, transgenic crops were grown commercially in all six continents of the world – North America, Latin America, Asia, Oceania, Europe (Eastern and Western), and Africa. Of the top four countries that grew 99% of the global transgenic crop area, the USA grew 66%, Argentina 23%, Canada 6% and China 4%. The other 1% was grown in the remaining 12 countries, with South Africa and Australia being the two countries that grew more than 100,000 hectares or a quarter million acres of transgenic crops.

In the USA there was an estimated net gain of 3.3 million hectares of transgenic crops in 2002; this came about as a result of significant increases in the area of transgenic maize and soybean, a modest increase in canola, and a decrease in the area of transgenic cotton which was associated with the general decrease of approximately 500,000 hectares in the national area planted to cotton in 2002 compared with 2001. The decrease in cotton plantings in the US was attributed to low international prices of cotton, making the crop less profitable than soybean and maize, both of which increased in total plantings at the expense of cotton. In Argentina, despite the severe economic crisis, a gain of 1.7 million hectares was reported for 2002 due to a significant growth in transgenic soybean and a modest increase in maize.

For Canada, a net gain of 0.3 million hectares was estimated with gains in both soybean and canola with the GM maize area remaining the same as 2001. For China, the area planted to Bt cotton increased by a significant 0.6 million hectares from 1.5 million hectares in 2001 to 2.1 million hectares in 2002.

A significant increase was reported for South Africa, where the combined area of transgenic maize and cotton and soybean is expected to be approximately 275,000 hectares. In Australia, a severe drought in 2002 led to only 125,000 hectares of transgenic cotton being planted in 2002 compared with 200,000 hectares in 2001. Romania tripled its area of GM soybean to 45,000 hectares in 2002, and Spain doubled its area of Bt maize to 25,000 hectares in 2002. Elsewhere in Europe,

Table 3. Global Area of Transgenic Crops in 2001 and 2002: by Country (Millions of Hectares)

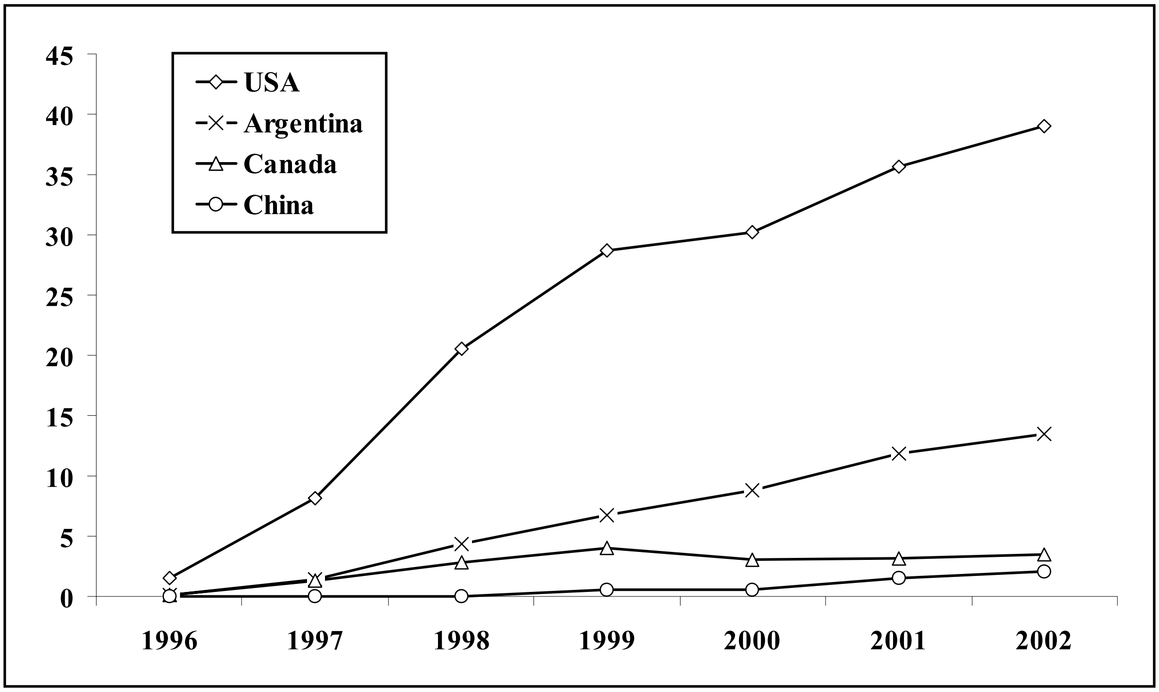
Country	2001	%	2002	%	+/-	%
USA	35.7	68	39.0	66	+ 3.3	+ 9
Argentina	11.8	22	13.5	23	+ 1.7	+ 14
Canada	3.2	6	3.5	6	+ 0.3	+ 9
China	1.5	3	2.1	4	+ 0.6	+ 40
South Africa	0.2	<1	0.3	1	+ 0.1	+ 50
Australia	0.2	<1	0.1	<1	- 0.1	- -
India	- -	- -	<0.1	<1	< 0.1	- -
Romania	<0.1	<1	<0.1	<1	< 0.1	- -
Spain	<0.1	<1	<0.1	<1	< 0.1	- -
Uruguay	<0.1	<1	<0.1	<1	< 0.1	- -
Mexico	<0.1	<1	<0.1	<1	< 0.1	- -
Bulgaria	<0.1	<1	<0.1	<1	< 0.1	- -
Indonesia	<0.1	<1	<0.1	<1	< 0.1	- -
Colombia	- -	- -	<0.1	<1	< 0.1	- -
Honduras	- -	- -	<0.1	<1	- -	- -
Germany	<0.1	<1	<0.1	<1	< 0.1	- -
Total	**52.6**	**100**	**58.7**	**100**	**+ 6.1**	**+ 12%**

Source: Clive James, 2002.

Germany continues to grow a small area of Bt maize and Bulgaria grows a small area of herbicide tolerant maize. Mexico has a small area of GM soybean and Bt cotton, Uruguay grows about 20,000 hectares of herbicide tolerant soybean and about 2,700 farmers continue to grow Bt cotton in South Sulawesi, Indonesia. In 2002, there was a significant increase in the total number of countries growing GM crops with three new countries joining the expanding global group of countries that are growing GM crops. Notably, India the largest cotton growing country in the world (8.7 million hectares) approved Bt cotton in May 2002; 54,000 farmers planted 45,000 hectares of Bt cotton during the Kharif season in India in 2002.

Colombia in Latin America also approved the planting for the first time of about 2,000 hectares of pre-commercial Bt cotton in 2002 in anticipation of full commercial approval for

Figure 3. Global Area of Transgenic Crops, 1996 to 2002: by Country (Million Hectares)



Source: Clive James, 2002.

2003. Also for the first time in 2002, Honduras became the first country in Central America to grow a GM crop with a pre-commercial introductory area of approximately 500 hectares of Bt maize, pending commercialization expected in 2003.

The country portfolios of deployed GM crops continued to diversify in 2002. Of particular interest was the approval of Bollgard® II for use in Australia in September 2002. It is expected that 3,000 to 5,000 hectares will be planted in 2002/03, with a plan for it to replace the single gene construct, INGARD®, entirely in 2004/05. Unlike the single construct INGARD®, which was limited to 30% of the area, Bollgard® II is not subject to the 30% restriction, and eventually will probably occupy 70% or more of the cotton area in Australia. Approval of Bollgard® II is pending in the US and is expected to be cleared imminently for introduction in the US in 2003. It is likely that Bollgard® I will be phased out of commercial production in the US after Bollgard® II becomes available. Bollgard® II is an important new element in the insect resistant management strategy for cotton insect pests; in conjunction with refugia, it provides an additional important tool for facilitating the implementation of IPM, and for optimizing the durability of Bt genes and the multiple and significant benefits they offer.

2.3 Distribution of Transgenic Crops, by Crop

The distribution of the global transgenic crop area for the four major crops is illustrated in Figure 4 for the period 1996 to 2002. It clearly shows the dominance of transgenic soybean occupying 62% of the global area of transgenic crops in 2002; the entire transgenic soybean hectarage is herbicide tolerant. Transgenic soybean retained its position in 2002 as the transgenic crop occupying the largest area. Globally, transgenic soybean occupied 36.5 million hectares in 2002, with transgenic maize in second place at 12.4 million hectares, transgenic cotton in third place at 6.8 million hectares, and canola at 3.0 million hectares (Table 4).

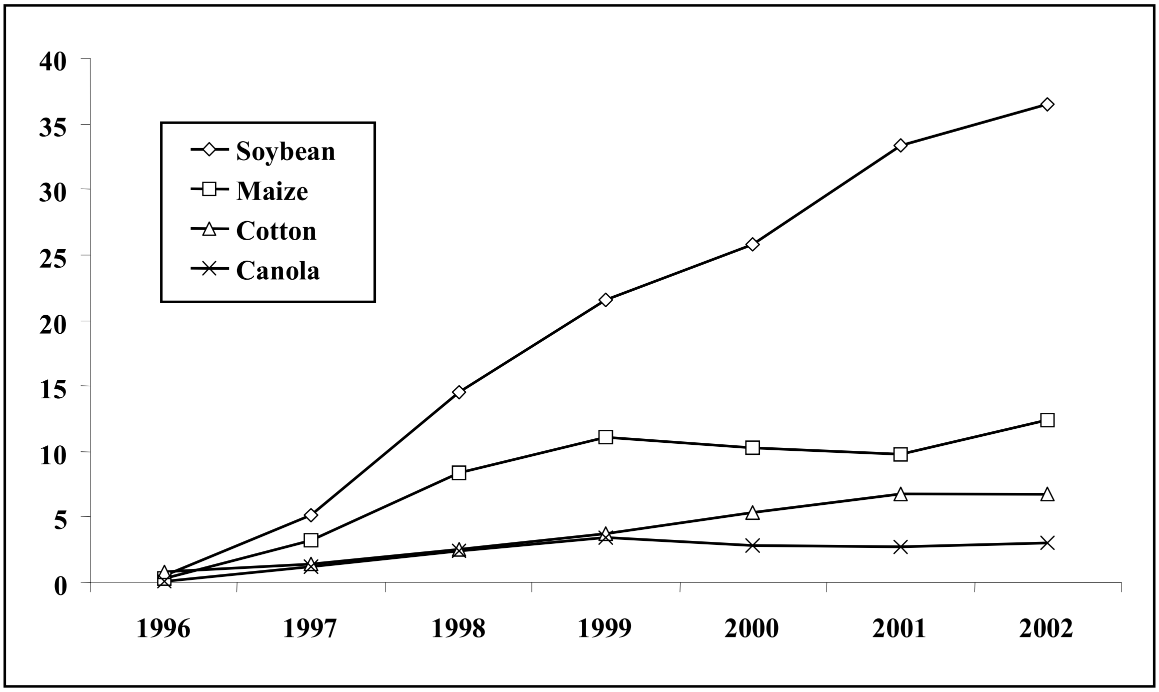
In 2002, the global hectarage of herbicide tolerant soybean is estimated to have increased by 3.2 million hectares, equivalent to a 10% increase. Gains of approximately 1.2 million hectares of transgenic soybean were reported for the USA in 2002 with 75% to 79% of the national soybean area of 29.5 million hectares planted to RR® soybean. Argentina reported a gain of 1.7 million hectares of GM soybean with adoption rates estimated at 99% of the 12.8 million hectares of soybeans grown in 2002; this is a remarkable achievement given the state of the economy in Argentina.

Whereas transgenic maize area decreased globally by about 500,000 hectares in 2001, it increased by a substantial 2.6 million hectares globally in 2002 with most of the increase occurring in the US (Table 4). Increases in transgenic maize were also reported for Argentina, South Africa and Spain. In South Africa, Bt yellow maize used for feed increased from 160,000 hectares (14%) of the crop in 2001 to 175,000 hectares, equivalent to 20% of the yellow maize crop in 2002. Notably, Bt white maize, used for food, first introduced in 2001 on 6,000 hectares equivalent to 0.3 % of the total white maize area, increased ten fold to 58,000 hectares, equivalent to 3 % of the 2002 white maize crop of 2.1 million hectares.

The area planted to cotton in the USA in 2002 was approximately 10% less than in 2001 and the GM cotton area was also down by approximately the same percentage. The combined decrease in GM cotton in the US and Australia of just over 0.6 million hectares was offset by an equal increase of Bt cotton in China and other countries resulting in the same GM cotton hectarage for 2001 and 2002.

The global area of transgenic canola in 2002 is estimated to have increased by 0.3 million hectares, from 2.7 million hectares in 2001 to an estimated 3.0 million hectares in 2002 with the increase equally shared between Canada and the US. In Canada 2.59 million hectares of the total of 4 million hectares of canola in 2002 was GM herbicide tolerant, with an additional 20% of mutagenic herbicide tolerant canola leaving only 16% of conventional canola.

Figure 4. Global Area of Transgenic Crops, 1996 to 2002: by Crop (Million Hectares)



Source: Clive James, 2002.

Table 4. Global Area of Transgenic Crops in 2001 and 2002: by Crop (Millions of Hectares)

Crop	2001	%	2002	%	+/-	%
Soybean	33.3	63	36.5	62	+ 3.2	+ 10
Maize	9.8	19	12.4	21	+ 2.6	+ 27
Cotton	6.8	13	6.8	12	0.0	- -
Canola	2.7	5	3.0	5	+ 0.3	+ 11
Squash	<0.1	<1	<0.1	<1	(- -)	- -
Papaya	<0.1	<1	<0.1	<1	(- -)	- -
Total	**52.6**	**100**	**58.7**	**100**	**+ 6.1**	**+ 19**

Source: Clive James, 2002.

2.4 Distribution of Transgenic Crops, by Trait

During the seven-year period 1996 to 2002, herbicide tolerance has consistently been the dominant trait with insect resistance being second (Figure 5). In 2002, herbicide tolerance, deployed in soybean, maize and cotton, occupied 75% of the 58.7 million hectares (Table 5), with 10.1 million hectares planted to Bt crops equivalent to 17%, and stacked genes for herbicide tolerance and insect resistance deployed in both cotton and maize occupying 8% of the global transgenic area in 2002. It is noteworthy that the area of herbicide tolerant crops increased significantly by 9% (3.6 million hectares) whereas the Bt crops increased at a much higher rate of 29% (2.3 million hectares) between 2001 and 2002. This increase in Bt crops reflects the significant increase in Bt maize in 2002, most of which occurred in the US, following higher infestation levels of European corn borer in 2001 compared with 2000. However, increases in Bt maize hectarage also occurred in Argentina and South Africa. The largest increase in GM maize in 2002 was in the single Bt gene. The stacked genes of Bt/herbicide tolerance, in both maize and cotton at 4.4 million hectares in 2002, gained 0.2 million hectares equivalent to a 5% increase over 2001.

2.5 Dominant Transgenic Crops in 2002

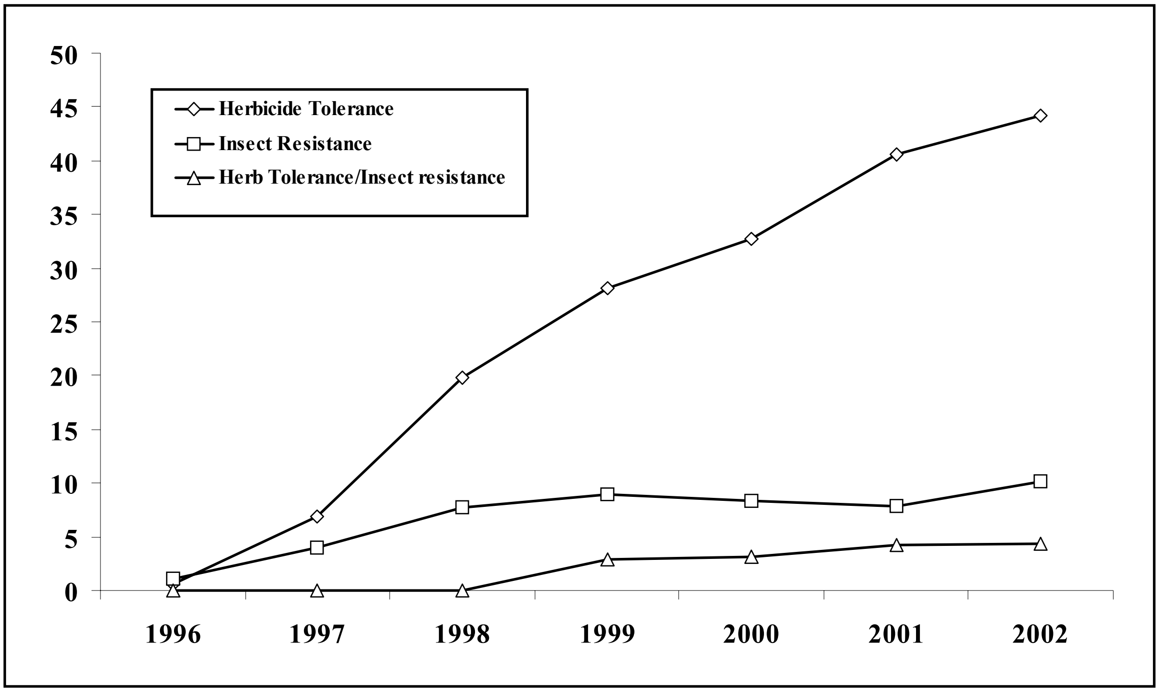
Herbicide tolerant soybean continued to be the dominant transgenic crop grown commercially in seven countries in 2002 – USA, Argentina, Canada, Mexico, Romania, Uruguay and South Africa (Table 6). Globally, herbicide tolerant soybean occupied 36.5 million hectares, representing 62% of the global transgenic crop area of 58.7 million hectares for all crops. The second most dominant crop was Bt maize, which occupied 7.7 million hectares, equivalent to 13% of global transgenic area and planted in seven countries – USA, Canada, Argentina, South Africa, Spain, Honduras and

Table 5. Global Area of Transgenic Crops in 2001 and 2002: by Trait (Millions of Hectares).

Trait	2001	%	2002	%	+/-	%
Herbicide tolerance	40.6	77	44.2	75	+ 3.6	+ 9
Insect resistance (Bt)	7.8	15	10.1	17	+ 2.3	+ 29
Bt/Herbicide tolerance	4.2	8	4.4	8	+ 0.2	+ 5
Virus resistance/Other	<0.1	<1	<0.1	<1	< 0.1	- -
Global Totals	**52.6**	**100**	**58.7**	**100**	**+ 6.1**	**+ 12**

Source: Clive James, 2002.

Figure 5. Global Area of Transgenic Crops, 1996 to 2002: by Trait (Million Hectares)



Source: Clive James, 2002.

Table 6. Dominant Transgenic Crops, 2002

Crop	Million Hectares	% Transgenic
Herbicide tolerant Soybean	36.5	62
Bt Maize	7.7	13
Herbicide tolerant Canola	3.0	5
Herbicide tolerant Maize	2.5	4
Bt Cotton	2.4	4
Herbicide tolerant Cotton	2.2	4
Bt/Herbicide tolerant Cotton	2.2	4
Bt/Herbicide tolerant Maize	2.2	4
Total	**58.7**	**100**

Source: Clive James, 2002.

Germany. The third most dominant crop was herbicide tolerant canola, which occupied 3.0 million hectares, equivalent to 5% of global transgenic area and planted in two countries, Canada and the USA. The other five crops listed in Table 6 all occupy 4% each of global transgenic crop area and include, in descending order of area: herbicide tolerant maize on 2.5 million hectares (4%); Bt cotton on 2.4 million hectares (4%); herbicide tolerant cotton on 2.2 million hectares (4%); Bt/herbicide tolerant cotton on 2.2 million hectares (4%); and Bt/ herbicide tolerant maize on 2.2 million hectares (4%).

2.6 Global Adoption of Transgenic Soybean, Maize, Cotton and Canola

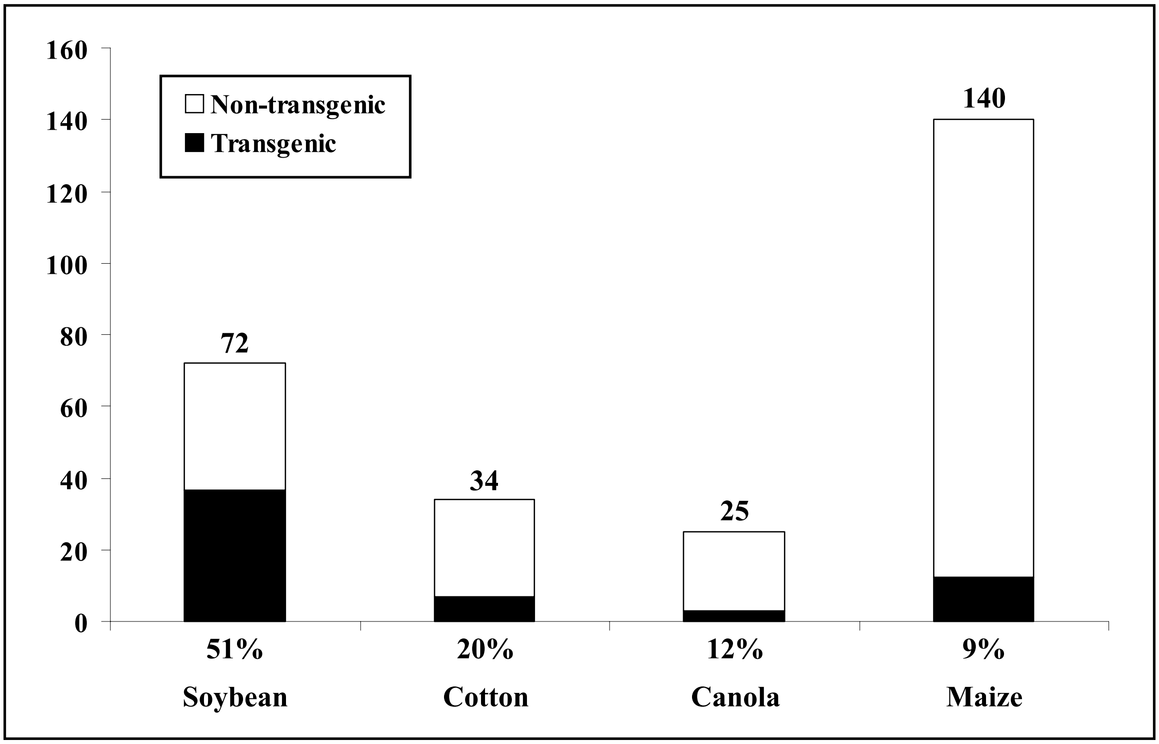
One useful way to portray a global perspective of the status of transgenic crops is to characterize the global adoption rates of the four principal crops – soybean, cotton, canola and maize – in which transgenic technology is utilized (Table 7 and Figure 6). The data indicate that in 2002, 51% of the 72 million hectares of soybean planted globally were transgenic - up from 46 % in 2001. Of the 34 million hectares of cotton, 20% or 6.8 million hectares were planted to transgenic cotton in 2002. The area planted to transgenic canola, expressed on percentage basis, increased from 11% in 2001 to 12 % or 3.0 million hectares of the 25 million hectares of canola planted globally in 2002. Similarly, of the 140 million hectares of maize planted in 2002, 9% was planted to GM maize up significantly from 7% in 2001. If the global areas (conventional and transgenic) of these four crops are aggregated, the total area is 271 million hectares, of which almost 22%, were GM - up from 19% in 2001. It is noteworthy that two-thirds of these 271 million hectares are in the developing countries where yields are lower, constraints are greater, and the need for improved production of food, feed, and fiber crops is the greatest.

Table 7. Transgenic Crop Area as % of Global Area of Principal Crops, 2002 (Million Hectares)

Crop	Global Area	Transgenic Crop Area	Transgenic Area as % of Global Area
Soybean	72	36.5	51
Cotton	34	6.8	20
Canola	25	3.0	12
Maize	140	12.4	9
Total	**271**	**58.7**	**22**

Source: Clive James, 2002.

Figure 6. Global Adoption Rates (%) for Principal Transgenic Crops (Million Hectares), 2002



Source: Clive James, 2002.

2.7 The Future

The experience of the past is often the best guide for the future. The experience of the first seven years, 1996 to 2002, during which a cumulative total of over 235 million hectares (over 580 million acres) of transgenic crops were planted globally in 19 countries, has confirmed that the early promise of biotechnology has been fulfilled. GM crops deliver substantial agronomic, environmental, economic and social benefits to farmers and, increasingly, to society at large. GM crops have met the expectations of large and small farmers planting transgenic crops in both industrial and developing countries.

The most compelling case for biotechnology, and more specifically GM crops, are their capability to contribute to: increasing crop productivity and thus contribute to global food, feed and fiber security; conserving biodiversity, as a land saving technology capable of higher productivity; more efficient use of external inputs and thus a more sustainable agriculture and environment; increasing stability of production to lessen the suffering during famines due to abiotic and biotic stresses; to the improvement of economic and social benefits and the alleviation of abject poverty in developing countries. It is critical that a combination of conventional and biotechnology applications be adopted as the technology component of a global food, feed and fiber security strategy that also addresses other critical issues including population control and improved food, feed and fiber distribution. Adoption of such a strategy will allow society to continue to benefit from the vital contribution that plant breeding offers the global population. GM crops offer the following important contributions:

- **Increase crop productivity and contribute to global food, feed and fiber security.**
  GM crops can contribute to continued annual increments in productivity achieved through genetic gains, which can also generate healthier and more nutritious food/feed products. For example, in 2001 the eight GM crops deployed in the US increased crop production by 1.7 billion kgs. and herbicide tolerant soybean in Argentina yielded 10% more than conventional soybean. Bt cotton in China increased seed cotton production by 514,000 metric tons.

- **Conserving biodiversity through the use of GM crops as a land saving technology.**
  Capability for increasing crop productivity per unit of land makes GM crops a land saving technology which, combined with conventional technology, will increase the probability that crop production can be confined to the current 1.5 billion hectares of global cultivable land where sustainable agriculture can be practiced. This will help ensure the conservation of the fragile ecosystems and environments, the in-situ centers of biodiversity, the wild life and the forests for future generations. Thirteen million hectares of forest, which are havens of biodiversity and provide watershed control, are lost every year in the developing countries to agricultural and industrial expansion.

- **More efficient use of external inputs and a more sustainable environment.**
  GM crops allow more efficient use of external inputs. To-date the use of GM crop protection applications as alternates for some conventional pesticide applications, using herbicide tolerance and/or Bt genes in soybean, maize, cotton, and canola have resulted in substantial savings in conventional pesticides. In the US in 2001, herbicide tolerant and Bt crops reduced conventional pesticide use by 20.7 million kgs. of active ingredient (a.i.) with positive implications for the environment. Similarly, in China in 2001, insecticide application on cotton was reduced by 78,000 tons of formulated product due to the deployment of 1.5 million hectares of

Bt cotton. The potential global saving of insecticides through optimizing deployment of Bt cotton alone is estimated at 33,000 metric tons (a.i) of the 81,200 tons (a.i.) applied globally on cotton in 2001. Biotechnology applications in the R&D pipeline may offer significant savings in fertilizer usage by increasing the efficiency of fertilizer use on crops which in turn will reduce the additional fertilizer needs and modulate fertilizer run-off into watersheds, aquifers and coastal waters.

- **Increasing stability of crop production to lessen suffering during famines caused by abiotic and biotic stresses.**
  The annals of history confirm that famines often result from instability of yield due to drought, unfavorable weather patterns, pest infestations and disease epidemics. Biotechnology offers the best promise for reducing the variability in yield due to both abiotic and biotic stresses, especially a complex trait such as drought tolerance; drought is a pervasive constraint that applies to at least one third of the 1.5 billion hectares of global cultivable land.

- **Economic and social benefits and alleviation of poverty.**
  Economic benefits from GM crops are substantial and apply to both small farmers in developing countries and large farmers in industrial countries. Farmers, not the developers of the technology, are the major beneficiaries from GM crops. In the US in 2001, the net economic gain to producers of GM crops was estimated at $1.5 billion. In China the economic gain for resource-poor Bt cotton farmers was $500/hectare equivalent to a national benefit of $750 million in 2001. Of the 5 million GM farmers globally in 2001, over 75% were small resource-poor cotton farmers mainly in China, as well as several thousand in the Makhathini Flats in South Africa. These resource-poor farmers derived significant economic benefits from Bt cotton, supporting the 2001 UNDP Human Development Report thesis that biotechnology can contribute to the alleviation of poverty. In terms of social benefits, GM crops significantly increase income and save time, which is particularly valuable for small resource-poor farmers in developing countries. In China, the increased income allows poor farm families to spend more on food and increase nutritional standards. In South Africa, where 50% of the cotton farmers are women, cultivation of Bt cotton allows them more time to care for children, the sick, and/or generate additional income from other activities.

The opportunities and constraints associated with public acceptance of transgenic crops continue to be important challenges facing the global community. Because of our thrice-daily dependency on food, agriculture touches the life of every individual in the global community of over 6 billion people. Unlike industrial countries, such as the US and countries of the European Union, with few exceptions, all developing countries are net importers rather than exporters of food, and where a high percentage of the population employed in agriculture are either small resource-poor farmers practicing subsistence farming or the rural landless who are dependent on agriculture for survival; 70% of the world's 1.3 billion poorest people are rural people, the majority of them resource-poor farmers and their families. Agricultural employment, as a percentage of total employment, was 80% in the developing countries in 1950, and is still projected to be 50% in 2010 when the population of the developing countries will be approximately 6 billion, equivalent to the global population of today. Improved food, feed and fiber crops derived from appropriate conventional and biotechnology applications for small resource-poor farmers are vital for increasing productivity and income to provide access to food in the rural areas where the majority of the poverty, hunger and malnutrition exists. Crops are not only the principal source of food but are the livelihood of farmers and agricultural workers. Increased crop productivity provides more employment and acts as the engine of economic growth in the rural communities. Producing more food, feed and fiber on small resource-poor subsistence farms, where most of it is consumed, has the significant advantage that the inevitable infrastructure constraints associated with transport can, to a large extent, be circumvented in that the produce is largely consumed at the same locations where it is produced.

Global society must seek equitable solutions that meet the different needs of people and nations and respect differing opinions re GM crops. Implementing an equitable policy is a challenge in a world where globalization, a web of international protocols and international trade are all impacting on the ability of sovereign nations in the developing world to access and utilize biotechnology and GM crops in their national food, feed and fiber security strategies, to meet domestic and export needs. This does not imply that biotechnology and GM crops are panaceas. Biotechnology, like any other technology, has strengths and weaknesses and needs to be managed responsibly and effectively as one tool in a toolbox of options. Biotechnology represents one essential link in a long and complex chain that must be in place to develop and deliver more productive crops, which are urgently required by small resource-poor farmers in developing countries. This will require the political will, goodwill and unfailing support of both the public and private sectors in the industrial and developing countries to work together in harmony, as pledged during the recent World Summit on Sustainable Development held in Johannesburg, August 2002.

From a technology viewpoint, the annual $4.4 billion investment in R&D in crop biotechnology, $4.22 million of which is invested by the industrial countries, represents a substantial investment which has delivered a new generation of safe and effective new products that have already had substantial impact on agriculture. The growing R&D investments in crop biotechnology by developing countries, notably by China and also by India, are seminal initiatives that other developing countries should carefully note. Special interest groups that are supporting on-going moratoria and requiring more demanding regulations are slowing the registration of products, which in turn will probably delay, by a few years, the planned delivery of quality traits that can deliver direct benefits to consumers. However, the current focus by industry on developing products will continue to generate a flow of new products, whilst striving to maintain longer-term R&D investments. Nutritionally-enhanced food products such as increased beta-carotene-containing rice and canola and enhanced animal feed products like increased lysine-containing maize continue to move forward, as do other nutritional enhancements in oil content, increases in protein content, and other nutritional properties.

New input trait products from industry include the dual Bt gene, Bollgard® II cotton product, approved in Australia in 2002, and expected to be available in the US in 2003, with another dual Bt gene cotton becoming available in 2004 as well as an insect resistant cotton with a novel Bt gene. A new trait in maize for the North American market, for corn rootworm control, will probably be available in the US in 2003. Over the next few years the availability of the corn rootworm trait should contribute to significant growth in GM maize acreage in the US, where approximately 18% of the maize hectarage of 31million hectares, currently treated with insecticides for corn rootworm, is likely to benefit rapidly from the technology. There is a significant overlap between areas infested with European corn borer and corn rootworm, and therefore some of the new products will have stacked traits for the control of these two insect pests, and other secondary pests. The global GM maize area with insect resistance and herbicide tolerance traits, as well as the stacked traits, is likely to increase significantly in the near term. This expansion of GM maize in the global hectarage of 140 million hectares will occur mainly in established GM country markets such as the US, Canada, South Africa and Argentina. GM maize will also be grown in new countries like the Philippines which introduced Bt yellow maize for the first time in 2003 for the control of Asian corn borer, and Honduras that grew pre-commercial Bt maize in 2002.

Bt cotton is also expected to increase significantly in 2003 and beyond as large established markets in countries like China and Australia continue to expand modestly, with significant new growth in India. Preliminary results from early harvests in India for Kharif 2002 suggest that Bt cotton is yielding 20 to 30% more than conventional cotton with a saving of at least half the number of insecticide sprays (a saving of 3 to 6 sprays) and that economic gains are in line with expectations. Modest growth in Bt cotton is also expected in new GM countries like Colombia that grew pre-commercial Bt cotton in 2002, and over the next few years there are likely to be more developing countries adopting the technology.

Despite the high rate of adoption in the US and market saturation in Argentina, herbicide tolerant soybean hectarage is likely to continue to grow on an absolute area basis in both countries and possibly modest growth in some new markets. Should Brazil approve RR® soybean then this would result in a significant one-step growth in the most important new and potentially large market for GM soybean globally.

Canola will probably feature in new markets such as Australia. Growth in GM canola will be modest, because the percentage of GM canola in Canada, which is by far the largest market, has plateaued at about 65% with a significant area (20%) in mutagenic herbicide tolerant canola, leaving only 16% conventional canola in Canada.

In the near term there is likely to be more balanced growth in GM crop area between the industrial and developing countries with the latter continuing to increase global share versus industrial countries. Countries in Eastern Europe are also likely to participate, which will feature the reintroduction of GM potatoes that performed extremely well in North America. Taking all factors into account, the outlook for the near term points to continued growth in the global hectarage of GM crops and the number of farmers. The global proportion of small farmers from developing countries growing GM crops is expected to increase as countries like India increase their GM hectarage of Bt cotton and approve other advanced products like GM mustard that are already under consideration. The increasing number and global share of resource–poor farmers growing and benefiting from GM crops has important implications because of the resulting economic, environmental and social benefits that contribute to the developmental goals of food, feed and fiber security and the alleviation of poverty.

In 2000 the market value of GM crops was $3.0 billion, increasing to $3.8 billion in 2001, when it represented over 12% of the $31 billion global crop protection market and 13% of the $30 billion global commercial seed market. In 2002 the global market value of GM crops is estimated to be approximately $4.25 billion. The market value of the global transgenic crop market is based on the sale price of transgenic seed plus any technology fees that apply. The global value of the GM crop market is projected at approximately $5 billion for 2005.

There is cause for cautious optimism that the global area and the number of farmers planting GM crops will again continue to grow in 2003, particularly in the six principal countries that grow GM crops - USA, Argentina, Canada, China, South Africa and Australia. Amongst the other ten countries growing transgenic crops in 2002, India is expected to increase its Bt cotton significantly and one or more new countries will also grow GM crops for the first time in 2003; Philippines approved Bt maize as its first commercial GM crop in early December 2002 with the first plantings in early 2003.

With India growing a GM crop for the first time in 2002 the three most populous countries in

Asia – China, India, and Indonesia, with 2.5 billion people, are all now commercializing GM crops. Two of the three major economies of Latin America – Argentina and Mexico are officially growing GM crops, plus South Africa on the African continent. In 2002 GM crops were grown in 16 countries with a combined population of 3.2 billion, living on six continents in the North and the South: Asia, Africa and Latin America and North America, Europe and Oceania. Thus, despite the continuing controversy about GM crops, the hectarage and number of farmers growing GM crops have continued to increase every year since their introduction in 1996, and for the first time in 2002, just over half the world's population live in countries where GM crops are officially approved and grown.

3. VALUE OF THE GLOBAL TRANSGENIC SEED MARKET, 1995 TO 2002

The value of the transgenic crop market is based on the sale price of transgenic seed plus any technology fees that apply. The estimates published here are the most recently revised estimates from Cropnosis Agrochemical Service (Cropnosis 2003) which exclude non-genetically modified herbicide tolerant seed. Global sales of transgenic seed have grown rapidly from 1995 onwards (Table 8). Initial global sales of transgenic seed were estimated at $1 million in 1995. Sales increased in value to $148 million in 1996, and increased by approximately $711 million in 1997 to reach $859 million. Sales increased by another $1,111 million between 1997 and 1998 to reach $1.97 billion in 1998. Sales continued to increase substantially in 1999 by an additional $977 million to reach $2.95 billion in 1999 and in 2000 plateaued at $3.044 billion. In 2001 there was a renewed significant increase of $795 million to $3.7 billion (revised), and the market exceeded $4.0 billion for the first time in 2002.

Table 8. Estimated Value of Global Transgenic Seed Market, 1995-2002 ($ Millions)

Year	Market Value $
1995	1
1996	148
1997	859
1998	1,970
1999	2,947
2000	3,044
2001	3,669
2002	**4,066**

Source: Cropnosis Agrochemical Service, 2003 (Personal Communication)

4. VALUE OF TRANSGENIC CROPS IN THE CONTEXT OF THE GLOBAL CROP PROTECTION MARKET

All the traits introduced to-date are crop protection traits, and thus it is useful and appropriate to discuss the value of total sales of transgenic crops as a percentage of the global crop protection market. Wood Mackenzie (2002) estimated that transgenic seed in 1998 accounted for 6.3% of the $31.25 billion global crop protection market at the ex-distributor market value. Between 1998 and 2002 the value of the transgenic seed market has increased steadily from 6.3% in 1998 to 9.5% in 2000, 12.4% in 2001 and 13.3% in 2002 (Table 9) equivalent to $ 4.066 billion out of a total crop protection market of $30.627 billion. It is noteworthy that the transgenic crops category is the only one of the five categories to show an increase in value between 2001 and 2002 (Table 9); transgenic crops increased by a significant 10.8%, whilst herbicides decreased by 6.8%, insecticides by –5.6% and fungicides by –0.3%.

The distribution of the sale of transgenic seed, based on value, is shown by region and product in Table 10. It is clear that the major market is in North America with its share valued at $2.947 billion equivalent to 73% of the global market; the second largest market is in Latin America with $837 million equivalent to 21% of the global market, followed by the Far East (developing countries of Asia) at $245 million or 6% of global market share. In terms of product, soybean has the major market share at $2.339 billion or 58% of the global market followed by cotton at $849 million (21%), maize at $ 658 million (16%) and canola $220 million (5%).

The data in Table 11 is a matrix of crop protection products, including GM biotech traits deployed in industrial and developing

Table 9. Global Crop Protection Market in 2002: by Product (Value in $ Millions)

Group	$ Millions	% Change from 2001
Herbicides	12,475	- 6.8%
Insecticides	7,314	- 5.6%
Fungicides	5,450	- 0.3%
Plant Growth Regulators and Others	1,322	- 1.9%
Transgenic Crops	4,066	+ 10.8%
Total	**30,627**	**- 3.1%**

Source: Cropnosis Agrochemical Service, 2003 (Personal Communication).

Table 10. Value of Global Transgenic Crops in 2002: by Crop and Region ($ Millions)

Crop	$ Millions
Soybean	2,339
Cotton	849
Maize	658
Canola	220
Total	**4,066**
Region	
North America	2,947
Latin America	837
West Europe	<2
East Europe	<3
Far East	245
Rest of the World	33
Total	**4,066**

Source: Cropnosis Agrochemical Service, 2003 (Personal Communication).

countries. It shows the relative distribution between industrial and developing countries in relation to the different types of pesticides. It is noteworthy that the value of the transgenic crop market in USA and Canada ($2.947 billion, Table 10) is already worth 10% of the global crop protection market of $31 billion and continues to grow annually – this compares with 3% for Latin America ($837 million), and <1% for the developing countries of the Far East. It is evident from the data in Table 11 that the value of the transgenic crop market is higher in the industrial countries, $2.966 billion equivalent to 73% of the global market, compared with $1.100 billion, equivalent to 27%, in the developing countries, 76% of which is in Latin America and with most of the balance in the Far East.

Of the total crop protection market of $20.309 billion in the industrial countries, $2.966 billion equivalent to 15% is transgenic crops. The corresponding figure for the developing countries is a total crop protection market of $10.318 billion of which transgenic crops are valued at $1.100 billion equivalent to 11%, up from 9% in 2001. Whereas, the value of the herbicide market in the industrial countries ($9.0 billion) is almost three times that in the developing countries ($3.5 billion), the countries of the South spend more on insecticides ($3.7 billion) than the countries in the North ($3.6 billion). However, the significant difference in herbicide usage between industrial and developing countries is likely to become less marked in the future. Agronomic practices such as zero or low tillage, availability, and cost of labor in developing countries will offer new opportunities for farmers to use more herbicide tolerant varieties, that allow improved conservation of moisture and nutrients that collectively contribute to a more sustainable agriculture. Efficient use of water in both rainfed and irrigated agriculture will become increasingly important and herbicide tolerance technology will be seen by farmers to be compatible with changing and emerging new needs.

Table 11. Global Crop Protection Market, 2002: by Industrial/Developing Country and Product ($ Millions)

	Herbicides	Insecticides	Fungicides	Others	Biotech	Total
Industrial Countries	9,004	3,617	3,757	965	2,966	**20,309**
Developing Countries	3,471	3,697	1,693	357	1,100	**10,318**
Total	**12,475**	**7,314**	**5,450**	**1,322**	**4,066**	**30,627**

Source: Cropnosis Agrochemical Service, 2003 (Personal Communication).

Of the total global crop protection market of $31 billion, about two-thirds is in the industrial countries ($20.309 billion) with the other one-third ($10.318 billion) in the developing countries (Table 11). The data in Table 12 indicate the global market share of the 14 principal countries in crop protection; the balance is assigned to the remaining "Others" category. Of the top 14 countries, 10 are industrial countries (USA, Japan, France, Canada, Germany, South Korea, Australia, Italy, UK and Spain) and four are developing countries (Brazil, China, Argentina and India). Expressed as a percentage of the global market, there are five countries with 5% or more of global market share.

The US is by far the biggest crop protection market (32% of the global $31 billion market), followed by Japan (9%), Brazil (7%), China (6%), and France (6%). The remaining ten countries listed in Table 12 have global market shares of between 2% and 4%. It is not surprising that the top four countries that grew 99% of the transgenic crops in 2002 (USA, Argentina, Canada, and China) are also in the top ten in the global crop protection market. Collectively the top four countries that grew transgenics in 2002 consumed 45% of the global pesticide market and are already benefiting from reduced and/or more efficient pesticide usage. Similarly, the four major transgenic crops, soybean, maize, cotton and canola include three out of the top five crops that consume pesticides globally (Table 13). Collectively, the four crops consume 38% of global pesticides and are already benefiting from reduced and/or more efficient pesticide usage, particularly in crops such as Bt cotton where major reductions are being realized in terms of insecticides and fewer health hazards to farmers in countries such as China and South Africa. Further reductions and increase in efficiencies in pesticide usage can be realized as more insect resistant crops and herbicide tolerant varieties are deployed. Coincidentally, these technologies will provide major benefits in terms of more flexible and improved conservation and management practices that farmers value highly and which collectively contribute to more sustainable farming systems.

Table 12. Global Crop Protection Market, in 2002: by Country Expressed as Percentage of Total Market

Country	% Global Market
USA	32
Japan	9
Brazil	7
China	6
France	6
Argentina	4
Canada	3
Germany	3
South Korea	3
Australia	2
India	2
Italy	2
UK	2
Spain	2
Others	17
Total	**100**

Source: Cropnosis Agrochemical Service, 2003 (Personal Communication).

Table 13. Global Crop Protection Market, in 2002: by Crop Expressed as Percentage of Total Market

Total Crop Protection Market by Crop	%
Fruit and Vegetables	25
Soybeans	15
Cereals	13
Maize	11
Cotton	10
Rice	9
Oilseed Rape/Canola	2
Sugar Beet	2
Other Crops	13
Total	**100**

Source: Cropnosis Agrochemical Service, 2003 (Personal Communication).

5. GLOBAL R&D EXPENDITURES IN CROP BIOTECHNOLOGY AND FUTURE GM CROP MARKETS

The advent of biotechnology in the early 1980s resulted in a significant change in the relative R&D investments of the public and private sectors in agriculture. Estimates of R&D investments in agricultural biotechnology in 1985 (Persley 1990) indicated that the total annual investments were $900 million with $550 million (61%) invested by the private sector and $350 million (39%) by the public sector. The life sciences concept embraced by the private sector in the early 1990s, which resulted in a spate of expensive acquisitions and mergers significantly increased the investment of industry in agricultural biotechnology. In 1995, R&D investment in agricultural biotechnology was $2 billion for the USA alone (James 1997b) and globally at $2.75 billion. Public sector investments in crop biotechnology continue to be substantial in the USA in 2001 and remain dominant in the global context. Australia is also committed to its public sector investments in crop biotechnology and three EU countries, UK, Germany and France, continue to support crop biotechnology. In Asia, Japan and South Korea have modest public sector investments in crop biotechnology (Kalaitzandonakes 2000).

In 1995 the private sector viewed crop biotechnology, prior to the commercialization of the first GM crops in 1996, as an important new opportunity for markets that would contribute to lowering crop production costs, increasing productivity, provide a safer environment and a more sustainable system for ensuring global food, feed and fiber security. Later in the 1990s the private sector judged the life science concept to be an inappropriate strategy for the future. There followed a series of spin-offs and mergers culminating in consolidation that resulted in six transnational North American and European based crop protection/biotechnology entities. By the late 90s, the rate of investments in R&D by the private sector in GM crops was slowing despite the fact that the technology had a great deal to offer society. The disincentive for industry was mainly the reluctance and strong opposition of the countries of the European Union to the commercialization of GM crops in the EU, with knock-on negative effects in developing countries and also the campaigns waged by some NGOs opposed to GM technology.

In 2001 and 2002, industry consolidated and restructured its crop biotechnology activities in order to conserve R & D investments. The current industry focus is on the commercialization of fewer products for the near-term market; this focus is expected to continue in 2003. The slower rate of investments by industry in mainstream GM crops has to some extent been offset by new investments in areas such as genomics and increased investments and interest by some key developing countries who view GM crops as important elements in their future strategy for food, feed and fiber security. Notable amongst the developing countries is China which made its initial investments in crop biotechnology in the mid 1980s. By 1999, there were 35 institutes in China conducting research on crop biotechnology with a staff of 1,200 plus another 800 staff at other institutions for a total of 2,000. The annual R&D budget in China for crop biotechnology in 1999 was $112 million (Huang et al 2002) with a commitment to increase it by 400% by 2005. China invests more than half of the R&D crop biotech budget of the developing countries estimated at $180 million. Other independent estimates by consultants suggest that crop biotechnology investments in China could be as high as $300 million (Kalaitzandonakes 2000). China, which conducts biotechnology research on 50 plant species and 120 functional genes, has approved 45 GM crop applications for field trials, 65 for environmental release, and 31 for commercialization. These crops include the three major food staples: rice for insect resistance (Bt and CpTi) and disease resistance (Xa 21), and herbicide and salt tolerance; wheat for BYDV virus disease resistance and quality improvement; and maize for insect resistance and quality improvement. As much as 90% of GM crop applications are focused on insect and disease resistance. About 9.2% of government R&D support for crop research is devoted to biotechnology (Huang et al 2002). The positive Chinese experience with Bt cotton provides home-grown evidence that some of the perceptions of antibiotech critics are not substantiated in practice and that the technology can deliver significant agronomic, economic, environmental health and social benefits to small resource-poor farmers and contribute to the alleviation of poverty.

India is also increasing its investment in crop biotechnology in both the public and private sectors. Following approval by the Government of India to commercialize Bt cotton in 2002, it was noteworthy that the Genetic Engineering Advisory Committee (GEAC) approved field trials of GM mustard and indicated its intent to consider applications for GM soybean and maize. The Indian Council of Agricultural Research (ICAR) is committed to biotechnology and is already developing its own Bt cotton and the indigenous private sector in India is increasing its investments in GM technology. It is estimated that India is investing $15 million per year in public sector research with an additional $10 million by the private sector for a total of $25 million.

In Latin America, Brazil is investing up to $3 million per year through its national agricultural research system, EMBRAPA, and The Sao Paulo Research Foundation is investing up to $10 million, plus private sector investment of $2 million for a total of $15 million per year.

Other developing countries that are investing in crop biotechnology include Pakistan and Malaysia, Thailand, Indonesia, Philippines and Vietnam in South East Asia. In Latin America, Brazil, Mexico, Cuba, Argentina and Chile have agricultural biotech activities. In Africa, the major investments are in South Africa, Egypt, Zimbabwe, and Kenya, with the President of Nigeria having committed $263 million per year in 2001, for three years for biotechnology in agriculture and medicine.

Table 14. Estimates of Global R&D Expenditures on Crop Biotechnology: 2001

	$ millions	
Industrial		**4,220**
Private	3,100	
Public	1,120	
Developing Countries**		**180**
China	115*	
India	25	
Brazil	15	
Others	25	
Total		**4,400**

Source: Compiled by Clive James, based on industry and public sector estimates. Global estimate for crop biotechnology of $4.4 billion courtesy of Freedonia Group Inc., 2002 Personal Communication. Breakdown of $4.4 billion from various other sources: * 1999 estimate (Huang et al 2002); public sector investments in China could be as high as $300 million (Kalaitzandonakes 2000): global investments in crop biotechnology (Huang et al 2002, James 1997b); ** Includes public (80%) and private sector (20%) expenditures.

Table 15. Global Value of Transgenic Crop Market 1996-2010

Year	Millions of $
1996	148
1997	859
1998	1,970
1999	2,947
2000	3,044
2001	3,839
2005	5,000
2010	10,000 to 15,000

Source: Wood Mackenzie estimates for 1996 to 2001, Projections by Clive James for 2005 and 2010

Reviewing investments by both the private and public sectors in crop biotechnology in 2001 (Table 14), the total R&D expenditure in crop biotechnology was estimated to be approximately $4.4 billion (Freedonia 2002). The industrial country investments (author estimates) comprised >95% of the total global investments at $4.22 billion, with the balance of $180 million invested by the developing countries, mainly by the public sector, with China investing the majority of the R&D resources. The success and return on investment that China has achieved with Bt cotton, which delivered total benefits of $750 million at a national level in 2001, of which at least half is attributable to the CAAS Bt cotton varieties, is an important experience that can catalyze and reinforce China's intent to quadruple its R&D investments to $450 million in crop biotechnology by 2005. Similar progress by India with Bt cotton could provide the incentive for India to accelerate and increase its investments in crop biotechnology.

A very recent paper (Huang and Wang 2003) reaffirms that Chinese policymakers view agricultural biotechnology as a strategic element for increasing productivity, improving national food security and being competitive internationally. China has stated that it intends to be one of the world leaders in biotechnology because Chinese policymakers have concluded that there are unacceptable risks with dependence on imported technologies for ensuring food security. It is noteworthy that despite the continuing debate on GM crops, China has not wavered in its commitment to biotechnology since its first investments in the mid 1980s and there are 12 GM crops being field-tested including maize and rice, prior to commercialization. The authors note that "the growth of government investment in agricultural biotechnology research has been remarkable". The research agenda has been formulated to meet national food/feed security objectives as well as the needs of farmers in high potential areas and the needs of small resource-poor farmers requiring abiotic and biotic stress resistant crops grown on marginal land. Huang and Wang 2003 note that China is cognizant of the need to better integrate its myriad of biotechnology activities and to improve biosafety management in order to ensure protection of the environment and consumers within the context of a more sustainable agriculture. The authors (Huang and Wang 2003) conclude that based on strong demand from both producers (higher productivity and profit) and consumers (more affordable prices), and the past success and increasing investments in agricultural biotechnology, "that products from China's plant biotechnology are likely to become widespread in China in the near future."

It is noteworthy that Pakistan, which has yet to deploy GM crops, has initiated collaboration with China in biotechnology as of August 2003, with particular focus on plant genomics. Pakistan has developed a national strategy in which improved crop yields have been assigned a high priority, with the Minister for Science and Technology declaring that "Pakistan can become a player in the global biotechnology market in the next three to five years". During the last three years Pakistan has invested $16.5

million in 50 biotechnology projects (Anonymous 2003).

China and India, the two most populous countries in the world, with a combined population of 2.3 billion and 250 million hectares of crop land could provide the role models and stimulus for other developing countries in Asia, Latin America, and Africa to make their own investments in crop biotechnology. The incentive for countries like China and India, two countries with a strong tradition in trading, is not only to develop GM products to meet their own food, feed and fiber needs, but also to develop new markets for their GM crops in other developing countries of the South, where the majority of the 1.5 billion hectares of crop land is cultivated, and where the need for food, feed and fiber is greatest.

Given the above status of R&D expenditures in crop biotechnology and the indications that global area of 58.7 million hectares of GM crops in 2002 will continue to grow in 2003 and beyond, the global deployment of GM crops is expected to increase to $5 billion by 2005 and up to $10 to $15 billion by 2010, (Table 15) with both agronomic and quality traits contributing to increased value. These estimates do not include the area of GM crops reported to be grown in countries such as Brazil, where official approval is still pending despite the fact that farmers have planted substantial areas of GM crops for several years.

6. OVERVIEW OF THE COMMERCIAL SEED INDUSTRY

The author estimates that, expressed as a proportion of the global commercial seed market, transgenic seed represents approximately 13% of the estimated $ 30 billion plus global commercial seed market in 2000 (FIS 2001).

Given that seed is the vehicle for incorporating and deploying transgenic traits, it is instructive to characterize the global commercial seed market to gain a sense of the scope, scale and size of the relative sub-segments of the global market classified by country, or seed, or exports. The latest estimate for the global commercial seed market is approximately $30 billion (FIS 2001), with almost 30% of the market in the developing countries. Six of the top ten country markets (Table 16) are in the industrial countries: USA ($ 5.7 billion), Japan ($ 2.5 billion), Commonwealth of Independent States ($ 2 billion), France ($ 1.4 billion), Germany ($ 1.0 billion) and Italy ($ 650 million). The four developing countries in the top ten are China ($ 3 billion), Brazil ($ 1.2 billion), Argentina ($ 930 million) and India ($900 million). Of the 13 countries that grew transgenic crops in 2000, nine are in the top twenty countries in terms of seed sales; the four exceptions are South Africa, Romania, Bulgaria and Uruguay.

Considering seed exports worldwide, the global market is valued at approximately $3.5 billion, equivalent to about 10% of the global market

Table 16. Latest Estimated Values (US $ Millions) of the Commercial Markets for Seed and Planting Material for the Top 20 Countries

Country	Internal Commercial Market
USA	5,700
China	3,000
Japan	2,500
CIS	2,000
France	1,370
Brazil	1,200
Germany	1,000
Argentina	930
India	900
Italy	650
United Kingdom	570
Canada	550
Poland	400
Mexico	350
Spain	300
Netherlands	300
Australia	280
Hungary	200
Denmark	200
Sweden	200
Total	**22,600***

* This total represents the sum of the commercial seed markets of the 20 listed countries. The commercial world seed market is assessed at US$ 30 billion.

Source: FIS, 2001.

valued at $30 billion (Appendix Table 1A). Maize is the most important seed export market, valued at $530 million annually. The top five crops that have export sales of more than $75 million annually are maize ($530 million), herbage crops ($427 million), potato ($400 million), beet ($308 million) and wheat ($75 million). Breaking down the seed export market by country, out of the top ten countries the top nine are industrial countries with annual exports of seeds valued from $799 million to $105 million. Given the ongoing debate in Europe re transgenic crops, it is noteworthy that approximately half of the global seed export sales are from European countries. Out of a total global market of $3.5 billion, the USA is ranked # 1 with $799 million (Appendix Table 2A), followed by the Netherlands ($620 million), France ($498 million), Denmark ($190 million), Germany ($185 million), Chile ($144 million) Canada ($122 million), Belgium ($111 million), Italy ($111 million) and Japan ($105 million) for a total of $ 2.9 billion. Only one of the top ten countries exporting seeds is a developing country - Chile with annual sales of $144 million.

7. OVERVIEW OF DEVELOPMENTS IN THE CROP BIOTECHNOLOGY INDUSTRY

The major developments in crop biotechnology in the private sector in 2002 are summarized in Table 17, as self explanatory events in the areas of acquisitions, mergers and spin-offs, genomics and product discovery, patents and licensing, re-registration, approvals and commercialization.

Table 17. Selected Highlights of Crop Biotechnology Developments in Industry, 2002

Month	Corporations and Organizations, Involved and Nature of Development
January	**APHIS** reported that one-third of the US states growing cotton have eliminated cotton boll weevil with the remaining two-thirds close to eliminating the pest following the treatment of 10 million acres with malathion.
February	In **Brazil**, one of the panel of three judges, Judge Selene Maria de Almeida, decided to lift the injunction on the ban of RR® soybeans in Brazil, whilst the other two judges requested more time to consider their judgement.
	Prodigene initiated commercial production of trypsin in plants. Production of trypsin in plants, as opposed to animals, has the advantage that: it precludes contamination with animal pathogens; lowers production costs and allows more flexibility to increase or decrease production. Trypsin is the third plant protein to be produced by Prodigene.
	Japan Tobacco licenced its PureIntro monocot transformation technology to **Dow Chemical Company.**
March	**Wood Mackenzie** reported that sales of agchemicals in 2001 fell by 6.5% to $27.1 billion. GM crops were cited as one of the reasons for the decline. Syngenta recorded the highest agchemical sales at $5.4 billion, followed by Aventis at $3.7 billion and Monsanto at $3.4 billion.
	USDA invited comments on **Monsanto's** request to deregulate two new Monsanto products: Event MON 863 that confers resistance to corn rootworm through the *cry3Bb1* gene and Bollgard® II Bt cotton containing the dual genes *cry2Ab* and *cry1Ac*.
	Bayer submitted its proposal for acquisition of Aventis CropScience for approval by the EU Commission.

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Table 17. Cont'd. Selected Highlights of Crop Biotechnology Developments in Industry, 2002

Month	Corporations and Organizations, Involved and Nature of Development
March	The Government of India approved three Bollgard® Bt cotton varieties for commercialization in India in 2002. The approval, granted to **Mahyco** (26% stake by Monsanto), was for the three hybrids, Mech–12, Mech–162 and Mech–184, is for three years and requires a 20% refuge. India has the largest cotton area in the world, but low yields, some of which are attributed to losses of 15% from cotton bollworm, which can be controlled by Bollgard® Bt cotton. The Genetic Engineering Approval Committee (GEAC) of the Indian Government stated it will now consider other GM crops including mustard, soybean and maize.
	Dow AgroSciences relocated its biotech R&D facilities from San Diego (formerly Mycogen labs.) to Dow's headquarters in Indianapolis.
	Affymetrix agreed to provide **Monsanto** with its Genechip technology for crop and disease development, using *Arabidopsis* as a model.
April	**Monsanto** and **DuPont** agreed to cross license their respective crop biotech applications relating to soybean, maize and canola.
	Myriad Genetics agreed to provide molecular genetic information to **Pioneer** to facilitate the development of improved seeds by Pioneer – the two year contract was valued at $24 million.
	The EU Commission approved **Bayer's** proposed acquisition of Aventis Crop Sciences for Euros 7.25 billion.
	Monsanto announced plans to reduce its workforce by 5%, equivalent to 700 positions. The majority of the downsizing will be in Asia and North America.
	The natural protein disease activator called Messenger (harpin) developed by **Eden Biosciences** received unconditional approval by EPA for use on all food commodities, fiber and other crops.
	Aventis CropScience and **Lynx Therapeutics** agreed to a five year extension of their collaboration to develop genomics discovery services.

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Table 17. Cont'd. Selected Highlights of Crop Biotechnology Developments in Industry, 2002

Month	Corporations and Organizations, Involved and Nature of Development
April	**Monsanto** and **Ceres** signed a $137 million contract for Ceres to develop genomic technologies for the improvement of crops by Monsanto. An important element of the collaboration is the commitment by both companies to make the technologies available to farmers in developing countries and for humanitarian initiatives not served by commercial markets.
	The joint venture between **Bayer** and **Exelixis**, called **Genoptera** announced the completion of the genomic sequence of the important pest, tobacco budworm, *Heliothis virescens*.
May	The Federal Trade Commission of the US approved the acquisition of **Aventis CropScience** by **Bayer**.
	The US farm bill was passed into law in the US authorizing approximately $180 billion to be spent on major crops during the six year period 2002 to 2007. This will impact on expenditures and subsidies on the principal GM crops, soybeans, maize, and cotton.
	The **Orynova** Joint Venture Agreement between **Syngenta** and **Japan Tobacco** was terminated. The initial 'joint venture', focused on rice biotechnology, was agreed to between Japan Tobacco and Zeneca which Syngenta acquired. Syngenta has acquired its appropriate rights for three rice hybrids and a low gluten rice. Japan Tobacco will continue its biotech research on crops including rice and maize using its patented monocot gene transformation system (PureIntro) to develop improved varieties of cereals.
	Delta and Pine Land founded the joint venture **DeltaMax Cotton LLC** with **MaxAg**, a subsidiary of Maxygen. The mission of the new joint venture is to develop and market GM traits for cotton. DPL has formed the joint venture in order to develop its own traits, which they expect to be available as of 2007.
	Delta and Pine Land and **Syngenta** signed an agreement in which insect resistant traits from Syngenta will be incorporated in well adapted cotton germplasm from Delta and Pine Land.

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Table 17. Cont'd. Selected Highlights of Crop Biotechnology Developments in Industry, 2002

Month	Corporations and Organizations, Involved and Nature of Development
June	**Bayer** announced the closure of its acquisition, **Aventis CropScience,** for \$6.6 billion, and the establishment of the new company **Bayer CropScience** that started operations at its Monheim headquarters in Germany on 4 June 2002. This represents a major consolidation and elevates Bayer CropScience to #1 in terms of reconfigured 2001 agrochemical sales at \$5.467 billion compared with Syngenta at \$5.385 billion and Monsanto at \$3.366 billion.
	Herculex® 1 Bt maize, that confers resistance to selected insect pests of maize, was approved for food and feed use in Japan. Herculex® 1 was co-developed by **Dow AgroSciences/Mycogen** and **DuPont/Pioneer**. Herculex® 1 has already been approved in the USA and approval is pending in Canada. Herculex® 1 has a new gene, *cry1Fa2* that confers effective control for the European corn borer, southwestern corn borer, fall armyworm, black cutworm, and intermediate control of corn earworm. Herculex® 1 is also tolerant to the herbicide glufosinate.
	Monsanto submitted an application to commercialize canola tolerant to glyphosate in Australia.
July	**Pharmacia** announced that it would spin off **Monsanto** by distributing its complete shareholding of 85% to current Pharmacia shareholders.
	Mahyco-Monsanto India Ltd. reported the launch of Bt cotton in India. Seed to plant approximately 45,000 hectares was sold mainly in areas where field trials have been conducted in recent years.
	Aventis CropScience submitted an application to commercialize glufosinate-tolerant canola in Australia; **Monsanto** submitted a similar application for glyphosate-tolerant canola in June 2002. The applications are being reviewed by the Australian Commonwealth Gene Regulator, which will review the data and conduct public consultations. The review is expected to be completed in mid 2003.
	Epicyte received a broad based US patent on production of antibodies in plants. The patent protects production of human or animal antibodies in plants for a market projected to reach \$8 billion by 2004; zip-codes of DNA sequences are used to control antibody production. Epicyte has also been granted analogous patents in Europe, Japan and Australia and has agreements with several companies, including **Dow Chemical** to produce antibodies.

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Table 17. Cont'd. Selected Highlights of Crop Biotechnology Developments in Industry, 2002

Month	Corporations and Organizations, Involved and Nature of Development
July	**Crop Design** (Belgium) agreed to provide **Stine Seed** (USA) with gene promoters for GM maize. The products of the collaboration will be the property of Crop Design, with Stine Seed receiving a non-exclusive licence to use the traits in their own germplasm.
	Prodigene signed an agreement with **Fibrogen** to produce a recombinant gelatin in maize, using Prodigene's proprietary technology for gelatin production.
August	**Prodigene** announced that it will implement Phase 1 clinical trials to test an oral vaccine that they have developed, in which the recombinant protein antigens were generated from GM maize plants.
September	**Monsanto** and **Dow AgroSciences** agreed to several non-exclusive cross licencing deals related to their respective insect resistant and herbicide tolerant traits. These arrangements involve Roundup Ready® and Bt from Monsanto and the Herculex® 1 Bt maize from Dow AgroSciences.
	Dow AgroSciences announced that it will downsize its workforce by 500 positions equivalent to a 5% reduction.
	Bayer CropScience reported that it has divested the products required by anti-trust authorities when the acquisition of Aventis CropScience was approved.
	Australia approved **Monsanto's** Bollgard® II cotton and the stacked genes for insect resistance and herbicide tolerance in Bollgard® II/Roundup Ready® cotton.
	Syngenta terminated its collaborative research project on wheat biotechnology with the John Innes Institute in the UK, initiated by Zeneca in 1999.
October	USDA announced the deregulation of **Monsanto's** new Bt maize (MON 863) with the Cry3Bb1 Bt toxin that confers resistance against corn rootworm. Environmental clearance from EPA for the product in the US is pending.

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Table 17. Cont'd. Selected Highlights of Crop Biotechnology Developments in Industry, 2002

Month	Corporations and Organizations, Involved and Nature of Development
October	**Dow Chemical** signed an agreement with the **University of Osaka** in Japan to exclusively acquire patents for the production of glycans in plants; glycans are necessary for the production of protein-related therapeutics. Using plants to produce glycans results in significantly lower production costs and Dow has agreements with **Epicyte Pharmaceuticals** to produce glycans in plants.
November	**Australia** delayed approval of herbicide tolerant canola until early 2003, pending finalization of documentation on technology stewardship and crop management.
December	**Monsanto** announced that Bollgard® II cotton gained full regulatory approval for commercial production in the US.
	Monsanto announced approval in the Philippines of Bt maize containing the *cry1Ab* gene that confers resistance to Asian corn borer which is a major pest in most parts of Asia. Bt maize is the first GM crop to be approved in the Philippines and the first major feed/food crop to be approved in Asia where Bt cotton has been approved in several countries.
	Syngenta and **Diversa** (US genomic company) signed a seven year $118 million agreement to jointly develop products in crop biotechnology, antibody production and for biopharma products.
	Syngenta's plant genomic activities will be re-located from the Torrey Mesa Institute in La Jolla, California, to Syngenta's facililty at Research Triangle Park, North Carolina.
	DuPont and **Bunge Ltd**. formed a joint venture called **Solae** for the production of speciality food ingredients. Protein Technologies of DuPont will be involved in the joint venture and will work with Bunge's food ingredients initiative.
	Agrinomia (Bayer CropScience and Exelixis joint venture) and **Renessen** (Monsanto and Cargill joint venture) agreed to collaborate to improve oil content of oil seed crops.
	Aventis/Bayer CropScience requested USDA to deregulate a GM cotton with a gene that confers tolerance to the herbicide glufosinate. Pending approval it is expected that limited quantities of seed of the GM cotton would be available for commercialization in 2003.

Source: Compiled by Clive James (2002) from various sources, including Wood MacKenzie.

8. Bt MAIZE

8.1 Introduction

This chapter is devoted to assessing the performance to-date of Bt maize/corn with the *cry1Ab* gene on a global basis; to assessing the future global potential for Bt maize, or maize with other novel genes that confer resistance to the major caterpillar/moths (Lepidoptera), particularly the borer complex; and a preliminary assessment of the new gene *cry3Bb1* for control of corn rootworm (Coleoptera). This complex includes a variety of species, such as *Ostrinia nubilalis, Ostrinia furnacalis, Diatraea grandiosella, Diatraea saccharalis, Elasmopalpas lignosellus, Sesamia cretica, Busceola fusca* and *Chilo partellus*. Other lepidopteran pests of maize, such as *Spodoptera frugiperda* and *Helicoverpa zea*, are important only in some countries. The corn rootworm pest complex (*Diabrotica spp.*) is a major economic pest of maize in the US and is also present in other countries in North and Latin America, including Canada, Mexico, Argentina and Brazil. Corn rootworm has also been detected in thirteen countries in Europe. In this text the words corn, used in North America, and maize, used more commonly elsewhere in the world, are synonymous, with maize being used consistently in this chapter, except for common names like corn rootworm where global usage dictates the use of the word corn. Unless otherwise stated, metric tonnes (MT) will be used throughout this document. The current methods for pest management in maize rely mainly on insecticides but farmers also use cultural practices, such as early planting and the use of biological control agents within the context of an integrated pest management (IPM) strategy. During the last seven years several countries have adopted genetically modified crops, featuring the Bt genes to control some of the principal pests of maize. Bt maize varieties expressing the *cry1Ab* gene were first adopted commercially seven years ago in 1996. In 2002, varieties with this Bt gene were deployed commercially in seven countries, four industrial countries (USA, Canada, Spain and Germany) and three developing countries, Argentina, South Africa and Honduras (pre-commercial); Philippines approved Bt maize in December 2002 and planted the crop for the first time in 2003. There is now considerable published and unpublished field trial and survey data, generated from independent studies by public sector institutions, that can be used to assess the impact of the commercialization of Bt maize to-date. These studies have documented its production, and the associated environmental, health, economic, and social impacts, in large and small scale farming systems, in developing and industrialized countries.

The content of this chapter is structured chronologically to provide the reader with a global overview of the maize crop, to present available data for assessing the performance of Bt maize to-date and to project its future global potential. The focus on developing countries is consistent with ISAAA's mission to assist developing countries in assessing the potential of new crop biotechnology applications. The principal aim is to present a consolidated set of data that will facilitate a knowledge-based discussion of the potential benefits and risks that Bt maize offers global society. The topics presented in this chapter are:

- The maize crop and its origins
- Global distribution of maize in developing and industrial countries, by area, production, consumption, imports, and exports as well as areas sown to hybrids, OPVs and farmer-saved seed and number of maize farmers and size of farms
- Maize production systems and maize germplasm development
- Maize utilization
- Maize demand in 1997 and projected for 2020
- Insect pests of maize
- Crop losses due to insect pests of maize and benefits from Bt maize
- The global maize insecticide market
- Use of Bt genes in maize and its global adoption and benefits
- Potential effect of maize on the environment
- Insect Resistance Management (IRM)
- Food and feed safety aspects of Bt maize
- Mycotoxins
- Trade issues
- Global potential for Bt maize: opportunities and challenges.

8.2 The Maize Crop and its Origins

Maize originated in Mexico about 6,000 to 7,000 years ago (Smith 1995). Maize is now the most prevalent cereal in many different global regions and is grown in more varied environments than any other cereal. Maize (*Zea mays. L*) belongs to the Graminae family which includes all the cereals and grasses. The closest relative of domesticated maize is the annual teosinte, which grows in Mexico, Guatemala and Nicaragua, and is thought to be the ancestor of maize as it has the same number of chromosomes (10). Maize has no known wild relatives of the same genera. Teosinte and maize can hybridize and produce fertile progeny under some circumstances, although gene flow from maize to teosinte is very limited due to a genetic barrier (Evans and Kermicle 2001). A major difference between the two genera is that teosinte disperses its own seeds, whereas maize does not.

The oldest evidence of domesticated maize is from archaeological sites in Mexico dating back 7,000 years, almost coincidental with the beginning of agriculture 10,000 years ago. It is most likely that maize spread from its center of origin in Mexico to Central and Latin America, the Caribbean and North America, although one hypothesis speculates that maize was also domesticated coincidentally in the Andean region by the Incas. In any event, European explorers of the Americas, transported maize to Europe and in turn, traders transported it to Asia and Africa.

The evolution of maize was strongly influenced by human beings, who probably initially selected ears from the annual self-sowing teosinte. By 1000 AD, this human intervention had resulted in the more productive multi-rowed maize ear that we know today. However, from a genome conservation viewpoint, because maize is an open-pollinated plant, it is important to acknowledge that much cross-pollination occurred during this process of selection. By the time Columbus arrived in Cuba in 1492, maize was being grown widely as a food crop. Columbus took some yellow flint maize from Cuba back to Spain and by the 1500s Portuguese and Spanish traders had introduced it to many other parts of the world. Arab traders probably introduced it to India and Pakistan along the silk route. By the mid 1600s, before the arrival of Magellan, it was established in both Thailand and the Philippines. By the mid 1700s, it was grown in southern China and it became established as a new food in both Japan and Korea (Dowswell et al 1996).

In the 19th century, 'farmer seedsmen' in the United States made significant progress with selection and developed some very productive open pollinated maize varieties. Crosses between the hard flints from the East and the soft dents from the South resulted in the first generation of high yielding dent varieties in the corn belt. By the 20th century knowledge of Mendelian genetics lead to the revolutionary hybrids that were developed in the US corn belt and are now used on 95 million of the 140 million hectares of maize grown throughout the world today.

Maize seed, planted at an appropriate depth in soil with adequate moisture, will emerge in about 8 to 14 days depending on temperature. Initially the maize seedling depends on the starch in the seed but quickly becomes self-sufficient for nutrients and does not require much moisture to survive. From emergence to tasseling, the vegetative period, maize, with its large broad leaves and very efficient C4 photosynthetic system, effectively utilizes the power of the sun to operate at full capacity. Prior to silking, maize is susceptible to moisture stress, which can reduce yields and fertility significantly. The critical stage for grain production is when the silks, emerging from the developing ears, are pollinated by pollen grains shed by the tassels during a one to two week period. Pollination occurs in 24 hours when the pollen tube grows down the length of the silk and fertilizes the ovule to form a kernel – about 2 to 3 days are required for all silks to be pollinated to form a complete ear of kernels. During the silking to maturity stage, the kernels fill and mature after which the 'dry-down' period begins, which eventually leads to kernels with about 15% moisture.

Of the three major world staples, maize is second only to wheat in total tonnage, with milled rice tonnage ranking third. Maize is the major cereal crop in Latin America and Africa and ranks third in Asia where about 90% of the world's rice is grown, as well as a significant production of wheat. In the industrial countries, maize ranks second after wheat. In 2002, 73 countries of which 53 were developing countries, and 20 were industrial countries, each harvested more than 100,000 hectares of maize (FAOSTATS 2002). Of all the cereals, maize is the most well adapted to different environments, growing at latitudes of up to 50^{O} North and South of the Equator, at altitudes up to 3,000 meters, in cool and hot climates, under irrigation, high rainfall or semi-arid conditions. The growing cycle for maize varies significantly depending on the environment, ranging from 3 months to 13 months (Dowswell et al 1996).

600 million MT of maize were produced globally in 2002 on about 140 million hectares of which approximately two-thirds were grown in developing countries. Despite the fact that only one–third of the production area was in industrial countries, these countries produced over half of global production. The average global yield in 2002 was 4.3 MT per hectare with a significant disparity between industrialized countries, with an average yield of over 6 MT/hectare, and developing countries, at half that level or about 3.0 MT/hectare. Under good management in a conducive environment, maize can yield 10 MT per hectare in the corn belt of the USA, or in France or Italy in Western Europe. However, resource-poor subsistence farmers in the developing countries will often only harvest 0.5 MT per hectare or less. The disparity in yield levels is a function of many factors related to the differences between high input, irrigated and mechanized production systems producing maize hybrids in industrial countries versus a low input system using land races and unimproved varieties grown in poor soils and arid conditions in many developing countries.

Whereas wheat and rice are used mainly as food for human consumption, maize is used in a much broader range of ways including food for human consumption, feed and fodder for animals and a multitude of industrial uses such as starch, sweeteners and ethanol production. Animal feed accounts for almost three-quarters of maize utilization in industrial countries whereas it remains the staple human food in many countries in Sub-Sahara Africa and Central America. Based on farmer and consumer preference, different types of maize germplasm are used around the world. Yellow maize hybrids are used in high-intensive maize production systems in industrial countries where animal feed and industrial uses predominate whilst in developing countries, low–input systems using lower yielding, unimproved white maize germplasm provide food for subsistence farmers. Maize grain types can be categorized into two major types by color and hardness – color, yellow maize for feed and white for food – hardness, flint grains which are hard and shiny and dent grains which are opaque with soft rather than hard starch.

Global trends in production indicate that in the last fifty years, in the industrial countries, about 90% of the increased production was contributed through increases in productivity, whereas in the developing countries only 50% was contributed by productivity increases with the other 50% gained through increasing areas planted to maize. The significant yield gap between industrial and developing countries, which still exists, has narrowed in the last decade and this trend is expected to continue in the future as developing countries are better able to access and deploy improved technologies, including GM crops such as Bt maize. Demand for maize is projected to increase significantly, particularly in the developing countries where population growth, income growth and change to diets incorporating more meat will fuel additional demand for maize relative to wheat and rice. Global trade in maize increased significantly from 15 million MT in 1950 to 80 million MT/year in 1980. Since the early 1980s, world trade has ranged between 60 and 75 million MT/year. International maize prices, adjusted for inflation, have declined from approx. $225 per MT in the 1960s to about $115 in the mid 1990s. The current nominal price per MT of No.2 yellow maize FOB from the Gulf Ports in the US in mid 2003 is $108 (World Bank 2003). Given that many countries do not participate in the international market for maize, domestic prices can vary significantly from the international price – this is the case for the European Union and particularly for many developing countries where prices can fluctuate significantly relative to demand and supply. Whereas it is stability that characterizes international maize prices, in contrast, it is significant fluctuations that characterize domestic markets, particularly developing country markets which are subject to more instability in domestic production and dumping of grain by exporters.

Future demand for maize is estimated to increase from around 600 million MT today to about 850 million MT in 2020 (IFPRI 2003), with major new shifts in favor of maize in developing countries. The world maize seed industry is expected to continue to respond and grow in line with increased market demand. Growth in maize production is expected to occur in both the industrial countries of North America and Europe, but most of the increased demand will have to be met by increased production in the developing countries where the proportion of imports is not expected to increase albeit that absolute tonnage of imports will increase. Accordingly, countries like China and India in Asia, Brazil and Mexico in Latin America, and South Africa on the African continent, will be required to increase productivity and production significantly if their future increased maize demands are to be met; in many developing countries, particularly Asia, the increased demand will be driven by a change in diets that require more meat which in turn requires more maize as feed.

Insect pests are estimated to decrease global production by more than 50 million MT annually. They will continue to be major constraints to reaching the needed increases in future productivity outlined above. The deployment of a number of Bt genes for the control of diverse insect pets is one of the most promising new technologies for capturing increased potential yields from improved maize germplasm. These potential yields are not being realized currently because of significant losses due to stem borers and other pests, for which Bt confers resistance. Additional benefits of deploying Bt technology are significantly decreased levels of harmful mycotoxins in food and feed products derived from maize grain and decreased dependency on insecticides, which may pollute the environment and endanger farmer health. These are important potential benefits associated with Bt maize that will be addressed and discussed in this chapter.

8.3 Global Distribution, Production, Imports and Exports

The global distribution of maize is shown in Figure 7 with each dot representing 75,000 MT per year.

8.3.1 Maize Distribution and Production

Of the approximate 140 million hectares of maize grown and harvested globally in 2002, two-thirds (66%) were grown in developing countries and one-third (34%) in industrial countries. Of the 92 million hectares in developing countries, 30% (42 million hectares) were in Asia, 19% (27 million hectares) in Latin America, and the balance of 17% (23 million hectares) in Africa (Table 18).

Of the top 10 maize producers in the world (Table 19), the USA accounts for almost 40% of global production, and China 20%, thus these two countries alone account for almost 60% of world production. In the top 10 maize

Table 18. Global Hectarage of Maize (Millions of Hectares) by Global Region, 2002

Region	Million of Has
Developing Countries	
Asia	42 (30%)
Latin America	27 (19%)
Africa	23 (17%)
Subtotal	92 (66%)
Industrial Countries	
North America	34 (25%)
Europe and Others	13 (9%)
Subtotal	47 (34%)
Global Total	**139 (100%)**

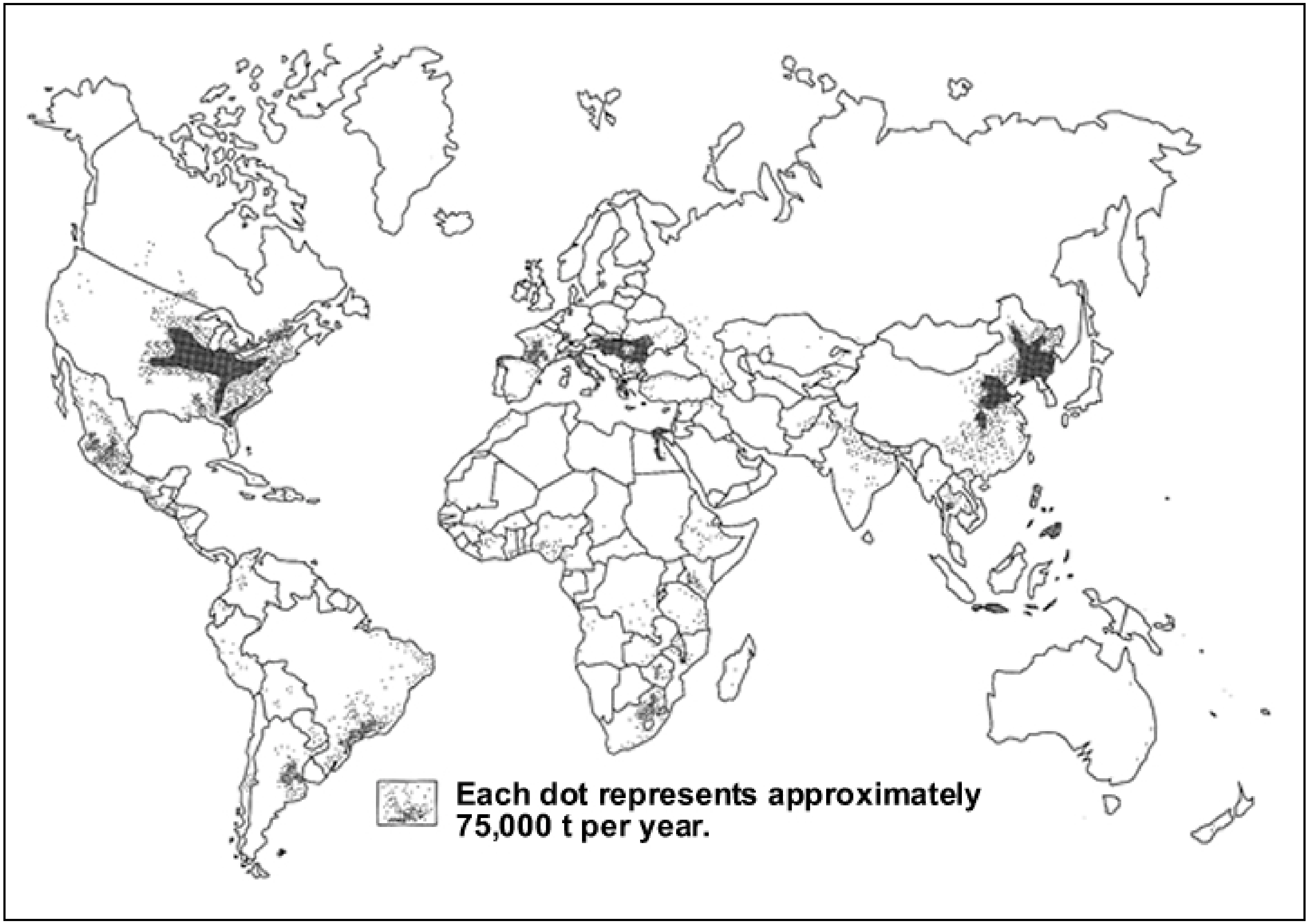
Source: FAOSTATS 2002.

Table 19. Top 10 Countries in Maize Production 2002

Country	Production (Million MT)
1. USA	228.7
2. China	124.2
3. Brazil	35.5
4. Mexico	19.0
5. France	16.0
6. Argentina	14.7
7. India	12.0
8. Italy	11.6
9. Indonesia	9.3
10. South Africa	9.1
Others	481.0
Global	**602.0**

Source: FAOSTATS 2002.

Figure 7. Distribution of World Maize Production



Source: Reproduced from Maize Seed Industries in Developing Countries, 1998. Ed M. Morris, with permission of CIMMYT; data is for early 1990s.

producers there are three industrial countries, USA, France and Italy, that together produce over 40% of world production, three countries from Asia, China, India and Indonesia, that produce one-quarter of world maize production, three countries from Latin America, Brazil, Mexico and Argentina, that account for over 10%, and finally South Africa on the African continent that produces between 1 and 2 % of world maize production.

The top 25 maize countries in the world, listed by harvested area, yield and production, are ranked in Table 20 – these countries account for almost 85% of world maize area and 95% of world production. Two countries stand out in terms of area and production, the USA with 28.5 million hectares and a production of 228.7 million MT, and China with 24.5 million hectares and a production of 124.2 million MT. Together these two countries, one industrial country from North America and one developing country in Asia, the most populous in the world, represent almost 40 % of the world maize area and 60% of world maize production. Yield is much higher in the USA at 8.0 MT/hectare compared with 5.1 MT/hectare for China. The third largest producer in the world is Brazil in Latin America with 11.8 million hectares, a production of 35.5 million MT with a yield of only 3.0 MT/hectare. Eight countries produce more than 10 million MT; listed in descending order, they are the USA, China, Brazil, Mexico, France, Argentina, India and Italy. Of the top 25 maize countries, it is noteworthy that only 8 are industrial or transitional economies - USA, Romania, France, Ukraine, Yugoslavia, Canada, Italy and Hungary, and 17 are developing countries: of these, 9 are in Africa, South Africa, Nigeria, Ethiopia, Kenya, Tanzania, Malawi, Congo, Mozambique and Zimbabwe; 5 are Asian, China, India, Indonesia, Philippines and Thailand; and 3 are Latin American, Brazil, Mexico and Argentina.

In terms of productivity, there are 7 countries with yields above 5 MT/hectare. Italy has the top yield at 10.9 MT/hectare, followed by France at 8.8 MT/hectare, USA at 8.0MT/hectare, Canada at 6.8 MT/hectare, Argentina and Hungary at 6.0 MT/hectare and China at 5.1 MT/hectare.

8.3.2 Maize Exports and Imports

Global exports of maize were of the order of 80 million MT in 2001 valued at $9 to $10 billion, based on current international prices of $108/MT. The US is by far the largest exporter at 47 million MT, followed by Argentina at 11 million MT, France (6 million MT) and Hungary (2 million MT). The only major exporter from the developing world is Argentina exporting approx. 11 million MT.

In terms of imports, the only major importer in the industrial world is Japan at 16 million MT, with South Korea as a transitional economy importing about 8 million MT. In Latin America, Mexico continues to rely on maize imports of 5 million MT per year with Colombia importing a more modest 2 million MT. In Asia, China reported a net import of 2 million MT with an equivalent tonnage of 2 million MT imported

Table 20. Maize Area, Yield and Production for Top 25 Maize Countries in 2002

Country	Harvested Hectares (Millions)		Yield MT/Hectare	Production (Millions MT)	
1. USA	28.5		8.0	228.7	
2. China	24.5		5.1	124.2	
3. Brazil	11.8		3.0	35.5	
4. Mexico	8.0		2.4	19.0	
5. India	6.2		1.9	12.0	
6. Nigeria	4.2		1.3	5.4	
7. South Africa	3.3		2.7	9.1	
8. Indonesia	3.3		2.8	9.3	
9. Romania	2.9		2.9	8.5	
10. Philippines	2.4		1.8	4.3	
11. Argentina	2.4		6.0	14.7	
12. France	1.8		8.8	16.0	
13. Ethiopia	1.7		1.8	3.1	
14. Kenya	1.5		1.8	2.7	
15. Malawi	1.5		1.1	1.6	
16. Tanzania	1.5		1.7	2.5	
17. Congo	1.4		0.8	1.1	
18. Ukraine	1.3		3.2	4.2	
19. Mozambique	1.3		0.9	1.1	
20. Yugoslavia	1.2		4.6	5.5	
21. Canada	1.2		6.8	8.2	
22. Thailand	1.1		3.5	3.9	
23. Italy	1.0		10.9	11.6	
24. Hungary	1.0		6.0	6.0	
25. Zimbabwe	1.0		0.8	0.8	
Subtotal	**116.0**	**(84%)**		**539.0**	**(95%)**
Others	22.9			63.0	
GLOBAL TOTAL	**138.9**	**(100%)**		**602.0**	**(100%)**

Source: FAOSTATS 2002.

by Malaysia. In the Middle East, Egypt imported 3 million MT. For the developing countries there is a negative net trade for maize, which is expected to steadily increase, in all three Southern continents of Asia, Latin America and Africa with the largest deficit in Asia followed by WANA (West Asia and North Africa), and by Latin America and Africa.

8.3.3 Number and distribution of maize farmers globally

There are estimated to be almost 200 million maize farmers in the world, which is the same as the number of rice farmers globally. Of the 200 million maize farmers in the world, 98%, equivalent to approx. 195 million grow maize in developing countries with less than 5 million, equivalent to 2% producing maize in the industrial countries (Table 21). There is no complete published set of statistics that documents the number and distribution of maize farmers worldwide. The data in Table 21 are only indications that allow order of magnitude comparisons between countries. The data were consolidated from different sources for estimates for the top 25 maize-growing countries. The data comprises information from Agricultural Statistics Departments for some countries, the 1990 FAO Agriculture Census, and in some cases, where information was not available, estimates were made for countries using data from the neighboring countries where farm size and maize distribution are most likely to be similar.

In terms of regional distribution, of the 200 million maize farmers in the world, about 150 million maize growers are in Asia, equivalent to more than 75% of global share (Table 22), between 15 and 20% in Africa, representing almost 35 million farmers, less than 5% in each of Latin America and Europe with less than 1% in North America (USA and Canada) that actually represent 22% of the world's 140 million hectares and produces approx. 40% of the 600 MT of global maize production.

China has by far the largest number of maize farmers at 105 million which accounts for half of all maize farmers in the world, with an average maize holding of 0.23 hectare, which is the smallest for all countries. The distribution of maize farmers, and maize area by region in China is given in Table 23. The largest number of maize farmers in China are in the Yellow River Region (38.9 million) followed by the South West (30.7 million) and the lowest number in the North West (4.8 million). The smallest maize holdings per farmer are in the South and South West (0.13 hectares) and the largest in the North East (0.69 hectares) and North (0.46 hectares).

The three countries of China (105 million), India (12.5 million), and Indonesia (6.1 million), total almost 125 million equivalent to about two-thirds of the world's maize farmers. In Africa, Nigeria, the most populous country on the continent with a population of 124 million people, has by far the largest number of maize farmers totaling 8.5 million, followed by Kenya, Malawi and Ethiopia, each with 3 million or more maize farmers, and the Congo, Tanzania, Mozambique and Zimbabwe with between 2 and 3 million each. The African continent has between 15 and 20% of the world's maize

Table 21. Number of Maize Farmers in the World and Average Maize Holding per Farm

Country/Region	Ha of Maize (Millions)	Number of Maize Farmers (Millions)	Average Maize Holding per Farm (Ha)
USA[2]	28.5	0.430	66.27
China[2]	24.5	105.000	0.23
Brazil[2]	11.8	2.540	4.65
Mexico[2]	8.0	2.750	1.06
India[1]	6.2	12.474	0.49
Nigeria[3]	4.2	8.400	0.50
South Africa[2]	3.3	0.260	12.60
Indonesia[1]	3.3	6.177	0.53
Romania[3]	2.9	1.450	2.00
Philippines[1]	2.4	1.771	1.35
Argentina[1]	2.4	0.096	25.00
France[1]	1.8	0.257	7.00
Ethiopia[3]	1.7	3.400	0.50
Kenya[2]	1.5	3.500	0.43
Malawi[3]	1.5	3.000	0.50
Tanzania[1]	1.5	2.216	0.69
Congo DR[3]	1.4	2.800	0.50
Ukraine[3]	1.3	0.650	2.00
Mozambique[3]	1.3	2.600	0.50
Yugoslavia[3]	1.2	0.600	2.00
Canada[1]	1.2	0.027	44.44
Thailand[1]	1.1	0.428	2.57
Italy[1]	1.0	0.473	2.11
Hungary[3]	1.0	0.500	2.00
Zimbabwe[2]	1.0	1.500	0.70
TOTAL	116.0	162.435	0.71
World Total	**140.0**	**196.042**	**0.71**

Source: [1]FAO, 2001, [2]Country Statistics, [3]estimated, based on neighboring countries.

Table 22. Number of Global Maize Farmers, Expressed as % by Region

Asia	77%
Africa	17%
Latin America	3%
Europe	2%
North America	<1%
	100%

Source: Compiled by Clive James, 2003.

farmers farming on average about 0.5 hectare of maize. In some of the developing countries there is a large maize hectarage farmed by a few large farmers and a small hectarage farmed by a large number of subsistence farmers. For example in South Africa there are an estimated 8,000 to 10,000 large scale farmers who farm a total maize area of 3.2 million hectares with an average maize holding per farmer of 320 hectares. In addition, there are an estimated 250,000 subsistence farmers growing 500,000 hectares of maize with an average of 2 hectares of maize per holding. Argentina in Latin America would have a somewhat similar distribution in terms of maize holdings with a large proportion of the maize area accounted for by 31,000 large farms with an additional 65,000 small farmers (Table 21). In Kenya there are 1,000 large scale farmers and 3.5 million small farmers. In France there are an estimated 30,000 commercial maize farmers and over 200,000 small holdings growing maize. Similarly in Italy, there are an estimated 20,000 commercial maize farmers with approximately 250,000 small holdings growing maize (Table 21).

Latin America represents less than 5% of the world's maize farmers. The key countries are Brazil, Argentina and Mexico; there are numerous countries in the Andean region and Central America where small subsistence farmers have small holdings of maize. Argentina has the largest maize holdings (25.00 hectares) in Latin America which is twenty-five times the average holding in Mexico at 1.0 hectare where the ejido system features small holdings by a large number of peasant farmers. Brazil, with the largest hectarage in Latin America at 11.8 million hectares is estimated to have 2.5 million farmers with an average holding of 4.6 hectares. Europe, which has about 2% of the maize farmers has about three to four million maize farmers, producing maize on holdings varying from 2.00 hectares in Italy and Hungary to 7.00 hectares per farmer in France. Finally, in North America, the US and Canada have only a total of approx. 450,000 farmers, less than 1% of the global total, with maize holdings ranging from 44 hectares in Canada to 66 hectares in the US. In terms of average maize holdings the largest are in the US at 66 hectares, followed by Canada at 44 hectares, Argentina at 25.00 hectares, and South Africa at 12.00 hectares; these are the only countries with an average maize holding of more than 10 hectares. In the next category of maize holdings there are several European countries that range from France at 7.00 hectares to Italy and Hungary at 2.00 hectares each. Small

Table 23. Number of Maize Farmers (Millions) in China, by Region, and Average Maize Area (Hectares) per Farm

Region	# of Maize Farmers (millions)	Average Maize Area/ farm (hectares)	Maize Hectarage/region (millions of hectares)
Yellow/Huai River	38.9	0.19	7.4
South West	30.7	0.13	4.0
South	13.6	0.13	1.8
North East	10.7	0.69	7.4
North	6.3	0.46	2.9
North West	4.8	0.27	1.3
TOTAL	**105.0**	**0.24**	**24.8**

Source: Chinese Academy of Sciences Personal Communication 2003.

holdings are the rule in most of Africa and Asia, and most of the countries in Latin America (Argentina and Brazil are exceptions) with maize holdings at 1.0 hectare (Mexico) or less. The countries of Africa have maize holdings that are an average 0.5 hectares (Table 21).

On a global basis it is estimated that between 200,000 and 250,000 farmers currently benefit from Bt maize in the countries where it has been commercially deployed, US, Canada, Argentina, South Africa, Spain, Honduras and the Philippines. Approval and adoption of Bt maize in China alone on 25% of its maize hectarage in the next five years could increase the number of beneficiaries from the current 250,000 one hundred fold to 25 million, a very high percentage of whom would be small resource-poor farmers who stand to gain substantially from the technology.

8.4 Maize Production Systems and Maize Germplasm

8.4.1 Maize Production Systems

The International Center for Maize and Wheat Improvement, CIMMYT, in Mexico has categorized maize growing areas into four mega-environments (Table 24):

- Lowland tropics
- Subtropics and mid altitude tropical zones
- Tropical highlands
- Temperate zones

These mega-environments are defined in terms of climatic criteria, such as mean temperature during the maize growing season, elevation, and day length. Globally there is an equal area of temperate and tropical maize, each occupying 70 million hectares for a global total

Table 24. Maize Hectarage Grown in the 4 Mega-Environments

Region	Mega-Environment				Total
	Tropical Lowland	Subtro-pical	High-land	Temperate	
Developing Countries					
Latin America	19	4	4	2	**29**
Sub Sahara	12	8	2		**22**
E/SE Asia	9	4	<1	21	**34**
South Asia	5	2	1		**8**
WANA	-	1	-	1	**2**
SUBTOTAL	**45**	**19**	**7**	**24**	**95**
Industrial Countries					
N. America		<1		30	**30**
W. Europe				10	**10**
E. Europe				5	**5**
SUBTOTAL		**1**		**45**	**45**
WORLD TOTAL	**44**	**19**	**7**	**70**	**140**

Source: CIMMYT 2000 modified by Clive James.

of 140 million hectares (Table 24). Over 90% of maize produced in industrial countries is grown in temperate zones, compared with only 25% of maize produced in temperate zones in the developing world, most of which is grown in China and Argentina. Of the 70 million hectares of maize produced in tropical environments about 65% is grown in the tropics, 25% in the subtropics/mid altitude zones, and about 10% in the tropical highlands (Table 24) (CIMMYT 2000).

In general, commercial maize production, as opposed to subsistence farming, in the developing world targets the feed sector rather than food. It is expected that this commercial sector in developing countries will be responsive to the predicted future of increasing demands. The private sector, both domestically and internationally, could accelerate its response to meet these needs if provided more liberal access through national programs, to supply improved maize germplasm, including GM traits, and provision of services ranging

Table 25. Current and Potential Yields (tonnes/hectare) in Developing Countries

	Tropical		Subtropical		Highland	
	Current	Potential	Current	Potential	Current	Potential
E/SE Asia	2.2	5.5	3.0	8.0	3.5	5.0
South Asia	1.4	4.5	2.6	7.0	0.7	5.0
W Asia/N Africa			3.2	4.5		
Sub Sahara	0.7	4.5	2.5	7.0	0.6	5.0
Latin Am/Caribb.	1.5	5.0	4.0	10.0	1.1	6.0

Source: CIMMYT 2000.

from seed distribution to supply of external inputs and technical support. It is the food-maize sector in developing countries that presents the most formidable challenge as the majority of tropical maize farmers continue to face major constraints in growing enough maize to meet their subsistence needs. About two-thirds of tropical maize is sown with improved seed, with the balance sown to local or traditional varieties.

The data in Table 25 clearly indicate that there is an enormous 'yield gap' between current and potential yield at the farm level which cannot be exploited in developing countries where even the best improved conventional germplasm does not possess the necessary degree of tolerance to biotic stresses resulting from damage by stem borers and other insect pests. Genes such as Bt can effectively confer resistance to the key pests and help to close the yield gap.

8.4.2 Global Areas Sown to Hybrids, OPVs and Farmer-Saved Seed

There are several classes of maize germplasm used and preferred by maize farmers throughout the world. Germplasm ranges from local, traditional land races used by subsistence farmers to open pollinated selected populations and varieties used by more progressive farmers, to hybrids used by the most advanced farmers in developing countries and considered the norm in industrial countries. The data in Table 26 shows the areas sown to maize hybrids and open pollinated varieties, (also collectively classed as improved seed), versus farmer-saved seed, which includes local land races and traditional germplasm used by subsistence farmers in developing countries.

It is noteworthy that on a global basis 80% of the global maize area of 140 million hectares is sown to improved varieties with approximately two-thirds sown to hybrids, with

Table 26. Area Sown to Maize Hybrids, Open Pollinated Varieties (OPVs) and Farmer-Saved Seeds in the Regions in the Industrial and Developing Countries in 1999

Region	Harvested Area	Hybrid (%)	OPV (%)	Improved [Hybrids + OPVs] (%)	Farmer-Saved Seed (%)
East Asia (China)	25.6	21.5 (84)	1.7 (6)	23.2 (90)	2.5 (10)
East and South Africa	15.4	12.5 (81)	1.7 (11)	14.2 (92)	1.2 (8)
West Asia	1.1	0.7 (67)	0.2 (15)	0.9 (82)	0.2 (18)
Southern Cone Countries of S. America	15.5	9.6 (62)	1.9 (12)	11.5 (74)	4.0 (26)
Andean Region	2.1	0.9 (43)	0.6 (27)	1.5 (70)	0.6 (30)
South East Asia	8.2	2.8 (35)	3.1 (36)	5.9 (71)	2.3 (29)
South Asia	8.1	2.4 (30)	2.0 (24)	4.4 (54)	3.7 (46)
Mexico and Central America	9.6	1.4 (15)	0.7 (8)	2.2 (23)	7.4 (77)
North Africa	1.2	0.1 (9)	0.4 (38)	0.5 (47)	0.7 (54)
West Central Africa	9.2	0.1 (4)	3.0 (32)	3.1 (33)	6.1 (67)
Total Developing	**96.0**	**52.0 (54)**	**15.3 (16)**	**67.4 (70)**	**28.7 (30)**
West Europe	4.5	4.3 (98)	0.2 (2)	4.5 (0)	0.0
East Europe	9.6	7.2 (75)	2.4 (25)	9.6 (100)	0.0
USA/Canada	30.0	30.0 (100)	0.0	30.0 (100)	0.0
Total Industrial	**44.1**	**41.5 (94)**	**2.6 (6)**	**44.1 (100)**	**0.0**
WORLD	**140.0 (100%)**	**93.5 (67%)**	**17.9 (13%)**	**111.5 (80%)**	**28.7 (20%)**

Source: CIMMYT, 2000. Modified from World Maize Facts and Trends, with new estimates for Eastern Europe.

the balance of 13% to OPVs and only 20% to farmer-saved seed; all of the latter is sown by subsistence farmers in the developing countries. In the industrial countries, 94% is sown to hybrids and the balance of 4% to OPVs with no farmers saving seed. In developing countries it is encouraging that 70% of the maize area is sown with improved varieties (54% to hybrids and 16% to OPV) with 30% sown to farmer saved seed. Thus, there are almost 68 million hectares of maize sown to improved seed in the developing countries. This is an encouraging situation because the significant area sown with improved seed lends itself for targeting with improved maize germplasm, including traits such as Bt that confer resistance to the stem borers, a major constraint to increased productivity. It is striking that in East and South Africa 92% of the maize area is sown to improved varieties, mainly hybrids. In fact, six of the regions listed, East Asia, East and South Africa, West Asia, the Southern Cone and Andean Region of South America, and South East Asia sow more than 70% of maize to improved varieties, the majority of which is hybrid as opposed to OPVs. South Asia and North Africa sow equal amounts of improved and farmer saved seed. It is only two regions, Mexico and Central America, and West Central Africa, where approx. 70% of the maize area is sown with farmer saved seed by subsistence farmers. The salient conclusion from the data in Table 26 is that contrary to the rhetoric of some critics of biotechnology, there is a large community of maize farmers in the developing world, farming 70% of the maize area, that have already adopted improved varieties, mainly hybrids, and therefore could have ready access to Bt maize through the same seed supply channels. That farmers of developing countries use only farmer-saved seed and, therefore, would be denied access to the new technologies provided through hybrids, is a misconception as is shown by the evidence presented in Table 26. For example, in China alone there are 105 million maize farmers farming one-quarter of a hectare of maize on average, 90% of whom already purchase improved seed at a premium, with 84% of the farmers purchasing hybrid seed annually because of the higher returns it provides.

8.4.3 Maize Grain Types

Maize grain types are categorized into two major types by color and hardness - yellow maize is used for feed and white for food – hardness, flint grains, which are hard and shiny, and dent grains which are opaque with soft rather than hard starch. Approx. 85% of global maize is yellow, 10-12% white, and the balance is made up of red, blue, purple and black grains. In countries where maize is the major food staple, white maize is used for food and yellow for feed. Hardness is associated with flint grains with kernels full of hard starch, which have a shiny surface. In contrast, dent grains are made up of soft starch that upon drying and shrinking produces a concave surface, hence the name, dent, and an opaque appearance. About 80% of global maize production is dent or semi-dent, 15% flints or semi-flints, and the balance made up of floury maize, characteristic of the Andean region, and waxy maize used in China. Irrespective of the grain type, yellow or white, flint or dent, kernels are genetically and nutritionally the same, except for grain pigment and shape.

8.5 Maize Utilization

There are marked differences in maize utilization between industrial and developing countries. In industrial countries over three-quarters of the maize grain is fed to animals, primarily cattle, swine and poultry, and the balance used for industrial uses including starch, sweetener, and ethanol production. In the US and Europe about half of the maize grain produced is retained by farmers to feed animals on their own farms. The balance is sold to the maize industry, which processes it to produce feed or it is used in different extractive processes to produce industrial products. Wet milling consumes a significant proportion of US maize and is used for the manufacture of starch, over 90% of which is converted to sweeteners. Wet milling also results in valuable by-products that include protein and fiber supplements used in animal feeds. They include gluten meal and feed, germ meal and steepwater, which can be used as a medium for culturing Penicillium and other antibiotic- producing organisms. Dry milling, which is a completely different process, consumes only about 2% of US maize and is used to prepare a range of food product ingredients, including grits, maize meal and maize flour, feed and industrial products. In Central America, maize is used to prepare tortillas which is the traditional food in countries like Mexico. Maize is also used as a composite flour to "extend" and supplement wheat flour. Composite flour is used in both Zimbabwe and Zambia and has potential in many other developing countries. Finally, the fermentability of maize starch and sweeteners make them appropriate products for the production of alcoholic beverages and for the production of ethanol as an extender for gasoline in a mixture of 10% ethanol and 90% gasoline. In the 1990s about 10 million MT of maize was used annually for the production of ethanol in the US. In terms of future trends, and concern about generating energy from non-renewable fossil fuels, ethanol production from maize is likely to be assigned high priority and could experience significant growth in the near-term.

The data in Table 27 detail maize utilization in terms of kg/capita/year and the percentage in food, feed and other uses. On a global basis maize utilization per capita is 94kg/year with 22% being used for food, 63% for feed and the balance of 15% for other uses. The highest utilization per capita is in the industrial countries with 274kg/year – 5% used as food, 76% as feed and 19% for other uses. Industrial country per capita maize utilization of 274 kg is in sharp contrast to developing country utilization where per capita consumption is less by three-quarters at 60kg/year; food use in developing countries is 7 times higher than industrial countries at 38% versus 5%, feed use is 51% compared with 76%, and other uses at 11% compared with 19%. Comparing different continents, per capita utilization is highest in Latin America at 149kg/year compared with 62kg/year for Africa and 46kg/year for Asia. Food use is highest in Africa at 64% compared with 34% for Asia, and 29% for Latin America.

Table 27. World Maize Utilization 1992 - 1994

Region	Utilization Kg/capita/year	% Food	% Feed	% Other
Developing Countries	60	38	51	11
Africa	62	64	23	13
Asia	46	34	72	10
Latin America	149	29	57	12
Industrial Countries	274	5	76	19
World	94	22	63	15

Source: Morris 1998. Modified.

Feed use is highest in Asia at 72% compared with 57% for Latin America, and only 23% for Africa.

In terms of future trends, utilization of maize will increase, albeit that growth rates will differ significantly in the three continents of the South. In Asia and Latin America increased incomes with demand for more meat products will fuel increased consumption of maize as feed whereas in Africa income growth is expected to be slower, leading to lower demands. These trends are discussed in more detail in the next section.

8.6 Maize Demand in 1997 Compared with Projections for 2020

The three major staples, maize, wheat and rice, provide more than 50% of our calorie needs on a global basis, and maize is a major feed source for animals. In 1997, global demand for the three major staples totaled 1.5 billion MT comprising equal demand for maize and wheat, 586 million MT of maize and 585 million MT of wheat and less demand for rice at 381 million MT (milled rice) (Table 28). Global cereal demand in 2020 is estimated at 2.1 billion MT (IFPRI 2003) and will, for the first time, show a major shift in favor of maize with demand estimated at 852 million MT compared with 760 million MT for wheat and 503 million MT for rice, for a total of 2.1 billion MT. Thus, global demand for maize in 2020 will increase by 45% (compared with 30% for wheat and 32% for rice), reflecting a substantial 72% growth for maize in developing countries but only 18% growth in industrial countries. This 72% increase in demand for maize in developing countries compares with only 44% for wheat and 33% for rice (Table 28). This increase in demand translates to 213 million MT of maize between 1997 and 2020 in developing countries compared with only 152 million MT of wheat and 120 million MT of rice.

Table 28. Maize, Wheat and Rice Demand Projections, 1997 and 2020, (Million Metric Tonnes [MT])

	MAIZE			WHEAT			RICE*		
	1997 Demand	2020 Demand	Change (%)	1997 Demand	2020 Demand	Change (%)	1997 Demand	2020 Demand	Change (%)
Global	586	852	266 (45)	585	760	175 (30)	381	503	122 (32)
Industrial Countries	291	344	53 (18)	245	268	23 (9)	17	19	2 (9)
Developing Countries	295	508	213 (72)	341	492	152 (44)	364	484	120 (33)

Source: IFPRI, 2003. *Milled Rice.

Table 29. Maize Demand for Developing Countries in 1997 and 2020 (Million Metric Tonnes [MT])

Region	1997 Demand	2020 Demand	Change (%)
E. Asia	136	252	116 (85%)
Latin America	75	118	43 (57%)
Sub Saharan Africa	29	52	23 (79%)
S.E. Asia	23	39	16 (70%)
WANA*	18	28	28 (56%)
S.Asia	14	19	5 (36%)

Source: IFPRI, 2003. *WANA - West Asia and North Africa

Table 30. Demand and Use of Maize in 2020

Region	Area[1]	Demand[2]	% Food	% Feed	% Other	Net Trade[3]
Global	158	852	15%	69%	16%	
Industrial	50	344	5%	76%	19%	+67
Developing	108	508	22%	64%	14%	-67
E. Asia	30	252	4%	82%	14%	-43
Latin America	32	118	25%	60%	15%	+5
Sub Saharan Africa	26	52	76%	10%	14%	-6
S.E. Asia	9	39	32%	58%	10%	-8
WANA	2	28	28%	63%	9%	-14
S. Asia	9	19	70%	13%	17%	-<1

Source: IFPRI, 2003. [1]Millions of hectares [2]Millions of metric tonnes (MT) [3]Millions of MT, exports(+), imports(-).

Within developing countries, the highest increase in demand for maize by 2020 will be for the countries of East Asia, dominated by China, requiring 252 million MT, which is equivalent to an 85% increase (Table 29). The next highest increase is in Sub Sahara Africa at 79% with a demand of 52 million MT, followed by S.E. Asia at 70% growth requiring 39 million MT, Latin America at 57% with a demand of 118 million MT, the WANA region at 56% requiring 28 million MT, and finally S. Asia at 36%, with a demand of 19 million MT in 2020 (Table 29). In the industrial countries, Japan is the major importer currently importing over 15 million MT and expected to remain at approximately the same level in 2020.

In 2020, of the 852 million MT of maize required globally 69% will be used for feed, 15% for food and 16% for non food/feed industrial uses (Table 30). Whereas only 5% of maize will be used for food purposes in the industrial countries, 22% will be used for food in the developing countries (Table 30). Within developing countries, the highest proportion of maize used for food will be in the countries of Sub Saharan Africa (76%), followed by South Asia (70%), which includes India, Pakistan and Bangladesh. In contrast, the developing countries of East Asia, principally China, will use only 4% of maize for food, with 82% used for feed, and 14% for other uses. In terms of overall demand for maize in 2020, East Asia is estimated to have the highest demand for maize at 252 million MT; this compares with 227 million MT for the USA, 118 million MT for Latin America, 52 million MT for Sub Saharan Africa and 40 million MT for the 15 countries of the European Union. There are currently only two major exporters of maize, the USA, currently at about 45 million MT is expected to increase exports to about 70 million MT by 2020 and Argentina, currently at 10 million MT is expected to increase to about 20 million MT by 2020. The only significant new exporters in 2020 are the countries of Eastern Europe, which could export up to 8 million MT (IFPRI 2003).

The challenge of producing an additional 266 million MT to meet an unprecedented global demand totaling 852 million MT of maize in 2020 is formidable. The challenge is even more daunting considering that over 80% of the increased demand of 266 million MT, equivalent to 213 million MT, will be required by developing countries. Furthermore, only around 10% is likely to be supplied through increased exports from industrial to developing countries leaving developing countries to produce most of their own additional maize requirements. Major importers will include E.Asia (43 million MT), WANA (14 million MT), S.E. Asia (8 million MT) and Sub Saharan Africa (6 million MT). Thus, of the 213 million extra MT required by developing countries, most will have to be produced in developing countries on almost the same area of land. The global area of maize is expected to increase by only 12%, from 140 million hectares in 2000 to 158 million hectares in 2020, thus 88% of the necessary increase in maize production will need to be generated through increased productivity resulting in higher yields per unit area of land. This is a daunting challenge for developing world farmers, many of them small and resource-poor, who grow two-thirds (approximately 100 million hectares) of the global maize area, with a current average yield of 2.8 MT/hectare. Their current productivity compares with 6.8 MT/hectare in all industrial countries with the highest yields of over 8 MT per hectare restricted to the USA and the countries of the European Union. Biotic stresses due to pests are severely constraining production in developing countries. Similarly, abiotic stresses due to drought, salinity, acid soils and deficiency or toxicity of micronutrients constrain productivity of large areas in developing countries. Overcoming these biotic and abiotic constraints, through conventional and biotechnology applications, would allow the potential of the current maize germplasm deployed in developing and industrial countries to be realized, resulting in significant yield increases.

The global cereal demand shift in favor of maize reflects rising incomes in many developing countries with consequent growth in meat consumption, which drives demand for maize as feed for poultry and swine. The demand for more maize is particularly strong in East Asia where demand is projected to rise from 136 million MT in 1997 to 252 million MT in 2020. Coincidentally, in Sub Saharan Africa, high population growth and pervasive poverty continue to drive a high demand for maize as a food source; the same is true for Central America and South Asia. Compared to its 1997 level, maize demand in Sub Saharan Africa is projected to almost double from 29 million MT to 52 million MT in 2020. Food maize demand in countries such as Mexico in Latin America is expected to remain high as incomes increase.

The substantial increased demand for maize in the next 20 years is a challenge to developing countries, because imports, which have typically supplied about 10% of developing country needs, are not expected to change significantly (CIMMYT 2000). The quantity of maize traded is projected to increase to 67 million MT by 2020, a 150% increase compared with the 1997 volume of maize traded. Thus, the only way that developing countries can meet their maize needs is to increase maize productivity per unit of land, where improved technology has traditionally been an important element. In the developing countries, particularly the more advanced larger countries, commercial maize production has a feed focus and the use of improved conventional technology, such as hybrids, as well as biotechnology applications, is expected to substantially increase. For example, 3 developing countries, Argentina, South Africa, and the Philippines already deploy Bt maize for the control of various stem borers whereas the major pest in Honduras is fall armyworm. The increased participation of the private seed industry could help meet increasing grain demand by increasing the efficiency of seed distribution and thereby access to improved technologies. Increasing the productivity of food maize, a sector dominated by subsistence farmers supported by technology coming from the public sector, presents more challenges, particularly for introducing improvements delivered by biotechnology applications. However, progress is being made in countries such as South Africa, where Bt white maize for food introduced in 2001, was well accepted, with the area increasing ten-fold to almost 60,000 hectares in 2002.

8.7 Meeting Increased Demands – the Role of Bt Maize

As noted in the earlier section increased demand for maize will require significant increases in production in both the industrial countries and developing countries. Whereas the industrial countries have the capability to increase production significantly, the challenge will be in the developing countries, particularly Africa, with limited access to improved technologies and a weak infrastructure to deploy them. Whereas technology will only be one element in a multiple thrust strategy that national programs will have to deploy to increase maize productivity, technology is nevertheless an essential core element in any strategy. Some developing countries experience significant constraints in even accessing improved conventional technology, and new technologies represent even greater challenges. However, the fact that GM technology is incorporated into the seed, makes GM crops a very appropriate technology for small farmers, as witnessed by the 5 million small farmers in Asia, Latin America and Africa who have already adopted Bt cotton. These resource-poor farmers are willing to pay a premium for Bt cotton, because of the higher returns that this proven technology provides. Bt maize offers small farmers in Asia, Latin America and Africa similar advantages to Bt cotton because of the productivity gains it offers, as well as lower input costs. Bt maize also offers advantages for maize farmers and consumers in industrial countries where pests that can be controlled by Bt, such as the stem borers and corn rootworm, are prevalent and economically important. Not only does Bt maize offer advantages in productivity and profitability for farmers, but it also offers the very important advantages of lower levels of harmful mycotoxins, elimination of insecticides for the targeted pests, and lower exposure to insecticides for farmers and the environment. These three cardinal attributes of Bt maize offer important advantages for farmers, the environment, consumers and society at large.

8. 8 Insect Pests of Maize

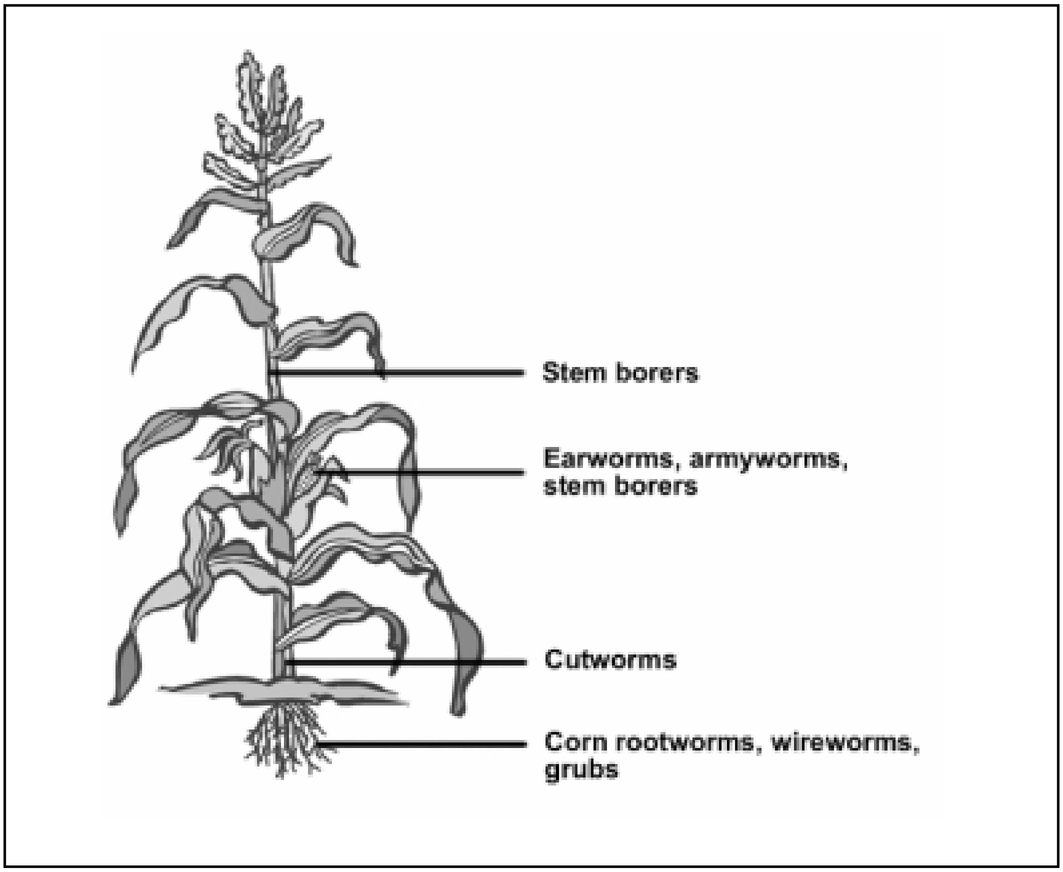
Maize insect pests are a major constraint to production because of the significant yield losses and grain quality degradation they cause. Infestation levels of specific insect pests vary enormously from year to year, and region to region, making global characterization of the distribution and economic importance of insect pests a challenging task. However, there is a relationship between the presence and importance of specific insect pests and the four mega-environments and the geography in which maize is grown (Table 31). The principal insect pests in each of the four mega-environments of tropical, subtropical, highland and temperate are listed in Table 31. In general, insect pests are more damaging in the tropical than temperate environments because the climatic conditions are more conducive for accelerated insect development with multiple and overlapping generations leading to high infestation levels and losses. Damage by insects occurs from the seedling stage (cutworms) through the vegetative stage, grain formation and storage (post-harvest weevils) – see Figure 8 for illustration of insect damage to maize. Insect pests damage the maize crop in a multitude of ways. Insects attack all parts of the plant throughout the growing season including: the ears and tassels (stem borers, earworms and armyworms); the stalks (stem borers); the leaves (armyworms, aphids, stem borers, thrips, mites and grasshoppers); the roots (rootworms, wireworms and grubs); and finally there are serious post-harvest pests damaging and consuming grain in storage (grain weevils, grain borers, Indian meal moth and Angoumis grain moth) - however this chapter focuses on field-pests of maize, principally the stem borers, rather than storage pests.

Stem Borers

As a key pest complex the stem borers are the most important and prevalent maize insect pests on a global basis and will be the major focus in this chapter on Bt maize. The distribution of the major stem borers that damage maize are depicted in Figure 9, which captures the global distribution of this most important group of insect pests, for which Bt proteins have been identified that confer resistance.

The most economically important species include the European corn borer (*Ostrinia nubilalis)* present in North America and Europe, with some countries in Europe also suffering from the Mediterranean corn borer (*Sesamia nonagroides*). In North America, the Southwestern corn borer (*Diatraea grandiosella*) is also important and in South America the sugar cane borer (*Diatraea saccharalis* and *Eldana saccharina*) and lesser corn borer (*Elasmopalpus*

Figure 8. Illustration of Sites on the Maize Plant Where Principal Insect Pests Cause Damage.



Source: Anonymous.

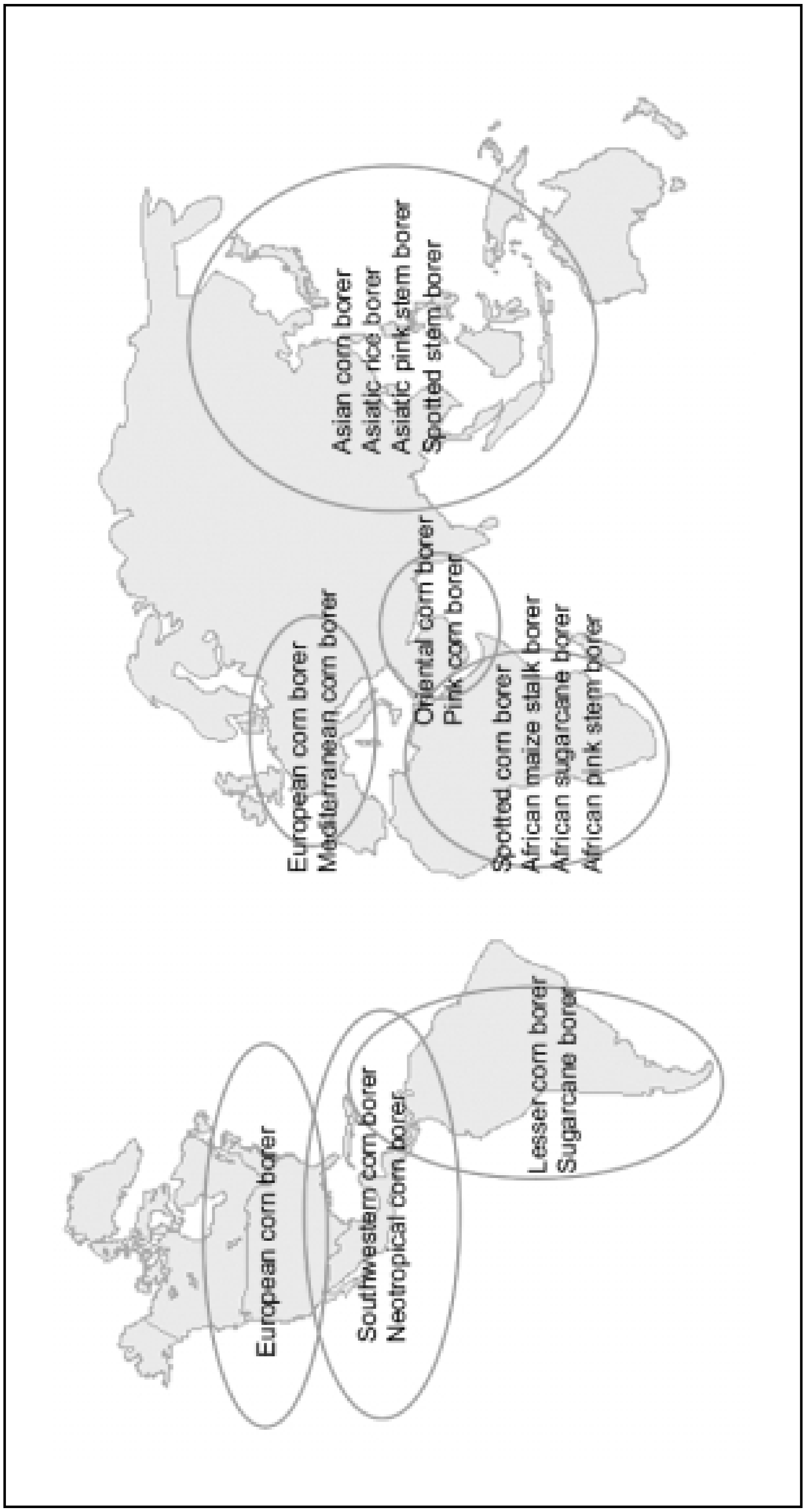
lignosellus) are also important pests. The most important borer in Asia is the Asian corn borer (*Ostrinia furnacalis*), followed by the spotted stem borer (*Chilo partellus*). On the African continent the most prominent borers are African stalk borer (*Busseola fusca*) and the spotted stem borer (*Chilo partellus*), followed by the pink stem borer (*Sesamia calamistis*) and the sugar cane borer (*Eldana saccharina*). Stem borers first attack the leaves and at a later stage they bore into stems and stalks and interfere with the movement of water and metabolites through the vascular system, as well as cause damage resulting in stalk breakage and ear drop. Stem borer infestation significantly decreases fertility and yield leading to serious economic consequences. Furthermore, the maize tissue damaged by the borers allows fungi, particularly *Fusarium* species, to colonize the damaged tissue, leading to stalk and ear rots and the accumulation of harmful mycotoxins. Fungal infection can result in degraded and toxic grain

Table 31. Major Insect Species Causing Economic Losses in Maize in Tropical, Subtropical, Highland and Temperate Maize Mega-Environments

Common Name	Scientific Name	Affected Regions
Tropical Environments		
Stem borers		
Spotted stem borer	*Chilo Partellus*	Asia, East Africa
Oriental corn borer (Asian corn borer)	*Ostrinia furnacalis*	Asia
Lesser cornstalk borer	*Elasmopalpus lignosellus*	Americas
Pink stem borer	*Sesamia cretica*	Africa
African pink stem borer	*Sesamia calamistis*	Africa
African maize stalk borer	*Busseola fusca*	Africa
African sugarcane borer	*Eldana saccharina*	Africa
Asiatic rice borer	*Chilo suppresalis*	Asia
Asiatic pink stem borer	*Sesamia inferens*	Asia
Sugarcane borer	*Diatraea saccharalis*	Americas
Neotropical corn borer	*Diatraea lineolata*	Central and South America
African leafhopper	*Cicadulina spp.*	Africa
Fall armyworm	*Spodoptera frugiperda*	Americas
Cutworm	*Agrotis spp.*	All regions
Termites	*Microtermes spp.*	Africa, Asia
Subtropical Environments		
Stem borers		
European maize borer	*Ostrinia nubilalis*	North Africa, Mideast
Lesser corn borer	*Elasmopalpus lignosellus*	Americas
Oriental corn borer (Asian corn borer)	*Ostrinia furnacalis*	Asia
Spotted stem borer	*Chilo partellus*	Africa
African maize stalk borer	*Busseola fusca*	Africa
Sugarcane borer	*Eldana saccharina*	Africa
Sugarcane borer	*Diatraea saccharalis*	Americas
Southwestern corn borer	*Diatraea grandiosella*	Americas
Fall armyworm	*Spodoptera frugiperda*	Americas
Corn earworm	*Helicoverpa zea*	Americas
Corn earworm	*Helicoverpa armigera*	Africa, Asia
Termites	*Microtermes spp.*	Africa, Asia
Temperate Environments		
Southwestern corn borer	*Diatraea grandiosella*	North America
Sugarcane borer	*Diatraea saccharalis*	Southern Cone, S. America
Lesser corn stalk borer	*Elasmopalpus lignosellus*	Southern Cone, South America Southern zone of North America
Oriental corn borer	*Ostrinia furnacalis*	East Asia
European corn borer	*Ostrinia nubilalis*	Europe, North America
Corn rootworm	*Diabrotica spp*	Americas and Europe
Mediterranean Corn borer	*Sesamia nonagroides*	Europe & Mediterranean
Fall armyworm	*Spodoptera frugiperda*	North and South America
Corn earworm	*Helicoverpa zea*	North America, Southern
Corn earworm	*Helicoverpa armigera*	Europe, Asia
Cutworms	*Agrotis spp.*	All
White grubs	*Phyllopsphaga spp* *Cyclocephala spp*	North and Central America
Tropical Highland Environments		
Corn earworm	*Helicoverpa zea*	Americas
Cutworms	*Agrotis spp including Ipsolan*	All

Source: Dowswell et al 1996. Modified by Clive James, 2003.

Figure 9. Maize Borer Map of the World.



Source: CIMMYT, Mexico

that contributes to food and feed safety hazards; mycotoxins will be dealt with separately in more detail in section 8.16.

Corn rootworms

The corn rootworm complex includes two species which are very important in the US where 13 million hectares out of 32 million hectares are infested. The two species are Western rootworm (*Diabrotica virgifera, virgifera)* and Northern rootworm (*D. barberi)* (Metcalf and Metcalf 1993). Corn rootworms are also important in Canada, in Mexico, and in Argentina and Brazil in Latin America. In Europe, Western corn rootworm was first detected in Yugoslavia in 1992 and in the last decade has spread to the 10 European countries of Hungary, Bulgaria, Romania, Slovakia, Italy, Switzerland, Ukraine, Austria, France and the Czech Republic. In 2003 corn rootworm spread further to the Netherlands, where an eradication program was implemented (Plantenziektenkundige Dienst 2003) and the UK (DEFRA 2003). Thus, corn rootworm has now been detected in 13 European countries. Figure 10 depicts the international distribution of this insect pest which is estimated to have infested 13 million hectares of the 28.5 million hectares of harvested maize in the US, 1 million hectares of the 1.2 million hectares of maize in Canada, 1 million hectares of the 8.0 million hectares of maize in Mexico, 5.0 million hectares of the 11.8 million hectares in Brazil, and finally 0.1 million hectares of the 2.4 million hectares of maize in Argentina. Thus, in the Americas corn rootworm has already infested over 20 million hectares and more insecticide is used for controlling this insect pest in the US than any other crop pest; up to 80% of all insecticides applied to maize are targeted to control corn rootworm (Oehme and Pickrell 2003, Cropnosis 2003). In Europe, the total infested area with corn rootworm was estimated to be 100,000 hectares in 1997, which is now believed to have reached over 280,000 hectares. Thus, corn rootworm has already established itself as a global pest in the Americas and has been detected in 13 countries in Europe where it continues to spread. The larvae feed on the roots of maize plants and the damage reduces the flow of water and metabolites in the vascular system, leading to decreased fertility and harvestable yield. Infested maize stalks eventually fall over (lodging) and break, resulting in significant losses in yield. Commercialized Bt maize with *cry3Bb1* gene was first deployed in the US in 2003 and confers resistance to corn rootworm root feeding.

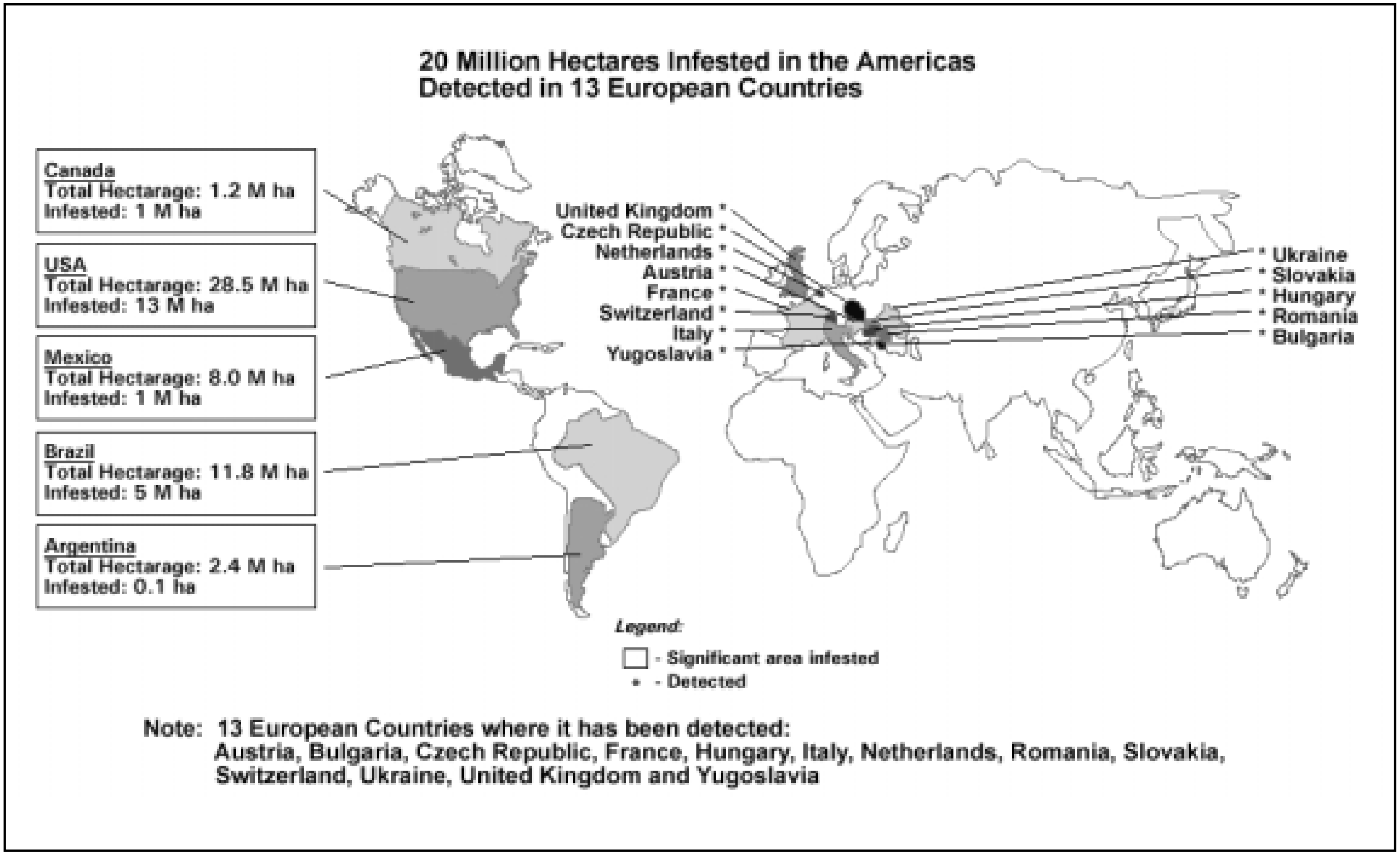
Corn earworms

Corn earworms (*Helicoverpa zea*) are prevalent on maize crops in all of the Americas from Argentina in the south to Canada in the north. Damage can take place at the early whorl stage but more importantly at the later silking stage when yield loss can be severe. The currently deployed *cry1Ab* provides effective control at the early whorl stage but only suppression (50 to 80%) at the later ear stage.

Armyworms

The *Spodoptera* spp. can cause serious damage as leaf feeders during the whorl stage, feed on

Figure 10. Global Distribution of Corn Rootworm



Source: Compiled by Clive James, 2003.

developing ears later in the season, and rarely penetrate stems. The fall armyworm *S. frugiperda* is prevalent in the Americas and is controlled primarily with foliar applied insecticides to prevent damage to the ear. Maize with a Bt gene (c*ry1Ab*) offers effective control at the whorl stage but only suppression at the ear stage. New Bt products should offer improved control of armyworms which make these products particularly important in Brazil, where *S. frugiperda* is the primary pest and also to a lesser extent in Mexico and Argentina where it is a more sporadic pest. Armyworms are also found in Africa (*S. exempta*); another prevalent species is the beet armyworm, *S. exigua* found in Asia and North America.

Cutworms

Cutworms, for which the Bt gene *cry1Ab* does not offer protection, are ubiquitous globally, and the most serious species is *Agrotis ipsilon*. The worms destroy or 'cut' seedlings, as the name implies. Currently, damage can be minimized through cultural controls and insecticide application. The newly approved, but not yet widely deployed *cry1Fa2* gene is expected to provide improved and effective control for black cutworms.

Post-harvest Pests

Post-harvest losses can be particularly serious in developing countries where storage conditions are not adequate and the climate is humid. The most important post-harvest insect pests affecting maize are grain weevils (*Sitiophilus* spp.) the larger grain borer (*Prostephanus truncatus*), Indian meal moth (*Plodia interpunctella),* and Angoumis grain *moth (Sitotroga cerealella)* which can be very damaging. Infestation with post-harvest pests often occurs in the field and is carried over to storage where they can cause very serious losses. Whereas losses due to these post-harvest insect pests are adequately controlled under commercial storage conditions, resource-poor farmers in developing countries often suffer very serious losses because storage conditions are not adequate and high moisture in grain exacerbates the losses. Bt maize *cry1Ab* provides some protection from the damage caused by post-harvest insect pests (Sedlacek et al 2001). The strategy for reducing post-harvest losses includes breeding for improved husk cover, drying grain to reduce the high losses associated with grain with high moisture and storing in sealed containers to diminish oxygen levels, which constrains insect development and facilitates fumigation by products such as pirimiphos-methyl.

8.8.1 Principal pests in the top three maize-growing countries USA, China and Brazil

The distribution and severity of infestations by insect pests in the three top maize producing countries, US, China and Brazil, are detailed in Tables 32, 33, and 34 respectively. Pest infestation levels for the different mega-environments in each of the countries are categorized as Trace, Low, Medium and High.

USA

There are two principal pests of maize in the US, each of which infests up to 40% of the 32 million hectares of maize in the US (Table 32). Infestation will vary by year, region and variety. Whereas only 2% of US maize is sprayed for European corn borer about 8.5 million hectares of Bt *cry1Ab* maize was deployed in 2002 for the control of European corn borer as well as control of Southwestern corn borer; the latter is estimated to infest only about 10% of the crop but damage can be severe. The increased adoption of Bt maize is due to the high farmer satisfaction with control by Bt maize compared to the less effective and more inconvenient and time consuming application of insecticides. The second major pest is corn rootworm that infests approximately 13 million hectares of maize of which 6 million hectares were treated with insecticide, mainly as larval soil applications in the spring, plus some additional mid-season adult beetle targeted foliar sprays; insecticide for corn rootworm represents from 60% to 80% of all insecticides applied to maize in the US.

China

Of the 25 million hectares of maize grown in China, 75% of the area is in a temperate mega-environment, 20% subtropical/tropical and 5% temperate/subtropical. The principal insect pest in China is the Asian corn borer, which is present at medium infestation levels in the temperate and temperate/subtropical areas, and at low levels of infestation in the subtropical/ tropical mega-environment (Table 33). Corn earworm is present at lower infestations than Asian corn borer. In the temperate and temperate/subtropical, earworm is present at low infestations and only at trace levels in the subtropical/tropical mega-environment.

Brazil

The lowland tropical maize mega-environment accounts for 70% of maize grown in Brazil, with 30% of the area in the subtropical mega-environment. The two principal pests, fall armyworm and lesser corn borer, are found at high infestations in the lowland tropics and at medium infestations in the subtropical areas.

Table 32. Distribution and Severity of Principal Insect Pests in the US

Principal Pest	Infestation in Temperate Mega-Environment
European corn borer	Medium
Corn rootworm	Medium
Southwestern corn borer	Low

Source: Dowswell et al 1996 modified.

Infestation categories based on percentage of national maize area infested: TRACE 1 to 10%, average of 5% of national maize area infested; LOW (L) 11 to 30%, average 20%; MEDIUM (M) 31 to 50%, average of 40%; HIGH (H) 51 to 70% average of 60%

Table 33. Distribution and Level of Infestation of Principal Insect Pests in China in Different Mega-Environments

Principal Pest	Temperate 75% of Area	Temperate/Subtropical 5% of Area	Temperate/Subtropical 20% of Area
Asian corn borer	Medium	Medium	Low
Corn earworm	Low	Low	Trace

Source: Dowswell et al 1996 , modified.

Infestation categories based on percentage of national maize area infested: TRACE 1 to 10%, average of 5% of national maize area infested; LOW (L) 11 to 30%, average 20%; MEDIUM (M) 31 to 50%, average of 40%; HIGH (H) 51 to 70% average of 60%

Sugarcane borer is reported at low infestation in both the lowland tropics and the subtropics (Table 34). Corn rootworm is estimated to affect 5 million hectares of maize in Brazil and is present at medium levels of infestation in the lowland tropics and the subtropical regions. Cutworms are reported at low levels of infestation in the lowland tropics and at medium levels of infestation in the subtropical area. White grubs can also be important in Brazil. Seventy percent of Brazilian maize is grown in the lowland tropics where post-harvest losses from insect pests are usually high, causing heavy losses if adequate protective measures are not implemented.

Infestations of grain weevils are high in both the lowland tropics and the subtropics whereas the grain moth causes medium losses in the lowland tropics and high in the subtropics. Post-harvest losses due to insect pests, which can be as high as 40%, are particularly serious at the small farmer level where inadequate storage and high grain moisture levels exacerbate the problem.

8.8.2. Global Distribution of Maize Pests

The data in Table 35 indicate the distribution of the principal maize insect pests in the top 25 countries. It is evident that stem borers are present as principal pests in all 25 countries whereas armyworms are a principal pest in only 9 countries in the Americas and the Philippines and with earworm present in 6 countries. Corn earworms can be important pests in six countries and corn rootworm in four countries in the Americas, with corn rootworm recently detected in five countries in Europe, Romania, France, Yugoslavia, Italy and Hungary that feature in the top 25 maize producers in the world.

The data presented in Table 36 estimates the area infested by major lepidopteran pests and rootworm in the top 25 maize growing countries. Four infestation categories are based on the average percentage of national maize area infested. *Trace* covers 1 to 10% with an

Table 34. Distribution and Severity of Principal Insect Pests in Brazil in Different Mega-Environments

Principal Pest	Lowland Tropical 70% of Area	Subtropical 30% of Area
Fall armyworm	High	Medium
Lesser corn borer	High	Medium
Sugar cane borer	Medium	Low
Corn rootworm	Medium	Medium
Cutworms	Low	Medium

Source: Dowswell et al 1996 , modified.

Infestation categories based on percentage of national maize area infested: TRACE 1 to 10%, average of 5% of national maize area infested; LOW (L) 11 to 30%, average 20%; MEDIUM (M) 31 to 50%, average of 40%; HIGH (H) 51 to 70% average of 60%

average of 5%, *low* covers the range 11 to 30% with an average of 20%, *medium* is 31 to 50% with an average of 40%, *high* 51% to 70%, with an average of 60%, and over 70% is *very high*. There is a distinct general pattern with temperate mega-environments generally in the medium category with an average of 40% of the national maize area infested and with the tropical and subtropical maize areas in the high category with an average of 60% of the maize national area infested. Caution must be used in interpreting infestation data because they are subject to significant fluctuations, between years, regions and growing conditions. Many countries such as China, have both temperate and subtropical maize mega-environments that contribute to variability in infestation levels. On average, about 45% of the 116 million hectares of maize grown in the top 25 countries are estimated to be infested with lepidopteran pests, mainly stem borers and also by fall armyworm, corn earworms and corn rootworms. It does not follow that all of the infested area lends itself for economic control because this will depend on the intensity of the infestation. For example, 13 million out of the 32 million hectares of maize in the US is infested with corn rootworm but farmers judge, rightly or wrongly, that only 6 million hectares have infestation levels that merit treatment with insecticides.

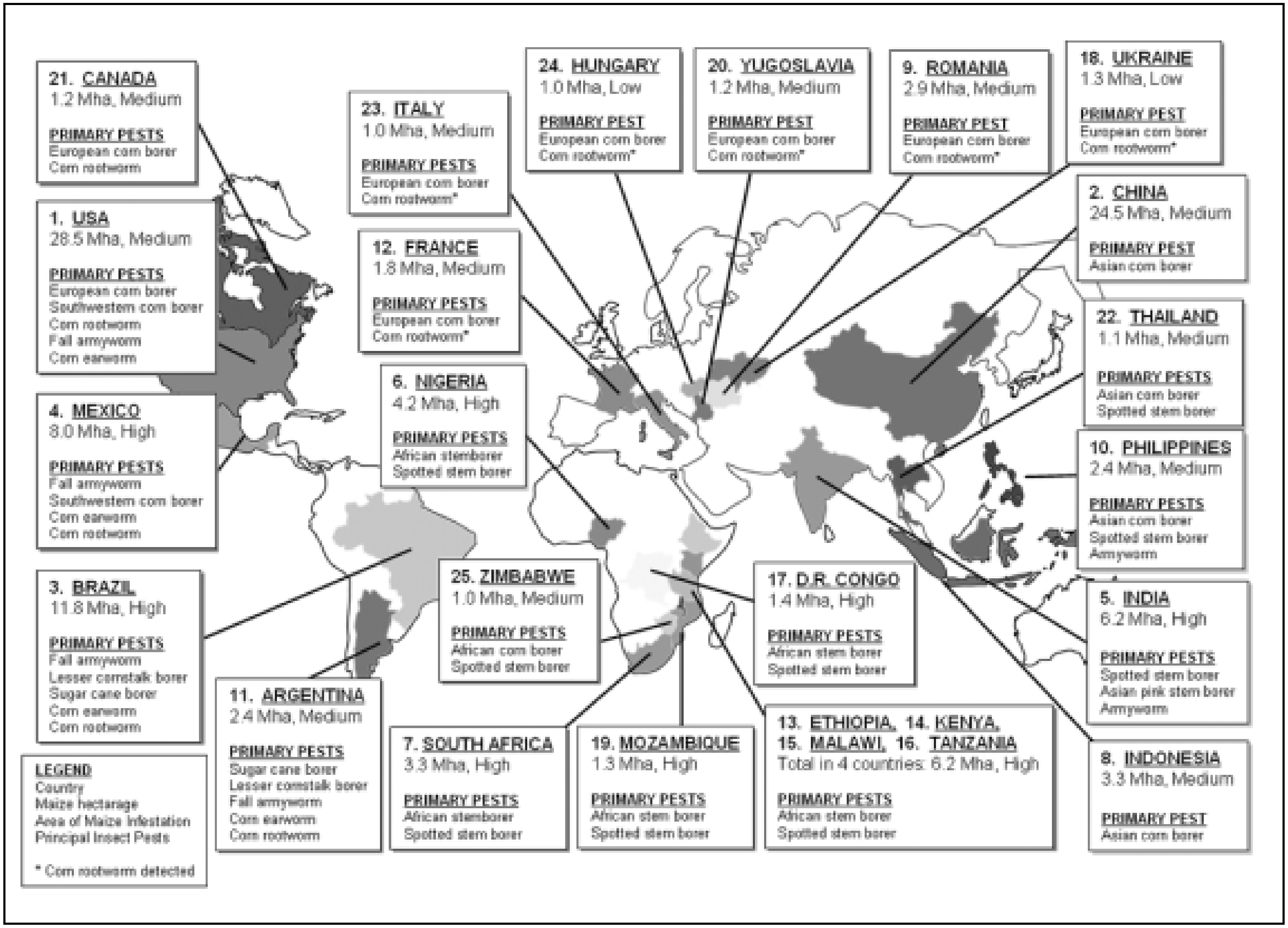
The salient information on maize insect pests globally is summarized in Figure 11 for the top 25 maize producing countries in the world. The data presented on the global map includes the ranking of the country in maize production (millions of MT), the national maize area (millions of hectares) harvested, the proportion of the national maize area infested (3 categories Low 20%, Medium 40% and High 60%) and a listing of the principal insects. It is evident that there is a pattern, with the distribution and

Table 35. Distribution of the Principal Maize Pests - Borers, Armyworms, Earworms (Lepidoptera) and Rootworms (Coleoptera) in the Top 25 Maize Countries with 1 Million Hectares, or More of Maize

Country		Hectares (millions)	Borers	Armyworms	Earworms	Rootworms
1.	USA	28.5	X	X	X	X
2.	China	24.5	X		X	
3.	Brazil	11.8	X	X	X	X
4.	Mexico	8.0	X	X	X	X
5.	India	6.2	X			
6.	Nigeria	4.2	X			
7.	South Africa	3.3	X		X	
8.	Indonesia	3.3	X			
9.	Romania	2.9	X			*
10.	Philippines	2.4	X	X		
11.	Argentina	2.4	X	X	X	X
12.	France	1.8	X			*
13.	Ethiopia	1.7	X			
14.	Kenya	1.5	X	X		
15.	Malawi	1.5	X	X		
16.	Tanzania	1.5	X	X		
17.	Congo	1.4	X			
18.	Ukraine	1.3	X			
19.	Mozambique	1.3	X			
20.	Yugoslavia	1.2	X			*
21.	Canada	1.2	X	X		
22.	Thailand	1.1	X			
23.	Italy	1.0	X			*
24.	Hungary	1.0	X			*
25.	Zimbabwe	1.0	X			
Subtotal		**116.0 (84% of global)**	**25**	**9**	**6**	**4**

Source: Maize hectarage data based on FAOSTATS 2003; information on distribution of pests compiled by Clive James.
* detected

Figure 11. 25 Top Maize Producing Countries, With Details of Maize Area (Million Hectares [Mha]), Proportion of Maize Area Infested (Low, Medium, High), and Principal Insect Pests



Source: Compiled by Clive James, 2003.

Table 36. Estimated Average Levels of Infestation of Major Lepidopteran Pests and Rootworm in the Top 25 Maize Countries with 1 Million Hectares or More of Maize

Country		Hectares (millions)	Infestation Level	Hectares Infested (Millions)
1.	USA	28.5	M	11.4**
2.	China	24.5	M	9.8
3.	Brazil	11.8	H	7.1**
4.	Mexico	8.0	H	4.3**
5.	India	6.2	H	3.7
6.	Nigeria	4.2	H	2.7
7.	South Africa	3.3	M	2.0
8.	Indonesia	3.3	M	1.3
9.	Romania	2.9	M	1.2*
10.	Philippines	2.4	M	1.0
11.	Argentina	2.4	M	1.0**
12.	France	1.8	M	0.7*
13.	Ethiopia	1.7	H	0.7
14.	Kenya	1.5	H	1.0
15.	Malawi	1.5	H	0.6
16.	Tanzania	1.5	H	0.9
17.	Congo	1.4	H	0.8
18.	Ukraine	1.3	L	0.2
19.	Mozambique	1.3	H	0.8
20.	Yugoslavia	1.2	M	0.5*
21.	Canada	1.2	M	0.5**
22.	Thailand	1.1	M	0.4
23.	Italy	1.0	M	0.4*
24.	Hungary	1.0	L	0.2*
25.	Zimbabwe	1.0	M	0.4
Subtotal		**116.0** (84% of global total)		**53.6** (46% of 116.0)

Source: Compiled from various sources by Clive James, 2003. Infestation categories based on percentage of national maize area infested: TRACE 1 to 10%, average of 5% of national maize area infested; LOW (L) 11 to 30%, average 20%; MEDIUM (M) 31 to 50%, average of 40%; HIGH (H) 51 to 70% average of 60%; VERY HIGH (VH) over 70% of maize area infested.

** Significant area infested by rootworm, * Rootworm detected.

relative importance of pests, related to geography and more importantly to the four maize mega-environments of tropical, subtropical, tropical highland and temperate. It is the climatic and related factors associated with the respective mega-environments that are probably the main determinants in governing the extent of infestation and ultimately the economic losses, which are considered in a later section.

In summary, the major economic insect pests of maize globally are the different borers in the stem borer family, followed, in the Americas, by the rootworm complex, with fall armyworm and earworms featuring as important pests in some countries. Currently deployed Bt maize products (*cry1Ab*) offer control for most stem borers and rootworms (*cry3Bb1*) as well as some suppression of some of the other important pests including corn earworm and fall armyworm for which the new *cry1Fa2* gene offers improved and effective control of fall armyworm and black cut worm.

8.9 Crop Losses and Cost of Control and Economic Gains due to Bt Maize

8.9.1 Global Overview

Maize insect pests are recognized to cause economic crop losses and to be a constraint to maize productivity on a significant proportion of the 140 million hectares of maize grown throughout the world. In the absence of any form of control measures achieved through resistant varieties, insecticides, cultural control and integrated pest management (IPM) systems, potential losses due to all maize insect pests on a global basis are estimated to be of the order of 14 to 18%, Table 37 (Oerke 2002). To put this into context, it is noteworthy that this is about half the corresponding losses estimated for insect pests of cotton, at 35 to 41% (Oerke 2002, James 2002b), which are the highest losses for insect pests on any crop worldwide.

Compared with the potential losses of 14 to 18% for all maize insect pests, the actual losses when controls are used, are estimated at 6 to 17%, (Table 37) which indicates that the increase in yield in areas where controls are applied through insecticide applications, and other forms of control, is of the order of up to 5%. Crop losses are related to the level of infestation, which will vary by year, by country and by variety. The data in Table 37 shows the range of actual and potential crop losses for different global regions. The data are general estimates and may under or overestimate the actual losses due pests at the farm level but are useful for detecting trends, patterns, and differences in order of magnitude. For example, for the potential losses there is a pattern indicating that Africa has the highest losses at 17%, followed by Asia at 16% and the Americas at 15%, whereas CIS, Europe and Oceania are all at 14%. The actual losses show a similar pattern with losses in Africa the highest at 14%, the CIS at 13%, followed by Asia at 12%, the Americas at 11%, with Europe and Oceania with the lowest losses at 9%. These patterns provide useful insights in that they reflect higher levels of potential and actual losses in the

Table 37. Range of Actual and Potential Losses from Maize Insect Pests for Different Global Regions

	Actual Loss % With Controls	Potential Loss % Without Controls
AFRICA	**14**	**17**
Eastern	17	18
Western	17	17
Southern	13	16
North	9	17
ASIA	**12**	**16**
South East	15	18
South	15	16
East	9	16
Near East	10	14
AMERICAS	**11**	**15**
Southern Cone	13	15
Andean	10	14
North America	6	14
Central	13	15
CIS	**13**	**14**
EUROPE	**9**	**14**
OCEANIA	**9**	**14**

Source: Oerke 2002 in CABI Crop Protection Compendium, 2002.

tropical and subtropical environments, as compared with the temperate environments, with the highest losses in Africa, followed by Asia, and Latin America. Comparing the potential and actual losses, it is also evident that the degree of control is less (1 to 4%) in Africa, Asia, Latin America and CIS, than North America (8%), Europe (5%) and Oceania (5%), This pattern is consistent with the use of more resistant varieties, more intensive application of insecticides in the industrial countries than in the developing countries. For example, almost half (40%) of the insecticide used globally on maize is used in the USA (Table 50) which only has 20% of the global maize area; about 60 to 80% of maize insecticides in the US is targeted at the corn rootworm. The data in Table 37 shows that the largest measure of control (8%) of maize pests is achieved in North America (14% potential loss versus 6%

actual loss), with good level of control in Europe, Oceania, East Asia (China) and North Africa.

Based on production data and the maize insect losses of Oerke 2002 (Table 37) the tonnage of crop losses due to maize insects can be calculated on a global basis, for each continent, and for subregions within continents. Thus, the actual global losses due to insect pests are estimated at 52.6 million MT (Table 38) equivalent to approx. 9% of global production of 600 million MT. Based on a mid 2003 international maize price (World Bank 2003) of $108/MT (No.2 Yellow FOB US Gulf Ports) the actual global losses to maize insect pests are valued at US$5.7 billion. The magnitude of the losses for each continent and subregion will be dependent on two factors, the maize production and the % loss. Thus, in terms of absolute losses the greatest loss is in the Americas with a total production of 250 million MT (40% of global production), and losses ranging from 6% in North America to 13% in Central America and the Southern Cone, that results in a 23.7 million MT lost to maize insects in the Americas. The figure of 23.7 for the Americas compares with 16 million MT for Asia, 6.3 million MT for Africa, 5.9 million MT for Europe, 0.7 million MT for the CIS countries and > 0.1 million MT for Oceania. The global maize production of approx. 600 million MT valued at the mid 2003 international price of $108/ton is worth approx. $65 billion. Accordingly the value of maize insect crop losses for the Americas is $ 2.6 billion, Asia $1.6 billion, Africa $0.8 billion, Europe $0.6 billion, CIS $0.1 billion, and Oceania $<0.1 billion for a total of $5 .7 billion.

8.9.2 Regional and Country Estimates of Crop Losses and Economic Gains due to stem borers controlled by *Cry1Ab*

There is a plethora of references on crop losses due to maize insect pests, but different methodologies have been used, which makes interpretation more challenging. The most extensive body of references has been generated in the US, which is the largest producer of maize in the world, consuming about half of global insecticides applied to maize and accounting for 85% of the global hectarage of 10 million hectares planted to Bt maize in 2002. This section focuses on:

- crop losses and cost of control associated with insect pests that can be controlled with Bt *cry1Ab* gene which controls the major pests comprising principally of the family of stem borers that attack maize throughout the world

- a preliminary assessment of the yield losses associated with the corn rootworm complex for which the *cry3Bb1* was approved and deployed for the first time in the US in 2003.

USA

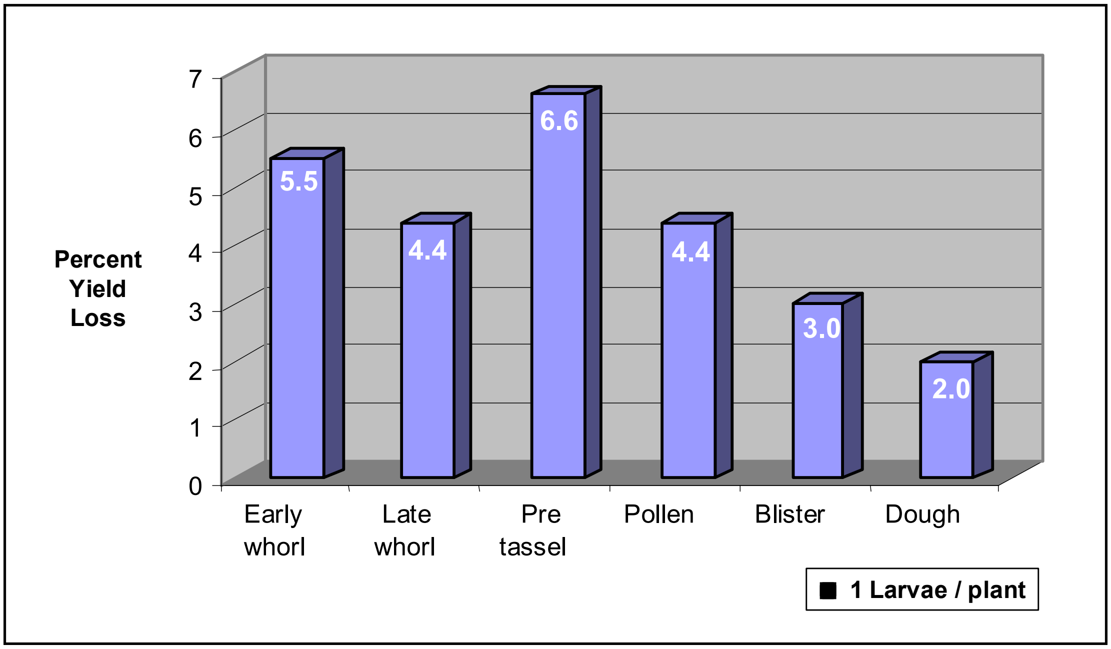
Research by Bode et al (1990), established that yield loss due to European corn borer was related to the stage of plant growth. Thus, one larvae/plant at the early whorl stage leads to a loss of 5.5%, late whorl 4.4%, 6.6% at pre-tassel, 4.4% at pollen stage, 3.0% at blister and

Table 38. Global and Regional Estimates of Crop Losses Due to Insect Pests of Maize

	Production Million MT	Production Value $ Billions	% Loss	Crop Loss MT millions	Value of Crop Loss $ Billions Due to Maize Insects
Americas					
North America	250.9	27.1	6	15.1	1.6
Andean Region	52.1	5.6	10	5.2	0.6
Central America	21.5	2.3	13	2.8	0.3
Southern Cone	4.7	0.5	13	0.6	0.1
Subtotal Americas	**329.2**	**35.5**		**23.7**	**2.6**
Asia					
East Asia	115.7	12.5	9	10.4	1.1
South East Asia	21.2	2.3	15	3.2	0.3
South Asia	14.3	1.5	15	2.1	0.2
Near East	3.5	0.4	10	0.3	<0.1
Subtotal Asia	**154.7**	**16.7**		**16.0**	**1.6**
Africa					
Eastern	13.6	1.5	17	2.3	0.3
Western	11.9	1.3	17	2.0	0.2
Southern	10.6	1.1	13	1.4	0.2
North	6.5	0.7	9	0.6	0.1
Subtotal Africa	**42.6**	**4.6**		**6.3**	**0.8**
Europe	65.2	7.0	9	5.9	0.6
CIS	5.6	0.6	13	0.7	0.1
Oceania	0.6	<0.1	9	<0.1	<0.1
WORLD TOTAL	**597.9**	**64.5**		**52.6**	**5.7**

Source: Compiled by Clive James, 2003, Based on current (mid 2003) international price of maize, $108/MT (World Bank, 2003), and insect loss estimates of Oerke, 2002, in CABI Crop Protection Compendium 2002.

Figure 12. Yield Loss from European Corn Borer



Source: Bode et al 1990, Purdue University

2.0% at the dough stage (Figure 12). It is important to note that estimates of loss in Fig. 12 are accumulative. Thus, the infestation of 1 larva per plant at the early whorl stage would result in a 5.5% loss which reduces yield potential from 100 units to 94.5 units. A further infestation of 1 larva per plant at the pollen stage would inflict another accumulative loss of 4.4 % on the already reduced potential yield of 94.5 units, further reducing the potential yield to 90.1 units, equivalent to a loss of almost 10% at the pollen stage. Successive infestations at the blister and dough stages would inflict further accumulative losses as the potential yield is eroded with each infestation resulting in significant overall losses. Actual losses will be influenced by the prevailing growing conditions, other abiotic and biotic stresses including damage by other pests.

The USDA has issued annual reports of the losses due to European corn borer for the period 1942 to 1974 (USDA 1975). Annual losses have varied from a low of 83,000 million MT in 1952 to 7.6 million MT in 1971, equivalent to a 5.3% loss on a US national maize production of 143 million MT in 1971. In addition to estimating the grain tonnage lost to maize insects, the cost of insecticides and other IPM approaches, for example the use of the wasp *Trichogramma* for biological control, represent a cost which should be included in estimating the overall costs associated with maize insect pests.

The extensive US data on crop losses due to European corn borer was recently reviewed (Marra et al 2002). The overall indication from the five national studies that were conducted was that the average yield increase associated with Bt maize, (or the crop losses due to insect pests controlled by Bt *cry1Ab*), in the US during the four year period 1997 to 2000 was 5% (Table 39); it is acknowledged that the percentage loss due to insect pests controlled by Bt will vary significantly by year and region. Accordingly, it is not surprising that the results of Marra et al (2002) summarized by Brookes (2002) show considerable variation (Table 39). The highest variation was for studies in Illinois where the average benefit was 12% with a range of 1.1 to 22.6%, whereas the least variation was in Nebraska with an average benefit of 5.5% with a range of only 3.2 to 7.9%. The average yield gains in the original work by Marra et al (2002), were converted from bushels/acre to tonnes/hectare by Brookes (2002) who reported that the average yield gain for the five studies, considered national studies, and conducted in the period 1997 to 2000, was 420 kg/hectare equivalent to a gain of 5.04% with a range of 2.5 to 9%. For the other 23 studies conducted in seven different states over a four year period the average gain in yield in favor of Bt maize was 8%.

A corresponding unpublished set of US data from industry is summarized in Table 40 (Industry Source 2003a). The data is for the 8 year period 1995 to 2002 and is based on a total of 8,866 comparisons (average of 1,108 comparisons /year) between a Bt maize variety and its corresponding conventional near isoline. The average yield during the eight year period was 8.15 MT per hectare with an average yield advantage of 423 kg/hectare, equivalent to an average gain of 5.2% over the eight year period. The yield advantage of the Bt maize in this data is negatively correlated with the European corn borer larvae index which was moderately high in 1996 at 1.4 borers/stalk, (see Figure 13) when the benefit was 500 kg/hectare – this compares with a benefit of 588 kg/hectare in 1997 when the index was 1.6 borers/stalk with a benefit of only 200 kg/hectare in 1998 (the lowest benefit on record) which was associated with the historically low level of only 0.3 borers/stalk in 1998. It is noteworthy that the three years, 1998 1999, and 2000 were the years when the European corn borer index was at historical lows of 0.3, 0.3 and 0.4 respectively and coincide exactly with the only three years when the yield gain in favor of Bt maize was less than 5 % (Table 40); for the other five years during the eight year period 1995 to 2002 the yield gain in favor of Bt maize ranged from a low of 6.1 % to a high of 9.1 %.

Comparing the set of data from the public sector (Marra et al 2002) and the data from the private sector in Table 40, the average benefit for the US from the public data set is 420 kg/hectare equivalent to an average gain over the period 1997 to 2000 of 5%, compared with 423 kg/hectare from the private sector study, equivalent to an average gain of 5.2% over eight years for the period 1995 to 2000. Both studies indicate that the yield gain due to Bt maize, or alternatively stated, the loss due to insect pests controlled by Bt, was consistent at approx. 5% over a four to eight year period for the US nationally.

Table 39. Summary of Farm Level Impact on Yield of Bt Maize in the US 1997-2000

State	Number of Studies Examined	Average Yield Benefit of Bt Maize: tonnes/hectare	Average Gain %	Range
Corn Belt	6	+0.68	+8.12	+4 to +12.8
Illinois	4	+1.02	+12.26	+1.1 to +22.6
Iowa	5	+0.45	+5.34	+2.2 to +9.2
Kansas	3	+0.49	+5.87	+2.8 to +9.0
Minnesota	1	+1.14	+13.69	+13.69 to +13.69
Nebraska	2	+0.46	+5.57	+3.2 to 7.9
South Dakota	2	+0.65	+7.75	+5.8 to +9.7
National USA	**5**	**+0.42**	**+5.04**	**+2.5 to +9.0**

Source: Brookes (2002) derived from Marra et al (2002).

Table 40. Yield Advantage of Bt Maize in the US 1995-2002

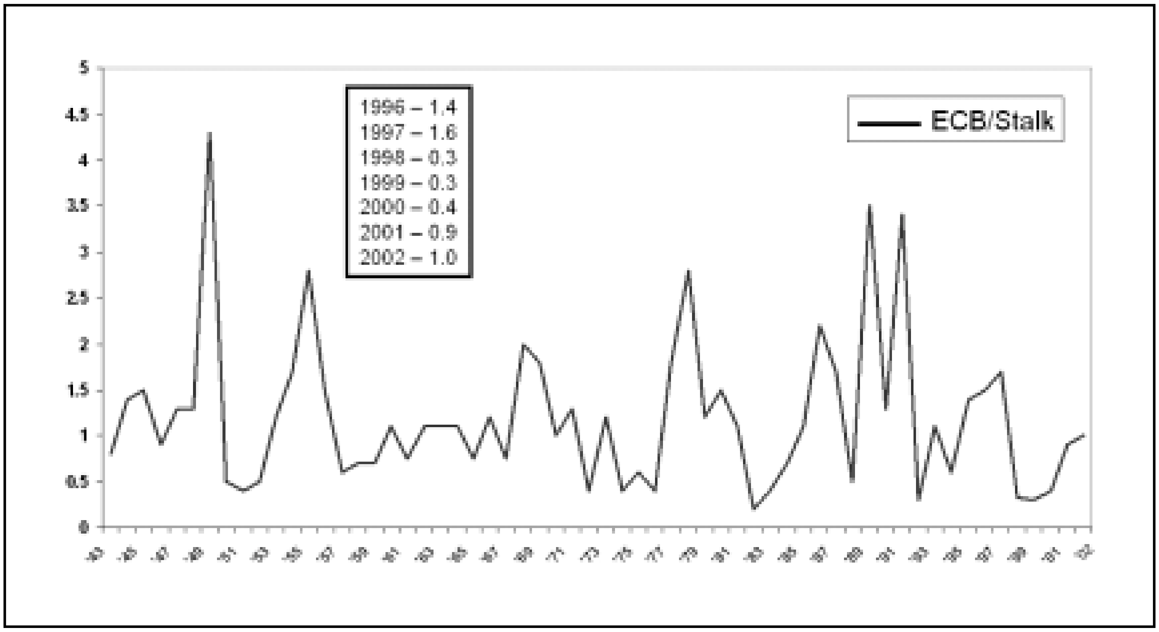
Year	Yield Kg/Hectare	Bt Maize Gain Kg/Hectare	Bt Maize Yield Gain (%)	# of Comparisons
1995	7.12	651	**9.1%**	495
1996	7.97	500	**6.3%**	2625
1997	7.95	588	**7.4%**	1048
1998	8.43	200	**2.4%**	1081
1999	8.39	213	**2.5%**	884
2000	8.59	288	**2.9%**	989
2001	8.67	451	**5.2%**	913
2002	8.15	500	**6.1%**	831
Average	**8.15**	**423**	**5.2%**	**1108**

Source: Industry source 2003a, modified by Clive James.

Figure 13 shows the densities of European corn borer recorded annually by the University of Illinois from 1943 to 2002. The highest level was recorded in 1949 at approx. 4.1 European corn borer larvae/stalk. During the initial planting of Bt maize in the US in 1996, when only about 0.3 million hectares were deployed, the European corn borer index was relatively high at 1.4 borers/stalk; however, given that the 1996 hectarage of Bt maize was low at 0.3 million hectares the benefits to farmers were estimated at only $12 million (James 2001a) – see Table 41. In the second year of Bt maize deployment, 1997, the borer index increased slightly to 1.6 from 1.4 in 1996, but Bt maize hectarage had increased tenfold to almost 3 million hectares and gains were estimated at $89 million Carpenter and Gianessi (2001). In 1998, although hectarage of Bt maize continued to increase, the borer index dropped to a historical low of 0.3 borers/stalk and continued at this level in 1999; due to low levels of European corn borer infestations Carpenter and Gianessi (2001) estimate that farmers planting Bt maize made a loss of $26 million and $35 million respectively in 1998 and 1999 (Table 41). No benefit/loss estimates are available for the US in 2000 but US farmers increased the area planted to Bt maize only marginally, probably because they concluded that the low level of European corn borer in 1999 would not merit Bt maize in 2000, on the rationale that infestation would continue to be low. The farmers were proved right because the borer index continued at a low level of 0.4 in 2000 and only farmers with historically high infestations planted Bt maize. However, in 2001 farmers decreased their Bt plantings by 500,000 hectares but the borer index more than doubled from 0. 4 to 0.9 (Fig 13); benefits to farmers in 2001 were estimated at $125 million (Gianessi et al 2002). An annual estimate of the benefits was not made for 2002, but farmers increased their Bt maize hectarage by more than 1 million hectares in the US in 2002 and this coincided with another high borer index of 1.0 borer/stalk; benefits were likely of the same order, $125 million, as in 2001.

The range of studies in the US on crop losses due to maize insect pests controlled by Bt, mainly European corn borer and Southwestern corn borer, or conversely the yield benefits associated with Bt maize compared with conventional maize have sometimes resulted in quite different conclusions. For example, a study conducted by Benbrook and others, typified by a recent study (Benbrook 2001), concludes that Bt maize does not offer farmers consistent and worthwhile advantages. On the other hand, several studies by Gianessi et al (2002) conclude that in the majority of cases, farmers planting Bt maize will gain in terms of yield and savings on insecticide, which in turn will result in an overall gain in most, but not all cases. The latest information from Gianessi et al (2003) concludes that in a typical year (estimates made in 2001) farmers that planted Bt maize on 6 million hectares realized a gain of 266 kg/ hectare, which is equivalent to a 3.3% yield gain for an overall return of approx. $125 million (Table 41). Marra et al (2002) reported overall gains of 5% based on five national studies over a four period 1997 to 2000 (Table 39) and summarized the economics of Bt maize with the following statement "Bt corn will provide a small

Figure 13. European Corn Borer Densities in Illinois, 1943-2002



Source: http://www.ag.uiuc.edu/cespubs/pest/articles/200224b.html

but significant increase in most years across the corn belt, and in some years and in some places the increases will be substantial" which is consistent with an average gain of 5 % over eight years with gains reaching 9% when European corn borer infestations are high.

Europe

Spain is the only country in the European Union that grows a significant hectarage of Bt maize; in 2001, 25,000 hectares of Bt maize were planted, equivalent to 5% of the national maize hectarage. Brookes (2002) recently conducted a survey and reviewed the literature on the economics of Bt maize to control maize borers in Spain. He concluded that whereas losses due to maize borers can be as high as 15% in some areas, the projected average yield loss in the one-third (36%) of national maize area infested with European corn borer was 5 to 7%; he projected that deployment of Bt on 36% of the maize area would result in a production gain of 88,000 to 124,000 MT, equivalent to a 1.8 to 2.5% increase in national production and valued at 11 to 15 million Euros. In addition to productivity gains, insecticide sprays, which are currently applied to 6 to 20% of the 0.5 million hectares of maize in Spain, could decrease by 59,000 to 89,000 hectares leading to further cost savings.

Spain's experience with growing two approved Bt maize varieties from 1998 to 2002 has been

Table 41. Estimates of Net National Economic Gains (Losses) to Farmers Planting Transgenic Bt Maize in USA 1996-2001

Country/Year	$ Millions
USA:	
1996	12[1]
1997	89[2]
1998	(26)[2]
1999	(35)[2]
2001	125[3]

Source: Compiled by Clive James 2003 from the following data: [1]James 1998, [2]Gianessi and Carpenter 2002, [3]Gianessi et al 2002

positive with producers realizing an additional 150 Euros/hectare due to increased productivity, plus a saving of 20 Euros/hectare on insecticides, for a total gain of 170 Euros/hectare (Fundacion Antama 2003). Based on this success and in response to strong farmer demand for additional Bt maize varieties, the Ministry of Agriculture approved five new varieties in 2003 when hectarage of Bt maize increased from 25,000 hectares in 2002 to 50,000 hectares in 2003. The varieties were developed by several companies including Syngenta, Pioneer, Monsanto, Nickerson and Limagrain. Brookes (2002) estimates that it would be economical to increase adoption in the borer infested areas up to 36% of the national maize crop. Gianessi et al (2003) project that equivalent adoption rates to provide a similar economic gain would be 40% of the 1.9 million hectares of maize in France, 50% of the 1.1 million hectares in Italy and 25% of the 0.4 million hectares in Germany.

Gianessi et al (2003) conducted surveys similar to those they conducted in the US for four countries in Europe, France, Italy, Spain and Germany, and the results are summarized in Table 42. The overall production gain associated with Bt maize, adopted on 1.5 million hectares, equivalent to 41% of the total European maize area, is projected to be 1.9 million MT valued at approx. $250 million; this is equivalent to a 5 – 7 % increase in production for the total national hectarage, not only for the infested area. In addition to this increase in production, a coincidental decrease of 52,600 kg of insecticide (a.i.) is projected, 85% of which would be realized in Spain, which uses most of the insecticides applied for the control of European corn borer. Gianessi et al (2003) report that 5 – 7 % of potential European maize production is lost annually to stem borers with yearly estimates of actual loss depending on the intensity of the infestation (Labatte et al 1997, and Manchini and Lozzia 2002).

In Europe, Bohn et al (1999) showed that for each larva of European corn borer per plant, yield is reduced by 6%. Damage from European corn borer increases in the warmer Mediterranean area of France, Italy and Spain where 2 to 3 generations of larvae are normal, compared with only one in the colder areas of Northern Europe. Several studies have been conducted to assess the crop losses associated with European corn borer and Mediterranean corn borer in Spain. One of the most detailed was conducted by Alcade (1999) when the

Table 42. Survey on Bt Maize Potential in Europe

Country	Ha adopted	(%)	Production Increase MT	Net Value $ Million	Insecticide Use Kg
France	765,000	(40)	+857,000	101	-5,500
Italy	554,000	(50)	+607,000	107	-1,100
Spain	181,000	(36)	+254,000	28	-45,200
Germany	99,000	(25)	+181,000	13	-800
Total	**1,599,000**	**(41)**	**1,899,000**	**249**	**-52,600**

Source: Gianessi et al (2003)

Table 43. Yield Comparisons of Bt and Conventional Maize in Spain 1997 (MT/Hectare)

Region	Bt average yields	Conventional crop yields	% Difference
Albacete	14.2	13.34	+6.4
Girona	13.63	12.07	+12.9
Huesca	13.35	12.54	+6.5
Lleida	13.72	13.13	+4.5
Madrid	14.70	14.28	+2.9
Zaragosa	12.01	11.32	+6.1
All regions above	**13.30**	**12.51**	**+6.3**

Source: Alcade E (1999). Results based on monitoring of trial plots of 1000 metres square in each region in 1997.

performance of Bt maize was compared with the corresponding conventional variety, in field trials in all regions of the country, using trial plots of 1,000 metres square. The data, summarized in Table 43 shows that the average yield loss in 1997 was 6.3 %, ranging from a low of 2.9% in the Madrid region to a high of 12.9% in Girona region.

Research conducted in the Rhine Valley (1998 to 2002), see Table 44, and in Eastern Germany (2000-2002), see Table 45, by Degenhardt et al 2003 indicate that 300,000 hectares are affected by borer and that Bt maize provided the most effective control (96% - 98% efficacy compared with 83% - 88% for insecticides and only 29% to 55% with *Trichogramma*).

Table 44. Comparison of Performance of Bt and Conventional Maize in the Rhine Valley in Germany 1998-2002

Treatment	Infestation	Efficacy of control	Grain yield %	Economic Gain Euro/Hectare
Bt	0	98	114	+84
Conventional	0.2	0	100	0
Trichogramma	0.08	58	103	-52
Insecticide	0.04	88	107	+18

Source: Degenhardt et al (2003)

Table 45. Comparison of Performance of Bt and Conventional Maize in the Oderbruch Region, Eastern Germany 2000-2002

Treatment	Infestation	Efficacy of control	Grain yield %	Economic Gain Euro/ha
Bt	0	96	115	+93
Conventional	0.8	0	100	0
Trichogramma	0.7	29	102	-57
Insecticide	0.2	83	110	+55

Source: Degenhardt et al (2003)

Compared with conventional maize, Bt maize yielded 14 to 15% more, versus 7 to 10% for insecticides, and only 2 to 3% for *Trichogramma*. Finally, in terms of economic gain Bt maize generated 84 to 93 Euro/hectare more than conventional maize compared with 18 to 35 Euro/hectare for insecticide treatment and a loss of 52 to 57 Euro/hectare for *Trichogramma* treatment, which is subsidized in Germany. In summary, Bt maize yielded about 15% more in yield and the area infested is estimated at approx. 300,000 hectares. Magg et al (2000) has also reported on gains in yield of Bt maize in Germany of approx. 12% for Bt maize, over conventional varieties for the 1998 and 1999 seasons. In the EU, Bt176 was approved for commercialization in 1997 and MON810 in 1998. Germany has grown a token hectarage of Bt maize since 2000 and this latest study (Degenhardt et al 2003) indicates that it could be adopted with economic benefits on up to 300,000 hectares.

In Italy maize borers are estimated to infest nearly all the maize hectarage of 1.1 million hectares with yield losses of 7 to 15% (Gianessi et al 2003), who reported that 5 to 7% of the potential maize grain production in Europe is lost annually to borers. The exception is Northwest Europe and Scandinavia where borers have not been a significant constraint on fodder maize. For Italy, Onorato and Snidaro (1993) report on levels of loss due to maize borers over an eight year period to range from 0 to 18% with an average of 7.9%. In field trials in Spain yield gains in favor of Bt maize have been reported at 11% (Novillo et al 2003) and 9% (Garcia Olmedo 2003). Other research on damage and losses caused by European corn borer in Italy includes a report by Coppolino et al (1985) indicating that a low infestation leads to a loss of 0.45/MT/hectare, medium 1.2/MT/hectare, and 2.1/MT/hectare with high infestation. Given that yields in Italy are around 10 MT per hectare the percentage loss would range from approx. 5% for low, 10% for medium, and 20% for high infestation. Unpublished data from industry (Industry Source 2003b), based on field trials conducted in 1997 are consistent with the above data, reporting increases in yield of approx. 10% in favor of Bt maize. In France, Anglade and Rautou (1970) reported losses of up to 15% to European corn borer.

Latin America

For Argentina, based on 1,500 data points extracted from unpublished reports from industry (Industry Source 2003c), an increase in yield is indicated of 10% in favor of Bt maize with *cry1Ab* gene, with the major pest suppressed being sugarcane borer followed by fall armyworm. A separate 2000 to 2003 industry report estimates yield benefits in favor of Bt maize at 8% for Argentina (Industry Source 2003d).

In Brazil the third largest maize growing country in the world, data from field trials in several states in 1999, 2000 and 2001 showed an average increase in yield of 24% in favor of Bt maize (Industry Source 2003e); the corresponding increase in yield in plots sprayed with insecticide was only 13%, approx. half the gain for Bt maize. By far the most important pest in the trials was the fall armyworm, with lesser corn borer, sugar cane borer and cutworms also present but at much lower average levels, whereas lesser corn borer has been, and continues to be an important pest, infestations of sugarcane borer seem to be increasing in recent years. Brazil with a large area of 11.8 million hectares of maize, with most of it growing in the tropical mega-environment, where pest infestation can be heavy, would likely benefit significantly from the deployment of Bt and other novel genes to control its principal maize pests. This is consistent with the fact that Brazil currently expends $100 million per year on maize insecticides, the second largest insecticide market in the world after the US. Use of maize insecticides in Brazil is covered in section 8.10 that characterizes the global market in maize insecticides.

For Honduras, yield trials in 2002 in four different regions of the country showed that yield increases in favor of Bt maize ranged from 6% to 21% with an average of 12.7% (Industry Source 2003f).

Asia

The large maize growing countries in Asia include China, India, Indonesia, as well as the Philippines and Thailand. Estimates of losses due to stem borers are provided for each country where available.

China

China, the second largest maize-growing country in the world, producing approximately 130 million MT of maize on 25 million hectares. By far the most common insect pest of maize in China is the Asian corn borer which can infest up to 70 to 80% of the maize area and is estimated to cause yield losses annually from 7 to 20% with an average yield loss of 10% (Industry Source 2003g). Current practice in China is to attempt to control Asian corn borer with Parathion, Trichogramma, a mercury-arc lamp and application of hormones, but none of these control methods are effective. Field experiments with Bt maize indicate that yield gains of 17% (Industry Source 2003h) in favor of Bt maize are possible, with medium infestation levels and up to 23% with severe infestation (Industry Source 2003i). In 1997, the average yield gain from Bt maize trials in seven provinces was 19%. Other estimates of losses due to borers in China include an estimate of 5-7% by He et al (2003) and 5 -10% by Wang (2003). Field trials with Bt maize show yield gains in favor of Bt maize ranging from 9% (Wang 2003) to 17% and 23% - see Table 47. The latter gains of 23% are consistent with the higher yield gains of 25% to 40% reported below from the Philippines (Gonzalez 2002) - see Table 47 for all the references for Asia. Value of losses in China is estimated at an average of 5% or 6 million MT valued at $650 million annually (Table 76).

Philippines

In 2001, Bt maize field trials were conducted in the Philippines at three different locations: Isabela (3), Bukidnon (1) and Camarines Sur (1). Average farm sizes were small and ranged from 1.1 to 1.9 hectares. The objective of the multi-location study was to conduct a socio-economic assessment of the performance of Bt maize, compared with conventional maize. Four different comparisons were made for yield increases, production costs, net profitability, and the subsistence level carrying capacity of maize production; the latter is defined as whether the net income from maize production could meet the cost of purchasing a daily food basket of 2,000 kilo calories per person for a farm family of five. For cost comparisons, price of Bt maize seed was assumed to be the same as the cost of conventional seed, 2,000 pesos/bag, plus 800 pesos/hectare for insecticide for a total of 2,800 pesos, compared with 2,000 pesos/bag for conventional seed. Comparisons of Bt maize field-trial results were also made with best farmer practices using field yields from a group of farmers with high yields and another with low yields.

The results from the Philippines trials (Gonzalez 2002) showed that Bt maize hybrids consistently out-yielded conventional maize hybrids by 41% in trials and by 60% compared with farmer practice. Cost of production of Bt maize was 24% lower than conventional maize in field trials, 13% better than farmer practice for the group of farmers with high yields, and 39% better than farmer practice for the group of farmers with low yields. The results of the comparisons re: the subsistence level carrying capacity of the technology showed that whereas Bt maize could meet the subsistence requirement of a family of five, conventional maize could not. Thus, in summary, Bt maize hybrids consistently performed better than their corresponding conventional maize hybrids, in terms of yield, production cost, profitability and in terms of capacity to meet subsistence needs of farm families. Based on this experience with Bt maize in these multi-location field trials, subsistence maize farmers in the Philippines expressed their interest and willingness to adopt Bt maize because of the higher yields and less requirements for insecticide. Previous field trials had indicated an increase in yield of approx. 25% in favor of Bt maize in the dry season and 40% in the wet season.

India

India cultivates approx. 6 million hectares with a net production of 7.5 million MT and a low yield of 1.2 MT per hectare. The largest area of maize is in Uttar Pradesh which has 1.2 million hectares, followed by Rajasthan, Madhya Pradesh and Bihar, each with about 800,000 hectares. Spotted stem borer (*Chilo partellus*) and armyworm are important pests (Hill 1983). Losses of 20 to 87% have been reported for spotted stem borer (Mathur 1998) and 30% loss for armyworm, and losses of 5% (Jayaraj 1990) to 37% (Dhaliwal and Arora 1996) for corn earworm. Asian corn borer is not an important pest in India but *Sesamia spp* borers can be. Whereas losses can be high for individual pests with high infestation, Dhaliwal and Arora (1996) estimate that on average the losses due to various insect pests are a modest 5%. No information from field trials with Bt maize is currently available to estimate the yield gain from Bt maize. Reviewing the trends in production and estimated losses due to insects per year during the 1970s and 1990s, the losses due to biotic stresses are increasing steadily and based on experience elsewhere in Asia, it could well be that the yield gains from Bt maize may be higher than the estimated loss in yield of 5% due to all insects (Table 47).

In the early 1970s production of maize in India was approx. 6 million MT and this has doubled to 12 million MT in 2002. With this increased productivity, insect pests exert a heavier toll in terms of a crop loss measured in kg/hectare and opens up new opportunities for deploying new Bt maize technology that can provide a significant return to farmers.

Africa

Larvae feeding results reported from South Africa confirm that the *cry1Ab* genes provide an effective control for both the spotted stem borer *Chilo partellus* and the African maize stalk borer *Busseola fusca.* The number of larvae of *Busseola fusca* that survived after 10 days were 7 in the control versus 0.2 for Bt; similarly only 0.5 larvae of *C. partellus* survived on Bt maize compared with 8 in the control. (Kirsten and

Gouse 2003). Based on analysis of commercial production of Bt yellow maize, the increase in yield in favor of Bt maize is of the order of 10% (Kirsten and Gouse, 2003). Profitability was higher for Bt maize, equivalent to 86 Rand/hectare, despite a premium of 60% for the Bt maize seed, which was more than offset by the savings on insecticides (Kirsten and Gouse 2003). Net income from Bt maize is estimated to be 250 Rand/hectare higher than conventional maize under irrigated conditions and 190 Rand/hectare (7 Rand = US $1.00) under dryland conditions (Table 46).

An extensive farmer survey on a nationwide basis was conducted to estimate losses due to stem borer in Kenya in 1998 (De Groote 2002). The average yield loss was estimated to be 12.9% equivalent to 0.39 million MT/hectare, estimated at a national loss in Kenya of $76 million. The crop loss levels were higher (15 to 21%) in the low maize potential areas and lower (10 to 12%) in the high maize potential areas. Given that percentage losses are lower in the high yielding areas, with higher percentage losses in lower yielding areas the absolute level of loss/hectare was fairly constant for both areas at 315 to 374 kg/hectare. The exception was the dry mid altitude zones where losses were at approx. half, equivalent to 175 kg/hectare. At the farm level in the main maize growing areas, the value of the losses range from $61 to $75/hectare due to stem borers, and at $34/hectare in the dry mid altitude areas. The most important stem borers in Kenya are the African maize stalk borer (*Busseola fusca*) prevalent in the cooler highlands and the spotted stem borer (*Chilo partellus*), found in the warmer tropical lowlands. A third borer, the African pink stem borer (*Sesamia calamistis*), is found at elevations up to 2,600 meters (De Groote 2002).

Table 46. Profitability of Bt Maize Versus Conventional Maize in South Africa

Production System	Profit, Rand/hectare, relative to conventional
Irrigated	250
Dryland	190

Source: Kirsten and Gouse, 2003.

In a later publication, De Groote et al 2003 estimate the annual losses due to maize stem borers in Kenya at an average of 13.5% or 0.4 million tons valued at US$80 million, over four growing seasons in 2000 and 2001. The Insect Resistant Maize for Africa (IRMA) project funded by the Syngenta Foundation and implemented by the Kenyan Agricultural Research Institute (KARI) and CIMMYT, was established in Kenya to develop Bt maize for Kenya. To-date Bt genes with resistance to *Chilo partellus*, *Chilo orichalcocillellus*, *Eldana sacharina* and *Sesamia calamitis* have been successfully incorporated into the elite CIMMYT maize inbred line CML 216 and bioassayed in Kenya. However, a Bt gene that confers complete control for *Busseola fusca*, the African maize stalk borer, has not yet been identified and this is the most important stem borer in Kenya in the high production moist transitional zones (De

Table 47. Summary of Yield Gains in Favor of Bt Maize *(cry1Ab)* and Estimates of Loss Due to Stem Borers

Country	Years	Data	Yield Gain/ loss hectares*	Reference
AMERICAS				
USA	1997-2000	28 studies	+1-14, **Avg 5% gain**	Marra et al 2002
USA	1995-2002	8,900 comparisons	**Avg 5% gain**	Industry source 2003a
USA	2001	Survey	3% loss	Gianessi et al 2003
Honduras	2002	Trials in 4 regions	6-21% **Avg 13% gain**	Industry source 2003f
Argentina	1990s-2002	1,500 data points	**Avg 10% gain**	Industry source 2003c
Argentina	2000-2003	Experiments	**Avg 8% gain**	Industry source 2003d
Brazil	1999-2001	Experiments	**Avg 24% gain**	Industry source 2003e
EUROPE				
Spain	2002	Survey and trials	**+5-7%** on infested 36%	Brookes, 2002
Spain	2001	Survey and trials	**Avg 5-7%** nationally	Gianessi et al 2002
Spain	1998	9 field trials	**Avg 11% gain**	Novillo et al, 2003
Spain	1997	Trials in all regions	3 to 13% **Avg 6% gain**	Alcade, 1999
Spain	1995	Trials	**9% loss**, eq to 941 kg/ha	Garcia Olmedo, 2003
Germany	1998-2002	Trials	**Avg 15% gain**	Degenhardt et al, 2003
Germany	1999	Trials	**Avg 12% gain**	Magg et al 2000
Italy	-	Survey	**Avg 7 to 15% loss**	Manchini, 2003
Italy	1993	Survey	**Avg 8% loss**	Onorato and Snidaro, 1993
Italy	1997	Survey/Trials	5 to 20% **Avg 10% loss**	Industry source 2003b
France	1970	Survey	**Up to 15% Avg loss**	Anglade and Rautou, 1970
AFRICA				
South Africa		Trials	**Avg of approx 10% gain**	Kirsten and Gouse, 2003
Kenya	2000/2001	Survey/Expts.	**Avg loss 13.5%**	De Groote et al 2003
Kenya	1998	Survey	**Avg 13% loss**	De Groote 2002
Ghana	1990s	Survey	**Avg 14% loss**	Aquino et al 1999
Cameroon	1990s	Survey	**Avg 14 to 17% loss** in savanna	Gounou et al 1994, Cardwell et al 1997
Ethiopia	1991	Survey	**Avg 8-9%** (1.8 larvae/pl)	Ferdu, 1991

continued...

Table 47 Cont'd. Summary of Yield Gains in Favor of Bt Maize *(cry1Ab)* and Estimates of Loss Due to Stem Borers

Country	Years	Data	Yield Gain/ loss ha*	Reference
ASIA				
China	2003	Survey Asian borer	**Avg 5-7-10% loss**	Wang, 2003
China	2002	Survey Asian corn borer	**Avg 5-7% loss** (6 to 9 mill MT loss/year on prod of 125 mill MT in 2002	He et al 2003
China	2000-2001	Field experiments	**Avg 9.3% gain**	Wang, 2003
China	1998	Field trials (Gov't)	**Avg 23% gain**	Industry source 2003i
China	1998	10 Isolines, 2 Experiments	**Avg 17% gain**	Industry source 2003h
China	1998	Experiments	7-20%, **Avg 10% gain**	Industry source 2003g
China	1997	Field experiments	**Avg 19% gain**	Industry source 2003j
India	1996	Survey	**Avg 5%** loss all maize pests	Dhaliwal and Ramesh Arora, 1996
Philippines	2001/2002	Trials	**25 to 40% gain**	Gonzalez, 2002
Thailand	2003	Survey	**2 to 3% loss**	Narong, 2003

Source: Compiled by Clive James from a literature review; specific citations are referenced in the body of the Table. *Yield gains from Bt maize are calculated from field trials comparing Bt maize and non-Bt maize, and % yield loss estimates are from field surveys for stem borers.

Groote et al 2003). *Chilo partellus* is the most important borer in the low potential area, in the moist mid-altitude regions and the dry mid-altitude and lowland tropical areas. Provided that a Bt gene effective against *Busseola fusca* can be identified and successfully incorporated, losses of the order of $48 million per year can be averted compared with $23 million for *Chilo partellus*. It is estimated that if the IRMA Bt maize project develops resistance to all the major maize borers in Kenya, the internal rate of return on investment over a 25 year period will be $208 million, compared to a project cost of $5.7 million (De Groote et al 2003).

In the Cameroon, Cardwell et al (1997) reported that the African maize stalk borer was the most important species, followed by the African sugarcane borer. Based on information from these studies and the work of Aquino et al (1999), De Groote (2002) estimates crop losses due to stem borers at a national level in Cameroon at 14%.

In Ghana, research work by Gounou et al (1994) concludes that losses due to maize borers were 14 to 17% in the savanna areas and 27% in the rain forest zones.

In Ethiopia, a survey of maize stem borers indicated that losses due to stem borers were of the order of 8 to 9% with an average infestation of 1.8 larvae per plant (Ferdu 1991). Thus, in Africa generally losses due to stem borers caused by *Busseola fusca* and *Chilo partellus* range from 8 to 14 %.

Summary

The literature review of crop loss estimates and yield gains associated with the *cry1Ab* Bt gene for the different global regions/countries already presented in this section are summarized in Table 47. Caution must be exercised in interpreting losses from field trials, which often tend to be located in the higher infestation areas and hence may over estimate losses. Taking into account the inherent variability involved in any such analysis, using both trial and survey results, a pattern of modest gains (5%) is representative for the more temperate environments of North America and Europe whereas higher gains (10% or more), are evident for the subtropical and tropical regions of Africa, Asia and Latin America. This pattern is consistent with fewer generations and lower infestations of borers in temperate environments compared with tropical areas. Given that the field trials to date have been conducted with varieties carrying the *cry1Ab* gene, the gains recorded would be largely related to borer control and somewhat related to control of fall armyworms and earworms, however this would not include control of corn rootworms and cutworms since these are not pests targeted by *cry1Ab*. The gains of an average of 5% in the temperate areas and 10% in the tropical areas is expected to increase as new Bt genes and other novel genes become available, that can provide more effective and broader control of principal pests other than borers. The first of these Bt genes, *cry3Bb1* for the control of corn rootworm, was recently deployed in the US for 2003 and a preliminary assessment of the yield gain associated with this event is reviewed later in this section. The *cry1Fa2* gene was first deployed commercially in 2003 in the US and provides improved and effective control of armyworm, black cutworm and intermediate resistance to corn earworm. When data become available for the assessment of yield benefits from the new generation of genes, *cry3Bb1* and *cry1Fa2,* a follow-up study is anticipated to assess the projected additional benefits that will accrue with the deployment of new Bt genes or novel gene varieties that will provide a broader spectrum and more effective control of the principal maize insect pests on a global basis.

8.9.3 *Preliminary assessment of losses due to corn rootworm in the US and the gains associated with deployment of the cry3Bb1 Bt gene*

Given that the *cry3Bb1* Bt maize for the control of corn rootworm was only first commercialized in 2003 in the US, and that there is a limited data base for assessing crop losses and for projecting benefits, this assessment will be a preliminary analysis with a view to conducting a more detailed assessment following a few years of commercialization.

Corn rootworms currently infest a total of over 20 million hectares in the Americas and have been detected in 13 countries in Europe (see Figure 10). In the Americas corn rootworm has infested 13 million hectares in the US, 5 million hectares in Brazil, 1 million hectares in each of Canada and Mexico, and 0.1 million hectare in Argentina (Table 48).

The two most important species of corn rootworm in the US are the Western corn rootworm (*Diabrotica virgifera, virgifera*) and the Northern corn rootworm (*Diabrotica barberi*) that cause serious losses. Initially, rotation with soybean was an effective way of controlling corn rootworm but the emergence of a soybean variant, that resulted in corn rootworm attack of first year maize, and the appearance of a second variant with extended diapause eroded the protection provided by rotation with soybean. Also, resistance has developed to many insecticides used to control corn rootworm, thereby reducing options for control with insecticides and rotation.

The Agricultural Research Service (ARS 2001) estimates that, on average, corn rootworms result in annual crop losses and control costs in the US valued at $1 billion. The area infested in the US is 13 million hectares of which approx. 6.0 million hectares (estimated at 5.7 million hectares in 2000) are treated with insecticide for the control of corn rootworm. It has been estimated that the *cry3Bb1* Bt gene increases yield by 9% to 28% compared with unsprayed conventional maize and 1.5 to 4.5 % (average of 3%) versus conventional maize treated with a soil insecticide for the control of corn rootworm (Mitchell 2002, Rice 2003, Glick and Pershing 2003). However, caution should be exercised in assessing yield effects at this early stage because they are based on initial evaluations. In 2000 it is estimated that farmers spent approx. $30/hectare on insecticide for control of corn rootworm for a total cost of $171 million (Alston et al 2002) using 3.4 million kg a.i. of insecticide, which is the highest use for any single insect pest in the US and represents

Table 48. Global Distribution of Corn Rootworm

Million hectares infested in Americas:		Detected in Europe:	
US	13.0	Yugoslavia	Hungary
Brazil	5.0	Bulgaria	Romania
Canada	1.0	Italy	Switzerland
Mexico	1.0	France	Slovakia
Argentina	0.1	Ukraine	Austria
		Netherlands	Czech Republic
		UK	
TOTAL	**20.1**	**13 Countries**	

Source: Glick and Pershing, 2003

about 60 to 80% of all insecticides used on maize in the US. Based on an international price for maize of $108/MT, a 3% increase in yield, despite application of insecticides, would be equivalent to $750 million plus $170 million for insecticides (without application costs) for a total of $920 million, or about $ 1 billion, which is consistent with the estimate of USDA.

At the farm level, assuming that the cost of control is the same for insecticides and the *cry3Bb1* gene, studies indicate that control with Bt will increase profitability by $20/hectare at low infestation levels, and $72/hectare at high infestation levels (Glick and Pershing 2003). Thus, average benefits from deploying Bt were estimated at $42/hectare for a total of $168 million on 4 million hectares. This substantial benefit does not include additional advantages to which farmers assign high priority including the convenience, flexibility, and efficiency of employing Bt technology versus insecticides, the reduced risk and insurance re. crop losses, and the lower exposure to pesticides for farmers and the environment.

An ex-ante study conducted by Alston et al (2002), estimated the impact of the Bt *cry3Bb1* technology, assuming Bt cost to be the same as insecticide control, on 100% of the maize area treated with insecticides for control of corn rootworm in 2000. The study projected a total benefit of $460 million, of which $ 231 million accrued to farmers in the form of increased yield; an additional $58 million accrued to farmers for time savings, reduced risks, and other benefits associated with reduction in insecticides for a total benefit of $289 million to farmers, equivalent to about two-thirds (63%) of the total surplus of $460 million. The technology developers and the seed companies accrued the balance of the surplus of $171 million representing about one third (37%) of total benefits (Table 49).

Table 49. Estimated Distribution of Benefits from Deploying Bt *cry3Bb1* in the US in a Simulation for 2000

Benefits and Beneficiaries	US$ Millions	%
Increased yield	231	50
Other farmer benefits	58	13
Sub total farmer benefits	289	63%
Tech. Development/Seed industry	171	37%
TOTAL	**460**	**100**

Source: Alston et al 2002.

The field trial data and ex-ante study data available from the US for *cry3Bb1* are not available for other potential near-term markets in Brazil, Canada and Argentina, where the potential is significant given that a total of more than 6 million hectares of maize is already infested in the three countries. In Europe, for the longer term, losses from corn rootworm could escalate if current infestations increase in intensity and losses become higher in the 13 countries already infested during the last decade and other countries at risk of becoming infested.

8.9.4 Benefits from controlling corn rootworm with *Cry3Bb1*

Prudence should be exercised in interpreting the yield loss data presented here for the US for corn rootworm, which should be considered as a preliminary assessment, because the data is based on initial evaluations of field trials and evidence from ex-ante studies based on 2000 data. Nevertheless, it is evident that control of corn rootworm through Bt technology offers enormous agronomic, economic, and environmental advantage, which can benefit farmers and global society. The major benefits expected from the *cry3Bb1* in the US are estimated to be as follows (Alston et al 2003, Glick and Pershing 2003, Rice 2003):

- Yield increase of 1.5 to 4% which translates to a national benefit in the US of $168 million equivalent to $42 per hectare on 4 million hectares

- Increased management efficiency valued at $41 million in the US equivalent to $10.32 per hectare

- Reduced insecticide use estimated at 2,400 MT a.i. in the US equivalent to 0.6 kg per hectare

- Reduced environmental waste through eliminating 1 million fewer plastic containers

- Reduced energy consumption equivalent to 21.9 million liters of fuel
- Reduced water consumption equivalent to 21.2 million liters

8.10 The global maize insecticide market

In 2001, the global insecticide market for 140 million hectares of maize was approximately 10,750 MT a.i., worth over $550 million (Table 50); this compares with the largest insecticide market in the world for a single crop, cotton, totaling 80,000 MT of insecticides worth $1.7 billion on 35 million hectares. In the 2001 global maize insecticide market, North America accounted for 40% of the global market followed by Latin America at 25%, with Europe, Far East/Asia-Pacific and the rest of the world at approx. 10% each. By far the largest markets are the US at 4,337 MT and Brazil at 2,069 MT, which together represent 60% of the world market for maize insecticides.

The market in the Far East Asia-Pacific (1,400 MT) is relatively small considering that Asia has 40% of the global hectarage of 140 million hectares of maize with China, India and Indonesia dominating in maize production. The European market is 1,075 MT with most (700 MT) of the maize insecticides used in France, Spain, Italy and Greece with the balance of 375 MT applied in Eastern Europe.

There are marked differences between the two large maize insecticide markets of the US and Brazil. For the US, it is estimated that approximately 80% of all maize insecticides are applied to soil, targeting the major pest, corn rootworm. This contrasts with only 45% of maize insecticides applied to soils in Brazil, because soil applications don't control the major pest, fall armyworm, but do impact white grubs, a more damaging pest in Brazil than corn rootworm, which is also present. Seed treatment, which is more effective against grubs than corn rootworm, accounts for 33% of total maize insecticide use in Brazil compared with only 4% in the US. Sprays, which can control leaf feeding by fall armyworm, account for 22% of total insecticide application in Brazil compared with 14% in the US, where foliar feeding is less of a concern (Table 51).

The US is the largest maize insecticide market (4,337 MT) in the world. In 2001, 60% of all maize insecticides (Table 52), equivalent to 2,472 MT was used to control the most important maize pest, corn rootworm; this was mostly applied to the soil, but sprays are also used to control adults feeding on silks and ears during the maize growing season. Efficacy of insecticides used to control corn rootworm through soil applications, is dependent on interaction with the variable soil ecological conditions which impact on the toxicity, volatility and solubility of the active ingredients. Therefore, control can be uneven because these factors can vary with application methods, formulations, soil and climatic conditions. Several insecticides are recommended for corn rootworm in the US with organophosphates and pyrethroids representing 80% of the product (Glick and Pershing 2003), primarily because of cost and efficacy. Some estimates (Oehme

Table 50. Value and Quantity (MT a.i.) of Global Maize Insecticide Market, by Region, 2001

Region/Country	$ Millions	MT a.i.	%
NORTH AMERICA	266	4,350	(40%)
United States	243	4,337	(40%)
LATIN AMERICA	135	2,719	(25%)
Brazil	102	2,069	(19%)
Rest of Latin America	33	650	(6%)
Subtotal North and Latin America	401	7,069	(66%)
EUROPE	85	1,075	(10%)
Western Europe*	64	700	(6.5%)
*France, Spain, Italy, Greece are the major users	60		
Eastern Europe	21	375	(3.5%)
Sobtotal Europe	85	1,075	(10%)
Far East/Asia Pacific	32	1,400	(13%)
REST OF WORLD	45	1,200	(11%)
GLOBAL TOTAL	**563**	**10,744**	**(100%)**

Source: Cropnosis (formerly Wood Mackenzie), 2003. Personal communication.

Table 51. Mode of Application of Insecticides in the USA and Brazil in MT a.i.

	Soil application	Seed Treatment	Sprays	Total
USA	3,578 (82%)	170 (4%)	589 (14%)	4,337
Brazil	930 (45%)	679 (33%)	460 (22%)	2,069

Source: Cropnosis (formerly Wood Mackenzie), 2003. Personal communication.

Table 52. Use of Insecticides on Maize in the US, by Target Pest, 2001

	Qty ('000 tonnes a.i.)	Expressed as %
1. Corn rootworm	2,472	57%
2. ECB and southwestern corn borer	477	11%
3. Corn earworm	520	12%
4. Others	865	20%
TOTAL	**4,334**	100%

Source: Cropnosis (formerly Wood Mackenzie), 2003. Personal communication.

and Pickrell 2003) indicate that in seasons of high corn rootworm infestation, 80% of all maize insecticides used in the US is targeted against this one pest; Oehme and Pickrell (2003) also reported survey results indicating that two-thirds of the farmers using insecticides for the control of corn rootworm would switch to a Bt gene product if it was available. It is estimated that, on average, 13 of the 32 million hectares of maize in the US are infested with corn rootworm and 6 million hectares are treated with insecticides. This is equivalent to treating 18% of the 32 million hectares of maize in the US making this the largest use of insecticide for any crop pest in the US, accounting for between 60% and 80% of total insecticide use on maize.

In contrast to the heavy insecticide usage in the US for corn rootworm, it is estimated that 10% (500 MT in 2001) or less, of maize insecticide applications are for stem borer control, the second most important maize pest complex in the US, mainly for European corn borer and Southwestern corn borer. For example, prior to the introduction of Bt maize it was estimated that in an average year about 500,000 hectares, or 2% of the 32 million hectares of maize, would be treated for borers. European corn borer is estimated to infest approx. 40% of the 32 million hectares of maize in the US and capable of significant losses of up to 7.5 million MT when infestations are high. However, the stem borers are not effectively controlled with insecticides leading farmers to apply insecticides only when infestations are severe. Stem borers feed deep within the maize plant, protected from surface applied insecticides, which render sprays ineffective. Thus, on a global basis it is estimated that only about 10% of the global maize insecticide tonnage of 10,750 MT is used for stem borer control, because of the low efficacy, with most of that used in the USA and Europe, with relatively small markets in Latin America and less still in Asia. The third principal pest of maize in the US, the corn earworm, consumes approx. 10% of total insecticides, equivalent to 500 MT per annum. The remainder, equivalent to 20% or about 870 MT, is used for a variety of insect

Table 53. Percentage of Maize Hectares Treated with Insecticides for Targeted Insect Pests in Brazil

Insect pest	% of total hectares treated with insecticide
Fall armyworm	60%
Corn rootworm	10-25%
Cutworm	5 to 10%
Corn earworm	1-10%
Borers	5%

Source: Various sources, compiled by Clive James 2003.

pests, which vary in infestation by year and region.

For Brazil, the other large maize insecticide market, the situation is quite different from the USA. The major pest in Brazil is fall armyworm for which up to 60% of the 12 million hectares is treated. Of the 12 million hectares of maize in Brazil, approx. 9 million hectares are in commercial production of high-yielding hybrids, where insecticide use is a standard part of agronomic practice. Approximately 5 million hectares are estimated to be infested with corn rootworm in Brazil, but only 10 to 25% of the 12 million hectares are treated with insecticides targeting this pest. In addition to controlling fall armyworm with insecticides, about 5 to 10% of total maize hectares are treated with insecticides for cutworm, 1 to 10% for corn earworm, and 5% for borers. Control of the stem borers, lesser corn stalk borer and sugarcane borer, requires special tractors and equipment to apply insecticides, and even then control is not very effective, so most farmers do not spray for borers even though borer infestation can cause significant damage and losses.

8.10.1 Potential for insecticide substitution

From a global perspective, usage of maize insecticides is relatively small at 10,750 MT per annum on 140 million hectares – equivalent to about 13% of the 80,000 MT of insecticide used annually on cotton, which consumes more insecticide than any other single crop. Bt or other novel genes for insect control, will impact insecticide use the most, in the near-term, if targeted to the control of corn rootworm in the US. Complete substitution of insecticides for corn rootworm in the US with Bt would displace 2,500 – 3,500 MT a.i., equivalent to 25% to 30% of the global maize insecticide market. This is consistent with the estimates of insecticide savings of 2,400 MT a.i. projected by Glick and Pershing 2003.

Genes that confer resistance to corn rootworm include the *cry3Bb1* already launched in 2003, the dual gene product, *cry34Ab1* & *cry35Ab1,* expected to be registered in 2005, and the full length modified *cry3Aa* expected to be launched in 2006. Thus, within the next three to five years there could be a substantial substitution of insecticides used for corn rootworm in the US with three new gene products. Significant substitution, albeit at a lower level than that for corn rootworm, could also impact insecticides used to control fall armyworm, mainly in the Americas, and more particularly in Brazil, where fall armyworm is the principal pest responsible for approximately 1,000 MT of insecticide applications per annum. Thus, globally, substitution for fall armyworm could be in the range of 1,000 to 1,500 MT. Whereas several of the current Bt gene products provide intermediate control of fall armyworm, the new hybrids containing the cr*y1Fa2* gene, widely available commercially in 2004, should provide very effective control of the pest. Substitution for insecticide applications used for stem borer control, particularly European corn borer and Southwestern corn borer, has already been realized in the US (Gianessi et al 2003) and the potential globally for this pest complex alone is estimated to be 1,000 to 1,500 MT. Finally, substitution for insecticides currently used for corn earworm, which is partially controlled by both Bt and insecticide applications, might provide additional savings of between 500 MT and 1,000 MT per annum. Thus, the global potential for substitution of the 10,750 MT of maize insecticides currently used, with Bt and other novel gene products, could total from 3,000 to 5,000 MT over the next five years as new gene products are commercialized in the US, and would be optimized if Brazil commercializes Bt maize. This is a significant potential substitution, equivalent to at least one third or more of the current maize insecticide market of 10,750 MT valued at $550 million.

The above estimates of insecticide substitution reflect the further development of a trend for pesticide substitution that is already underway. The rapid increase in transgenic crops in the USA and Canada coincided with the first significant decline in pesticide sales in North America. In 1999, sales decreased by 10.9 % to $ 7.19 billion. Many factors including low commodity prices were also responsible for the decrease but the major factor was the increased area of transgenic crops. In 1999, US insecticide use decreased by 5.3 % to $ 1.38 billion due to the adoption of Bt maize and cotton (Wood Mackenzie Agrochemical Services 2001, Personal communication).

Farmers' exposure to insecticides remains a concern with 18,000 to 26,000 cases of non-fatal poisonings in the US every year, with 8,000 requiring evaluation for organophosphate-carbonate poisonings. Farmer surveys indicate a high preference for Bt maize rather than insecticides to control maize pests and this is confirmed with farmers adopting 8.5 million hectares of Bt maize for control of European corn borer in the US in 2002 (Oehme and Pickrell 2003). There is a high probability that farmers in the US will also elect to use Bt maize products in preference to insecticides for corn rootworm control, and this should result in a substantial reduction of up to 3,500 MT over time, which will also reduce exposure of farmers to insecticides. In a survey of farmers in the US, 30% of respondents indicated that they expected to benefit from lower exposure to pesticide from Bt maize targeted at control of corn rootworm.

It is noteworthy that Asia, with 40% of the global maize area, is using only 1,400 MT of maize insecticide. Asian corn borer is known to infest a high percentage of maize in countries like China, but insecticide control is not very effective for this pest, hence the usage only in areas of very high infestation. Low use of insecticides for Asian corn borer in the Far East/ Asia Pacific does not mean that management of pests is not important; on the contrary given the significant yield increases recorded for Bt maize in China and the Philippines, Asia represents a significant new market for Bt maize that insecticides have not been able to capture because of the low efficacy of insecticide control for the principal pests.

Thus, in summary, the major opportunity for substitution of insecticides with Bt maize and maize containing other novel pest resistance genes is principally for corn rootworm and armyworm, followed by stem borers and earworms. Continued growth in use of biotechnology could substitute one-third or more of the current 10,750 MT of insecticide a.i. applied for these targeted pests. Bt products have also the potential of capturing new markets in Asia and Latin America, in particular where insecticides have not had the efficacy to control important pests such as Asian corn borer and sugarcane borer respectively. These potential new markets for Bt maize will become more attractive as increasing productivity will increase the value of maize production per hectare, making deployment of Bt products more attractive and profitable for farmers.

8.11 The use of Bt genes in maize

Bacillus thuringiensis (Bt) is a spore-forming bacterium species that is commonly found in soil. Bt contains a native crystal protein that when ingested by insect pests, causes a lethal paralysis in the digestive tract. Bt foliar sprays have been used for 50 years to control insect pests and have a long history of safe use. Bt sprays are one of few insecticides permitted for use in organic farming.

8.11.1 Approved Bt genes in maize

The approved Bt maize events contain genes from the isolate *B. thuringiensis*, ssp *kurstaki* that produces Cry1Ab protein, from *B. thuringiensis*, var *kumamotoensis* that produces Cry3Bb1 protein and from *B. thuringiensis*, var *aizawi* that produces Cry1Fa2 protein. All the Bt maize currently deployed contains one synthetic gene, a promoter and other sequences - see Table 54 for the genetic characteristics of the different events currently used in commercial Bt maize.

The first Bt maize product with *cry1Ab*, Bt 176, was approved in 1995 and deployed in the US in 1996 (Shelton et al 2002). The events with the *cry1Ab* gene are listed in Table 55 and provide information on the name of the event and gene and the countries where they have been approved. They include event 176 developed by Syngenta and approved in the US in 1995, approved in Canada in 1996 and Argentina in 1998; Bt 11 from Syngenta, approved in 1996; and MON 810 developed by Monsanto and approved in 1996. Monsanto proceeded to gain approval for MON 810 in Canada and South Africa in 1997, in Argentina and the EU in 1998, Bulgaria in 2000, the Philippines and Honduras (pre-commercial) in

Table 54. Genetic Characteristics of Bt Maize

Event	Genes	Promoter and Sequence
MON 810	*cry1Ab (Bacillus thuringiensis subs. kurstaki)*	Enhanced CaMV 35S; mize HSP70 intron
Bt 176	*cry1Ab (Bacillus thuringiensis subs. kustaki, Btk)*	Gene copy 1: maize phophoenolpyru-vate carboxylase gene and CaMV35S terminator; Gene copy 2: calcium-dependent protein kinase gene and CaMV 35S
Bt 11	*cry1Ab* (delta-endotoxin) (Btk HD-1) (*S. viridochromogenes*)	CaMv 35S; IVS 6 intron from the maize alcohol dehydrogenase gene
MON 863	*cry3Bb1* isolated from *B.t subsp. Kumamotoensis* (B.t.k.)	CaMV 35 S promoter Intron of the rice actin 1 sequence (ractl)
TC1507	*cry1Fa2* (*cry1F* delta-endotoxin from *Bacillus thuringiensis var. aizawai*) from ORF25	

Source: Carpenter et al 2002 modified

2002, and Uruguay in 2003. Similarly, Syngenta proceeded to gain approval for Bt 11 in Canada and Japan in 1996, and in Argentina in 2001.

The *cry1Ab* gene is generally targeted at the family of different stem borers that are economic pests in the countries where Bt maize is grown commercially today – USA, Canada, Argentina, Honduras, South Africa, Spain, Germany and the Philippines. Of the three events with *cry1Ab*, MON 810, Bt 176 and Bt 11, MON 810 was estimated to account for over 80% of Bt maize planted in 2002.

An event that does not appear in Table 54 is event CBH-351 with *cry9C* for European corn borer control. The event, known as Starlink, was approved for use only for feed and only in the US and was later voluntarily withdrawn by its developer, Aventis CropScience. Even though this event is no longer approved, for completeness, an overview of developments related to Starlink is presented here. In September 2000, representatives of a US consumer organization reported that StarLink corn, was detected in a food product, Kraft's Taco Bell tortillas. Because Starlink was not

Table 55. Bt Maize Events that have been Approved for Commercial Planting

Event	Gene	Year approved	Country	Product Name	Company
MON 810	*cry1Ab*	1996	USA	Yield Gard®	Monsanto
		1997	Canada	Corn borer	
		1997	South Africa		
		1998	Argentina		
		1998	EU		
		2000	Bulgaria		
		2002	Philippines		
		2003	Uruguay		
Bt 11	*cry1Ab*	1996	USA	Yield Gard®	Syngenta
		1996	Canada		
		1996	Japan		
		2001	Argentina		
176	*cry1Ab*	1995	USA	Knockout®	Syngenta
		1996	Canada		
		1997	EU*		
		1998	Argentina		
MON 863	*cry3Bb1*	2003	USA	Yieldgard®	Monsanto
		2003	Canada	Rootworm	
TC 1507	*cry1Fa2*	2001	USA	Herculex® 1	Pioneer Hi-Bred
		2002	Canada		- DuPont and
			Japan		Mycogen Seeds -
					Dow Agro Sci.

Source: Benedict and Ring (In Press) (modified). *regulated by hybrid registration which have been registered in France, Spain and Portugal; cultivation up to 500 hectares in Germany.

approved for use in food, the unverified detection initiated a voluntary recall of all products that might contain Starlink corn. While other varieties of maize have been approved in the US with a *Bt* gene, and grown commercially to confer pest resistance, StarLink corn varieties were the only ones commercialized containing Cry9c protein. StarLink corn was grown on only approximately one–half of one percent of all maize acreage in the US in 2000; it was the only Bt maize variety approved for use in animal feed without concurrent approval for use in foods for human consumption. While there are no known health risks associated with Starlink there were some questions about its allergenic potential that remained unanswered.

The Environmental Protection Agency convened a special Scientific Advisory Panel (SAP) meeting in July 2001 to evaluate information available on StarLink corn. The final report reaffirmed previous conclusions of the panel and provided new recommendations. The panel still concluded that there was a "low probability of allergenicity" in the exposed population based on levels of StarLink corn in the US diet. The Panel endorsed USEPA's conclusion that the process of wet-milling maize removed almost all of the Cry9C protein from products made by that process. Also, the panel stated that there was not enough information to establish with scientific certainty that exposure would not be harmful to public health and they could not establish a specific tolerance level for Cry9C. Therefore, based on the panel's recommendations, establishing a tolerance for StarLink in human food products was not supported. The SAP also agreed with EPA estimates that StarLink corn would essentially be eliminated from the US maize grain supply by 2002 (USEPA 2001). The product is no longer planted and the registration for StarLink corn has been withdrawn. Further information can be found on the CAST 2000 website (www.cast-science.org/biotechnology/20000925.htm) and at the USEPA website (http://www.epa.gov/oppbppd1/biopesticides/index.htm).

Based on the experience with StarLink corn, the following protocol now applies: the USEPA will only grant biotech product registrations if tolerance exemptions for plant incorporated protectants (PIPs) for both food and feed are scientifically supported. It has also been proposed that: USEPA require that testing methods for detection of PIPs, be validated in grain and processed fractions, and be available prior to registration; and that USDA establish laboratories to validate commercially available methods for detecting PIPs in commodity grains intended for both internal trade and export. The PIP rule effective September 2001 clarifies that the DNA of PIPs is exempted from the requirement of tolerance.

The information in Table 56 provides LC_{50} data for lepidopteran sensitivity to bacterially expressed Cry1Ab delta endotoxin fed in an artificial diet to some of the important insect pests of maize. It is evident that the low LC_{50} values for Southwestern corn borer, beet armyworm, corn earworm and European corn borer are indicators for effective control of these pests whereas the high level of LC_{50} value for

Table 56. Efficacy of Cry1Ab Protein in Controlling Selected Lepidopteran Maize Insect Pests; Acute Sensitivity to Cry1Ab Endotoxin Protein

Insect Pest	LC_{50} µg/g
Southwestern cornborer	0.08-0.15
Beet armyworm	3.18
Corn earworm	3.45
European cornborer	3.60
Black cutworm	>80.00
Fall armyworm	95.89

Source: Wolt et al 2003, based on data of Chakrabarti et al 1998, Lutrell et al 1999 and MacIntosh et al 1990.

black cutworm and fall armyworm indicates suppression rather than effective control. The *cry1Ab* gene is expressed in maize tissues throughout the maize cycle providing season–long control.

Even though the *cry* gene is the same in MON 810, Bt 11, and 176, the expression of Bt protein is affected by the gene construct that is introduced into a specific event. The expression is also influenced by the conditions under which maize is grown and the pest infestations that develop. For example, event 176 contains lower levels of the Cry1Ab protein in the leaves than in Bt 11 or MON 810 and also is not expressed in the grain, and, therefore, lends little protection for ear infestations.

The estimated level of control for different pests at the field level in various countries for the MON 810 event, the most widely deployed globally, is shown in Table 57. Excellent and effective control is provided for European corn borer, Southwestern corn borer, sugarcane borer, southern corn stalk borer, Asian corn borer, *Chilo* spp and corn earworm at the whorl stage. In addition, the following pests are suppressed, if not highly controlled: corn earworm (ear), fall armyworm (whorl and ear), with variable control of African stalk borer and some species of *Sesamia* such as *S .inferens*.

To summarize, the advantages of the *cry1Ab* gene in Bt maize versus application of insecticides are as follows:

- Active protein provides moderate to high dose control that allows fair to excellent control of selected important lepidopteran pests
- Active protein expressed in the parts of the plant that are susceptible to attack by the targeted insect pests
- Active protein expressed throughout the season, hence timing of insecticide applications in relation to an infestation is not a concern
- Wash-off of insecticide during rain, and degradation in sunlight are not concerns as they are with spray formulations
- Reduced farmer exposure to insecticide
- Labor saving technology, due to elimination or reduction of insecticide sprays

Table 57. Performance of MON 810 (*cry1Ab*) for Controlling Selected Maize Insect Pests in Yield Gard® Maize

Excellent/Effective Control	Intermediate Control/Suppression
European corn borer	Corn earworm (ear)
Southwestern corn borer	Fall armyworm (whorl and ear)
Sugarcane borer	African stalk borer
Southern corn stalk borer	Some *Sesamia spp. e.g. inferens*
Corn earworm (whorl)	
Asian corn borer	
Chilo spp.	

Source: Personal communication 2003.

- Decreases production risks and provides peace of mind and insurance to farmers at cost-effective control rates

- Contributes to, and provides the foundation for an IPM strategy

8.11.2 Newly released Bt genes

Event MON 863

A more recent addition to the family of Bt genes in maize resulted from the early 2003 regulatory approval of MON 863 in the US and Canada that allowed the introduction of Yield Gard® rootworm in the US in 2003. MON 863 contains the *cry3Bb1* Bt gene which provides effective control for corn rootworm, which is a very serious pest of maize in the US and consumes more insecticides than any other pest in the US; it also infests significant hectarage in Brazil, Canada, Mexico and Argentina. Over the next few years the availability of the corn rootworm trait should contribute to significant growth in GM maize hectarage in the US, where approximately 18% of the maize hectarage of 32 million hectares, is currently treated with insecticides for corn root worm and is, therefore, likely to benefit rapidly from the technology. There is a significant overlap between areas infested with European corn borer and corn rootworm, and thus some of the new products will have stacked traits for the control of these two insect pests, and other secondary lepidopterans. The global Bt maize area, including stacked traits, is likely to increase significantly in the near term. The expansion of Bt maize in the global hectarage of 140 million hectares will occur mainly in established *cry1Ab* Bt maize country markets such as the US, Canada, South Africa and Argentina. Bt maize with *cry1Ab* will also increase in new countries like the Philippines, which introduced Bt yellow maize for the first time in 2003 for the control of Asian corn borer, and Honduras, that grew pre-commercial Bt maize in 2002.

Event TC 1507

Event TC 1507 is also a recent addition to the Bt maize options, approved in the US in 2001, and Canada and Japan in 2002. Commercialization was initiated in the US in 2003 with large-scale commercialization anticipated in North America in 2004. The TC 1507 event has the *cry1Fa2* gene that provides a broader spectrum of activity that includes excellent protection against 1st and 2nd generation European corn borer, Southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, and intermediate suppression of corn earworm (Table 58).

Table 58. Efficacy of TC 1507 with the *cry1Fa2* Gene in Herculex® 1 Bt Maize

Excellent/Effective Control	Intermediate Control/ Suppression
European corn borer	Corn earworm
Southwestern corn borer	
Black cutworm	
Fall armyworm	
Western bean cutworm	

Source: Dow AgroSciences 2003

Selection of Stacked genes

Following introduction of maize expressing the first Bt genes in 1996, technology developers began to combine or stack Bt genes with genes for herbicide tolerance. The practice of stacking meets the needs of farmers who usually have to contend with multiple constraints related to biotic stresses due to pests, weeds and diseases at the same time. Stacking is a trend that will become more prevalent as new genes become available, not only for biotic stresses but also for abiotic stresses related to drought and salinity, and traits for enhancing nutritional qualities. Stacking genes with different mechanisms of resistance in one variety offers the important opportunity to optimize diversity and hence the durability of resistance genes for a specific pest or group of pests, and to deploy them within the context of an IPM strategy. This has already been done in the development of Bollgard® II cotton which has dual genes for lepidoptera resistance with different modes of action. As the second generation of insect genes become available in maize, parallel developments to Bt cotton will be realized. Some of these new products are discussed in the next section, which summarizes the next generation of genes for insect pest control in maize.

8.11.3 Next generation of insect resistance genes in maize

There are five new products in the pipeline, subject to regulatory approval they are planned for launch between 2004 and 2006 and are listed in Table 59.

1) Yield Gard® Plus – anticipated launch, 2004

This product, in development at Monsanto, combines two genes, *cry1Ab* and *cry3Bb1,* both of which have already been approved and commercialized as single events (MON810 and MON863). It is expected that Monsanto will offer three products for maize farmers in the US: the single *cry1Ab* (YieldGard® corn borer), the single *cry3Bb1*(YieldGard® Rootworm), and the combined *cry1Ab* and *cry3Bb1* (YieldGard® Plus). These options coincide with different farmer needs, some of whom will only require to control European corn borer with *cry1Ab*, others who will only require to control corn rootworm (*cry3Bb1*) and others who will require to control both European corn borer and corn rootworm with the stacked genes *cry1Ab and cry3Bb1*. The latter is potentially a significant market because of the considerable overlap in areas infested with both European corn borer and corn rootworm in the US.

2) The genes cry34Ab1/cry35Ab1 for corn rootworm control – anticipated launch, 2005

Dow AgroSciences has developed a product which utilizes two separate Bt genes in concert, *cry34Ab1* and *cry35Ab1* for the control of corn rootworm. The mode of action of the two gene products are complementary and similar to the *cry1* genes (Moellenbeck et al 2001). Dow AgroSciences and Mycogen Seeds, in conjunction with Pioneer Hi-Bred International/ DuPont, expects to launch this product in 2005, pending regulatory approval. This product provides an alternate source of corn rootworm resistance to MON 863, based on a different mode of resistance.

Table 59. Future Gene Products Conferring Resistance to Insect Pests of Maize

Gene Source	Principal Target Insect Pests	Company/ies	Product Name Anticipated Launch
cry1Ab and *cry3Bb1*	Corn rootworm and selected Lepidopteran pests	Monsanto	Yield Gard® Plus 2004
cry34Ab1 and *cry35Ab1*	Corn rootworm	Dow AgroSciences/ Pioneer-DuPont/ Mycogen Seeds	2005
Full length *cry1Ab*	European corn borer	Syngenta	2005
Stacked genes of full length *cry1Ab* and *vip3A*	Broad range of lepidopteran pests	Syngenta	2006
Full length modified *cry3Aa*	Corn rootworm	Syngenta	2006

Source: Information provided by respective companies, and compiled by Clive James, 2003

3) Full length cry1Ab – anticipated launch, 2005

This product in development by Syngenta is for the control of European corn borer and will be an addition to the products that are already deployed for the control of this important insect pest.

4) Stacked genes of full length cry1Ab and vip3A - anticipated launch, 2006

This stacked gene product being developed by Syngenta is aimed at providing control of a broad range of lepidopteran pests. In addition to the *cry1Ab* gene that already features in several products deployed, it incorporates a new *vip3A* gene which will provide diversity in terms of mechanism of resistance. Subject to regulatory approval it is planned for launch in 2006.

5) Full length modified cry3Aa – anticipated launch, 2006

This gene product under development at Syngenta is aimed at the control of corn rootworm and features a new gene *cry3Aa*. Pending approval, the launch is planned for 2006 when it is expected to join two other products (*cry3Bb1*) launched in 2003 and *cry 34Ab1/cry35Ab1* expected to be launched in 2005.

What is already being witnessed is a rapid increase in the number of genes and in the mode of action of genes available for controlling insect pests in maize and a broadening of the number of pests that can be effectively controlled. Thus, the initial *cry1Ab* gene used for control of European corn borer and other selected lepidopteran pests is being initially fortified in terms of different varieties being available to farmers with genes that will include *cry1Fa2* and later the full length *cry1Ab* and also the dual gene product, *cry1Ab* and *vip3A* gene, to provide diversity in modes of resistance. This increased diversity in modes of action of resistance genes is a critical contribution to the effective and responsible management of resistance within the context of an IRM strategy for effectively controlling the lepidopteran pests. Similarly, the first gene deployed for corn rootworm, *cry3Bb1*, is expected to be complemented in the marketplace with different varieties being available to farmers with other genes that will include the dual gene product *34Ab1* and *35Ab1* in 2005 and by the full length modified *cry3Aa* gene in 2006. The stacked genes in products such as *cry1Ab/cry3Bb1* provide control of selected lepidopteran pests and corn rootworm. These are very encouraging developments which provide the confidence and trust that biotechnology is capable of contributing rapidly to the required diversity of resistance that is a pre-requisite for the operation of an effective and responsible IRM strategy that will allow optimization of the durability of resistance genes. In practice, this will allow farmers to have access to more options that better suit their specific pest management needs. This is very important, particularly for the maize crop, which is grown in more environments than any other cereal crop, and thus requires the broad range of options that the new generation of pest resistant genes in maize offer. The same philosophy of optimizing options applies to all the quality genes that will become available in maize in due course, catering to different maize utilization markets in food, feed or industrial uses, grown in the four quite different mega-environments of tropical, subtropical, highland and temperate. Of all the GM crops, maize will probably be the one that will offer the most options in terms of different combinations of pest management and quality genes to suit a very diverse market. Indeed, biotechnology already offers a very broad range of options for pest management and is approaching a stage when it can better tailor its suite of insect resistance traits for maize germplasm development in direct response to the demand-driven needs of the diverse global maize market.

8.12 Adoption of Bt maize

It is noteworthy that Bt maize is second only to RR® soybean in terms of global GM crop adoption and represented 17% of the global GM area in 2002. Between 1996 and 2002 a total of 43.3 million hectares of Bt maize was grown worldwide in nine countries. To put this hectarage into context, this is equivalent to almost one-and-a-half times the area planted to maize in the US annually, which is around 30 million hectares. In 2002, global Bt maize hectarage (9.9 million hectares) almost reached the historical milestone of 10 million hectares or 25 million acres, which is likely to be exceeded in 2003. Bt maize hectarage increased by 29% between 2001 and 2002 and is expected to continue strong growth in the near-term in traditional *cry1Ab* markets, with new market segments developing as a result of new products deployed for corn rootworm in the US and Canada, plus enhanced Bt products such as the *cry1Fa2* that provide broader control of pests such as fall armyworm and cutworms.

The adoption of Bt maize on a global basis is captured in Figure 14 based on data detailed in Table 60. The adoption curve starts at 0.3 million ha in 1996, all of which was grown in the US, leading up to 9.9 million hectares in 2002. Notable features are that the number of countries adopting Bt maize increased from one industrial country in 1996 to seven countries in 2002, four industrial - US, Canada, Spain and Germany, and three developing countries, Argentina, Honduras and South Africa. The Philippines adopted its first Bt maize in 2003.

Whereas the US was the only country to adopt Bt maize in 1996, it was joined in 1997 by Canada (Table 61). 1998 was a watershed year for Bt maize with four new countries adopting Bt maize for the first time – Argentina, South Africa, from the developing countries and two countries from the European Union, Spain and France growing token hectarages of Bt maize. Portugal joined the group of Bt maize adopters in 1999 but withdrew the registration a year later. In 2000, Germany started to grow a small hectarage of Bt maize and has continued to grow a few hundred hectares of Bt maize for the last three years. Although there was a slight consolidation from 8.2 million hectares to 7.7 million hectares globally in 2001, growth revived in 2002 to reach almost 10 million hectares, equivalent to 7.1% of the global maize

Figure 14. Global Adoption of Bt Maize (Bt and Bt/Herbicide Tolerance) 1996 to 2002 (Millions of Hectares)

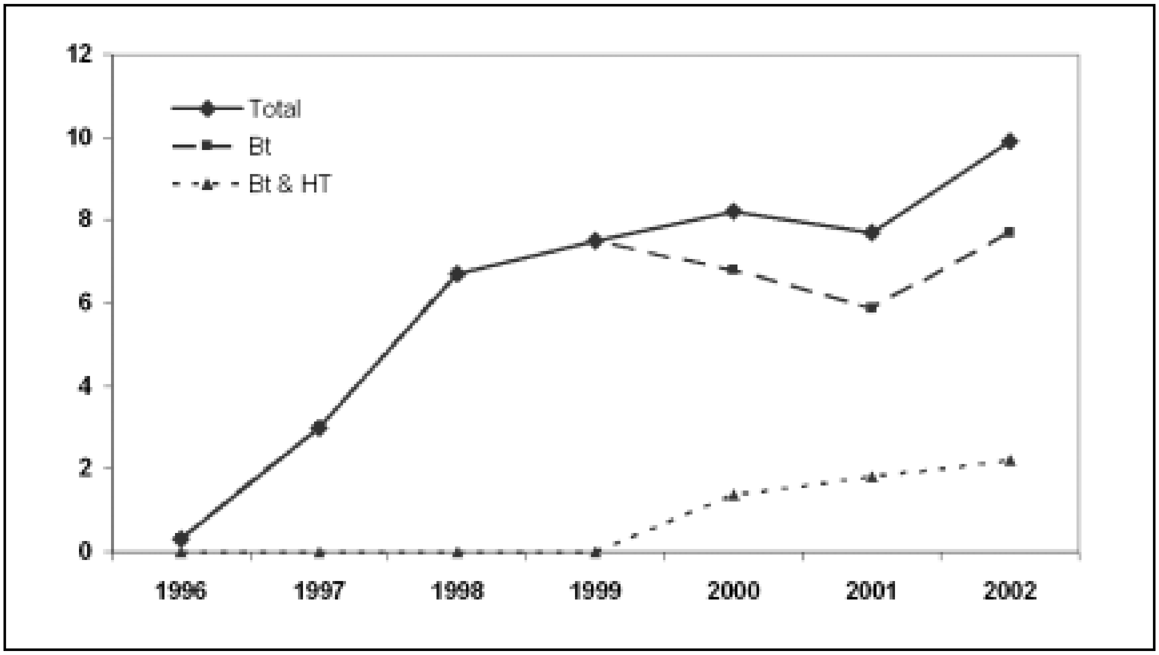


Table 60. Global Adoption of Bt Maize (Bt and Bt/Herbicide Tolerance) 1996 to 2002 (Millions of Hectares)

Trait	1996	1997	1998	1999	2000	2001	2002	Total
Bt	0.3	3.0	6.7	7.5	6.8	5.9	7.7	37.9
Bt and HT	0.0	0.0	0.0	0.0	1.4	1.8	2.2	5.4
Total	**0.3**	**3.0**	**6.7**	**7.5**	**8.2**	**7.7**	**9.9**	**43.3**

Source: Clive James, 2003. HT is herbicide tolerance area of 140 million hectares. France grew a small amount of Bt maize only in 2000 and 2001. Honduras grew Bt maize on a pre-commercial basis for the first time in 2002 and the Philippines planted its first Bt maize in 2003. The approval of Bt maize (*cry1Ab*) in the Philippines in 2002 has strategic implications because it was the first major food/feed crop to be approved for commercial production in Asia, which has 40% of the world area of maize with China being the dominant player with 24.5 million hectares. Asian corn borer is known to be a significant biotic constraint in the temperate maize area of China, which is the most important production region in the country, thus prompting China to field test Bt maize. India, with 6.2 million hectares, also has significant potential for Bt maize where spotted stem borer, Asian pink stem borer, and armyworm are important pests. Indonesia, with 3.3 million hectares, and Thailand, both suffering economic losses from Asian corn borer, could probably benefit significantly from Bt maize technologies.

The US continues to be the major adopter of Bt maize, growing more than three-quarters of the global total. The USA is the world's largest producer of maize, which occupies 32 million hectares, about one quarter of the area of all US crops. The US maize crop is valued at close to $20 billion annually, which is approx. 20% of the value of all crops in the US. In 2002 the US grew 85% of global Bt maize, followed by Argentina at 8%, Canada at 4% and South Africa at 2% with the balance grown in Spain, Honduras and Germany. However, steady growth is continuing in countries other than the US. For example, Argentina has increased its hectarage from the initial plantings in 1998 to over 750,000 hectares in 2002 and this is expected to increase significantly in 2003. Similarly, South Africa, which first grew Bt maize in 1998, increased its plantings to 230,000 hectares in 2002. In South Africa, Bt yellow maize used for feed increased from 160,000 hectares (14%) of the crop in 2001 to 175,000 hectares, equivalent to 20% of the yellow maize crop in 2002. Notably, Bt white maize, used for food, first introduced in 2001 on 6,000 hectares, equivalent to 0.3 % of the total white maize area, increased ten fold to 58,000 hectares, equivalent to 3 % of the 2002 white maize crop of 2.1 million hectares. Significant increases in productivity have been reported from Bt maize field trials in the Philippines, 25% in the dry season and 40% in the wet season, and 2003 should have provided the first assessment of the performance of Bt maize in commercial production; unfortunately the July 2003 typhoon destroyed several thousand hectares of Bt maize in the Philippines; preliminary indications are that the Bt maize that survived the typhoon performed very well. Early field trials in China indicate that Bt maize can increase yields by over 15%, which is significant because China has 25 million hectares of maize.

It is very important to acknowledge the progress made in Spain with Bt maize and to recognize that it is the only country within the EU that grows a substantial commercial hectarage of a GM crop, Bt maize. Spain has recently elected to double its hectarage from 25,000 hectares in 2002, representing 5% of the national maize area, to 50,000 hectares in 2003, equivalent to 10 % of the national maize area. This increase was coincidental with Spain approving five new Bt maize varieties in 2003. It is estimated that approx. 40% of the maize hectarage in Spain could benefit from the *cry1Ab* gene to control both European corn borer and Mediterranean corn borer (Brookes 2002). France, Italy and Germany, the other major maize producers in Europe, could collectively increase production by 1.9 million MT, valued at $ 250 million, by deploying *cry1Ab* expressing maize varieties (Gianessi et al 2003).

Cry1Ab expressing materials were first deployed in 1996 and it was not until 2000 that products with two stacked genes, a herbicide tolerant gene and a Bt gene, were introduced in the US, followed a year later with introduction into Canada. In 2000, the stacked gene products occupied 17% of the global total of 8.2 million maize hectares, increasing to 22 to 23 % in 2001 and 2002 respectively, with expectations that the stacked genes, as a percentage of the total will continue to increase.

In 2001 Bt maize area decreased globally by about 500,000 hectares (Table 60) with the major decrease in the USA and some in Canada. Some observers attributed the principal cause of the 2001 decrease in Bt maize in the USA to lower plantings by farmers who concluded that the low infestation of European corn borer in 2000 did not merit the use of Bt maize in 2001, on the assumption that infestation would continue to be low. Others have suggested that farmer uncertainty about markets for transgenic maize during the planting season may have led to decreased plantings of transgenic maize in 2001 by a small proportion of farmers. Decreases in Bt maize in the USA and Canada in 2001 were

Table 61. Adoption of Bt Maize, by Country, by Year 1996-2002

Country	1996	1997	1998	1999	2000	2001	2002
US	X	X	X	X	X	X	X
Canada		X	X	X	X	X	X
Argentina			X	X	X	X	X
South Africa			X	X	X	X	X
Spain			X	X	X	X	X
France			X	X	X		
Portugal				X			
Germany					X	X	X
Honduras							X
TOTAL	**1**	**2**	**6**	**7**	**7**	**6**	**7**

Source: Clive James, 2003. Note Philippines adopted Bt maize in 2003 largely offset by significant increases in Bt maize in Argentina, where adoption rates increased from 5 to 20% of the national maize crop, as well as an increase in Bt maize in South Africa.

The decrease of 500,000 hectares in Bt maize plantings in 2001 was followed by an unprecedented increase of 2.2 million hectares in 2002 with most of the increase taking place in the US. Some speculate that farmers increased their Bt hectarage in 2002 because of the high European corn borer index in 2001 (0.9 larvae per stalk). Of the increase of 2.2 million hectares of Bt maize in 2002, 82 % was due to an increase in the single gene Bt varieties and only 18 % due to the increase in the stacked varieties, Bt/HT, indicating that the major cause of the shift in Bt hectarage in 2002 was related to Bt and not to herbicide tolerance considerations.

Benefits of Bt maize with the cry1 Ab gene in the US

The benefits of deploying Bt maize with expressed *Cry1Ab* in the US are basically the same for all eight countries that currently adopt it - USA, Canada, Argentina, Honduras in the Americas, Spain and Germany in the European Union, South Africa on the continent of Africa and the Philippines in Asia. Benefits will be directly proportional to the level of infestation by maize borers acknowledging that there are different types of borers and other pests whose economic importance as pests will vary with geography; for example fall armyworm is the principal target in Honduras. Detailed studies in the US (Carpenter and Gianessi 2001) report that the benefits for farmers deploying Bt maize in the US are mainly associated with the following factors:

- Bt maize has, for the first time, provided farmers access to a technology that enables cost-effective control of corn borers which are very difficult to control with insecticides and for which there is an inadequate level of pest resistance in improved conventional maize varieties.

- Increases in yield of US maize production is a result of the elimination of significant yield losses to European corn borer. Annual increases in production of up to 7.5 million MT per year are likely in the US when there are severe infestations of European corn borer. Bt maize farmers in the US realized increases of production of 1.5 million MT in 1998 and 1.7 million MT in 1999 even when European corn borer infestation was at its lowest historically.

- It is expected that deployment of Bt maize will result in net economic gains to farmers in 3 years out of 4 for lepidopteran pests in North America, and every year in the sub tropics and tropical areas; economic gains are expected every year from Bt maize for corn rootworm control in the infested areas of the US.

- Elimination of the need for insecticides to control European corn borer. This translates to a modest reduction in insecticide usage on Bt maize for lepidopteran pests at the national level in the US, but significant gains from Bt maize for rootworm control with associated environmental safety implications.

- Lower levels of mycotoxin are found in Bt maize compared with conventional maize, resulting in potentially safer and healthier food and feed products derived from Bt maize.

A distribution analysis to assess the economic impact of Bt maize in the US was recently conducted by Wu (2003), when 6.5 million hectares, equivalent to 20% of the 32 million hectares was planted to Bt maize. The analysis assesses whether there is benefit to the US maize market, the impact on the environment and health, and examines benefits and risks for the different stakeholders and society. The study concludes that the net benefit of Bt maize to US society is $432 million of which $217 million is associated with yield increases, $32 million associated with insecticide reduction, $32 million for improved maize grain value due to lower mycotoxins, $128 million to the technology developers and the seed suppliers (Table 62).

An analysis of the total benefits to US society from Bt maize shows that the major beneficiaries are consumers gaining $530 million equivalent to 63% of Bt maize total benefits (Table 63). Bt maize growers are the second beneficiaries gaining $190 million, equivalent to 22% and the balance of 15%, equivalent to $128 million, accrues to industry, including the developers of Bt maize and seed suppliers. There is also a net loss of $416 million to non-Bt maize growers because of the reduced maize price, equivalent to a decrease of 6.7% (Table 63).

Table 62. Gains Associated with Bt Maize in the US

Category	$ millions	(Bounds)
Yield increase	217	(-59 to 780)
Insecticide reduction	32	(16 to 48)
Mycotoxin reduction	32	(8 to 114)
Technology developer	128	(96 to 160)

Source: Wu, 2003

Table 63. Distribution of Bt Maize Benefits to Different Stakeholders in the US

Category	$ million	(Bounds)
Consumers	530	(0 to1,200)
Bt maize farmers	190	(-33 to 822)
Industry	128	(96 to 160)
Non Bt maize farmers	-416	(0 to 960)
Total gain	432	(63 to 1,290)

Source: Wu, 2003

The study notes that whereas yield increases represent the most significant benefit for farmers, the reduction in the mycotoxin fumonisin is important, with modest savings on insecticides. Given that mycotoxins levels are generally much higher in developing countries the health benefits would be infinitely more important than in the US. China in Asia (Li et al 1980), Brazil (van der Westhuizen et al 2003) in Latin America and South Africa (Marasas 1996) on the African continent have all reported fumonisin levels that far exceed the guidance level of 2 ppm and the regions where fumonisin levels are high are also the regions reporting high incidence of esophogeal cancer.

In assessing the risk and benefits of Bt maize in the US and acknowledging that the new EU regulations on traceability and labeling could impact on trade of US maize, the study (Wu 2003) reports on the cost of segregating Bt maize from non Bt maize in all grain elevators in the US, which is estimated at $416 million. The study is instructive in that it demonstrates how a distributional analysis can quantify the benefits and risks to all the stakeholders and the usefulness of the study findings to facilitate informed decision making by policy makers and regulators.

8.13 Potential effect of Bt maize on the environment

A great deal of effort has been expended to conduct rigorous experiments to generate scientific data for the consideration by society and regulators of any conceivable potential effect that Bt maize may have on the environment. These studies were conducted by the members of the academic scientific community, as well as by the developers of the technology and government researchers, to satisfy the regulatory needs and the scientific standards set by society. The studies include potential effects on non-target organisms, gene flow from GM crops to landraces and wild relatives, and the potential to impact biodiversity. Organic farmers are concerned about flow of transgenes that could diminish the value of their certified organic products; studies have also been conducted on the potential effect of Bt maize on surface and soil water and on aquifers including the implications of applying fewer insecticides, made redundant through the use of Bt maize.

8.13.1 Potential Effect on Non-Target Organisms

Prior to registration of the first Bt maize in 1995, USEPA did extensive reviews of studies on the potential effects of the Cry proteins and concluded that Bt maize posed no unreasonable adverse effects on non-target organisms (USEPA 1995). In 1999 similar concerns that pollen from Bt maize was harmful to the North American Monarch butterfly population led to additional extensive laboratory and field tests, conducted by academic and government scientists, that concluded that assertions of harm to the Monarch could not be supported; similar allegations of possible negative effects of Bt maize on the black swallowtail butterfly and the lacewing also proved to be unfounded (Shelton et al 2002, Williams et al 1998, Wraight et al 2000). The Monarch butterfly experience is detailed as a case study later in this section.

The general conclusion from the many experiments that have been conducted to determine the potential effect of Bt maize on non-target species, is that no studies show there is a negative effect on non-target organisms. Indeed, compared with the application of broad spectrum insecticides, which are known to negatively impact non-target beneficial insects, including predators of maize pests (Carpenter et al 2002), the deployment of Bt maize has resulted in a marked improvement on beneficial predatory insect populations in Bt fields. Furthermore, given that only insects of the order Lepidoptera are sensitive to the Cry 1 Bt proteins and there are no lepidopteran predators of maize pests, there can be no direct effect of Cry1Ab expressing Bt maize used on 43 million hectares in the last seven years; indirect effects on predators are possible but none have been verified. The Cry3 Bt proteins used for corn rootworm control are also order specific in their activities but in this case they are only active on beetles (order *Coleoptera*). The deployment of new Bt genes to control rootworm, which belong to the beetle order *Coleoptera*, which does include beetles that are predators of maize pests, was also tested extensively for possible impacts on non-targets; populations of these beneficial insects are continuing to be monitored now that maize containing these Bt genes is being planted commercially in North America. Two recent publications have determined that maize pollen from Cry3Bb1 expressing plants does not affect the fitness of an important non target species, *Coleomegilla maculata* De Geer, that is an important polyphagus predator in maize (Lundgren and Wiedenmann 2002, Duan et al 2002).

The summary of published reports on the potential effects of Bt maize on non-target organisms, including beneficial predators, is presented in Table 64. None of these peer-reviewed publications indicate any deleterious effect of Cry1Ab protein on non-target organisms. Cry1Ab expressed in maize provides effective control of European corn borer and hence the population of parasitic and predaceous beneficial insects feeding exclusively on European corn borer will be expected to decrease accordingly. Some laboratory studies have suggested indirect secondary effects on European corn borer predators, but these studies utilized artificial diets with Bt toxin levels which were orders of magnitude higher than in Bt maize and therefore direct extrapolation is not appropriate. Monitoring commercial fields of Bt maize for population impacts on beneficial non-target organisms over several years confirmed that beneficial insects were not negatively affected.

The Monarch Butterfly Experience

Premature speculation and extrapolations by vocal critics of biotechnology regarding the work reported two years ago by Losey and co-workers (Losey et al 1999) led to highly publicized, alarming inferences that caterpillars of monarch butterflies were being poisoned and killed by pollen from commercial Bt maize planted in the USA (Anonymous 2001). A set of six papers published by the US National Academy of Sciences (Hellmich et al 2001, Oberhauser et al 2001, Pleasants et al 2001, Sears et al 2001, Stanley-Horn et al 2001 and Zangerl et al 2001) collectively concluded that,

Table 64. Summary of Published Reports on the Potential Effect of Bt Maize Expressing Cry1Ab Protein on Non-Target Organisms and Predators

Study and Conclusion	Reference
1. No difference in predator ground beetle (*Carabidae*) population between Bt and non-Bt maize.	Lozzia and Rigamonti 1998
2. Confirmation of results in Study 1 above	Lozzia 1999
3. No significant difference in number of predators in Bt and non-Bt maize	Orr and Landis 1997
4. No significant differences observed in predator population of *Orius* species, a predator of European corn borer and thrips	Al-Deeb, Wilde and Higgins 2001
5. No indirect effects on *Orius*, a predator of thrips	Zwahlen et al 2000
6. No detrimental effects of Bt maize on predators	Pilcher et al 1997
7. Lab study indicated longer development time for lacewing larvae. However extrapolation to field conditions not supported by data of Hillbeck	Hilbeck et al 1998
8. Results suggest negative effect of Bt maize on green lacewings but only second instar larvae significantly affected and no dose response effect for Cry1Ab demonstrated. Conclusions are contrary to similar studies by Lozzia 1997 and others	Hilbeck et al 1999
9. Insignificant amount of Cry1Ab in corn leaf aphid and black cutworm, both prey insects, when fed on Bt maize, therefore indirect effect of Bt maize on predatory insects negligible	Head et al 2001
10. Given the low level of Bt toxin in aphids feeding on Bt maize, the indirect effect of Bt maize on aphid predators, such as ladybird beetles, is likely to be nil.	Raps et al 2001
11. Feeding *Chrysoperla carnea with Tetranychus urticae* which contained *Cry1Ab* and *Rhopaalosiphum padi* which did not ingest the toxin, did not affect the survival of *C ,carne* whereas an increase in mortality was indicated when *C.carnea* fed on *Spodoptera littoralis* larvae reared on Bt maize	Dutton et al 2002

contrary to the earlier claims, Bt maize planted in the USA is not a threat to monarch butterfly caterpillars feeding on milkweed on which maize pollen is deposited. More specifically, there were five principal findings in the set of six papers supporting the finding that Bt maize pollen is not a threat to the monarch butterfly population. Firstly, with the possible exception of one Bt event (which only occupied 2% of Bt maize in the USA, and which was subsequently withdrawn from commercial sales for other reasons), commercially grown Bt maize in the US does not pose a significant toxic hazard to monarch caterpillars (Hellmich et al 2001). Secondly, it has been shown (Pleasants et al 2001) that maize pollen tends to accumulate on the middle leaves of milkweed, whereas monarch caterpillars tend to feed on the upper leaves. Thirdly, this lower density of Bt pollen on the upper leaves did not result in significant toxicity in caterpillars (Sears et al 2001). Fourthly, the current practice of applying broad-spectrum insecticides to control insect pests of maize was recognized to have the same potential to affect monarchs as other technologies including transgenic crops (Oberhauser et al 2001). Lastly, the destructive effect of broad spectrum insecticides was confirmed by Stanley-Horn et al (2001), who showed that the current and widely used maize insecticide, lambda-cyhalothrin, has, unlike Bt maize, a damaging effect on monarch butterflies. Collectively, the results from the set of six papers confirm the EPA's original evaluations of the potential risks posed by Bt maize to non-target butterflies and moths (Ortman et al 2001).

With regard to Bt maize impacting other potential non-target organisms, USEPA also conducted routine risk assessments of general ecological toxicity, which included studies of toxicity to avian species (quail), aquatic species (catfish and daphnia), beneficial insects (honeybee, parasitic wasp, green lacewing, ladybird beetle), soil invertebrates (springtails and earthworms) and mammals (mice) (USEPA 1995, 2000, 2001). These tests provide a basis for assessing potential toxicity to non-target species and indicator organisms, and serve as a basis for developing longer-term studies (Ortman *et al* 2001).

In a parallel development, a group of 22 eminent maize entomologists and ecologists wrote a collective letter to the editor of *Bioscience* (Ortman *et al* 2001) disagreeing with some of the conclusions of an earlier paper (Obrycki 2001) published in *Bioscience*, which was critical of Bt maize. The group of scientists noted that the scientific community has rigorously examined the risks and benefits of Bt plants more than any other biotechnology application, as is evident from the vast literature, scientific discussions, and numerous public meetings facilitated by the USEPA, the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) on this subject.

The 22 scientists reported that "the evidence to date supported the appropriate use of Bt corn as one component in the economically and ecologically sound management of lepidopteran pests." The group concluded that the performance of Bt maize had validated earlier positive USEPA assessments of the technology and stressed that the positive and negative effects of new technologies must be compared to current best practice and cautioned about rejecting technologies simply because they are new. A paper by Shelton and Sears (2001) reflects on the scientific interpretations of the monarch butterfly controversy. The authors conclude that "we believe a retrospective view may be useful for providing insights into the proper roles and responsibilities of scientists, the media and public agencies and the consequences when they go awry."

The lessons to be learned from the monarch butterfly experience are that inferences about the impact of new technologies at the field level are premature if based only on extrapolation from laboratory experiments, and that any such claims should be verified in the field before reaching conclusions. Furthermore, this misleading information can result in long lasting and permanent incorrect public opinion, which can delay or preclude the deployment of a useful technology such as Bt maize even though this product offers society significant environmental and crop production benefits. Bt maize offers significant real benefits to ecosystems and human health, including those associated with the reduction in use of more broad-spectrum foliar insecticides, (AMA 2000, APS 2001, NRC 2000).

8.13.2 Gene Flow

An issue that has received considerable press over the past two years is the concern that the transgenes in GM crops could flow, through outcrossing, into conventional germplasm, land races or wild relatives; for the latter, the concern is that introgression of the transgenes might impact on the integrity of the wild germplasm, with possible impact on biodiversity, including the development of so-called super weeds. The concern is that transgenes might confer a selective advantage that could potentially allow the hybrids to colonize land at the expense of other less competitive species. Snow et al (2002) reported that Bt sunflower hybrids produced more seeds than conventional hybrids but no increased competitiveness in natural environmental settings has been demonstrated. Experimental evidence indicates the contrary conclusion, i.e. that GM crops, including Bt maize, will have no selective advantage (Crawley et al 2001). The issues relative to gene flow are more pertinent if the crop is outcrossing, as opposed to self-pollinating, and if there are many wild relatives with which the GM crop is compatible growing in regions of commercial production, allowing the production of fertile hybrids.

Maize is an outcrossing crop, but it has only one wild relative, teosinte, with which it crosses. However, the direction of gene flow is from teosinte to maize, and not from maize to teosinte, due to genetic barriers that act to limit introgression of maize genes into teosinte (Evans and Kermicle 2001). Furthermore, teosinte is restricted to specific environmental zones of Mexico, Guatemala and Nicaragua that have been well mapped. Thus, the concern of maize outcrossing with wild relatives is not an issue in global maize production areas, and it is premature to draw conclusions about Mexico. There is a grass species in the US, gamma grass

Tripsacum dactyloides, which USDA/APHIS has determined will cross with maize, but the hybrids are usually sterile or have reduced vigor, resulting in no risk of introgression into the grass population. The other important factors in relation to gene flow from GM maize to conventional maize are the mode of seed dispersal and pollen flow. Although the ancestor of maize, teosinte has the ability to self disperse seed, maize cannot. Pollen flow of maize is restricted, by and large, to within approx. 220 meters (Bauman and Crane 1985); this knowledge is founded on long term experience using 220 meters separation for the production of certified hybrid seed in the US (Jarvis and Hodgkin 1999) with 350 meters considered by some to be a more appropriate separation that provides the additional assurance.

Maize landraces in Mexico

A letter to '*Nature*' by Quist and Chapela (2001) raised the concern that introgression of the promoter CaMV35S, used in the MON 810 and Bt 11 events for Bt maize, had occurred in maize land races in Mexico. Quist and Chapela's much publicized conclusion was based on an inverse PCR-based procedure, which was challenged by the Editorial Board of the *Journal of Transgenic Research* (Christou 2002), and by two publications in *Nature* (Kaplinsky et al 2002, and Metz and Futterer 2002). Despite the fact that Quist and Chapela published further evidence (Quist and Chapela 2002), it still did not satisfy the critics who insisted that claims of introgression had to be supported by repeating some of the molecular tests and growing out the F1 hybrids to provide conclusive evidence.

Following these various challenges, the journal '*Nature*' which had published the original letter (Quist and Chapela 2001) commented on the situation with an editorial note on 4 April 2002: "Nature has concluded that the evidence available is not sufficient to justify the publication of the original paper. As the authors nevertheless wish to stand by the available evidence for their conclusions we feel it best simply to make these circumstances clear, to publish the criticisms, the authors' response and new data and to allow our readers to judge the science for themselves."

The debate was sparked more over conclusions by Quist and Chapela that introgression would lead to a loss of biodiversity than by potential for introgression per se. However, it is important to place the debate in the context of how maize germplasm and landraces in Mexico are grown and managed by farmers. Unlike the US, where hybrids are solely used for maize production, farmer practice in Mexico is to grow different landraces close to each other under conditions where outcrossing is high. In the Cuzalpa region of Mexico the probability of outcrossing has been estimated at 38% (Louette 1997). It is estimated that one-third of local maize varieties have introgressed genes from non-local or improved varieties (Gonzalez and Goodman 1997). Thus, the view that landraces are pristine sources of biodiversity is misguided, and the introgression of transgenes should be viewed within the broader context of the massive genetic exchange that has already occurred in Mexican maize landraces over a long period of time, with the direct intervention of farmers in the continuous selection process.

Recognizing that there is a need to conserve the genetic variability in landraces used by farmers over time, gene banks have been established to conserve material for use in current breeding programs and for future generations. The International Center for Wheat and Maize Improvement (CIMMYT), based in Mexico, has a large maize gene bank and it has reported none of its 43 Oaxacan landraces has detectable levels of CaMV 35S promoter (CIMMYT 2001).

Mexico has in place a moratorium on the planting of transgenic maize, pending an assessment of the implications of the debate over introgression and the potential impact on biodiversity. What is clear is that genetic flow has occurred in maize germplasm in Mexico over generations and continues today. Thus it is evident that the way in which improved maize is grown in Mexico, in proximity with landraces, will lead to genetic exchange through cross pollination with any type of maize whether it is transgenic or not; the more pertinent question is what are the implications of this gene flow, including exchange with Bt maize. Mexico has a high cultural and food dependency on maize and imports approximately 5 million MT/year to meet its needs. Biotechnology can contribute to increased maize productivity and the challenge for the Government of Mexico is to develop a policy that allows it to harness the power of the new technology and at the same time have a strategy in place to conserve maize genetic variability and biodiversity. A policy of coexistence, where the in-situ locations for genetic conservation are identified and protected by physical separation from commercial production areas using improved conventional and biotech maize is one option. The policy of coexistence also offers the option to provide the isolation which growers of both non-GM and GM maize crops require to conserve the integrity of their respective products. During this debate, the voice of the small subsistence farmers growing maize landraces in Mexico seems to have been missed or relegated to secondary consideration; an effort to canvass the opinion of subsistence farmers as the practitioners who have shaped with their own hands the maize landraces of Mexico, and whose livelihood depends on maize, seems to be an important consideration, that has not received the attention it merits.

It is important to place the unresolved Mexican debate re. maize landraces and wild relatives, and the potential loss of biodiversity into a global context. Mexico recognizes the value of maize genetic diversity and has access to a maize gene bank that has conserved material that can be utilized in current and future breeding programs. Subsistence maize farmers in Mexico have been actively engaged in a selection improvement program that has been subject to significant genetic flow that has occurred through cross pollination in their open pollinated varieties over a very long period of time. Maize is a cross-pollinator, and teosinte is the only wild relative with limited potential for genetic exchange with maize and is restricted to Mexico, Guatemala and Nicaragua. Ninety-five percent of maize is grown in over 70 countries throughout the world in areas where teosinte does not grow and is not an issue for the rest of the maize growing world. Acknowledging that maize is a predominantly cross-pollinating crop, whose seeds are not self dispersed and pollen flow is limited to within 350 meters, the Mexican landraces have been subject to gene flow from local and non-local germplasm over a long time, and at this time, there is no conclusive evidence that biodiversity is threatened based on the evidence presented by Quist and Chapela. The findings of the research that is underway to assess the impact of the implications on maize biodiversity in Mexico should be the basis for the Mexican Government, in consultation with recognized authorities on maize germplasm conservation and development, to put into place a policy that will conserve maize biodiversity and not deny Mexico the significant benefits that crop biotechnology offers.

8.13.3 Impact of Cry1Ab proteins in soil and surface water

Carpenter et al (2002), conclude that for the Cry1Ab protein to have a potential to impact on water aquifers, its presence in soil must be demonstrated. Studies have demonstrated that the Cry1Ab exudes from the roots of Bt maize (Bt 11 and MON 810) but most of it is absorbed on clay surfaces. The data in Table 65 show that the environmental concentrations of the Cry proteins are extremely low (Crecchio and Stotzky 2001) with no evidence of toxicity for earthworms and springtails. In practice, under field conditions the impact of Cry1Ab protein on surface water habitat is considered to be negligible because it is unlikely to be transported by water runoff and, even if it is, it will likely be desorbed into the water column where it will be deactivated by microbial action or by sunlight (Carpenter et al 2002).

8.13.4 Impact of Bt maize on contamination of aquifers with insecticides

The maize hectarage sprayed with insecticides for the control of stem borers in the US is relatively small (2% of 32 million hectares) compared with the significant application of insecticides for the control of corn rootworm. In fact insecticides applied for the control of rootworm is the single largest application of any insecticide to any pest in the US. Thus, the impact of Cry1Ab on approx. 8.5 million hectares of Bt maize in the US in 2002 is likely to result only in a modest impact on decreasing levels of insecticide in aquifers. However, the situation with corn rootworm is entirely different. It is estimated that up to 3,400 MT of insecticide a.i. is used for corn rootworm control annually in the US. Therefore, the deployment of MON 863, registered in 2003, and other similar traits in the biotech pipeline, should eventually have a significant positive impact by substituting tiny quantities of Bt protein for the insecticides used on the up to 6 million hectares treated annually for corn rootworm control, which will, in turn, decrease significantly the amount of insecticide residues that can enter surface water systems and aquifers.

To put the potential savings on insecticides through the substitution of corn rootworm Bt

Table 65. Comparison of Bt Toxin No-Observable-Effects-Concentration (NOEC) in Soil, Relative to the Estimated Environmental Concentrations (EEC)

Biotechnology-derived Bt corn	EEC (mg/kg soil)	Earthworm NOEC (mg protein/kg soil)	Springtail NOEC (mg protein/kg soil)
Monsanto YieldGard: *Cry1Ab*	NA	>200	>200
Novartis: *Cry1Ab*	0.00042	"non-toxic"	0.08

Source: USEPA 2000; USEPA 2001.

maize into context, the annual savings of insecticides due to the US introduction of Bt cotton were estimated at approx. 1,000MT/a.i. year (James 2002b, Benedict and Altman 2001, Carpenter and Gianessi 2002). The potential saving on corn rootworm insecticides of 3,400 kg a.i. per annum is almost 3.5 times the 1,000 MT a.i. savings associated with Bt cotton. The impact is likely to be particularly important because corn rootworm insecticides are mainly applied to the soil in early spring, before the crop emerges, at a time when heavy rainfall exacerbates runoff into aquatic systems where it can result in toxic effects on aquatic invertebrates (Carpenter et al 2002).

Thus, the potential decrease in insecticides usage with deployment of Bt genes for the control of corn rootworm can lead to significant decreases in insecticide runoff into watersheds and aquifers and generally into the non-farm environment. Whereas the insecticides that are currently approved meet at least the minimum environmental safety requirements of regulatory bodies, many insecticides have lethal effects on non-target organisms, including aquatic animals in ponds and streams (Edge et al 2001). This is of particular concern in developing countries where monitoring is not always undertaken to detect pollution of natural resources.

Several recent studies in the US have used computer models, employed by USEPA in conducting risk assessments for potential impacts on aquatic environments of the use of pesticides, to study the potential effects of commercialization of transgenic crops on water quality in aquifers and watersheds. Predictions suggested that the substitution of conventional insecticides with Bt cotton would impact positively on water quality. Some initial experiments to monitor water quality have confirmed the predictions that transgenic crops have the potential to have a significant positive impact on water quality. The computer model predictions of Estes et al (2001), suggest that the substitution of conventional insecticides by Bt cotton, Bt maize and herbicide tolerant maize is likely to impact positively on water quality by significantly reducing pesticide concentrations in ground and surface water.

8.14 Insect resistance management (IRM)

8.14.1 Resistance to Insecticides

The European corn borer and corn rootworm situations are quite different relative to development of resistance to various control measures, particularly chemical insecticides. On the one hand, a very small hectarage of US maize is sprayed for European corn borer, approx. 2% or around 500,000 hectares, and thus there has been low selection pressure on European corn borer to develop resistance to insecticides. On the other hand, roughly 18% of the maize crop, equivalent to 6 million hectares, is being treated every year for corn rootworm control – this exerts a much greater and significant pressure on corn rootworm to develop resistance. The first reports of resistance in the corn rootworm were for aldrin in Nebraska at the start of the 1960s (Ball and Weekman 1962). As resistance spread, it was observed that the spread was in a southerly direction consistent with beetles moving south in a prevailing wind blowing from the northwest. As the organophosphates and the carbamates replaced the earlier insecticides that had become ineffective because of resistance, improved control was achieved, but by the mid 1970s they also became ineffective. However, in the case of the newer insecticides, resistance was probably not the principal cause of the ineffectiveness. Ineffectiveness was more likely due to enhanced biodegration in the soil as insecticides were normally applied 30 to 60 days before the first hatch of larvae. The phenomenon of enhanced biodegration seemed to be exacerbated with repeated use of some insecticides (Felsot 1989); the same phenomenon was reported for Canada (Suett and Walker 1988). In the 1980s, a new strategy was introduced using prophylactic insecticides to reduce the adult beetle population so that the potential for egg laying could be decreased. However, over time, resistance to these adulticides has continued to develop and during the last few years carbaryl, often used in conjunction with feeding baits, has became less effective as a control strategy for corn rootworm.

8.14.2 Evolution of corn rootworm to overcome control by crop rotation

Corn rootworm has not only developed resistance against insecticides but has also evolved variants in two ways that overcome the traditional practice of using soybeans in rotation to break the cycle of infestation. Firstly, in the early 1980s a strain of corn rootworm was discovered that prolonged the usual over winter diapause to at least two years, thereby overcoming the break associated with a one year rotation of soybean (Levine and Oloumi-Sadeghi 1991). Secondly, in the mid to late 1990s, a variant of corn rootworm was discovered which lays eggs in soybean fields and thus eliminates the benefit of using soybean as a rotation crop.

8.14.3 Management of Bt maize for European corn borer and corn rootworm control

Irrespective of the mode of insect control, whether by insecticides or any other pest management strategy, there is a need to implement strategies that limit pest adaptation in order to preserve the performance and benefits of pest management. Hence it is important to develop an Insect Resistance Management (IRM) strategy before the deployment of insect control technologies when potential resistance to alleles are rare. Experience in the past with development of adaptation to insecticides, cultural practices and resistant varieties led to the conclusion that the development of a proactive, rather than a reactive, strategy for the management of insect adaptation in Bt crops was the logical stewardship approach. IRM plans have been successfully implemented in the US for both Bt maize and Bt cotton. A recent publication (Tabashnik et al 2003) notes that 62 million hectares of Bt crops have been grown globally in the seven year period, 1996 to 2002 (James 2002a) with no documented increase in the frequency of resistance, caused by exposure to Bt crops, clearly demonstrating the success of the IRM programs that have been implemented.

To-date, no heritable European corn borer adaption to Bt maize has been discovered in US commercial maize production, despite the planting of over 35 million hectares of Bt maize in the US since 1996. However, lab studies have identified potential resistance alleles in European corn borer, but none have yet been shown to provide adaptation under field conditions. The implementation of an effective IRM stewardship strategy prior to the release of Bt maize has likely been a major factor in precluding the development of resistance in the field to-date. The current IRM program for Bt maize in the US is based on the dual strategies of high dose and the planting of an obligatory refuge and has the following requirements:

- Growers can plant up to 80% Bt maize, but must plant at least a 20% non-Bt maize refuge; note that for maize planted in a cotton area the ratio changes to 50% Bt maize and 50 % non-Bt maize since the two Bt crops together increase selection intensity in *Helicoverpa zea* populations.

- Refuge areas may only be treated with insecticides if pest levels exceed economic thresholds and they cannot be treated with foliar-applied-Bt insecticides; farmers are dissuaded from spraying insecticides on refugia because spraying could significantly decrease the effectiveness of the refugia.

- Refuge areas must be placed within one-half mile, or preferably within one-quarter mile of Bt maize.

- In-field, non-Bt refuge strips may be used but they must be at least four but preferably six rows wide.

- Plantings of Bt maize and non-Bt maize seed mixtures potentially increase the risk of resistance and are not allowed.

A refugia policy similar to that for Bt maize resistant to European corn borer also applies to corn rootworm Bt maize during the first deployment of the Cry3Bb1 event in the US in 2003. In 1999, industry unified to propose a standard IRM strategy across all Bt maize products for control of stem borers in North America. Since the USEPA and CFIA (Canada) first approved this proposal, the only major change has been the introduction of the Compliance Assurance Program (CAP) which is designed to address grower compliance with IRM requirements. The Bt maize IRM strategy practiced in the US is obligatory, required as part of the USEPA registration, and part of the contract that the farmer signs when purchasing the seed.

Management of corn borer resistance to Bt maize includes expression of a high dose of Bt protein as well as deployment of a refuge. The high dose strategy, as implemented with Bt maize expressing Cry1Ab, relies on plant protein expression levels which are 25 times higher than the dose necessary to kill 99% of the susceptible target pests. In practice this high dose is designed to kill all the heterozygous target pests, i.e., those individuals having both a recessive adaptation gene and a dominant susceptible gene. This high-dose refuge IRM strategy is based on four principles (Carpenter et al 2002):

- Expression of a high dose of the Bt toxin in the maize tissues infested by the pest;
- Recessive inheritance;
- Random mating between susceptible and resistant insects resulting in heterozygous susceptible, not homozygous resistant insects; and
- Low initial frequency of the resistant genes, <1 in 500.

Development of IRM strategies vary, not only because of the properties of the plant, but they also vary based on the biology of the key pest species. For example, the need for a refuge of a given size, or indeed, any planned refuge at all, is also impacted by the insects' ability to survive on plants other than maize and which also grow in the production area. These alternate hosts, which can include weeds as well as other crops, must be capable of producing individuals that can mate with insects surviving in the maize fields. Other biology factors, beyond alternate hosts, that should also be considered when designing an IRM strategy include insect movement and migration, mating behavior, generations per year, and area-wide crop diversity.

In conjunction with the IRM strategy implemented for Bt maize in the US, the USEPA also requires the technology developers to implement a monitoring program to track pest susceptibility over time so that timely and effective remedial actions can be implemented if resistance develops (USEPA 2001). Both private and public organizations are involved and cooperate in monitoring programs not only in the US (Venette et al 2000) but also in Spain (Gonzalez-Nunez et al 2000).

It is evident that the implementation of an IRM strategy requires grower level infrastructure to be in place and more importantly systems for grower awareness and education on IRM concepts, and ways of guiding grower behavior to follow required IRM practices that comply with the IRM strategy. This is feasible in an industrial country but often difficult to implement in a developing country lacking infrastructure and communication tools. Offsetting this disadvantage, developing countries have a spatial distribution of crops that feature very small fields, with a mosaic or patchwork of different crops that emulate a refuge system where susceptible and resistant crops are mixed. More research is needed to quantify the robustness of this system, which needs to be studied on a case-by-case basis for each insect pest/crop combination. Other important considerations are the scale of planting of Bt maize and other crops like Bt cotton where both crops can be attacked by the same key pest; for example both the US and China have very large hectarages of maize and cotton, with maize holdings in the US in big blocks, compared with small farms in China where the average holding of maize is one-quarter hectare in highly dispersed farming systems. As more Bt crops are deployed, the interaction between Bt crops and their polyphagus pests will be an increasingly important parameter; this is already addressed in the US with the requirement for larger refugia for Bt maize in areas where cotton is grown and vice versa.

The efficacy of IRM strategies will be considerably fortified with the increased availability of diverse genes with different modes of action and will provide valuable tools for resistance management. These different genes will be deployed by technology developers in different varieties and more than one gene can also be stacked in one variety by a technology developer to increase the diversity of modes of action in one variety which in turn contributes to durability of resistance. The ultimate goal of IRM is allowing resistance genes to be deployed optimally in the most effective and responsible manner. Thus, the c*ry3Bb1* event, launched in the US in 2003, in improved Bt maize varieties by one technology developer is expected to be complemented with the deployment of the dual gene product c*ry34Ab1/cr*y35Ab1 in other varieties by another technology developer in 2005. The diversity that these Bt genes offer in mechanisms of resistance is being further diversified by vip genes, (*cry34Ab1* and *vip3A*), and undoubtedly there will be other novel genes discovered for controlling important insect pests of maize with complete different modes of action for resistance.

Whereas the implementation of IRM strategies offers significant advantages, they can also be undermined if they are not part of a stewardship program, or if other developments preclude proper implementation of IRM. This is the case with illegal planting of Bt crops, which is occurring in several developing countries. The fact that the crops are not recognized to be present by governments means that de facto they cannot benefit from implemented IRM programs required as a national policy. Thus, national programs that condone the planting of illegal Bt crops not only put their own crops at risk to pest adaptation, but also pose an international risk for all countries that currently benefit from Bt crops, including those with responsibly managed IRM strategies in place. The challenge is for the international agricultural community to develop, educate, and implement a practical, flexible international protocol for IRM that, hopefully, can preclude the few from jeopardizing the significant long term benefits that Bt maize, properly managed with IRM, offers global society.

From a global viewpoint, the challenge is how to manage the expansion and deployment of Bt maize in a responsible and effective manner so that more countries can benefit from the significant advantages that Bt maize offers, without incurring undue risks. Past experience in coordinating international activities in agriculture, such as quarantine, are fraught with difficulties and bureaucracy that will often preclude the implementation of an effective strategy. Thus, caution should be exercised in considering ambitious plans that are not pragmatic and practical. Nevertheless, now is the time to start thinking about the needs of the future in terms of managing insect adaptation to Bt proteins internationally in maize, a crop that occupies 140 million hectares in approx. 75 countries. The considerations of managing a comprehensive IRM strategy at the international level are complex. While similar to implementing IRM strategies at the national level, global strategies for responsibly managing and optimizing the durability of resistance will need to be extremely adaptable to meet the spatial and temporal deployment requirements of different GM varieties carrying different sources of resistance, for a varied pest complex, under different agronomic and climatic conditions. Whereas globalization presents such IRM challenges, it also presents new opportunities for more countries, particularly developing countries, to access new biotechnology-derived crops, such as Bt maize that offers significant agronomic, economic, social, environmental and health benefits such as lower mycotoxin levels.

8.15 Food and feed safety aspects of Bt maize

In order to provide the reader with a framework of the food safety process employed for assessing the food and feed safety of the cry proteins used in Bt Maize, the following is an overview of the procedures that are followed:

8.15.1 Overview and framework for food/feed safety assessments:

- The strategy for assessing safety of Bt cry proteins is well established and based on international guidelines
- Deployed Bt maize have been rigorously assessed for food, feed, and environmental safety
- Cry proteins introduced into Bt maize approved for food use have a history of safe use

Background Information

- The safety assessment of food and feed derived from Bt maize is a multidisciplinary process
- The procedures are based on internationally accepted standards
- The safety assessment process includes:
  - Assessment of the trait
  - Assessment of the genes involved
  - Assessment of the potential intended and unintended effects of the new genotype vis-a-vis public health
  - Analyses of the protein
    - Potential toxicity
    - Allergenicity
  - Comparison of Bt maize as food, feed, or processed fractions with traditionally bred crops following protocol of "substantial equivalence"
    - Compositional studies – nutrients, minerals, etc.
    - Animal feeding studies
  - Bt maize was determined to be substantially equivalent to its conventional counterparts prior to deployment

Safety Assessments for Cry Proteins Introduced into Bt Maize

- The safety assessment of cry proteins introduced into Bt maize follows a different procedure compared with safety assessments of chemical xenobiotics (pesticides)
  - Xenobiotic chemicals are usually small compounds with molecular weights of 200-600
  - Cry proteins are large macromolecules typically composed of 100-300 amino acids with molecular weights over 11,000
- Compared to xenobiotic chemicals cry proteins have reduced systemic exposure because they degrade rapidly in the intestines

Protein Safety Assessments

- Cry proteins introduced into Bt maize were compared to endogenous and safe dietary proteins through
  - Digestibility Studies
    - Safe dietary proteins must be digestible to provide a source of amino acids, hence one safety check was to assess the potential digestibility of the cry proteins *in vitro* using simulated gastric and intestinal fluids

- Sequence Comparisons
    - Cry proteins were sequenced to identify structural and functional relationships between the cry proteins and potential allergens or toxins. Sequencing can also establish the degree of relatedness between the Cry proteins and proteins already present in food and feed with a long history of safe use and consumption

Safety Assessments

- Knowledge of the mode of action of the cry proteins was a pre-requisite to designing an appropriate safety assessment
    - Mode of action of the Bt maize insect control proteins has been well established (Betz et al 2000)
    - The Bt maize Cry proteins were subjected to an acute hazard assessment to confirm safety despite their history of safety use (Betz et al 2000)
    - Acute dose was administered by gavage to rodents
    - Dose of cry proteins administered to rodents was at least 1000X higher than any potential human dietary exposure
    - No adverse effects were observed in dosed animals with Cry proteins (Betz et al 2000)
- Cry proteins are considered to have no mutagenic, teratogenic, or carcinogenic activity (FAO/WHO 2000)

Whole Food Safety Studies for Bt Maize

- Acknowledging that Bt maize has been shown to be substantially equivalent to its conventional crop counterpart and the safety of the introduced protein(s) has been established, then no further testing was necessary (FAO/WHO 2000; OECD 2000)
- When appropriate, properly designed animal feeding studies can help to resolve questions relating to potential unintended effects and confirm substantial equivalence.

Summary

- The safety assessment of food and feed derived from Bt maize is a multidisciplinary process
- The Cry proteins introduced into Bt maize were compared to endogenous and safe dietary proteins used as benchmarks
- Knowledge of the mode of action of cry proteins was a pre-requisite to designing an appropriate safety assessment
- Bt maize was shown to be substantially equivalent to its conventional crop counterpart and the safety of the cry protein was established, and this satisfied all the regulatory requirements (FAO/WHO 2000; OECD 2000).

Food safety of all GM crops is strictly regulated and all GM products must meet at least the standards that are applied to conventional crops; in practice GM crops usually exceed standards for conventional crops. The government agencies in the different countries are legally empowered to ensure food and feed safety, not only for GM crops, but for all crops, and apply common principles and policies. In addition to monitoring the level of the Bt proteins and the stability of the Bt genes, and other elements introduced in the event, the food and feed toxicity of the novel proteins are checked as well as the allergenicity and the degree of potential human exposure, for example through consumption of Bt grain. Acknowledging that each event is different, evaluations are made on a case by case basis. Data is collected on potential consumption, including the effect of cooking and processing on the cry proteins. Prior knowledge of the relationship of the specific Bt proteins to other known toxins is always considered but is not a substitute for detailed feeding tests on various animals ranging from rats to chickens; this is done to identify the potential effect of near-term high dose exposures and to assess the long-term chronic exposure that would, for example, detect any potential carcinogenic effects.

8.15.2 Assessment of Potential Health Implications

The general concern about potential health issues related to GM crops (which applies to Bt maize) is that there might be unintended effects associated with potential epistatic and pleiotropic effects related to random gene insertion (Carpenter et al 2002). Human health issues can be conveniently classified into four categories:

- Pathogenic properties of the introduced DNA
- Toxic or allergenic properties of the GM product
- Change in nutrients and/or anti-nutrients
- Development of antibiotic resistance to marker genes

Whether the protein is a pesticide or not, as is the case with the Cry1Ab, the pathogenic properties of introduced DNA are checked directly by studying the expression of the gene and the stability of its inheritance, and indirectly through toxicity and allergenic tests.

Two types of toxicity tests are undertaken. The first is the LD_{50} test which is administered as a single or short term exposure – LD_{50} is the lethal dose at which 50% of the test animals die. The second is the NOEL test (No-Observable-Effect-Level) which is administered through multiple doses over a period of time. The USEPA results (Table 66) of the NOEL test for the Cry1Ab events MON 810, Bt 11 and Bt 176 show that the NOEL level is safe at > levels 3,250 mg/kg, rapid digestion in less than 2 minutes and no homology with known food allergens.

In addition to assessing the safety of the Cry1 protein, the other elements used in events, for example, the promoter CaMV 35S has also been scrutinized in relation to safety, and has been determined not to pose any safety problems.

Table 66. No-Observable-Effect-Level (NOEL) for Mortality Following Exposure of Rats to Purified Bt Toxic Protein

Registered transgene	NOEL (mg/kg) (Based on LD50 acute testing)	Digestibility in simulated gastric medium	Homology to known food allergens
MON810 Cry1A(b)	>4000	Rapidly degraded (<2 minutes in gastric fluid)	None
Bt 11	>4000	Rapidly degraded (<2 minutes)	None
Bt176 Cry1A(b)	>3280	Rapidly degraded (<2 minutes)	None

Source: Carpenter et al, 2002, modified

Bt maize is inherently different to herbicide tolerant maize in that a new Bt plant protein is produced. However, the Bt proteins have had a safe history of 40 years in use as a biopesticide. In 1998 all the data on Bt was reviewed by USEPA which concluded "that the data overwhelmingly support the safety of Bt to humans and non-target organisms"; accordingly USEPA re-registered all the Bt formulations and waived the need for submitting additional data on food safety (Carpenter et al 2002). Many studies have confirmed that the Bt proteins are only toxic to selected insect pests and the data in Table 66 confirms that even when very high doses are fed to rats, there are no detectable toxic effects. Another criterium that would increase the probability of risk is very high levels of Bt proteins in maize tissues. However, the data in Table 67 confirm that the levels of Bt protein are extremely low ranging from 0.005 micrograms per gram of plant tissue to 8 micrograms per gram. Bt maize from all the approved Bt maize events have been fed to livestock as part of their diets with no effects reported. The plethora of studies on food and feed safety of the Cry Bt proteins represents a clean bill of health for the products and there is no indication that any secondary toxic products have been generated as a result of pleiotropic effects.

Current knowledge indicates that the Cry proteins are only toxic when they bind to the gut cells of selected insects – mammalians do not have such binding sites and this is consistent with no reports of toxicity with *cry* genes in mammals. This finding is supported by the fact that Cry proteins are rapidly digested, which is not the case for allergenic or toxic proteins.

Table 67. Concentration of Protein (Microgram per Gram of Wet Plant Tissue) in Various Maize Tissues at Plant Maturity and Estimated Grams of Protein per Acre of Maize

Registered transgene	Whole plant	Leaf	Roots	Pollen	Grain	Grams Bt protein per hectare
		Micrograms transgene per gram plant tissue µ/g				
Cry1A(b) MON810 (Yieldgard®)	3.65-4.65	7.93-10.34	NA	0.09	0.19-0.39	464
Cry1A(b) Bt 11 (Yieldguard®)	NA	3.3	NA	0.09	8.2	639 g
Cry1A(b) Bt176	0.6	4.4	<0.008	7.1	<0.005	59

Source: Carpenter et al, 2002, modified

Allergenicity

Approx. 2 to 3% of the population suffer from food allergies, and virtually all food allergens are proteins; peanuts, soybeans, wheat and tree nuts account for almost all the crop-related allergies. An allergenic condition becomes evident when the immune system reacts abnormally to an allergenic protein in food; symptoms include itching, nausea, hives and asthmatic spasms. Regulatory agencies follow FAO and WHO United Nations criteria to assess new proteins and the key considerations are:

- Source of genetic material and its relationship to known allergens.
- Similarity between DNA sequence of protein and known allergens.
- Test for immune reactivity of protein, if it is related to known allergens.
- Digestibility of protein and effect of pH.
- Stability of protein to heat and processing.

To date the allergenicity studies for the Cry1Ab, Cry1Fa2 and Cry3Bb1 exhibit no relationship to known allergens and break down rapidly in digestive systems. All the currently approved Bt maize products have undergone rigorous testing for allergenics and the results are normal indicating that there is is no cause for concern. An exhaustive study, conducted by Bernstein et al (1999) found no evidence that Bt proteins were associated with any allergenic reaction.

Although it is not feasible to use human sera for allergenicity tests, the characteristics of allergens are well known, size ranges from 10 to 80 KDA, and they are acid and heat stable. The tests performed on all approved Bt events proved negative indicating no allergenic properties.

Effect on Nutrients Status

Change in nutrients and anti-nutrient are assessed by examining these parameters in both Bt maize and its isogenic equivalent. The principle of substantial equivalence endorsed by WHO, FAO and OECD (Kuiper and Kleter 2000) is used to assess the results – in the case of all approved Bt events the GM product was determined to be substantially equivalent. The principle of substantial equivalence 'asserts that if a new food or feed derived from conventional breeding or genetic engineering is substantially equivalent in standard nutritional parameters to its conventional counterpart, then the new food should be considered equally safe (Carpenter et al 2002).

Potential for Development of Antibiotic Resistance

From the very outset, some groups have speculated about the potential for the antibiotic resistance marker genes to transfer resistance, firstly to bacteria in the soil, and secondly to bacteria in human digestive systems. Smalla et al (2000) have conducted a comprehensive review of the literature. They concluded that transfer may not occur at all, or if it does it would be at extremely low frequency in soil. Transfer may occur in digestive systems, but this will also be at low frequency.

More importantly, Smalla et al (2000) stressed that antibiotic resistance is already ubiquitous and that GM crops including Bt maize, will not materially change the incidence of antibiotic resistance in bacteria. In any event, without prejudice, the developers of GM crops are phasing out antibiotic markers – this will cease to provide critics a diversion from the task of focussing on a more balanced assessment of Bt crops including the multiple and significant environmental health and economic benefits that can contribute to a more sustainable agriculture.

8.16 Mycotoxins

One of the major concerns of consumers, particularly in Europe, is the safety of food and feed products derived from genetically modified (GM) crops. At this time, these concerns are not supported by several independent reviews which have reported GM products to be safe. They include the French Academy of Medicine, Royal Society of London UK, American Council of Science and Health, United Nations/FAO, Food Standard Agency, International Council for Science, the European Network Safety Assessment of Genetically Modified Food Crops, the National Research Council (US) and the Codex Alimentarius Commission - see references for website details. Following rigorous reviews, all these international organizations have concluded that the existing GM-derived food and feed products in the marketplace meet the standard of safe food and feed and declared them to be as safe as conventional foods. In the case of Bt maize, which has been genetically engineered to produce the Cry1Ab protein derived from *Bacillus thuringiensis* (Betz et al, 2000), there is now clear evidence that food and feed products from Bt maize are often safer than the corresponding products from conventional maize because of lower levels of the mycotoxin fumonisin. This section is devoted to documenting the impact of the mycotoxin fumonisin, produced by *Fusarium verticillioides*, and the opportunity for decreasing levels of fumonisin through the use of Bt maize. Fumonisin is found in maize affected by *Fusarium* kernel rot. Comparisons of Bt maize and a corresponding non Bt maize have shown that in some environments Bt maize has significantly reduced concentrations of fumonisin in food and feed where *Fusarium* kernel rot is a chronic problem; this has important implications for the value of the crop, for more efficient animal production and for the safety of food.

Fungi frequently colonize cereal grains, groundnuts and treenuts and some other commodities both in the field and in storage. Aside from yield losses and damage, which can be significant, certain species contaminate the crop with secondary metabolites, called mycotoxins. There are five agriculturally important mycotxins

- fumonisin, the most prevalent and intensively studied is Fumonisin B1, produced mainly *by Fusarium verticillioides* and some related species (found in maize),
- deoxynivalenol, produced by *Fusarium graminearum* (found in maize and small grains),
- zearalenone produced by *Fusarium graminearum* (found in maize and small grains),
- aflatoxin, produced mainly by *Aspergillus flavus* (found in maize and nuts),
- ochratoxin A, produced by *Penicillium verucosum* and several species of *Aspergillus* (found in maize, small grains, grapes, coffee and other commodities (Miller 2000; IARC Monograph 82).

Grain is carefully monitored in industrial countries for contamination with mycotoxins but this is not the case in developing countries, which lack resources and infrastructure. In general, developing countries have warmer and more humid climates that are more conducive to the accumulation of mycotoxins. Inadequate storage conditions exacerbate the problem. Accordingly, the gravity of the problems associated with mycotoxins on maize are likely to be far more serious in developing countries, particularly where maize is used directly as food by a significant proportion of the population, in regions such as Sub-Sahara Africa and parts of Asia and Central America.

The Council for Agricultural Science and Technology (CAST) in the US recently published a report that estimated losses due to mycotoxins in the US at almost $ 1 billion annually (CAST 2003). The losses are due to various factors including contaminated grain failing to meet food and feed standards. Rejection of grain as food leads to downgrading of price when it is used as feed, and rejection as feed leads to a major economic loss or total loss. In developing countries, with the capacity to export foods, the problem is more serious because there are no support programs to assist farmers with precautionary measures to control mycotoxins and this can lead to loss of exports and in turn the loss of an industry and increased poverty (Otsuki et al. 2001; Bhat & Miller 1991). In industrial countries, it is generally accepted that there is little or no increased human morbidity or mortality resulting from mycotoxins because of regular monitoring and enforcement of food safety regulations. A study of the impact of aflatoxin in three Asian countries found that the majority of the economic loss was from the impact of aflatoxin on human health (Lubulwa and Davis 1994).

In maize, the accumulation of several mycotoxins including deoxynivalenol, zearalenone, fumonisin and aflatoxin are related to the level of insect infestation (Miller 1995). With the widespread use of Bt maize, principally in the USA, Canada, Argentina, South Africa and Spain, it was observed that concentrations of these toxins could be lower in Bt genotypes compared to their non-transgenic isolines and other commercial hybrids. Mycotoxins are prevalent on maize throughout the world (IARC Monograph 56, 82; JECFA 2001) and FAO estimates that on average, one-quarter of all grain in the world, equivalent to 150 million MT, is contaminated with mycotoxins (Shephard et al 1996).

The fifty-sixth report of the joint FAO/WHO expert committee on food additives developed provisional maximum tolerable daily intakes (PMTDIs) for a series of mycotoxins including fumonisin (JECFA 2001)). The question of a PMTDI for fumonisin has been independently taken up by the US Food and Drug Administration (CFSAN 2001) and the Scientific Committee for Food of the European Union (SCF 2003). There is international agreement that improvements in population health will occur to the extent that fumonisin concentrations in maize-based food are managed such that the PMTDI is not exceeded.

Carpenter et al (2002) note that if mycotoxins were pesticides they would be categorized as dangerous from a toxicity viewpoint. The serious health conditions caused by fumonisins in different animal species and the circumstantial evidence linking fumonisin with medical conditions in humans is documented in Table 68 (Hammond et al 2003). Fumonisins cause liver toxicity in rabbits and in horses, neurotoxicity, cardio-toxicity and liver and kidney toxicity. Ruminants (sheep and cattle) have suffered kidney and liver toxicity from fumonisins and swine have suffered pulmonary edema, cardiotoxicity and liver toxicity. Liver toxicity has been reported in poultry. Several feeding studies in rodents have also reported liver and kidney toxicity; chronic studies have also reported liver and kidney cancer in rodents. Neural tube damage has been found in mice administered fumonisin. In primates, cardio- and liver toxicity has been reported as well as atherogenic effects. Fumonisin B_1 in maize produced by *Fusarium verticillioides et al.* has been classified as a B2 carcinogen (possible human carcinogen) by the International Agency

Table 68. Health Effects of Fumonisins in Various Species

Species	Health effect	Reference
Rabbit	Liver, kidney toxicity Neurotoxicity	CFSAN, 2001 Bucci et al 1996
Horse	Neurotoxicity Cardiotoxicity, Liver and kidney toxicity	Marasas et al 1988 Kellerman et al 1990 Ross et al 1993 Wilson et al 1992 Haschek et al 2003 IPCS 2000
Sheep	Kidney and liver toxicity	Edrington et al 1995
Swine	Pulmonary edema Cardiotoxicity Liver toxicity	Colvin & Harrison 1992 Harrison et al 1990 Hascek et al 2001 Kreik et al 1981 Osweiler et al 1992 Ross et al 1990 Constable et al 2000 CFSAN 2001
Cattle	Liver and kidney toxicity	Mathur et al 2001
Poultry	Liver toxicity	IPCS 2000 CFSAN 2001
Rodents (rats, mice)	Liver and kidney toxicity Liver and kidney cancer	Voss et al 2001 Gelderblom et al 1991 Gelderblom et al 1993 Howard et al 2001
Mice	Neural tube defects	Gelineau-van Waes et al 2002 Sadler et al 2002

Continued ...

Table 68. Cont'd. Health Effects of Fumonisins in Various Species

Species	Health effect	Reference
Primate	Cardiotoxicity, liver toxicity Atherogenic effects	Kreik et al 1981 Fincham et al 1992
Humans	Linked to esophageal cancer	Cheng et al 1985 Chu and Li 1994 Doko and Visconti 1994 Rheeder et al 1992 Sydenham et al 1990 Marasas 2001 Wang et al 2003
Humans	Linked to liver cancer	Wang et al 2003 Gelderblom et al 2001 Li et al 2001 Lian et al 2003
Humans	Linked to neural tube defects	Hendricks 1999

Source: Hammond et al 2003.

for Research on Cancer (IARC Monographs 56 and 82).

Human exposure assessment remains very difficult for fumonisin B_1 which hampers epidemiological studies. Several studies suggest that the consumption of maize in endemic areas is associated with esophageal cancer and neural tube birth defects (IARC monograph 56; Marasas et al 2003). Populations at special risk appear to be in Southern Africa (Marasas 1996), the Linxian region of China (Li et al 1980) and North East Italy (Franceschi et al 1995).

The consumption of maize, used as food, varies from a low of about 20g per day in countries such as the USA and France, to 200g per day in countries such as Colombia, to 400g per day in a country like Kenya where maize is the staple food. It is evident that the higher the consumption of contaminated grain the greater the risk of exceeding permitted levels of toxin at lower levels of contaminated grain. The intake of fumonisins by an adult, consuming 19g, 200g and 400g per day of maize grain contaminated at 1 ppm, 5 ppm, 10ppm, and 20 ppm fumonisins has been calculated in Table

69 (Hammond et al 2003) as derived from previous assessments (Gelderblom, unpublished data). The intent is to estimate the impact on the PMTDI; the guidance level for fumonisin is 2 µg per kg of body weight per day (JECFA 2001). In Table 2, a person in Kenya eating the normal intake of 400 grams a day with only 1 ppm fumonisin contamination exceeds the PMTDI three fold, whilst a counterpart in Colombia consuming 200gms per day only reaches the permitted PMTDI, and the counterpart in the US consuming only 19 g per day reaches only 0.1 of the PMTDI. Given that maize grain with contamination of 1 ppm is not uncommon (Hammond et al 2003) there are risks for people consuming high amounts of contaminated maize. One way to reduce the risk for people who consume contaminated grain is to take the necessary action to reduce the level of contamination in the grain.

The insect pest of maize, European corn borer, for which Bt maize confers resistance, helps spread the spores of *Fusarium* from maize leaves that it eats, to the ears. Pest damage to the ears of maize by European corn borer provides further points of entry for *Fusarium* which colonizes the damaged maize tissues in which *Fusarium* produces fumonisin (Dowd 1998). The *Fusarium* species involved include *Fusarium verticilloides*, and *F. proliferatum* which produce fumonisins on grain. Damage and feeding of maize by European corn borer provides easy points of entry for *Fusarium* to colonize. Hence reduction of damage by corn borers, through the deployment of Bt maize, leads to lower levels of infection by Fusarium which in turn leads to lower levels of mycotoxins in maize grain (Munkvold and Desjardins 1997, Sobek and Munkvold 1999). The deployment of Bt maize in the last seven years in seven countries has resulted in effective control of European corn borer and southwestern corn borer in the US, European corn borer and Mediterranean corn borer in Spain, African stem borer and spotted stem borer in South Africa, lesser corn borer and sugar cane borer in Argentina, and Asian corn borer in the Philippines. The Cry1Ab protein produced in Bt maize provides season-long protection for borers and this has resulted in significantly lower levels of mycotoxins in maize grain. Evidence generated by scientists working in different countries throughout the world confirms the early findings of the pioneer researchers (Munkvold et al 1999) that Bt maize has lower levels of mycotoxins than conventional maize. Reduction in fumonisin levels has important implications for maize-fed animals and for humans consuming food, such as polenta in northern Italy, and in all other maize-based food products which are the staple food in the countries of Sub-Saharan Africa and Central America.

One option for lowering fumonisin levels in maize is to spray insecticides to control insect pests that spread *Fusarium* in the field, but this has negative impact on the environment and exposes farmers to insecticides (Dowd et al 1998, Dowd 2001). Another option is to use Bt maize which has neither of the disadvantages associated with insecticides and because of its mode of action in controlling stem borers and ear rots, Bt maize may be more effective at

Table 69. Impact of Maize Grain Consumption and Fumonisin Level on the PMTDI

Country Examples	Maize Consumption (g/day)	Fumonisin Level (p.p.m. in grain)	PMTDI[1]
Kenya	400	1	3
		5	16
		10	32
		20	64
Colombia	200	1	1
		5	8
		10	16
		20	32
USA	19	1	0.1
		5	0.7
		10	1.4
		20	2.8

Source: Hammond et al 2003 [1] PMTDI (Provisional Maximum Total Daily Intake) = 2 µg fumonisin/kg body weight/day

reducing fumonisin concentrations in the crop under conditions where *Fusarium* kernel rot are common.

Because of the intense European interest in food safety the issue of contaminated maize with mycotoxin has been assigned high priority, resulting in many published papers on the subject (Bakan et al 2002, Carpenter et al 2002, Pietri and Piva 2000, Castella et al 1999, Scudamore and Patel 2000, Visconti and Doko 1994). The results of investigations in Italy by Pietri and Piva (2000) presented in Table 70 confirm the significant decrease in ergosterol in Bt maize, (a quantitative measure of the amount of *Fusarium* present) and the decrease in fumonisin levels, compared with conventional maize. Experiments were conducted over a three year period, 1997 to 1999 to capture the variation between seasons, which is known to be significant; ergosterol levels ranged from 11.9 in 1999 to 49.3 in 1998 which was the worst year for Fusarium. Ergosterol levels were consistently lower in Bt maize, compared with conventional maize and on average, there was a three-fold difference in favor of Bt maize. The highest levels of ergosterol recorded in 1998 corresponded to the highest levels of fumonisin indicating the consistency of the results. However, the most important finding was that Bt maize consistently decreased the level of fumonisin; on average,

Table 70. Fumonisin (ì g/kg) and Ergosterol (mg/kg) Levels in Maize Kernels in Italy 1997, 1998 and 1999

	Fumonisin (ì g/kg)		Ergosterol (mg/kg)	
	Bt	Non-Bt	Bt	Non-Bt
1997	2,021	19,759	9.8	34.2
1998	5,448	31,632	15.7	49.3
1999	1,394	3,902	3.9	11.9
Average	2,954	18,431	9.8	31.8

Source: Pietri and Piva 2000.

there was over a six-fold decrease in the level of fumonisin from 18,431 to 2,954.

A further detailed study in Spain and France in 1999 (Bakan et al 2002), showed that Bt maize effectively controlled Fusarium. Levels in conventional maize were higher in Spain than France at 9 ppm and 3 ppm respectively in the conventional maize compared with approx. 0.1 to 0.2 ppm in the Bt maize – thus the decrease in Spain was close to 50 fold or more. In France, the levels of fumonisins in the conventional maize were much lower ranging from 0.3 ppm to 3.0 ppm with zero ppm in the Bt maize. Thus, the overall result for both Spain and France was close to zero ppm for all the Bt maize compared with 0.3 to 9 ppm for the conventional maize. As Carpenter et al (2002) appropriately note, the most important conclusion is that Bt maize allowed the level of mycotoxin to be lowered to below the guidance level of 2 ppm whereas the higher level of conventional maize in Spain of 9 ppm is almost five times higher than the guidance level.

An analysis of the literature shows that all studies, designed to compare levels of mycotoxins in Bt maize and non-Bt maize have shown significant decreases in mycotoxin (Bakan et al 2002, Dowd 2000, 2001, Munkvold et al 1999, Hammond et al 2002; Hammond et al 2003, Hammond et al 2004). On the other hand, there is an increasing body of evidence confirming that the mycotoxin levels can often be well above the guidance levels of 2 ppm in conventional maize. For example, the data in Table 71 show that even in industrial countries levels of fumonisin can be high. In Italy, levels of up to 60 ppm have been recorded (Doko and Visconti 1994); high levels of fumonisin at 26 ppm have also been recorded in China (Wang et al 2003), 26 ppm in the US (Hammond et al 2003), and 27 ppm in Argentina (IPCS 2000).

Given the prevalence of fumonisin in conventional grain maize around the world and the need to ensure that the levels are below the guidance level of 2ppm, (note that Switzerland

Table 71. Levels of Mycotoxins, Fumonisin Recorded in Conventional Maize Grain

	ppm	Reference
Italy	60	Doko and Visconti 1994
US	27	Hammond et al 2003
Argentina	27	IPCS 2000
China	26	Wang et al 2003

Source: Hammond et al 2003

is using 1 ppm), Bt maize with the *cry1Ab* gene offers a critically important advantage for consumers concerned about food safety. To opt not to use the Cry1Ab protein to reduce the level of fumonisin runs the risk of maize grain being contaminated at above the guidance levels with the corresponding health and economic consequences. In terms of economic benefits resulting from toxin reductions, a recent study conducted by Wu, (2003) reported that the use of Bt maize in the US increased value to producers by $32 million per year. Under conditions suitable for *Fusarium* kernel rot, the Cry1Ab protein not only confers benefits in terms of increased production but also offers the important safeguard that will ensure that consumers of maize grain, both human and animals are provided useful protection against grain with a highly toxic compound. In countries with commercial maize production and chronic *Fusarium* kernel rot, Bt maize can make the difference between a significant proportion of the crop meeting fumonisin guidelines or not and this is very important in a world that is becoming increasingly conscious of food and feed safety. Thus, an important benefit of deploying Bt maize in Argentina South Africa and Spain where fumonisin levels have been reported well above the guidance level of 2 ppm is the multi-fold decrease in fumonisin level to limits below the guidance level that will ensure safe food and feed products from maize.

8.17 Trade Issues re GM Crops

This is not intended to be an in-depth analysis of the complex issues of agricultural trade and the role of the WTO. On the contrary, the aim is to provide:

- a brief overview of the background to the WTO suit filed by the US and its partners, against the EU re the GM crop moratorium in Europe, which has directly impacted on US Bt maize exports to Europe;
- the implications of the proposed new and more stringent European regulations re labeling and traceability (2001/18/EC); and
- the critical need for an equitable agreement on agricultural trade and GM crops at the WTO round of talks in Dhoa in late 2003.

In May 2003 the US and its partners, initiated action by filing a suit with WTO against the EU for allowing a de-facto moratorium on GM crops to operate since 1998 through failure to approve new GM crops for the last five years (Pew 2003). Agricultural trade between the US and EU represents a large market. In 2002, the US exported $6.1 billion worth of agricultural products, mainly grains and their by-products to the EU, which in turn exported $7.9 billion to the US mainly involving wine and alcoholic beverages. The major exports from the US to the EU are maize, soybean and cotton, of which 40%, 81% and 73% respectively were GM in the US in 2003 (USDA/NAAS 2003), plus important products like maize gluten which represented 46% all US exports to the EU in 2002; US maize gluten exports to the EU dropped from 5.5 million tons in 1995/96 to 4.4 million tons in 2000/2001 (American Corn Growers Association 2002). Products such as high fructose maize syrup are also important US exports to the EU.

Concern about GM foods and feeds started in Europe in the late 1990s when new labeling rules were approved in the EU which lead to the de-facto moratorium in 1998. Given that Bt and conventional maize are not segregated in the US, exports of US maize to the EU have declined sharply, leading to an estimated loss of $300 million per year in US maize exports to the EU. Prior to 1998, two Bt maize events had been approved in Europe, Bt 176 and MON 810. In 1998, 1.5 million MT of maize worth $35 million was exported to Spain and Portugal, and by 2002 these exports had declined to 30,000 MT valued at $2.7 million. To put these exports into context, US maize exports to Europe accounted for 4% of total US agricultural exports in 1998 and by 2002 they represented less than <0.1%. The major US maize exports in 2002 were to Asia (44%), North America (20%), Africa (14%), and the balance of 20% to other countries (USDA 2003b).

Table 72. Agricultural Trade between US and EU: 2001

Trade	$ billions
US exports to EU	6.1
EU exports to US	7.9

Source: Pew 2003

Table 73. US Maize Exports to Different Regions, 2001 Expressed as Percentage of Total Maize Exports

Global Region	%
Asia	44
N. America	20
Africa	14
Others	22

Source: Pew 2003

Factors contributing to European concerns about GM foods include lack of confidence in food regulatory bodies following the mad cow disease, tainted chicken meat in Belgium and more recent outbreaks of foot and mouth disease. In a food surplus situation Europeans do not perceive significant benefits from more productive and efficient GM crops to

Table 74. US Exports of Maize to the EU

Maize Exports from US to EU	1998	1999	2000	2001	2002	% change 1998 to 2002
Millions MT	1.56	0.32	0.01	0.07	0.03	-98%
Value $ millions	35.3	1.4	8.1	1.8	2.7	-93%
% of Global US Ag exports	4%	1%	0.1%	0.1%	<0.1%	-97%

Source: Pew 2003

consumers, and hence do not feel inclined to change their supply of food, although the Eurobarometer poll is showing a decline in concern about GM foods. In addition, some special interest groups who are opposed to biotechnology are concerned that science is interfering with nature and reject it on ethical grounds. Thus, despite declarations from the EU Commission following a rigorous scientific assessment that GM food is as safe as conventional foods, the moratorium in Europe persists; this has led many observers to conclude that the root- cause of mistrust in GM products is political rather than scientific. Thus, in the late 1990s the debate on GM crops, and opposition to them was fuelled by support from the Green party political representatives in the European Parliament and in the parliaments of member states. This political support in conjunction with environmental and consumer groups led to a broad opposition to GM crops with countries like Austria and Luxembourg banning GM crops in 1997, followed by Italy, Greece and Germany. However, during the same period four countries, Spain, Germany, France and Portugal in the EU have commercialized small areas of Bt maize, with Spain now growing approx. 50,000 hectares of Bt maize in 2003 representing 10% of the national maize crop. It is also noteworthy that two of the Eastern Europe accession countries planning to join the EU in 2004 (Romania and Bulgaria) are already commercializing GM crops. EU regulation on GM crops will be impacted by the ten accession countries from Eastern Europe that seek membership of the EU in 2004 because GM crops, including Bt maize, feature as commercialized or field tested GM crops in several of these accession countries. Each of the ten accession countries is participating in Biosafety Networks supported by the EU, and are also involved in the UNEP Biosafety Initiative, with a view to establishing regulatory frameworks for GM crops in the near term. Hungary has approved almost 70 GM field trials in the last four years, mainly featuring maize, including Bt maize. Poland has also conducted GM maize trials as well as Croatia, Romania, and Ukraine. Other accession countries including Bulgaria are commercializing small areas of maize and the Czech Republic has advanced field trials.

In July 2003 the EU Council of Ministers approved new and stricter regulations to 'label' and 'trace' GM crops, which if implemented could lift the moratorium, but the US and its partners in the WTO suit have concluded that the proposed standards of the new EU regulations are not workable, not based on scientific assessment, and therefore violate WTO regulations. The new regulations are expected to apply 90 days after gazetting of the law, which is expected in October 2003.

In contrast to the current EU regulations (9/220/EC) that requires labeling of GM products if the product contains detectable DNA, the new proposed law (2001/18/EC) requires labeling of all GM-derived products irrespective of whether DNA is present or not, and the tolerance for adventitious presence is set at 0.9% of GM material. Furthermore, for the first time animal feed products fall under the same requirements as food products. However, animal products (meat, eggs and milk) from GM fed animals do not require labeling. Contrary to, and inconsistent with the labeling requirements for GM food and feed, cheese, beer and wine made with biotechnology-derived enzymes do not require labeling. Traceability demands require that GM foods and feed can be traced back 'from the fork to the farm' and records have to be kept for five years. All food requires documentation confirming freedom from GM even when no GM can be detected. Whereas current regulations are jointly administered by member governments and the EU Commission, the new regulations will be administered by the new European Food Safety Authority. Finally, for GM products not approved for release under the new regulation, but endorsed by the appropriate EU Scientific Committee, they can be released provided they contain less than 0.5 % of GM product.

The EU Commission rationale for requiring the new stricter regulation (2001/18/EC) is that labeling and traceability are essential to restore consumer confidence in regulatory oversight for food safety in Europe. Traceability is deemed necessary to facilitate any withdrawal of products from the market place. Both labeling and traceability are viewed by the Commission as necessary steps to implement an approval process for GM crops and for the lifting of the moratorium.

Although the US and its partners, who filed suit with WTO, did not object to the new labeling and traceability in the WTO suit, they have been critical of the proposed new regulations for the following reasons: the new regulations will result in disruption of international trade; they are costly; unworkable and unenforceable; and discriminate against GM products without providing any food safety or environmental advantages. There is also a concern that GM conscious consumers in Europe will perceive the labeling as a negative warning and this will lead to further loss of market in Europe that could reach $4 billion annually. The knock-on effect from any negative developments in Europe, particularly in terms of impact in developing countries could further escalate concerns to an international level. Of particular concern is the impact on countries in Africa which may opt to forego the significant advantages that GM crops offer because of the potential loss of important export markets to Europe. The US has emphasized the moral issues re. EU policy on GM foods impacting the policies of African nations, which have declined GM food, despite the threat of famine and suffering to millions of people. Thus, adoption of EU policy re. GM crops by developing countries would not only result in denial of food for survival but in a global-scale disruption of trade. Bt maize has played a central role in all the transactions related to US food aid to Africa and is likely to continue to be the principal GM crop involved because it already occupies 10 million ha in eight countries and likely to be adopted by more countries, both industrial and developing, in the near term.

Whereas WTO is the principal international body that regulates world agricultural trade, including trade in GM crops, there are several other organizations that have important roles in relation to GM crops. The Codex Alimentarius Commission, established by WHO and FAO is currently developing international guidelines for food safety and risk analysis with implications for both labeling and traceability. The Convention on Biological Diversity recently ratified, will invoke the Cartagena Biosafety Protocol, which will require new standards to be met in trans-boundary shipments of living modified organisms (LMOs) which will impact significantly on trade in GM crops. Also OECD, of which both the EU and the US are members, are involved in activities designed to harmonize trade issues in relation to biotechnology.

The next two years will involve intense and important discussions on various aspects of GM cops that will impact on trade, in which Bt maize could play a central role as a model of an important food/feed crop that has the potential to deliver multiple significant benefits to society, ranging from environmental, economic, health and social benefits, including the very important contribution to food and feed security. Failure to reach reasonable agreements to the GM crop issues at the WTO round of talks at Dhoa would deny the developing countries access to a vital technology that can contribute to the alleviation of poverty and a better quality of life for millions of poor people, which the global community pledged to support at Johannesburg in 2002. The developing countries were not heard, or well served, by the last round of WTO talks in Uruguay. It would be tragic if their urgent needs were not heard again at Dhoa, where their pressing priorities and humanitarian needs for food and feed must be addressed. An equitable agricultural trade resolution at Dhoa, must address both subsidies and GM crops, and Bt maize provides an excellent example of the significant and multiple benefits that GM crops offer developing countries. An equitable agreement at Dhoa would allow the world to move on, after five years of debate, to harness the enormous benefits that biotechnology offers global society, who must learn to live together harmoniously in today's global village where free agricultural trade and freedom of choice for the countries of the South re crop biotechnology are prerequisites to global economic growth with equity, which in turn can contribute to a more secure world.

8.18 Global Potential of Bt Maize: Opportunities and Challenges

The history of the past is usually the best way of predicting the future. Accordingly, in attempting to assess the global potential for the first generation of Bt maize (*cry1Ab*) technology, the information in this review on the principal lepidopteran pests of maize, particularly the family of stem borers, and their control with Bt, provides a historical knowledge base on which assumptions and future projections of potential benefits can be based. A preliminary assessment of corn rootworm has also been made on the basis that a more detailed review will be more appropriate after the new generation of Bt gene products have been commercialized for a few years.

In 2002 Bt maize planted globally on 9.9 million hectares almost reached the historical milestone of 10 million hectares, or 25 million acres, which is likely to be exceeded in 2003. Of all the GM crops, maize will, in the near term, probably be the crop that will offer the most options in terms of different combinations of pest management and quality genes to suit the very diverse environments throughout the world where maize is grown and marketed.

It is evident that the major lepidopteran pests, particularly the family of stem borers, are a major constraint to increased productivity, and are of economic importance in most maize-growing countries throughout the world. Just under half (46%) of the maize area in the 25 key maize-growing countries have medium (40% of maize area infested) to high levels (60% of maize area infested) of lepidopteran pest pressure (Table 36). The evidence in support of an estimate of an average of 40% infestation by stem borers in the temperate mega-environments countries is not only supported by the evidential data in the published and unpublished literature on the incidence and severity of lepidopteran maize pest infestations, but also by the fact that 30% of the maize area in Argentina was already occupied by Bt maize in 2002 and expected to reach 40 % in 2003. Similarly, the area of Bt maize in the US was 21% in 2001, 24 % in 2002, climbed to 29% in 2003 and is expected to continue to increase. The evidence in support of the higher levels of 60 % infestation by lepidopteran pests in tropical mega-environments, such as Brazil, is that infestation levels confirm that tropical environments are more conducive for multiple and overlapping generations of pests. This is consistent with the fact that 60 % of the maize area in Brazil is already being treated with insecticides for control of lepidopteran pests, with fall armyworm being the principal pest with stem borers not being amenable to effective control with insecticides.

It is important to stress that tonnage of insecticide currently applied is not a good indicator of the importance of stem borers, because insecticides are not very effective for controlling borers which conceal themselves in the stem where insecticides cannot penetrate; hence the majority of farmers do not use insecticides despite the fact that they know that stem borer losses are high, and the situation is made more complex by the seasonal variation in the pest. However, Bt maize, unlike insecticides, can consistently provide effective and secure control of a broad range of stem borers, and has the potential to occupy an infinitely larger area than that currently treated with insecticides for stem borer control. For example, prior to the introduction of Bt maize in 1996 in the US, on average only 2% of the 32 million hectares of maize was treated with insecticides for control of stem borers whereas 24 and 29% of US maize hectarage was Bt maize in 2002 and 2003 respectively (USDA/ NAAS 2003); thus the ratio between area treated with Bt expressed in maize plants versus insecticides was 12-fold in 2002 and almost 15- fold in 2003 (2% versus 29%). The same comparison in Argentina where Bt maize occupied 30% in 2002, and is expected to occupy 40% of the maize hectarage in 2003, would indicate a higher ratio in favor of Bt maize because the percentage of maize area treated with insecticides for stem borers in Argentina is also low compared with the Bt maize area. The situation in South Africa where 20% of the maize area in 2002 was already occupied by Bt maize, and expected to continue to climb in 2003, is similar to that of Argentina.

Based on current evidence, acknowledging that damage to maize from insect pests will vary and is dependent on the level of pest infestation from year to year and region to region, a 40% infestation of the maize area by lepidopteran pests in temperate mega- environments and 60 % in tropical-subtropical environments is an appropriate assessment, consistent with evidential data.

In assessing the global potential of Bt maize, it is useful to appraise its potential from different but complimentary viewpoints:

- Potential global area of maize that lends itself for Bt maize adoption in the near to mid-term
- Potential for productivity and production gains
- Substitution and saving of insecticides
- Safer food and feed products with lower levels of mycotoxin
- Farmer's viewpoint

8.18.1 Potential global area for Bt maize in the near to mid-term

Given that the global maize area of 140 million hectares is equally divided between the temperate area (50%) and the tropical, subtropical and highland tropical (50%) (Table 24), the potential area for Bt maize on a global basis is 40% of the 70 million hectares of temperate maize, equivalent to 28 million hectares, and 60% of the 70 million hectares of tropical maize, equivalent to 42 million hectares, for a total of 70 million hectares. However, acknowledging that, in the near to mid -term, Bt maize will be adopted, by and large, in hybrid maize systems, the 70 million hectares has been down-adjusted, based on a 90% use of hybrids in the temperate regions, including China and Argentina, and a 43% hybrid use in the tropical areas, which projects a total potential global area of 43 million hectares of Bt maize (Table 75); the 43 million potential hybrid hectares compares with the current Bt maize area of 10

Table 75. Potential Global Area for Bt Maize (*cry1Ab*)

	Potential hectares (millions)	Hybrid hectares (millions)
Tropical	42	18
Temperate	28	25
TOTAL	**70**	**43**

Source: Clive James, 2003

million hectares, all of which are hybrids. Thus, the potential for the temperate mega-environments in both industrial and developing countries (including China) is 25 million hectares, and 18 million potential hectares in the tropical/sub-tropical mega-environments in developing countries. It is important to correct a mis-perception, often perpetuated by critics of biotechnology, that developing countries use only farmer-saved seed or OPVs. In fact hybrids are the predominant seed type in many developing countries and therefore provide an established distribution channel for Bt maize. This is the case for China where 84% of all maize seed is hybrid, and East and Southern Africa at 81%. Regions that have lower usage of hybrids include Mexico and Central America (15%), North Africa (9%) and West and Central Africa (4%). In these latter regions, where improved seed (hybrid and OPVs) account for less than 50%, a special effort must be made by aid and development agencies to develop and deliver Bt maize through OPVs and farm-saved seed through international development programs working in partnership with the private sector to facilitate GM crop transfer and focussed on serving the needs of small resource-poor farmers.

Whereas further adoption of Bt maize will be subject to many constraints including regulatory capacity, acceptance of the technology, intellectual property rights, and trade constraints which will affect both industrial countries and developing countries, adoption of Bt maize in developing countries faces significantly more constraints including:

- Traditional constraints associated with lack of infrastructure, regulatory systems, finance, human resources, weak institutions, and an inadequate supply of quality seed and distribution systems

- Fifty-four percent of maize is hybrid in developing countries compared with 94% in industrial countries; to date all Bt maize has been introduced through the hybrid system and this is likely to continue in the near term, followed later by OPVs; development of Bt maize through non-hybrid systems will be predominantly through international organizations like CIMMYT and philanthropic biotechnology transfer organizations such as ISAAA and national programs working in partnership programs with the private sector. For example, CIMMYT operates a Syngenta Foundation funded program (IRMA) in conjunction with KARI in Kenya, designed to incorporate insect resistance in maize with the use of Bt genes.

- Low productivity/hectare is linked to low value/hectare and will deter adoption of Bt maize unless the cost of the technology/ hectare is adjusted for developing countries.

- Savings in production costs are likely to be incidental because few insecticides are currently applied for borer control.

Offsetting the above constraints in developing countries, are the following characteristics that provide more incentives for developing countries compared with industrial countries:

- Losses due to pests on a percent basis are significantly higher in developing countries because of more intensive infestations and overlapping generations of insect pests.

- Accordingly, yield gains in favor of Bt maize are significantly higher on a percent basis, despite the fact that average yields are lower in developing countries.

- Seed incorporated Bt technology is more appropriate for small farmers because it does not require the equipment, knowledge and information required for insecticide applications and it reduces farmer exposure to insecticides; this is particularly important for small farmers applying insecticides by hand sprayer.

- Given that more maize is used as food, and that mycotoxin levels are significantly higher in developing countries, the use of Bt maize to lower mycotoxin levels to below guidance levels is infinitely more important in developing countries.

- Finally, and most importantly, the increased productivity would directly impact on food and feed security, food/feed safety and the increased income from higher productivity would contribute to alleviation of poverty in the rural areas where the need is greatest; developing countries will have to produce 80% of their growing demands for maize which globally amount to 266 million MT by 2020 – only 20% of the increased demands of developing countries will be met through imports.

Taking all the above into account it is projected that Bt maize has, in the near to mid-term, the technological potential to deliver benefits on 40 to 45 million hectares compared with the 10 million hectares it occupies today; the major constraints will be related to lack of regulatory capacity, which is considered to be the major constraint, along with acceptance, and trade issues particularly in relation to Europe. Bt maize is likely to continue to experience high growth rates in the near to mid-term in the traditional markets of the US, Canada, Argentina, South Africa, Spain, Philippines and Honduras. Subject to regulatory approval, Asia offers significant new markets in China, India and Indonesia, and Brazil in Latin America. Trade considerations and lack of regulatory capacity and a resolve to approve Bt maize will be the major factors impacting on adoption by countries such as Egypt, Kenya, and Nigeria on the African continent. Political considerations will be the major factor governing approval and adoption in Eastern European countries such as Romania and Hungary, which are EU accession countries. In Western Europe, France, Italy and Germany have much to gain from the technology, but political considerations related to acceptance have continued to result in rejection of the technology except in Spain where Bt maize has been an unqualified success. In summary, technologically Bt maize has the potential to deliver benefits on 25 million hectares through hybrid systems in temperate mega-environments, amongst which China offers the most important opportunity; productivity constraints associated with Asian corn borer in China are significant and the yield gain offered by Bt maize is substantial. Countries in both Eastern Europe and Western Europe growing maize in temperate mega-environments could also benefit from Bt maize, and its adoption in these countries would provide the stimulus for broader acceptance on a global basis. In the tropical environments with a potential of 18 million hectares of Bt maize through hybrid systems, by far the most important opportunity is in Brazil, followed by Mexico. Potential countries on the African continent include Nigeria, Kenya and Egypt. Acknowledging that there are significant constraints to Bt maize adoption in developing countries, the substantial and multiple benefits that Bt maize offers in terms of agronomic, environmental, health and economic benefits that contribute to alleviation of poverty, can collectively provide the incentive and stimulus for global society to ensure that developing countries are not denied what current Bt maize technology can deliver now, plus the improvements that the second generation technology offers, which should be available over the next three years.

8.18.2 Potential for Bt maize to increase productivity and production

In the absence of a comprehensive set of field trials to measure the yield performance of Bt maize versus conventional maize in the top 25 maize-growing countries, infestation levels and corresponding estimates of yield loss from field trials and surveys from selected countries were used to project yield gains from adopting Bt maize. Yield loss estimates generated from field trials and surveys provide indications of productivity gains and actual gains are related to specific pest infestation levels. Based on yield gains from a range of Bt maize trials data (Table 47) conducted in the key maize growing countries, an average of 5% gain was used for the Bt maize gain for the temperate areas and 10% gain for the tropical areas. These are considered conservative estimates of yield gain, given that in many of the field experiments increases of 10% or more in the temperate areas are common and 15% or more for the tropical environments. To accommodate this range in yield gains, projections for Bt maize are estimated for both the infested area and the national maize area to provide a range of yield gain, rather than a single point estimate. Thus, in the case of the US, the estimate of gain would range from 4.6 million MT, based on a 5% loss on the infested area of 40%, to 11.4 million MT, for a 5% loss based on the total maize area, with the actual gain likely to be closer to 11.4 million MT. The estimate of 5% in the US is considered conservative and is consistent with the most comprehensive review of yield gains associated with Bt maize (Marra et al 2002) in which five national studies, conducted during

Table 76. Estimated Potential Gains from Deploying Bt Maize with the *cry1Ab* Gene for the Control of Maize Pests, Mainly Stem Borers, in the Top 25 Maize Growing Countries

Country *Gain Category* *(Million MT)*		Hectares harvested (millions)	Production on MT millions	Infestation Category	Yield Gain %	Min.Gain million MT	Range of Gain million MT
Category 1: >10 m. MT							
1.	USA	28.5	228.7	M	5	4.6	4.6 to 11.4
Category 2: 5-10 m. MT							
2.	China	24.5	124.2	M	5	2.5	2.5 to 6.2
Category 3: 1-5 m. MT							
3.	Brazil	11.8	35.5	H	10	2.1	2.1 to 3.6
4.	Mexico	8.0	19.0	H	10	1.1	1.1 to 1.9
5.	Argentina	2.4	14.7	M	10	0.6	0.6 to 1.4
6.	India	6.2	12.0	H	10	0.7	0.7 to 1.2
Category 4: 0.5-1m. MT							
7.	Indonesia	3.3	9.3	M	10	0.2	0.2 to 0.9
8.	France	1.8	16.0	M	5	0.3	0.3 to 0.8
9.	Italy	1.0	11.6	M	5	0.2	0.2 to 0.6
10.	Nigeria	4.2	5.4	H	10	0.3	0.3 to 0.5
11.	South Africa	3.3	9.1	M	5	0.2	0.2 to 0.5
Category 5: <0.5 m. MT							
12.	Romania	2.9	8.5	M	5	0.1	0.1 to 0.4
13.	Philippines	2.4	4.3	M	10	0.1	0.1 to 0.4
14.	Canada	1.2	8.2	M	5	0.2	0.1 to 0.4
15.	Thailand	1.1	3.9	M	10	0.2	0.2 to 0.4
16.	Ethiopia	1.7	3.1	H	10	0.2	0.2 to 0.3
17.	Kenya	1.5	2.7	H	10	0.2	0.2 to 0.3
18.	Tanzania	1.5	2.5	H	10	0.2	0.2 to 0.3
19.	Yugoslavia	1.2	5.5	M	5	0.1	0.1 to 0.3
20.	Hungary	1.0	6.0	L	5	0.1	0.1 to 0.3
21.	Malawi	1.5	1.6	H	10	0.1	0.1 to 0.2
22.	Ukraine	1.3	4.2	L	5	0.1	0.1 to 0.2
23.	Congo	1.4	1.1	H	10	0.1	0.1 to 0.1
24.	Mozambique	1.3	1.1	H	10	0.1	0.1 to 0.1
25.	Zimbabwe	1.0	0.8	M	10	<0.1	<0.1 to <0.1
Subtotal		**116.0 (84%)**	**539.0 (95%)**			**14.8**	**14.8 to 32.8**
OTHERS		22.9	63.0			0.7	0.7 to 1.6
TOTAL		**138.9 (100%)**	**602.0 (100%)**			**15.5**	**15.5 to 34.4 Average 24.95**

Source: Compiled by Clive James. Infestation Categories based on percentage of national maize area infested: TRACE 1 to 10%, average of 5% of national maize area infested; LOW (L) 11 to 30%, average 20%; MEDIUM (M) 31 to 50%, average of 40%; HIGH (H) 51 to 70% average of 60%; VERY HIGH (VH) over 70% of maize area infested.

the four year period 1997 to 2000 showed an average gain of 5%, with 23 other studies in selected states showing an average of 8% increase in yield over the same period. A corresponding industry study confirmed that 8,866 comparisons of field trial data between Bt maize and the conventional isolines during the period 1995 to 2002 also resulted in an average gain of 423 kg/hectare equivalent to a 5.2% gain over an eight year period.

The data in Table 76 indicate that on a global basis the projected gains, listed in descending order, of deploying Bt maize on a global basis would be 15.5 to 34.4 million MT, equivalent to a 3 to 6% gain, with an average of 4.5% gain, equivalent to 25 million MT, valued at $2.7 billion at the international price of $108 per MT (World Bank 2003). This is consistent with the estimates of Oerke (2002) who concluded that actual losses due to all insect pests were 9% (Table 37). The data in Table 77 indicate that deployment of the Bt gene *cry1Ab* would result in a 4.5 % gain through control of the stem borer family of pests and intermediate control of armyworm, with the remaining 4.5% loss associated with all other pests: these would include corn rootworm in the US, and other pests for which only intermediate control can be provided, i.e. armyworms, earworms and cutworms which are ubiquitous. The next generation of Bt and novel genes promises to provide more efficient control for armyworms and cutworms through broader control which would provide further gains in yield over and above the 4.5% yield gain from the first generation of Bt maize incorporating the *cry1Ab* gene.

In order to facilitate the identification of the key potential beneficiary countries for Bt maize, the projected yield gains from deploying Bt maize *(cry1Ab)* in the top 25 maize growing countries in Table 76 have been classified into five categories based on potential maximum gain in production at the national level. Category 1 with gains of over 10 million MT includes only the US, which deployed 8.4 million hectares of Bt maize in 2002 and produces approximately 40% of the global production of maize. Category 2 with projected national gains of 5 to 10 million MT includes only China, the second largest producer of maize in the world, which has advanced Bt maize field trials underway. Category 3 with national gains of 1 to 5 million MT includes the three large economies of Latin America, Brazil, Argentina and Mexico, and India in Asia, of which Argentina is the only country to currently benefit from Bt maize. Category 4 (gains of 0.5 to 1 million MT) includes Indonesia, France, Italy, Nigeria and South Africa, of which the latter is the only country to benefit from Bt maize. The balance of 14 countries in Table 76 are all in Category 5 with national gains of less than 0.5 million MT annually. Thus, the data in Table 76 confirm that, as expected, the larger gains are in the countries with large hectarages and high production. The top five countries that would gain are USA 4.6 to 11.4 million MT, China 2.5 to 6.2 million MT, Brazil 2.1 to 3.6 million MT, Mexico 1.1 to 1.9 million MT, and India 0.7 to 1.2 million MT. The other 20 countries listed in Table 76 all have projected gains below 1 million MT. The fact that the absolute gain is below 1 million MT and global

Table 77. Estimation of Global Losses Due to Maize Pests and Gains from Bt Maize

Loss or Grain	1998
Actual losses due to all maize insect pests	- 9.0% loss
Yield gain from pest control with cry1Ab	+ 4.5% gain
Balance of loss due to other insects	- 4.5% loss

Source: Clive James, 2003

Table 78. Projected Relative Gains in Yield for Different Regions from Deploying Bt Maize with *cry1Ab*

Global Region	Gains, millions MT (% of Global)	$ Value of Gain
North America	4.7 to 11.8 (34%)	0.8 to 1.2 billion
Asia	3.7 to 9.1 (26%)	0.4 to 1.0 billion
Latin America	3.8 to 6.9 (20%)	0.3 to 0.8 billion
Africa	1.4 to 2.3 (7%)	0.1 to 0.02 billion
Europe	0.8 to 2.4 (7%)	<0.1 to 0.3 billion
Others	1.1 to 1.9 (6%)	0.1 to 0.2 billion
WORLD	**15.5 to 34.4 (100%)**	**1.7 to 3.7 billion**

Source: Compiled by Clive James. Value of maize based on international price of $108/MT as of mid 2003 (World Bank 2003)

share is small for these 20 countries should not lead to the misconception that the potential benefits are not significant for these countries and that Bt maize would not merit adoption. On the contrary, there are several countries listed in Table 76, including South Africa and Argentina, with projected gains of less than 1 million MT, where the benefits of Bt maize at the farmer level represents significant advantages and has already provided farmers with the incentive to increase area planted to Bt maize every year since first adopted, simply because the returns merit the investment in Bt maize. Thus, from a relative viewpoint, Bt maize offers similar advantages to both small and large countries as well as to commercial and subsistence farmers.

From a global perspective the larger gains associated with Bt maize will be related to the production of maize in a particular region and the level of infestation. The data in Table 78 indicate that the larger gains would accrue to North America, which produces more maize (227 million MT) than any other region, and equivalent to almost 40% the global production of 600 million MT. The USA and Canada are jointly projected to gain up to 11.8 million MT, valued at up to $1.2 billion per year – this represents 34% of the total global gain projected at 34.4 million MT valued at $3.7 billion. Asia, with large countries including China, India and Indonesia, as well as the Philippines and Thailand, is projected to gain up to 9.1 million MT valued at $1.0 billion representing 26% of global gains.

If the field trial results in China with Bt maize are representative of gains at a national level, the projections in Table 76 are conservative. China alone with 25 million hectares of maize and using 84% hybrids is in a position to implement a rapid adoption program for Bt maize, which would emulate the accelerated adoption of Bt cotton in China on more than 50% of the national hectarage by 5 million small farmers in China in only five years. The maize crop in China is more than five times the area of cotton and whereas the relative potential gains per hectare will be lower than Bt cotton, the national gains of adopting Bt maize would be greater because of the larger hectarage of 25 million hectares of maize compared with 5 million hectares of cotton. Latin America is projected to gain 20% of global gains with Brazil being the principal beneficiary followed by Mexico, which has to decide on an appropriate strategy vis-à-vis GM crops given that it is the center of diversity for maize, and the recent allegations re. introgression and potential implications for biodiversity. Mexico has a great deal to gain from the new technologies and its assessment of the issues and proposed strategy re. Bt maize is a critical decision which will determine whether Mexico can benefit from the significant benefits that the new technologies offer.

Africa features prominently with eight countries in the top 25 maize producing countries in the world that would stand to gain from adoption of Bt maize. They include South Africa which already has successfully deployed both Bt yellow maize for feed and white maize for food. Several countries in East and Southern Africa, including Kenya, Tanzania, Ethiopia and Malawi, where 81 % of the maize seeds sold are hybrid, could benefit significantly from Bt maize because losses due to stem borers in Kenya have been estimated at 13%. Nigeria has the largest hectarage of maize in Africa (4.2 million hectares) and is keen to benefit from what crop biotechnology offers. The Congo in Central Africa grows over 1million hectares and would also benefit. The overall projected gain for Africa is estimated at up to 2.3 million MT, valued at $200 million per year and representing 7% of global share in yield gains. Europe has four countries featured in the top 25 maize growing countries, France, Italy, Romania and Hungary. Western and Eastern Europe are projected to gain up to 2.4 million MT annually, which is consistent with the estimate of Gianessi et al (2003), who projected a gain of 1.9 million MT per annum for only France, Spain, Germany and Italy.

8.18.3 Substitution of insecticides and lower levels of mycotoxin

Unlike Bt cotton, the global savings in insecticides from deploying Bt maize for lepidopteran control will be modest. Projected estimates of global insecticide savings for Bt maize are 3,000 to 5,000 MT annually, equivalent to only 10 to 15% of the corresponding potential 33,000 MT savings on cotton insecticides from Bt cotton. However, reducing insecticide application on a food/feed crop has enormous environmental and health implications and is assigned high value by both farmers and society. Food and feed safety issues related to GM crops are becoming the focus of interest and attention, particularly in Europe, where Bt maize is already demonstrating its value in Spain, and could also benefit the neighboring countries of France, Germany and Italy. The Spanish experience with Bt maize clearly demonstrates to its neighboring countries a troika of advantages (Brookes 2002) that are difficult to contest or reject. Firstly, Spain has confirmed that productivity increases of 5 to 7% can be realized consistently resulting in annual economic gains of $28 million (Gianessi et al 2003). Secondly, studies in Spain (Castella et al 1999) and Italy (Pietri and Pavia 2000) have shown that mycotoxin levels in conventional maize in the region can be as high as 20 ppm (ten times in excess of the guidance level of 2 ppm), whereas the corresponding Bt maize has levels below the guidance level of 2 ppm. Thirdly, Spain has been able to eliminate the application of insecticides for the target pests of European corn borer and Mediterranean corn borer in areas where Bt maize has been adopted. These three important advantages associated with Bt maize represent a compelling case in favor of adoption of Bt maize in France, Germany and Italy, which place the highest value on food and feed safety and yet make the contradictory decision to reject Bt maize even though it is known to have lower levels of fumonisin, a known toxin; this seems contrary to the rationale of the precautionary principle followed in Europe. Coincidentally, key potential beneficiary countries like China, with very large hectarages of maize, are field testing Bt maize at a time when Spain is increasing its adoption and several of the EU accession countries in Europe are also conducting intensive field tests of Bt maize.

8.18.4 The Farmers' viewpoint

Farmers' experience with Bt maize is positive and they have assigned it a high value because it is a convenient technology that allows them to manage risk in an uncertain environment and offers insurance against significant crop losses in years when pest infestations are heavy. In contrast to using insecticides and other measures in an IPM strategy, which requires time consuming scouting and applications of insecticides tailored to economic threshold levels in weather conditions that are not always optimal, the convenience of seed-incorporated control through Bt maize is assigned a very high priority by farmers.

The information from the Bt maize-growing countries, and countries where field trials have been conducted comparing Bt maize and non-Bt maize, reviewed in this chapter, confirms that the technology is safe and provides effective control of the lepidopteran pests and corn rootworm, resulting in increased yields, reduced dependency on insecticides, leading to increased profitability because of lower production costs and higher yields. Information on severity of pest infestation indicates that countries such as the USA in temperate mega-environments with approximately 40% of the maize area infested have already benefited significantly from Bt maize and can gain even more in the future as new Bt and other novel genes become available in the next three years. On the other hand countries like China, where most of the maize is grown in a temperate mega-environment, which has not adopted Bt maize to-date stand to gain significantly from the deployment of the Bt genes that are currently commercialized and from the next generation of Bt and novel genes for insect resistance. This conclusion is supported by the fact that adoption in the US, which has a medium level of infestation (40% of maize area infested), already reached 24% adoption of Bt maize in 2002, and climbed to almost 30% in 2003 (USDA/NAAS 2003), with continuing growth expected in the future as adoption of new gene products will provide more effective control of the principal pests.

A recent survey of Bt maize growers in the US (Pilcher et al 2002) indicated that farmers are becoming more aware of yield losses due to European corn borer and have a preference for the flexibility that Bt maize offers. After gaining first hand experience with Bt maize and achieving excellent control, US farmers are now convinced that the European corn borer has been causing higher losses than they suspected in their conventional maize; this provides the stimulus for more farmers to grow Bt maize. Countries other than the US growing maize in a temperate mega-environment such as Argentina are also benefiting from Bt maize with the percentage of national maize hectarage planted to Bt maize having increased every year from its first adoption in 1998 to 18% in 2000, 24% in 2001, 30% in 2002 and expected to increase to 40% in 2003. Similarly, Bt yellow maize adoption rates in South Africa have increased every year from 1998 when first adopted, to 14% in 2001, to 20% in 2002 and is expected to increase again in 2003. Bt white maize, first introduced in South Africa in 2001 occupied 0.3 % in 2001, increased 10 fold to 3% in 2002 and is expected to increase again in 2003. For developing countries like Brazil, which has not yet adopted Bt maize, the potential gains are higher than for the temperate countries like the US or China. The reason for this is that Brazil grows maize in a sub tropical/ tropical mega-environment where the level of infestation is high (60% area infested) compared with temperate mega-environments like the US and China with relatively lower infestations, with 40% of the maize area infested.

8.18.5 Opportunities and Challenges

From a global perspective the potential for Bt maize in the near term is considered better than for any other GM product at this time. There are several reasons for this.

- Firstly, the *cry1Ab* gene has provided effective control of several of the primary pests of maize, principally the stem borers and intermediate control for other pests including armyworm and earworm. The successful performance of Bt maize *(cry1Ab)* has resulted in its rapid adoption on 43 million hectares in seven countries, since its introduction in 1996.

- Secondly, new Bt products are already being launched including the *cry3Bb1* gene for corn rootworm control in the US in 2003 and the *cry1Fa2* gene that has enhanced control for both fall armyworm and black cutworm. In addition there are five new Bt and novel gene products that are anticipated for launch in the next three years that will provide the necessary diversity in modes of action to allow even more effective control of a broader range of the principal insect pests of maize.

- Thirdly, in addition to the significant advantages that Bt maize offers as a pest management tool, the product offers safer feed and food products than conventional maize with lower levels of mycotoxins, which will probably become an increasingly important attribute as food and feed safety continues to be assigned higher priority.

- Finally, of the three major staples, maize, wheat and rice, to-date maize is the only one that offers the significant benefits of biotechnology. Bt maize can now offer an increasing range of options to meet the very diverse needs of the environments in which maize is grown and characterized by mega-environments in key countries of opportunity discussed in this chapter.

Approximately 75 countries in both the industrial and developing world grow at least 100,000 hectares of maize each, totaling 140 million hectares producing 600 million MT per year, valued at $65 billion annually. The global losses due to all insect pests of maize result in losses of 9% equivalent to 52 million MT, valued at $5.7 billion annually. The *cry1Ab* gene has the potential to increase maize production by up to 35 million MT valued at $3.7 billion and decrease losses by half from 9% to 4.5%. The newly released *cry3Bb1* and the *cry1Fa2* are the first of a new generation of genes to complement the original *cry1Ab* which has made a substantive contribution and opened up new and more effective modes of managing pests. The current family of Bt genes are expected to be complemented by another five new gene products in the next three years which will include: the dual gene *cryAb1/cry3Bb1*; the dual gene *cry34Ab1/cry35Ab1*; a full length *cry1Ab*; the stacked genes of full length *cry1Ab/vip3a*, and a full length modified *cry3Aa*. This impressive family of single and stacked Bt and novel genes will result in a marked improvement in maize pest management systems. It will also feature a diversity of genes that will allow maize insect pests to be controlled in well managed pest management programs utilizing insect research management (IRM) strategies that will optimize the durability of the Bt and novel genes and allow them to be deployed sustainably, effectively and responsibly for the benefit of global society.

The potential yield gains of up to 35 million MT attainable from the first generation of Bt maize *(cry1Ab)*, with more gains to come from the second generation of Bt maize and novel gene technology, is not only considered desirable, but judged to be a critical contribution to the increased global demand for maize by 2020, when for the first time ever maize demand will exceed the demands for both wheat and rice. The challenge is to produce an additional 266 million MT globally to meet an unprecedented global demand totaling approximately 850 million MT of maize by 2020. The 35 million MT potential gain from Bt maize amounts to almost a 15% contribution to the additional 266 million MT needed by 2020. Of the additional 266 million tons required globally in 2020, 80%, or 213 million MT, will be required by developing countries and the formidable challenge for them is to optimize domestic production to meet most of their own personal needs, with imports expected to continue to provide around 10%. It is projected that Bt maize has the technological potential to deliver benefits on 40 to 45 million hectares in the near to mid-term compared with the 10 million hectares it occupies today. This should provide the incentive for major maize consuming developing countries, such as China and Brazil to approve and adopt Bt maize and benefit from the multiple and significant benefits it offers in terms of a safer and more affordable food and feed which can coincidentally make a major contribution to food and feed security and to the alleviation of hunger and malnutrition which claims 24,000 lives a day in the developing countries of Asia, Africa and Latin America.

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Table 1A. Latest Estimates for Seed Exports Worldwide, by Crop (US$ millions)

Crops	Seed Exports
Maize	530
Herbage crops	427
Potato	400
Beet	308
Wheat	75
Other Agricultural crops	750
Horticultural crops	1,150
Total	**3,640**

Source: FIS, 2001

Table 2A. Latest Estimates for Seed Exports: Major Exporting Countries (US$ millions)

Country	Agricultural Seeds	Horticultural Seeds	Total
USA	560	249	799
Netherlands	420	200	620
France	373	125	498
Denmark	150	40	190
Germany	150	35	185
Chile	84	60	144
Canada	104	18	122
Belgium	111	n.a.	111
Italy	70	41	111
Japan	5	100	105
Total	**2,027**	**868**	**32,895**

Source: FIS, 2001

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