Global Review of the Field Testing and Commercialization of Transgenic Plants:

1986 to 1995

The First Decade of Crop Biotechnology

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Chair, ISAAA Board of Directors

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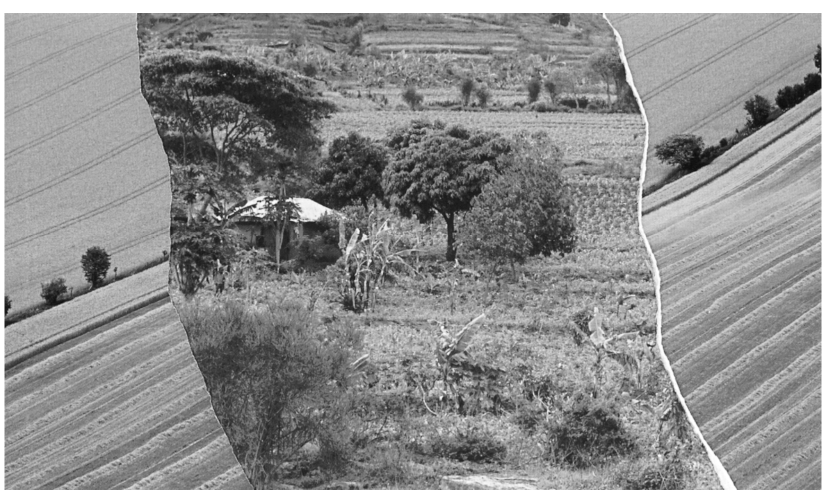

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Executive Summary

The international scientific and development community now recognizes that doubling or tripling of world food, feed and fiber production by the year 2050 to meet the needs of an 11 billion global population cannot be achieved without biotechnology. Genetic engineering of crops has been a controversial subject since 1971 when the first genetically modified organisms were developed. Concern about biosafety has led to Government regulation of transgenic crops in contained and field experiments to assess potential risk before the genetically engineered crops are approved for commercialization. The first field trials of transgenic crops featured herbicide resistance, used as a marker gene in tobacco in the USA and France in 1986. In the interim period, more than 3,500 field trials of transgenic crops have been conducted on more than 15,000 individual sites, in 34 coun-tries with at least 56 crops, mostly in North America and the European Union. 91% of the trials have been conducted in industrialized countries, 1% in Eastern Europe and Russia and the balance of 8% in the developing countries with most in Latin America and the Caribbean, only 2% in the developing countries of Asia, almost exclusively in China, and very few in Africa, almost all in South Africa. The majority of the trials have been conducted in the USA, Canada, France, United Kingdom, the Netherlands, followed by Belgium, Argentina, Italy, China, Germany, Australia, Chile and Mexico.

China was the first country to commercialize transgenics in the early 1990s with the introduction of virus resistant tobacco, and later a virus resistant tomato. The first approval for commercial sale of a genetically modified product for food use in an industrialized country was in the USA in May 1994 when Calgene marketed its Flavr-Savr™ delayed ripening tomato. By year-end 1995, 35 applications or petitions had been granted to commercially grow 9 transgenic crops, involving 8 traits in 6 countries plus the European Union, with most approvals in the USA (20) and Canada (8) which together account for 80% of the number of approvals worldwide. An additional 11 limited approvals by 3 countries have been granted for use of a product from a transgenic crop for food and/or feed use or for breeding or import. Another 28 applications are pending in 4 countries, seeking approval to either grow transgenic crops or use products derived from them. It is estimated that over 3 million acres of genetically engineered crops have been planted in the USA in 1996 for seed multiplication or as commercial crops. The major transgenic crops approved for commercial production in the USA in 1996 are: tomato with delayed ripening qualities (also approved in Mexico); cotton with insect resistance conferred by the *Bt* gene, and herbicide resistance; soybean with herbicide resistance (also approved in Argentina); corn/maize with insect or herbicide resistance or male sterility; canola/ rapeseed with modified oil quality; an insect resistant potato; and squash with virus resistance. Canada is com-mercializing transgenic canola with herbicide resistance or modified oil, corn with insect resistance or herbicide resistance and potatoes with insect resistance in 1996. Countries of the European Union have approved commercial production of only transgenic tobacco, with limited approval for food and/or feed use of imported products of herbicide resistant canola, and cotton oil as well as delayed ripening tomatoes. Applications for commercial production of additional transgenic crops are pending in several industrialized countries and are expected to be approved in the imminent future.

It is noteworthy that with the exception of China, which is reported to be growing more than 2.5 million acres of transgenic tobacco and tomato, all the approvals to-date in the industrialized countries have been granted to private sector corporations which have the majority of the investments in biotechnology. Public sector institutions in various countries are conducting field trials with transgenics, however they represent a small percentage of the total; an exception is Australia where the majority of applications in 1995 were from the public sector.

The impact and the constraints to increased adoption of transgenic crops as well as the future outlook for products from crop biotechnology is discussed. The projected value of the global market in transgenic crops is estimated at between $2 billion and $3 billion dollars for the year 2000 increasing to $6 billion in 2005.

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Introduction

Current world population is approximately 5.5 billion and this is expected to double to 11 billion by the year 2050; 97% of this population increase will occur in the developing countries, with Asia being by far the most populous continent (Swaminathan, 1995). The 1995 Asian Development Bank's policy paper on agriculture (ADB, 1995) reports that currently 700 to 800 million of the world's one billion poor people live in Asia and the Pacific region and that about 500 million live in absolute poverty. A large proportion of the poor people in the developing countries live in the rural areas and are depen-dent on agriculture for most of their meager income for survival. For the future, one of the most forbidding challenges is how to foster economic growth in the developing countries, increase food production to alleviate poverty and feed, clothe, shelter and provide gainful employment to double the current working population. Food production will have to be doubled or preferably tripled by the middle of the next century on the same or existing area of land, practicing sustainable agriculture that coincidentally conserves natural resources.

The enormity of the challenge of future global food security is best illustrated by the fact that in the next 50 years the global population will consume twice as much food as has ever been consumed before since humans started to practice agriculture 10,000 years ago, and most of that food, feed and fiber will be consumed in the developing countries. Agricultural research, new technologies and improved seeds will continue to be a prerequisite for increasing agricultural productivity, for enhancing income of farmers who can in turn produce more food for the billions of people in the developing world. The principal question is how to double food production. There is now consensus in the global scientific and development community that conventional technology alone will not allow food production to be doubled to feed a global population that will reach 11 billion by 2050—the new technologies, referred to collectively as biotechnology, will be essential to augment, not to substitute, the conventional technologies that are currently being used. Of particular importance is the application of genetic engineering in biotechnologywhich involves the use of transgenic crops in which a gene or genetic construct has been introduced by molecular techniques (OECD, 1993).

The greatest need for the new technologies will be in the countries of the South, where most of the population growth will occur. In the past, developing countries and the institutes which have assisted them with agricultural research, had the privilege of accessing non-proprietary conventional technologies from the public sector in the North: the acquisition of the dwarf genes that contributed to the green revolutions in rice and wheat are the best examples. However, the situation with the new biotechnologies is different because they have been developed primarily by the private sector in the North, not the public sector, and are proprietary technologies.

The testing of transgenic crops has been regulated by governments in both industrialized and developing countries because of the need to safeguard the environment and that transgenics represent new products that are unfamiliar to the scientific community and the lay public. Thus, the process of testing and developing appropriate legislation has taken some time to develop and implement prior to the adoption of transgenic crops which is now starting to occur at a significant rate in several countries.

The principal purpose of this paper is to: firstly, review the global status of transgenic crop field trials, often referred to as releases by regulators, that have been tested worldwide in the first decade of crop biotechnology from 1986 to 1995; secondly, review the status of approvals, and pending applications, to grow transgenic crops on a commercial basis, as well as more limited approvals to use products from transgenic crops for food and/or feed, or for breeding, import or any other restricted use at this time. In presenting this information the different types and status of regulations governing the testing and adoption of transgenic crops in various countries are briefly reviewed as well as the constraints and potential impact resulting from the adoption of genetically modified crops.

Regulation of Transgenic Crops

Unfamiliarity with genetically modified organisms and concern about biosafety led Governments in both industrialized and developing countries to regulate transgenic crops. Two types of regulations apply: firstly, there is a set of regulations that apply to contained experiments in laboratories and greenhouses; these are designed to protect the health and safety of the personnel conducting the experiments. There is a second set of regulations that govern the field experiments with transgenic crops (field releases) which are designed to initially contain transgenic crops and safeguard the environment as well as protect the health and safety of workers conducting the experiments.

Conceptually, there are two schools of thought about regulation for transgenic crops (for a detailed discussion see Dale [1995]). One school views transgenic crops as a progression of conventional crop improvement and judges that the guidelines that have been responsibly followed by the research community and plant breeders in the past are adequate for transgenic crops. The other school of thought judges that there is a need to develop new and more detailed regulations to govern a new and unfamiliar technology. All countries have adopted some degree of regulation and they have been classified as vertical and horizontal (Dale, 1995). The USA and Canada have evolved a vertical regulation, which is a selective product-based system which aims to define the characteristics of crops that require them to be regulated without requiring that all products from the transgenic process be regulated. The European Union (EU) employs a horizontal, process-based system that requires all plants produced by the transgenic process to be regulated. The Organization for Economic Co-operation and Development (OECD) recently conducted a survey of countries employing both vertical and horizontal systems and concluded that the data assessed in both systems are similar (Dale, 1995).

The issue of biosafety first arose following the development of genetically modified organisms in 1971. The first regulations were prepared by the National Institutes of Health of the USA in 1976 and applied to laboratory procedures (51 Federal Regulation No. 16958). The development of regulations for testing of transgenic crops in the field, and more laterally for adoption as commercial crops was a more complex process. The USA, as an early entrant into biotechnology research, was an innovator in developing regulations for the field testing of transgenic crops. The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), established several of the key aspects of regulations, advocating the need for case by case, and step by step evaluation. This approach to legislation has been adopted by some other countries, including developing countries such as the Philippines. Most OECD countries have regulations in place but OECD member countries differ significantly in their scale and scope of regulation implementation. Most developing countries lack operational field testing regulations; exceptions are Argentina, Brazil, Chile, China, Costa Rica, Cuba, India, Mexico, Philippines and Thailand. Other countries either have *ad hoc* committees or are in the process of adopting regulations and these include Bolivia, Colombia, Indonesia, Kenya, Malaysia, Nigeria, Venezuela and Zimbabwe. The absence of regulations has led to some concerns that genetically modified organisms (GMOs) will be tested in developing countries lacking regulations (UNEP, 1993). Given that it is the developing countries, not the industrialized countries, that are centers of diversity for the principal crops, an important consideration is the assessment of the possibility of transgenics outcrossing with wild species. For these reasons, it is important that developing countries urgently adopt appropriate regulations. Failure to do so will result in delayed access to transgenic crops that will directly impact on their ability to increase crop productivity and their competitive advantage in terms of crop production in the domestic and international market place.

Regulation governing the commercialization of transgenic crops is often subject to independent approvals from more than one regulatory agency in one country with each agency responsible for different usage or aspects of the product. For example, in the USA whereas USDA/APHIS issues permits for field trials, and later for general environmental release, any crop containing a gene for a pesticide also requires approval from the Environmental Protection Agency (EPA). Furthermore, if the product from a transgenic crop is for food or feed use, the Food and Drug Administration (FDA) are also involved in the approval of the product. In 1993, APHIS introduced a "Notification system" for the six transgenic crops with which the agency already had an extensive experience in processing and monitoring applications; the six crops are corn, tomato, soybean, potato, cotton and tobacco. The notification system does not obligate applicants to require a permit and allows the conduct of the trial if there is no objection from APHIS after the notification from the applicant has been reviewed and it has been determined that it requires no further consultation.

A significant effort has been invested by various international organizations to explore the feasibility of harmonizing regulations between countries and some developing countries have elected to harmonize some of their regulations with specific industrialized countries. For example, South Africa, has harmonized its regulations for use of products from transgenic crops with the USA. Accordingly, applicants in South Africa no longer need to seek a permit for using a product from a transgenic crop if that specific product has been approved for use in the USA; under these circumstances the applicant simply notifies the regulatory authority, SAGENE, in South Africa, which reserves the option to further consult on a case by case basis. However, South Africa does require applicants to submit applications for field trials, and biosafety/environmental clearances must be obtained as well as approval to grow any transgenic crop commercially.

In the countries of the European Union, regulation is complex because Directive 90/220 was only enacted in 1990 after several of the EU member countries had already established their own procedures. In addition, full regulatory integration of EU member states is still in process. Hence, in practice the regulation of transgenic crops is at both the country and Union level. For example, for a transgenic crop to be tested in the field, approval from a national regulatory body is required. For commercial production two steps need to be completed. The first is a growing permit (also referred to as biosafety clearance) issued under Directive 90/220. The second is variety registration which is required for all new varieties irrespective of whether the crop is transgenic or not; this requires one to three years of field testing, except for tobacco where variety registration does not apply. Theoretically, once a product has been approved in one EU country it also applies to any other EU country, however for marketing purposes companies prefer to register the product in each of the EU countries separately. The above legislative steps apply to the commercial growing of transgenic crops, but many countries, including EU countries, allow limited approval that can apply to specific uses, for example, for breeding purposes, or to only allow import of a product from a transgenic crop for food and/or feed purposes. Before products from transgenic crops can be "placed on the market", for food and/or feed use in the EU, a decision of the Commission is required: there is no specific legislation for this at present but four such decisions have been taken and based on Directive 90/220. The intent in describing the approval process in this publication is not to provide specific details of the regulations of different countries, but to highlight the fact that approval for a transgenic crop is not a simple process and is very complex and specific in terms of application and requirements.

Methodology for Data Collection and Definitions

Whereas many public and private international organizations and institutions maintain data bases on transgenic crops, lack of uniformity in data compilation and limited access to current and detailed information precludes the use of any one data base for obtaining a comprehensive assessment of the global status of transgenic crops in terms of field trials and stage of commercialization. Thus, this publication integrates data from several sources in an attempt to provide a credible and current global assessment, in the knowledge that it is impossible to capture all the data that is being generated continuously from official and informal sources; therefore, any publication of this nature will have omissions, and to some extent, will have to rely on value judgments. In the interest of continuity, the methodology used by Krattiger (1994) has been used to update the principal data sets in this publication for field experiments conducted until 31 December 1995; the latest data has been included for the commercialization of transgenic crops, including where available, information for 1996.

Current data for the USA and Canada, and most European countries are readily available and have been reviewed extensively in the past (Chasseray and Duesing, 1992; Ahl Goy and Duesing, 1993; Ahl Goy *et al.*, 1994; Ahl Goy and Deusing, 1995; OECD, 1993; Krattiger, 1994; Dale, 1995). Equivalent data for Africa, Asia and Latin America and the Caribbean are more difficult to obtain or corroborate. Most of the articles cited above, as well as this publication, have made use of a comprehensive data base maintained by the Green Industry Biotechnology Platform (GIBiP), an association of major European Plant Biotechnology companies; the GIBiP data base provided information to the end of 1993. For countries with established regulatory mechanisms, information has been obtained from official field trial data, readily available from the respective governmental agencies. In addition, the EU keeps records of field releases for its member states but these are not always current and OECD countries are required to disclose data on their releases.

The availability of data in developing countries is more problematic because it is less accessible and more difficult to corroborate and sometimes is consolidated on an *ad hoc* basis. Countries with biosafety committees (e.g. Chile, Argentina, Thailand) make their data readily available, including information on the current status of applications and rejected applications. Other countries with formal biosafety or biotechnology committees (e.g. Costa Rica) treat applications in strict confidence. In either case, the committees, understandably, only provide information related to field trials that have officially been approved. For data that was generated prior to the establishment of official committees and for countries where official committees have yet to be established, data has, by and large, been obtained through informal contacts. Thus, the information presented in this paper has, whenever possible, been obtained through official channels, and when official data are not available, data have been obtained through informal contacts; the latter applies to most of the data for developing countries.

The various published data bases are not consistent vis-à-vis the definition of what constitutes a field trial and hence data from different data bases are not always comparable. For example, a trial (release), can be one crop at one site in one year, or it can be a category of a crop at a number of sites within a country. In industrialized countries the number of sites for any one trial can be large whereas for developing countries, a trial may be conducted at only one or few locations. In the USA, a "Release Permit", equivalent to "trial" in this publication is applicable to a particular year for one precisely defined crop with a known modification and may be tested at more than one site in more than one state. Each proposed trial site must be listed in applications to APHIS and the permit obtained from APHIS indicates the sites where field trials may proceed—an exception to this is "notifications", discussed elsewhere in the text. In this publication, unless stated otherwise, the definition of a field trial is consistent throughout and is equivalent to the "release permit" issued in the USA, defined above. Perennial crops (e.g. trees, strawberries, sugarcane) which are tested over a period of years are counted as one trial in the establishment year of the trial and not counted again for the consecutive years when the same trial is continued.

The traits that have been conferred through the introduction of genes into transgenic crops have been grouped into several categories, namely bacterial resistant (BR), fungal resistant (FR), herbicide tolerant (HT), insect resistant (IR), marker gene(s) (M), male sterility (MS), quality characteristics (Q), and virus resistant (VR). Categories used by APHIS are slightly different and are explained in the tables and figures. Given that this is a general review, different mechanisms for conferring the same trait have not been distinguished. For example, for virus resistance no distinction has been made between coat protein-mediated resistance, or satellite or 54kb replicase technology. Industrialized production refers to a specific enzyme production (e.g. in soybean) and is included in the category of quality characteristics along with other traits such as delayed ripening (tomato), increased protein production (e.g. high amino-acid composition in potato), decreased protein production (e.g. low gluten content for brewing rice), low allergen production (e.g. low gliadin in rice), and pigment production in flowers. Modified fatty acid composition (e.g. the bay thioesterase gene in rapeseed producing laurate) was classified as a quality trait although it is used as a component in detergent and other manufactured items. Throughout this publication the words corn and maize are synonymous and interchangeable. Similarly, canola, initially coined in Canada, is now gaining international acceptance and is synonymous and interchangeable with rapeseed oil.

Countries Which Have Conducted Field Trials with Transgenic Crops, 1986 to 1995

The data in Table 1 indicate that 34 countries have conducted field trials with transgenic crops. The first field trial was conducted in the USA and France in 1986 and featured a marker gene in tobacco. During the period 1986 to 1995 the number of field trials increased from 5 to 3,647. The trials were conducted in 18 industrialized countries, 3 countries that were formerly centrally planned economies and in 13 developing countries of Latin America (8), Asia (2), and Africa (3). The majority of the trials have been conducted in the USA (1,952), Canada (486), France (253), the United Kingdom (133), the Netherlands (113), Belgium (97), Argentina (78), Italy (69), China (60), Germany (49), Australia (46), Chile (39) and Mexico (38); China was the first country to commercialize transgenics in the early 1990s.

Transgenic Crops Tested in Field Trials, 1986 to 1995

Following the first field trial with transgenic tobacco in the USA and France in 1986, a total of 56 transgenic crops have been tested in field trials. The data in Table 2 indicate the relative frequency of transgenic crops featuring in field trials and three classes are defined: crops for which more than a 150 trials have been conducted; crops featured in 25 to 150 trials; and those that are still at the experimental stage with less than 25 trials conducted to-date. The 8 crops featured in more than 150 trials and which have already been commercialized in one or more countries are cotton, corn/maize, melon, canola/rapeseed, potato, soybean, tobacco and tomato. The 8 crops that have been commercialized to some extent, or are near-term commercial prospects are alfalfa, cantaloupe, carnations, flax, rice, squash, sugarbeet and sunflower.

At the outset, monocotyledons proved more difficult to transform than dicotyledons and the major cereal staples of maize, rice and wheat required considerable effort, but after the initial constraints, all were transformed. Initially, *Agrobacterium* was used as a vector to transport the genes into crops and later this was supplemented by various biolistic methods using a gun to shoot genes into plant cells.

Figure 1 shows the most frequent crops tested in trials globally during the period 1986 through December 1995. The 8 most frequent crops were corn/maize with 1,024 trials equivalent to 33%, canola/rapeseed with 665 (21%), potato with 362 (11%), tomato with 353 (11%), soybean with 278 (9%), cotton with 224 (7%), tobacco with 161 (5%), and melon and squash with 92 (3%).

Table 1: Total Number of Transgenic Crop Field Trials in Different Countries Worldwide
(1986 through 31 December 1995)

Country	Total Number of Field Trials
Argentina	78
Australia	46
Belgium	97
Belize	5
Bolivia	6
Bulgaria	3
Canada	486
Chile	39
China	60
Costa Rica	17
Cuba	18
Denmark	16
Egypt	2
Finland	10
France *	253
Germany	49
Guatemala	3
Hungary	22
Italy	69
Japan	25
Mexico	38
New Zealand	15
Norway	1
Portugal	5
Russia	11
South Africa	22
Spain	30
Sweden	18
Switzerland	2
Thailand	2
The Netherlands	113
United Kingdom	133
United States	1,952
Zimbabwe	1
Total	**3,647**

- Permits issued for more than one year have been counted as one year only.

Traits Modified by Plant Transformation

In most of the data bases, traits have been classified into various categories. Whereas these categories are not identical in the different data bases the degree of similarity makes them comparable. The first genes to be incorporated were marker genes, including selectable markers such as GUS and genes that conferred resistance to various antibiotics particularly kanamycin, which has been widely used. The first beneficial genes tested in field trials conferred resistance to diseases and pests, more specifically virus diseases, and insect resistance, herbicide tolerance and genes that contributed to product quality through modification of agronomic properties. Genes that confer resistance to fungal and bacterial diseases as well as nematode resistance are now becoming more prominent. Figure 2 shows the frequency of the most common traits tested in transgenic crop field trials worldwide during the period 1986 to 31 December 1995. The most frequent trait categories were herbicide tolerance with 1,450 trials equivalent to 35%, product quality (including agronomic traits) with 806 (20%), insect resistance with 738 (18%), viral resistance with 466 (11%,)

Table 2: List of Transgenic Crops Tested in Field Experiments Worldwide
(1986 through 31 December 1995)

Large number of field trials (commercialized or near commercialization; >150 trials)	**Medium number of field trials** (commercial development; 25-150)	**Low number of field trials** (experimental; 1-25)	
Canola/Rapeseed	Alfalfa	*Amelanchier laevis*	Grape
Cotton	Cantaloupe	Apple	Kiwi
Maize corn	Carnations	*Arabidopis thaliana*	Lettuce
Melon	Flax	Asparagus	Lupins
Potato	Rice	Barley	Papaya
Soybean	Squash	Belladonna	Pea
Tobacco	Sugarbeet	Birch	Peanut
Tomato	Sunflower	Cabbage	Pepper
		Carrot	Petunia
		Cauliflower	Plum
		Chicory	Poplar
		Chrysanthemum	Raspberry
		Clover	Serviceberry
		Cranberry	Spruce
		Creeping bent grass	Strawberry
		Cucumber	Sugarcane
		Eggplant	Sunflower
		Eucalyptus	Sweetpotato
		Gerbera	Walnut
		Gladiolus	Wheat

Figure 1: Number and (%) of Transgenic Crop Field Trials Worldwide: Most Frequent Crops
(1986 through 31 December 1995)

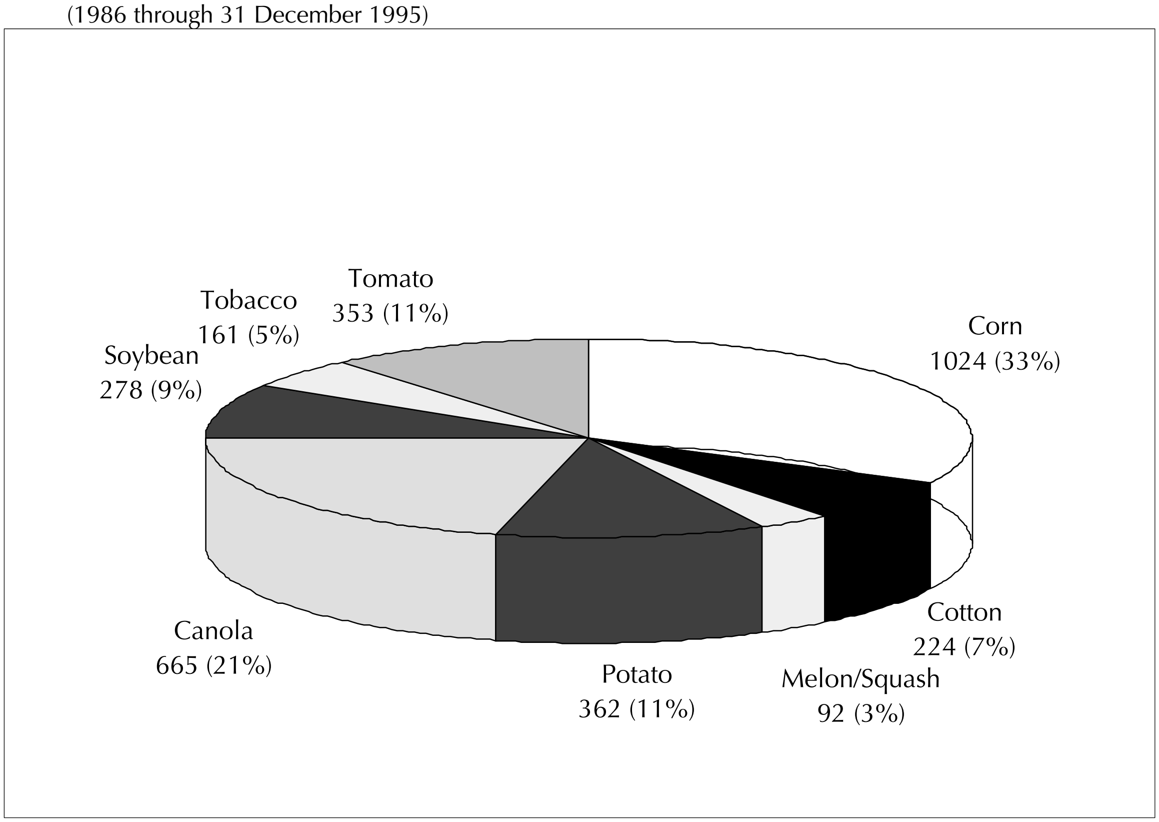
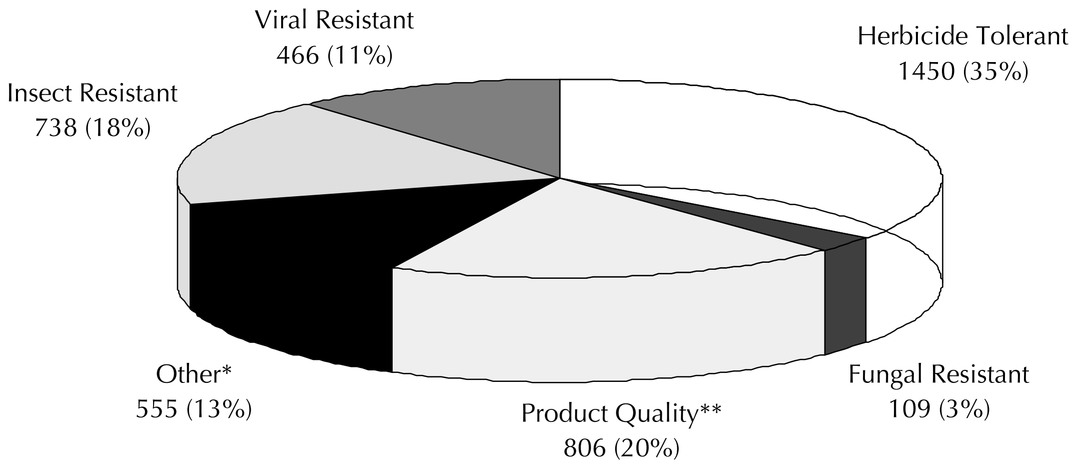


Figure 2: Number and (%) of Transgenic Crop Field Trials Worldwide: Most Frequent Trait Categories (1986 through 31 December 1995)



* Other includes marker genes, selectable markers, bacterial resistant and nematode resistant.
** Includes agronomic characters.

fungal resistance with 109 (3%) and a final category of other applications which comprised 555 trials equivalent to 13% of the total and included traits such as marker genes, selectable markers, bacterial, and nematode resistance.

A more detailed list of the traits that have been modified through incorporation of genes with molecular techniques worldwide and the corresponding number of field trials in the different trait categories in the USA are listed in Table 3. Whereas virus and insect resistance were two of the first categories of genes to be initially incorporated, herbicide tolerance and product quality have now become more prominent in field trials in the USA in the 1990s.

Overview of Field Trial History and Current Status

The first field trials were conducted in 1986, with herbicide tolerance used as a marker gene in tobacco, in the USA and France. Belgium, the United Kingdom and Chile followed in 1987 and by 1990 ten countries had conducted transgenic crop field trials. By the end of 1995, all industrialized countries of the OECD, with the exception of Austria, Greece, Iceland, Ireland, Luxembourg and Turkey, had authorized field trials. The data in Table 4 summarizes information on the number of transgenic crop field trials conducted in both the industrialized and developing countries. The data indicate that for the ten-year period, 1986 to 1995, the industrialized countries of the USA, Canada, the EU and Asia accounted for 3,320 of the total of 3,647 trials, equivalent to 91% of the trials worldwide. The balance of 9% were conducted in the developing countries of Latin America (5%), Asia (2%), Africa (1%), with 1% in the countries of Eastern Europe and Russia. Within the industrialized countries of North America, Europe and Asia, the significant majority of the trials, almost 74%, were conducted in the USA and Canada, 24% in the countries of the European Union and less than 3% in the Asian industrialized countries of Australia, Japan and New Zealand. Within the developing countries of the South approximately 70% were conducted in Latin America, 21% in Asia and 9% in Africa.

Table 3: List of Traits Modified by Transformation

Trait/Modified Characteristic	Number of field releases in the USA (1986-12/1995) *
Herbicide tolerance	590
2,4-Dichlorophenoxyacetic acid	
Asulam	
Atrazine	
Bromoxynil	
Fosametin	
Glufosinate/Phosphinothricin	
Glyphosate	
Pyridine	
Sulfonylurea	
Product Quality	570
Delayed ripening	
Dry matter content	
Improved processing	
Increased soluble solids	
Increased yield	
Modified oil content	
Phytase content	
Seed storage proteins	
Starch metabolism	
Stress tolerance	
Insect resistance	492
Antifeedant protein	
Bt protein	
Viral resistance	244
Alfalfa mosaic	
Cucumber mosaic	
Papaya ringspot	
Plum pox	
Potato leafroll	
Potato virus X	
Potato virus Y	
Rice stripe	
Viral resistance continued	
Soybean mosaic	
Sweet potato feathery mottle	
Tobacco etch	
Tobacco mosaic	
Tomato mosaic	
Watermelon mosaic 2	
Zucchini yellow mosaic	
Fungal resistance	62
Acetyltransferase	
Chitinase/glucanase	
Lysozyme	
Osmotin	
Other	172
Production of specialty chemicals/ medicines	
Enkephalins	
Fatty acids	
Human serum albumin	
Sugars (monomers, thermoplastic polymers)	
Vaccines (e.g., hepatitis, bacterial infections)	
Bacterial resistance	
Cercopin	
Marker genes (resistance to/expression of	
Chloramphenicol	
Gentamycin	
GUS	
Hygromycin	
Kanamycin	
Neomycin	
Mannose	
Xylose	
Stress Resistance (abiotic)	
Unspecified and confidential business information	

Source: Modified and updated from Dale (1995).

* Not all characters have necessarily been released in the USA for testing. The total number of field releases in this table exceeds the total number of field releases in the USA during that period because some field releases are with multiple traits.

To date, more than 70 crop species have been transformed and at least 54 have been field tested with the great majority of tests conducted with eight crop species, namely corn/maize, canola, potato, tomato, soybean, cotton, tobacco and melon. These crops can routinely be transformed, with other crops such as cucurbit species, rice, and sugarbeet also becoming more prominent in field trials.

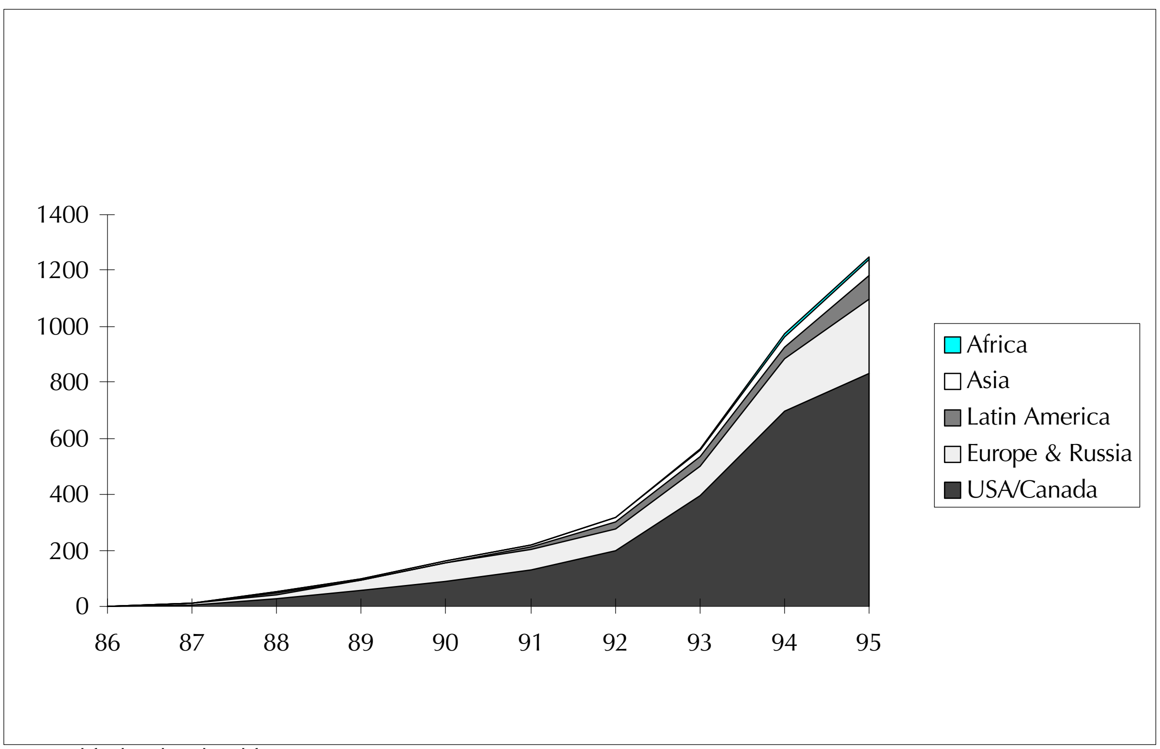
Most countries have one or more crops that are prominent because of their contribution to the economy. Corn is the most important crop in the USA, and cotton in Australia and South Africa. In Canada, canola accounts for approximately two thirds of all transgenic crop field trials.

Of all trials in industrialized countries in 1995, herbicide tolerance represented the highest proportion of trials followed by product quality, insect resistance and virus resistance. Corn/Maize (33%) occupies the first place in the number of trials, followed by canola (21%), potato (11%), tomato (11%) with the balance represented by soybean, cotton and melon. Figure 3 shows the relative number of field trials conducted in the various regions of the world. The data show the dominance of North America followed by Europe. Initially field trials were usually conducted at only one or a few sites, and this continues to be the case for pilot trials with a new trait and for trials in developing countries. However, most trials are now conducted in many locations.

It should be noted that the number of trials in Table 4 and Figure 3 are based on the number of permits and notifications rather than sites/locations, and thus the numbers are only a fraction of the total number of field experiments actually conducted at different locations. For example, in the USA in 1995 the number of trials were 707, whereas the number of experiments actually conducted in that year was more than five fold higher at 3,728. In 1993, a permit was issued for one cotton trial in the USA that was conducted in 39 locations. Permits in the Netherlands average 5 to 10 locations with one potato trial conducted at 38 locations and another at 49 locations. Thus, the total number of field experiments, as opposed to trials, conducted with transgenic crops worldwide during the period 1986 to 1995 is estimated to be approximately 15,000. This is a significant experimental experience by any standard, and the fact that this has been satisfactorily overseen and implemented by both regulators and developers of biotechnology from both the private and public sector reflects well on the appropriateness and potential of biotechnology for agriculture. Like any other technology, there will be a need to continue to monitor the application of biotechnology when it is applied on large acreages commercially, which is usually the time when some of the practical challenges related to large scale application become evident. Trial results indicate that the potential benefits of biotechnology to agriculture in both the industrialized and developing countries can be significant.

The significant experience with field trials to date will hopefully allow countries that have not yet conducted trials to benefit from the experience of others. It is prudent and appropriate to optimize the utilization of the considerable experience from the 15,000 field experiments

Figure 3: Number of Transgenic Crop Field Trials Worldwide: By Region[1]
(1986 through 31 December 1995)



Source: Modified and updated from Krattiger (1994).

[1] The number of field trials in Africa is small (9 in 1995) and only shows up as a thin line in this graph.

Table 4: Number of Transgenic Crop Field Trials Worldwide
(1986 through 31 December 1995)

Industrialized Countries		1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
North America												
Canada				10	28	40	39	40	89	113	127	486
USA	Permits	3	5	16	30	51	90	160	117	69	87	628
	Notifications								189	515	620	1,324
Subtotal		**3**	**5**	**26**	**58**	**91**	**129**	**200**	**395**	**697**	**834**	**2,438**
Western Europe												
Belgium			1	4	9	14	14	12	19	15	9	97
Denmark						2	1	3	4	5	1	16
Finland				1	1	2		3	1	2		10
France *		2	5	9	14	26	31	22	29	53	62	253
Germany						1	1	1	3	11	32	49
Italy					1	1		1	7	20	39	69
Norway								1				1
Portugal									2	2	1	5
Spain				2	4	5			3	11	5	30
Sweden					1	1	1	2	3	3	7	18
Switzerland							1	1				2
The Netherlands				1	1	1	13	16	20	27	34	113
United Kingdom			1	1	4	11	13	13	11	29	50	133
Subtotal		**2**	**7**	**18**	**35**	**64**	**75**	**75**	**102**	**178**	**240**	**796**
Asia (Industrialized)												
Australia							1	6	7	17	15	46
Japan							2	0	4	8	11	25
New Zealand			0	4	4	3	1	1	1	1	0	15
Subtotal				**4**	**4**	**3**	**4**	**7**	**12**	**26**	**26**	**86**
Total (Industrialized)		**5**	**12**	**48**	**97**	**158**	**208**	**282**	**509**	**901**	**1,100**	**3,320**

continued...

conducted with transgenic crops thus far, with a view to harmonization of regulations that offers significant advantages to all parties; these include: farmers, the end users of the technology who can benefit from earlier access to the biotechnology applications; Government through more cost effective implementation of responsible and efficient regulation; developers of biotechnology applications who can realize a return on their long-term and significant investments in R&D which in turn will allow reinvestment to develop more and better superior biotechnologies; environment through a more sustainable agriculture and a safer environment through improved crop protection and less dependency on pesticides on food crops, particularly horticultural crops and fiber crops, particularly cotton; finally, consumers who can reap the benefits that biotechnology offers in terms of lower post-harvest losses, higher productivity, more and safer food at cost effective prices. It is equally important to continue to be vigilant to monitor unforeseen events in field trials so that timely, prudent and corrective action can be implemented.

Table 4 continued...

Developing Countries	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
Africa											
Egypt						1				1	2
South Africa					1	1	1	6	5	8	22
Zimbabwe									1		1
Subtotal					**1**	**2**	**1**	**6**	**6**	**9**	**25**
Asia											
China				2	2	2	5	9	10	30	60
Thailand									1	1	2
Subtotal				**2**	**2**	**2**	**5**	**9**	**11**	**31**	**62**
Latin America											
Argentina						4	9	13	18	34	78
Belize							4	1			5
Bolivia						3	1		1	1	6
Chile		1					4	7	6	21	39
Costa Rica						1	4		2	10	17
Cuba					1	1	2	4	5	5	18
Guatemala				1					1	1	3
Mexico			2				4	11	8	13	38
Subtotal		**1**	**2**	**1**	**1**	**9**	**28**	**36**	**41**	**85**	**204**
Total (Developing)		**1**	**2**	**3**	**4**	**13**	**34**	**51**	**58**	**125**	**291**

Eastern Europe/Russia	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
Eastern Europe and Russia											
Bulgaria										3	3
Hungary								2	10	10	22
Russia									2	9	11
Subtotal								**2**	**12**	**22**	**36**
Total Eastern Europe/Russia								**2**	**12**	**22**	**36**
Grand Total (worldwide)	**5**	**13**	**50**	**100**	**162**	**221**	**316**	**562**	**971**	**1,247**	**3,647**

Source: Modified and updated from Krattiger (1994).

* Permits issued for more than one year have been counted as one year only.

Transgenic Crops in the Industrialized Countries, Eastern Europe and Russia

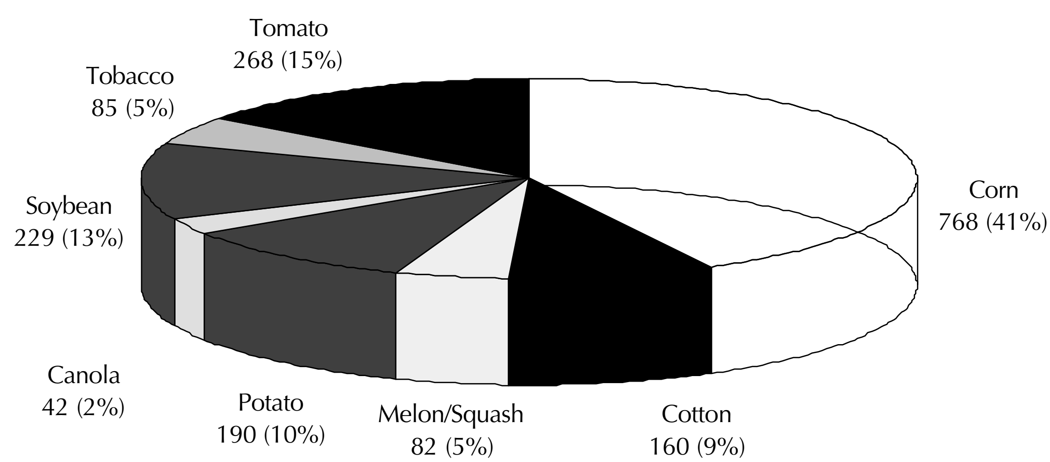
North America

North America has conducted 2,438 trials, the USA (1,952) and Canada (486), which is equivalent to two-thirds of the total conducted worldwide and to approximately three-quarters of the total conducted in the industrialized countries (3,320). The USA has conducted more transgenic crop field trials than any other country, numbering 1,952 during the ten year period 1986 to 1995 inclusive; this is equivalent to 54% of the global total of transgenic crop field trials and has involved 7,098 individual field experiments. The USA has also by far the most comprehensive national data base which is available on the Internet and updated regularly that provides uniformly recorded and current data. Until 1993, all the field trials required permits granted by USDA/APHIS subsequent to the submission of successful applications by companies and institutions seeking to field test the technology. As noted elsewhere in the text, in 1993, in addition to permits, APHIS introduced a notification system and it is noteworthy that the initial experience of APHIS in evaluating the permits for the six major crops (corn, tomato, soybean, potato, cotton and tobacco) resulted in a degree of familiarity and confidence that allowed the agency to implement the notification system which is more efficient but equally effective as the permit system.

Figure 4 shows the most frequent crops tested in trials in the USA during the period 1986 to 31 December 1995. Of the 17 transgenic crops tested in field trials, the 8 most frequent crops were corn/maize with 768 trials equivalent to 42%, tomato with 268 (15%), soybean with 229 (13%), potato with 190 (10%), cotton with 160 (9%), tobacco with 85 (5%), melon and squash with 82 (5%) and canola/rapeseed with 42 (2%). Of the 1,952 transgenic crop trials conducted in the USA during the period 1986 to 31 December 1995, the most frequent trait categories (Figure 5) were herbicide tolerance with 590 trials equivalent to 28%, product quality (including agronomic traits) with 570 (27%), insect resistance with 492 (23%), viral resistance with 244 (11%), fungal resistance with 62 (3%) and a final category of other applications which comprised 172 trials equivalent to 8% of the total and included traits such as marker genes, selectable markers, bacterial, and nematode resistance.

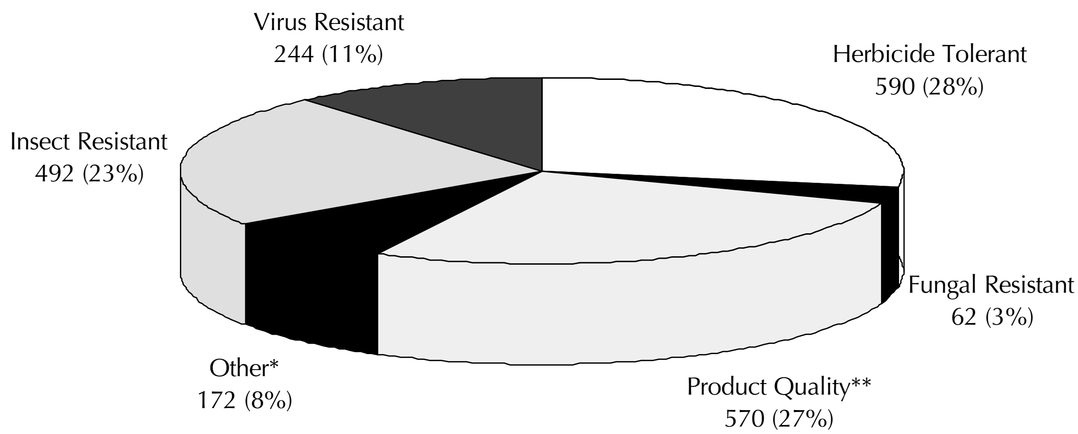
Figure 6 exhibits the number of field releases (trials) from 1986 to 1995 in the USA and the respective numbers of permits and notifications approved by APHIS during the period 1993 to 1995. It is noteworthy that the percentage of notifications increased from 61% in 1993 to 88% in 1995 and that the corresponding number of notifications increased by more than three fold from 189 in 1993 to 620 in 1995. Thus, the introduction of the notification system has allowed APHIS to continue to discharge its regulatory responsibility and, coincidentally, significantly increase the efficiency and capacity of its regulatory system for dealing with the six principal crops.

Figure 4: Number and (%) of Transgenic Crop Field Trials in the USA: Most Frequent Crops
(1986 through 31 December 1995)



Source: Modified from APHIS (1996).

Figure 5: Number and (%) of Transgenic Crop Field Trials in the USA: Most Frequent Trait Categories
(1986 through 31 December 1995)

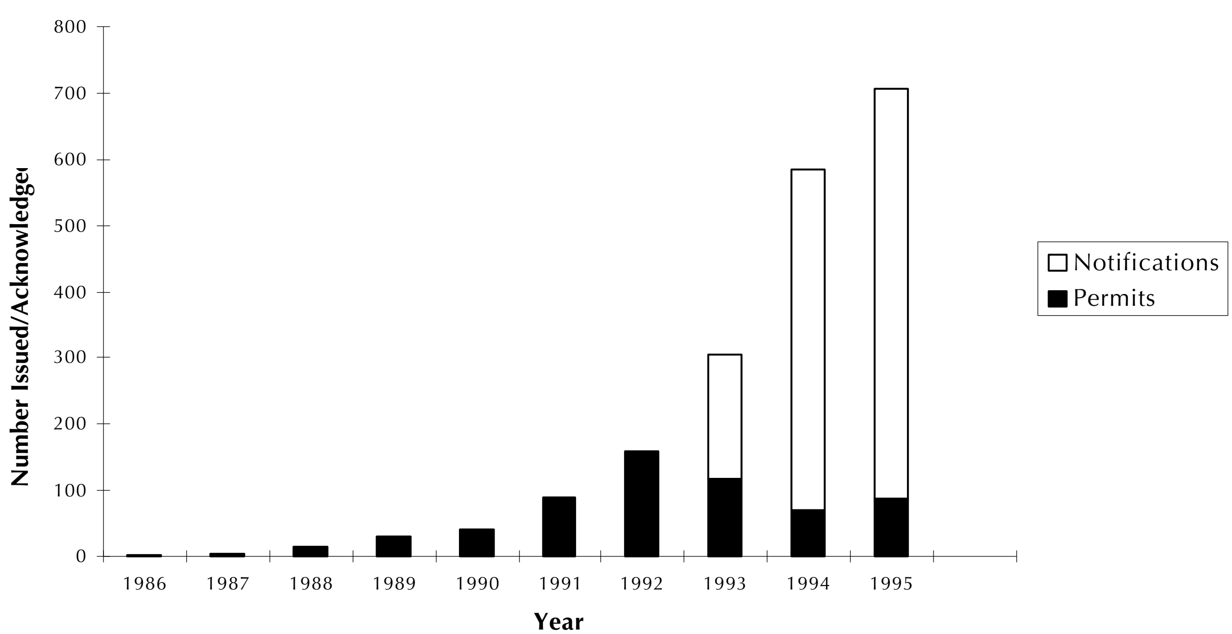


* Other includes marker genes, selectable markers, bacterial resistant and nematode resistant.

** Includes agronomic characters.

Source: Modified from APHIS (1996).

Figure 6: Number of Permits and Notifications for Transgenic Crop Field Trials in the USA
(1986 through 31 December 1995)



Source: Modified from APHIS (1996).

In order to provide the most recent data from the USA and to assess the relative importance of crop and trait priorities in field trials, Table 5 shows summary data for the 194 notifications filed in the 9 month period 1 September 1995 to 31 May 1996. Corn represented more than half (54%) of the notifications, followed by tomato (13%) and potato (13%) with the three other crops, cotton, tobacco and soybean each representing less than 10% of the total. In terms of traits, insect resistance (24%), herbicide resistance (22%) and product quality (22%) were equally important and collectively represented 70% of the notifications. For corn trials the major traits were insect resistance, which was featured in 33 trials out of a total of 105, and herbicide resistance in 29 out of 105. For potato, the second most important crop, pest and disease resistance accounted for the majority of the traits. Product quality (delayed ripening) was the major trait for tomato, herbicide and insect resistance for cotton, herbicide resistance and product quality for soybean, and virus resistance and herbicide resistance for tobacco. It is noteworthy that 80% of the notifications were from private sector companies with most of the balance (15%) submitted by universities in the public sector and 5% from Government institutions. Monsanto and Pioneer Hi-Bred International were the companies with most notifications, together accounting for between 15 and 20% of total notifications from both the private and public sector.

Canada has a similar regulation product-based system to the USA and has conducted more trials (486) than any other country except for the USA. Many of the products tested in the USA have also been tested in Canada. A feature of the trials conducted in Canada is that two thirds of the trials are devoted to canola, which is an extremely important crop in Canada. In recent years canola has even surpassed wheat in terms of export earnings. Another feature of Canadian trials is the work on herbicide resistance in flax.

European Union Countries

France was the first EU country to conduct a transgenic crop field trial in 1986 followed by the United Kingdom and Belgium in 1987. As a group, the 13 EU countries that have conducted transgenic crop field trials have completed approximately 22% of the trials worldwide; this is equivalent to only one third of the number completed in North America, which has conducted two thirds of the transgenic crop trials worldwide. Within the EU, three countries have conducted about two-thirds of the trials; France has conducted approximately one third with the United Kingdom and the Netherlands making up the other third and with Belgium and Italy contributing about 10% each. Crops such as canola have featured prominently along with corn/maize, tobacco and tomato. Prominent traits are herbicide resistance, insect and virus disease resistance, delayed ripening genes in tomatoes and others that affect product quality in crops such as canola.

Eastern European Countries and Russia

Only three countries have conducted transgenic crop trials in Eastern Europe: Hungary, Russia and Bulgaria (Table 6). The first trials were conducted in Hungary in 1993 followed by Russia in 1994 and Bulgaria in 1995. The total number of trials in all three countries (36) represents only 1% of trials conducted globally and two thirds of the trials have been conducted in Hungary, and with the exception of the 3 trials in Bulgaria, the balance have been conducted in Russia. The principal crops have included corn, potato, tobacco, canola, alfalfa and eggplant. The major traits tested are, in descending order of priority, virus resistance (particularly in potatoes), insect resistance and herbicide resistance.

Industrialized Countries of Asia

The industrialized countries of Asia initiated the bulk of their field testing in the early 1990s (2 to 4 years later than their counterparts in North America and Europe), although the first test was conducted in New Zealand in 1988. Collectively the three industrialized countries in Asia - Australia, Japan and New Zealand have conducted 86 trials equivalent to approximately 2% of the total worldwide. Within the Asian Pacific Rim industrialized countries, Australia has conducted half of the trials (46) of which approximately half (20) have featured cotton, with insect and herbicide resistance being the principal traits (Table 7). Japan has conducted only 25 trials in which rice (6 trials), tomato and canola have been the principal crops with virus resistance being by far the most important trait, followed by quality and herbicide resistance. New Zealand has devoted most of its efforts to potatoes, testing virus resistance and herbicide tolerance. Unlike other industrialized countries, where the transgenic crop trials are conducted almost exclusively by the private sector, in Australia the majority of applications in 1995 were from the public sector.

Table 5: Characteristics of 194 "Notifications" Submitted to APHIS in the Nine Month Period of 1 September 1995 to 31 May 1996

Crop	IR	HR	PQ	AP	VR	FR	Other	Total
Corn	33	29	12	14	1	3	13	105
Tomato	2	0	19	0	3	0	2	26
Potato	7	2	5	0	4	6	1	25
Cotton	5	7	2	0	0	0	0	14
Tobacco	0	2	1	1	5	1	3	13
Soybean	0	3	4	0	0	0	4	11
Total	47	43	43	15	13	10	23	194

Source: APHIS (1996).

AP: Agronomic Properties
FR: Fungal Resistant
HR: Herbicide Tolerant
IR: Insect Resistant
Other: Include marker genes, selectable markers, bacterial resistant and nematode resistant.
PQ: Product Quality
VR: Virus Resistant

Table 6: Transgenic Crop Field Trials in Eastern Europe and Russia: By Crop and Trait
(1986 through 31 December 1995)

Country		1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
Bulgaria	Alfalfa										M	**1**
	Tobacco										BR, VR	**2**
	Subtotal										**3**	**3**
Hungary	Alfalfa									IR	IR	**2**
	Corn									2HT, 2IR	2HT, 2IR	**8**
	Canola									HT	HT	**2**
	Eggplant									IR,VR	IR,VR	**4**
	Potato								VR	VR	VR	**3**
	Tobacco								VR	VR	VR	**3**
	Subtotal								**2**	**10**	**10**	**22**
Russia	Corn										3IR, 3HT	**6**
	Potato									2VR	3VR	**5**
	Subtotal									**2**	**9**	**11**
Total Eastern Europe/Russia									**2**	**12**	**22**	**36**

Source: Modified and updated from Krattiger (1994).

BR: Bacterial Resistant
FR: Fungal Resistant
HR: Herbicide Tolerant
IR: Insect Resistant
M: Marker Gene
MS: Male Sterility
Q: Quality Characteristics
VR: Virus Resistant

Table 7: Transgenic Crop Field Trials in the Industrialized Countries of Asia: By Crop and Trait
(1986 through 31 December 1995)

Country		1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
Australia	Apple									M		**1**
	Canola							A				**1**
	Carnation							2HT+ Q		2 Q	2Q	**6**
	Chrysan-themum								Q			**1**
	Clover									HT+Q	HT+Q	**2**
	Cotton							IR	2IR	7IR, HT	6 IR, 3 HT	**20**
	Lupins									HT	HT+ Q	**2**
	Potato						VR	A	A, VR	Q ,VR	VR	**7**
	Rose									Q		**1**
	Sugarcane								M			**1**
	Tobacco									IR	IR	**2**
	Tomato							Q	Q			**2**
	Subtotal						**1**	**6**	**7**	**17**	**15**	**46**
Japan	Canola										4 HT	**4**
	Carnation										Q	**1**
	Corn										HT	**1**
	Melon								VR			**1**
	Petunia								VR	Q		**2**
	Potato									VR		**1**
	Rice								2VR	2 Q, 2 VR		**6**
	Soybean										HT	**1**
	Tobacco						VR			VR		**2**
	Tomato						VR			Q	2 VR, 2 Q	**6**
	Subtotal						**2**		**4**	**8**	**11**	**25**
New Zealand	Asparagus			M								**1**
	Broccoli					HT						**1**
	Corn									IR+HT		**1**
	Kiwi						Q					**1**
	Potato			2M, HT	2 HT, M, Q	2 VR+M		VR	VR			**11**
	Subtotal			**4**	**4**	**3**	**1**	**1**	**1**	**1**		**15**
Total Asia (Industrialized)				**4**	**4**	**3**	**4**	**7**	**12**	**26**	**26**	**86**

Source: Modified and updated from Krattiger (1994).

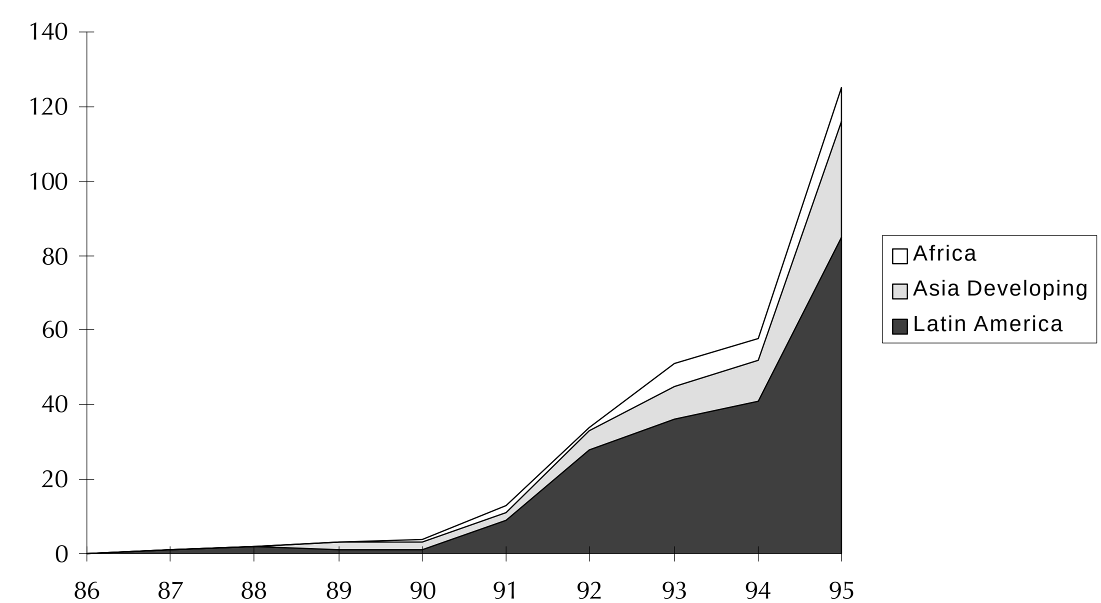
BR:	Bacterial Resistant	IR:	Insect Resistant	Q:	Quality Characteristics
FR:	Fungal Resistant	M:	Marker Gene	VR:	Virus Resistant
HR:	Herbicide Tolerant	MS:	Male Sterility		

Collectively, approximately a dozen developing countries have conducted 291 trials equivalent to 8% of the number conducted globally. The general data for the developing countries are shown in Table 4 and Figures 7, 8 and 9. More detailed data for Latin America and the Caribbean are provided in Table 8, Asia (Table 9) and Africa (Table 10). Overall, the highest activity has been recorded in Latin America but it should be noted that China probably has more individual sites tested and thus may have by far the highest activity overall.

With the exception of the transgenic crops tested in China and Cuba, the potato, tomato and maize trials conducted by the national research institute CINVESTAV and maize trials by the Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT: International Maize and Wheat Improvement Center) in Mexico, all the transgenic crop material tested in developing countries has been developed externally and imported by the developers of the technology subsequent to obtaining approval for trial implementation.

The most frequent crops tested in the developing countries (Figure 8) were corn with 68 trials equivalent to 27%, cotton with 44 at 18%, soybean with 36 at 15%, tobacco with 35 at 14% tomato with 33 at 13% and canola/rapeseed with 16 at 7%. Corn, soybean and tomato are the crops most often tested in Latin America, whereas tobacco dominates Asia followed by cotton and tomato, and in Africa cotton is the principal transgenic tested, with all cotton trials conducted in South Africa. The most frequent traits tested in developing countries (Figure 9) were herbicide tolerance with 112 trials equivalent to 37%, followed by insect resistance with 80 at 26%, virus resistance with 63 at 21%, product quality with 29 at 9%, and fungal resistance with 4 trials at 1%; the other traits totaled 19 trials equivalent to 6% of the total.

Figure 7: Number of Transgenic Crop Field Trials in the Developing Countries of Africa, Asia and Latin America and the Caribbean (1986 through 31 December 1995)



Source: Modified and updated from Krattiger (1994).

Figure 8: Number and (%) of Transgenic Crop Field Trials in Developing Countries: Most Frequent Crops
(1986 through 31 December 1995)

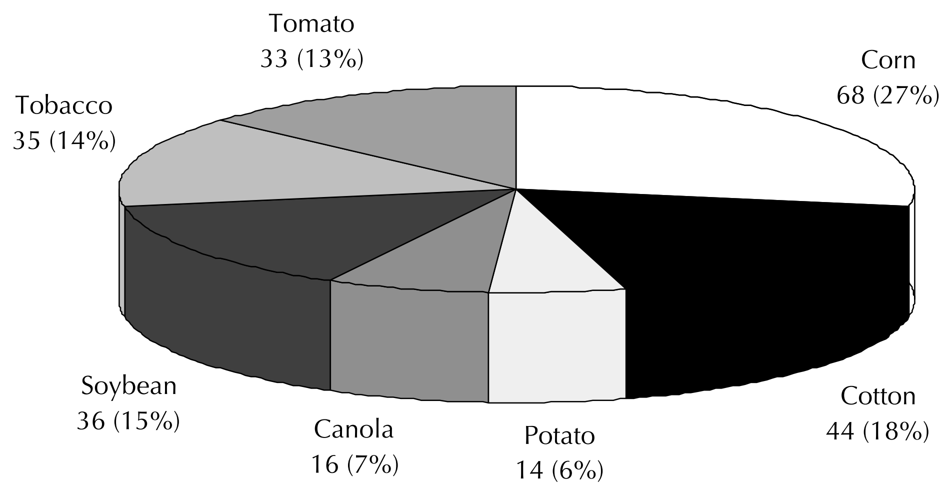
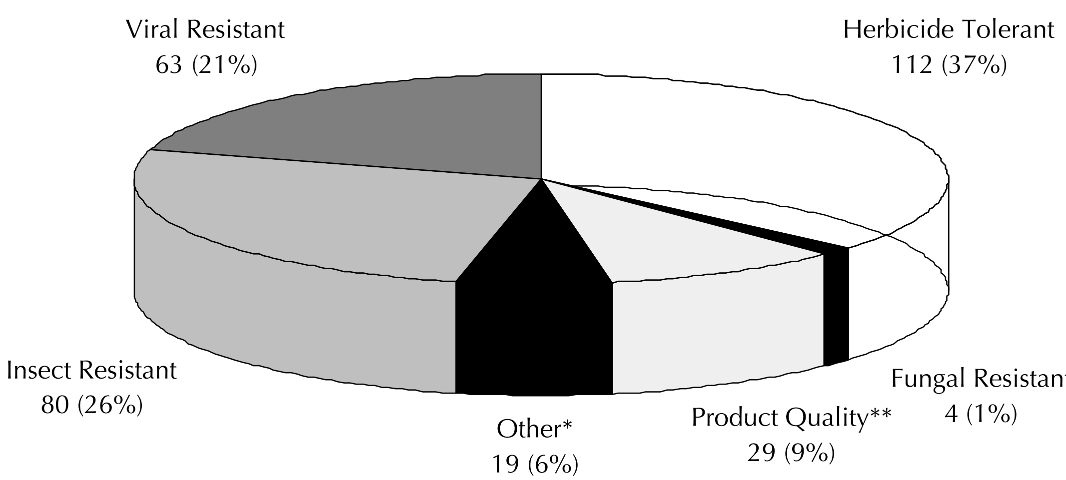


Figure 9: Number and (%) of Transgenic Crop Field Trials in Developing Countries: Most Frequent Trait Categories
(1986 through 31 December 1995)



* Other includes marker genes, selectable markers, bacterial resistant and nematode resistant.

** Includes agronomic characters.

Latin America and the Caribbean (LAC)

Countries in the LAC region represent almost 6% of global trials and 70% of all the trials in developing countries. Table 8 gives a list of the eight countries in LAC that have field tested transgenic crops, and details of the individual crops and traits for each country. Argentina, Chile and Mexico are the countries where the highest number of trials have been conducted and overall there has been a steady increase in the number of trials from one in 1987, when the first trial was conducted in Chile, to a total of 85 in eight countries by 1995. Argentina has conducted over one third of the trials in LAC and approximately half of its 78 trials have featured maize followed by soybean and cotton. Chile and Mexico have each conducted half the number of trials executed by Argentina with Mexico emphasizing tomatoes, and Chile focusing on maize. Chile, like Argentina, conducted many tests before the establishment of a formal regulatory process. Chile established a National Committee for the Protection of Agriculture (Resolution of 9 October 1993) under the Ministry of Agriculture and the number of trials increased rapidly from 6 in 1994 to 21 in 1995.

In some of the smaller countries such as Belize a few trials were conducted in 1991, and these were undertaken by private corporations maintaining winter nurseries in these countries. The trials were conducted under practices stipulated by APHIS but none have been registered since 1993 in Belize. With the establishment of regulatory mechanisms in other countries of the region that lend themselves for winter nurseries (e.g. Argentina, Chile, Costa Rica, Mexico), companies now tend to favor countries where a formal regulatory process has been established. Costa Rica formally established a Biosafety Advisory Committee in 1992 (Macaya, 1994) which has reviewed a series of applications. The number of trials increased rapidly from 2 in 1994 to 10 in 1995. The trial listed for Guatemala in 1989 may have been conducted in a screen or net house, and if so, would not be eligible for consideration as a field trial. However, tomatoes with a quality trait were tested in Guatemala in 1994 and in 1995. Similarly, potatoes with an agronomic trait were tested in Bolivia in 1994 and 1995.

In Cuba, field testing has exclusively been done by the Centro de Ingeneria Genetica y Biotecnologia (CIGB). The Center was the first to transform sugarcane (Australia followed later) and this is considered an important achievement by Cuba. The potato trials initiated in 1993 with PVX, PVY and PLRV are the most numerous and continued in 1995. Cuba is also the first to field test sweetpotato with insect resistance and is expected to field test some novel products in the imminent future. Boniato (*Ipomoea batatas*) has been engineered for resistance to "tetuan" (*Cilas formicarius* var. *elegantulus*) and for the improvement of protein content of the tubercles. Also expected for imminent field release in Cuba are potato and tobacco lines with hydrolytic enzymes (e.g. glucanases, AP-20) to confer resistance to fungal infections.

In addition to the national programs in the LAC region, the International Agricultural Research Centers (IARCs) of the CGIAR which are based in Latin America, have also been considering field testing of some of their transgenic products. The Centro Internacional de Agricultura Tropical (CIAT: International Center for Tropical Agriculture) in Colombia has not yet conducted any transgenic crop field trials but are discussing the matter with Colombian authorities who are currently preparing guidelines which are under review by the Ministry of the Environment. CIAT is also considering the possibility of trials in other Latin American countries such as Argentina, Brazil and Mexico that already have guidelines in place and have conducted trials. Transgenic projects underway at CIAT in containment facilities include: rice, with the marker genes GUS, npt II, bar; viral gene for resistance to hoja blanca; ribosomal inactivating protein for resistance to *Rhizoctonia* species protection: cassava, with marker genes GUS, npt II, bar; insect resistance Cry1A for resistance to *Chilomina*; genes to modify quality and quantity of starch; beans, with marker genes GUS and hygromycin: *Brachiaria* with marker genes GUS and hygromycin; *Stylosanthes* with marker genes GUS, npt II, and bar. In Peru, the Centro Internacional de la Papa (CIP: International Potato Center) has considered field releases in the Andean region. It is understood, but not confirmed, that CIP conducted field trials on frost tolerance in Bolivia in the period 1994 to 1995 and with insect and bacterial resistance in Peru. CIMMYT in Mexico is working with transgenic material in the laboratory and confined glasshouse and sought and obtained a permit to import transgenic maize calli into Mexico for laboratory research (Carreon-Zuniga, 1994). Like the other IARCs, CIMMYT follows the general CGIAR policy to experiment with transgenics only after formal authorization has been granted by the host developing country. Dr. David Hoisington reported that CIMMYT initiated its transgenic crop field tests in Mexico in 1996 with insect resistance in maize. Two trials were submitted for consideration and approved by the Mexican Government's Biosafety Committee. The first trial was planted in early 1996 and the maize was destroyed prior to flowering. The second trial will be planted in mid 1996, subjected to infestation by insects, rated for insect resistance, with the anthers destroyed before they mature.

Table 8: Transgenic Crop Field Trials in Latin America and the Caribbean: By Crop and Trait
(1986 through 31 December 1995)

Country		1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
Argentina	Canola							HT	2 HT, Q, MS	HT	HT	**7**
	Corn						M	2 HT, IR	2 IR, 4 HT, MS	3 IR, 5 HT, M	12 HT, 6 IR, MS	**39**
	Cotton						IR, HT	2 IR, HT	IR	IR, HT	HT, 2IR	**11**
	Potato										VR	**1**
	Soybean						HT	HT	HT	4HT	9HT	**16**
	Sugarbeet							HT				**1**
	Sunflower									M, IR		**2**
	Wheat										HT	**1**
	Subtotal						**4**	**9**	**13**	**18**	**34**	**78**
Belize	Corn							HT, IR	HT			**3**
	Cotton							IR				**1**
	Soybean							HT				**1**
	Subtotal							**4**	**1**			**5**
Bolivia	Cotton						HT, IR					**2**
	Potato						M	Q		A	A	**4**
	Subtotal						**3**	**1**		**1**	**1**	**6**
Chile	Canola		HT					Q			Q, 2HT, HT+MS	**6**
	Corn							HT,Q	IR, HT, HT,M	HT,HT, IR	2 HT, 2 IR, MS+HT, 2IR+HT,IR +HT+MS	**17**
	Soybean								HT	HT	IR,IR+HT, Q, 2HT	**7**
	Sugarbeet								VR+ HT	HT	HT	**3**
	Tobacco										VR	**1**
	Tomato							Q	Q	Q	Q	**4**
	Wheat										HT	**1**
	Subtotal		**1**					**4**	**7**	**6**	**21**	**39**
Costa Rica	Banana										Q	**1**
	Corn							IR			VR	**2**
	Cotton							2 IR+HT, IR				**3**
	Soybean						HT			2 HT	8 HR	**11**
	Subtotal						**1**	**4**		**2**	**10**	**17**
Cuba	Cabbage								IR			**1**
	Canola								M			**1**
	Potato								VR	3VR	VR, VR FR	**7**
	Sugarcane							IR	IR	IR	IR	**4**
	Sweetpot.								IR	IR	IR	**3**
	Tobacco					IR	IR	IR				**3**
	Subtotal					**1**	**1**	**2**	**4**	**5**	**5**	**18**
Guatemala	Squash				VR							**1**
	Tomato									Q	Q	**2**
	Subtotal				**1**					**1**	**1**	**3**
Mexico	Corn								HT, FR	M	IR	**4**
	Cotton										3 IR, 3 HT	**6**
	Cucurbit								VR			**1**
	Melon								VR		VR	**2**
	Potato							VR		VR	VR	**3**
	Rice										M	**1**
	Squash								4VR		VR	**5**
	Tobacco									FR	VR	**2**
	Tomato			Q,IR				IR, 2Q	2Q,IR	Q,IR, 3Q	Q	**14**
	Subtotal			**2**				**4**	**11**	**8**	**13**	**38**
Total Latin America/Caribbean			**1**	**2**	**1**	**1**	**9**	**28**	**36**	**41**	**85**	**204**

For abbreviations and source, see footnote to Table 7 on page 16.

Asia

Despite the advanced status and relatively high absorptive capacity for technology in many developing countries in Asia, only two countries, China and Thailand, have tested genetically modified plants (Table 9) with almost all of the trials, 60 out of 62, conducted in China; this contrasts with Latin America where a total of 204 transgenic field trials have been conducted in eight countries. However, China is an exception in that it initiated transgenic crop field trials early in 1989 and has conducted a relatively large number of field trials at many locations. For example, the virus resistant tobacco, tomato and potato trials of 1993 and 1994, were tested in 15, 4 and 2 provinces respectively, and at 20 to 30 locations within each province. The three most important crops tested in China are tobacco, cotton and tomato. Approximately half the trials in China to date have been conducted with tobacco (29 trials), cotton (10) and tomato (9). Virus resistance is the dominant trait followed by insect resistance which is being tested in tobacco, cotton and tomato. Noteworthy is the field testing of virus resistant pepper which has been identified as a priority need in many South East Asian countries. Thailand has reviewed several applications for transgenic crops and field-tested the Flavr-Savr™ tomato in the field in 1994 and 1995 and has *Bt* cotton in a screened field experiment in 1996. The University of Kasetsart, Thailand, has developed a transgenic papaya to confer resistance to papaya ringspot virus (PRSV) and expects this to be tested imminently.

The two crop IARCs based in Asia, the International Rice Research Institute (IRRI) for rice in the Philippines and the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in India for crops in the semi-arid regions of the world, have not field tested transgenics. However IRRI does have a substantial program in biotechnology, supplemented by the Rockefeller Foundation's significant investment in rice biotechnology. IRRI already has transgenic rice with resistance for insect pests (*Bt*) and bacterial disease (*Xa*) genes at an advanced stage of development and ready for field testing when national programs in Asia are in a position to approve transgenic field trials. In India, public institutions and private companies have significant activities underway in crop biotechnology in laboratories and greenhouses but to date no field trials have been reported, although there were some indications that insect resistant cotton might be tested in screened field experiments in 1996.

With the exception of China, which was the first country in the world to grow transgenic crops on large areas, and the two trials in Thailand, other developing countries of Asia have not conducted any transgenic crop field trials. This is noteworthy given the relatively progressive agriculture in many developing countries of Asia and the continent's capacity and reputation for quickly absorbing other advanced technologies such as electronics. The public perception of biotechnology in Asia, influenced by the views of special interest groups vis-à-vis biotechnology in agriculture, has undoubtedly been a principal factor in constraining the conduct of transgenic crop field experiments. Public perception has contributed to cautiousness among Governments to develop and establish formal operational regulatory agencies to consider applications. Compared with North America and the EU countries, Japan has adopted a more gradual approach to biotechnology, and this could be a contributory factor to the slow introduction of transgenic crop field trials in the developing countries of Asia. Japan's approach to biotechnology is quite contrary to its usual dominant progressive role with other advanced technologies, such as electronics, which it has aggressively promoted through trade and other avenues in the developing countries of Asia.

Africa

A total of 25 trials have been reported for three countries in Africa: South Africa, Egypt and Zimbabwe; however, the vast majority (22 trials) equivalent to 90%, have been conducted in South Africa (Table 10). Over half the trials in South Africa have been conducted on cotton featuring herbicide tolerance and insect resistance and three trials have featured maize with insect and herbicide tolerance. Egypt has conducted trials with a marker gene in tomato in 1991 and one on virus resistant potatoes in 1995. Zimbabwe is understood to have conducted one trial with a quality gene (likely to be the delayed ripening gene) in tomato in 1994. The low level of activity in Africa is related to few countries having regulatory procedures in place and seed companies which are not as well established as they are in Latin America and Asia. Another reason is that biotechnology research activities in much of Africa are at the exploratory stage and hence little national demand has been generated to field test genetically modified plants. However with transformation of rice becoming routine and transformation of cassava and sweetpotato becoming increasingly possible, and with national programs such as Kenya and Zimbabwe in Sub-Saharan Africa placing high priority on biotechnology, the situation is likely to change rapidly.

Table 9: Transgenic Crop Field Trials in the Developing Countries of Asia: By Crop and Trait
(1986 through 31 December 1995)

Country		1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
China	Canola										MS	**1**
	Cotton										10 IR	**10**
	Pepper								VR	VR	2 VR	**4**
	Petunia										Q	**1**
	Potato								VR	VR	2 VR, BR	**5**
	Rice										VR	**1**
	Tobacco				VR, VR+VR	VR, VR+VR	VR,VR + VR	2VR, 2(VR+VR)	2VR, VR+ IR, 2(VR+VR)	3VR, VR+ IR, 2(VR +VR)	5VR,MS,2 IR	**29**
	Tomato							IR	IR, VR+ IR	IR, VR+IR	4 VR+IR	**9**
	Subtotal				**2**	**2**	**2**	**5**	**9**	**10**	**30**	**60**
Thailand	Tomato									Q	Q	**2**
	Subtotal									**1**	**1**	**2**
Total Asia (Developing)					**2**	**2**	**2**	**5**	**9**	**11**	**31**	**62**

For abbreviations, see footnote to Table 10 below.

Table 10: Transgenic Crop Field Trials in Africa: By Crop and Trait
(1986 through 31 December 1995)

Country		1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Total
Egypt	Potato						M					**1**
	Tomato										VR	**1**
	Subtotal						**1**				**1**	**2**
South Africa	Alfalfa								HT			**1**
	Canola								HT			**1**
	Corn								HT		HT+IR,IR	**3**
	Cotton					HT	HT	HT	HT,IR	2HT,2IR	IR, HT, 2HT+IR	**13**
	Forage								HT			**1**
	Soybean										HT	**1**
	Strawberry									HT	HT	**2**
	Subtotal					**1**	**1**	**1**	**6**	**5**	**8**	**22**
Zimbabwe	Tomato									Q		**1**
	Subtotal									**1**		**1**
Total Africa						**1**	**2**	**1**	**6**	**6**	**9**	**25**

Source: Modified and updated from Krattiger 1994).

BR:	Bacterial Resistant	IR:	Insect Resistant	Q:	Quality Characteristics
FR:	Fungal Resistant	M:	Marker Gene	VR:	Virus Resistant
HR:	Herbicide Tolerant	MS:	Male Sterility		

Status of Commercialization of Transgenic Crops

Table 11 lists the crops for which commercial clearance has already been approved (A) or pending (P) in several countries. It is important to note that commercial clearance can apply to different uses of the crop, and these are distinguished in Table 11. Approvals denoted with (A), without a superscript, indicates that the crop is cleared for growing on a commercial basis and for use as food or feed in a particular country or group of countries, as is the case with countries of the EU. Applications that have been approved for limited clearance are denoted with (A) and a superscript, with a footnote to indicate the specific limitation; this may require that the transgenic crops be used only for breeding, or that only the products (e.g. grain from the transgenic crop) can be imported for limited use as a food and/or feed.

The data in Table 11 indicates that as of mid 1996 (1 July), a total of 35 approvals had been granted to commercially grow 8 transgenic crops and one flower crop of carnations, with 8 different traits in 6 countries plus the EU. In addition, 12 approvals have been granted by 3 countries for limited use of a product from a transgenic crop for breeding, food and/or feed use or import only; there are also 28 applications pending in 4 countries seeking approval to either grow the transgenic crops or use derived products from them for food and/or feed or other purposes such as crop improvement. It is noteworthy that with the exception of China, which is reported to be growing more than 2.5 million acres of transgenic tobacco, and tomato, all the approvals in the industrialized countries have been granted to private sector corporations which have the majority of the investments in biotechnology. Public sector institutions in various countries are conducting field trials with transgenics, however they represent a small percentage of the total.

Of the 35 applications granted worldwide to commercially grow transgenic crops, the USA has granted 20 approvals equivalent to more than half (57%) of the global total, followed by Canada with 8 approvals (22%), China and Australia with two each and Argentina, Mexico and the European Union with one each. Corn is the principal transgenic crop to be grown commercially with 8 (23%) applications granted, tomato and canola with 5 each (14%) cotton 4 (11%), potatoes 3 (9%) soybean, tobacco and carnation with 2 (5%) each and 1 approval for squash. In terms of traits for crops approved for commercial production the most prominent are herbicide resistance with 13 approvals (37%), insect resistance 8 (23%), delayed ripening in tomatoes 6 (17%), virus resistance 3 (9%) and quality traits 2 (5%).

The first country to grow a commercial transgenic crop was the Peoples Republic of China. Transgenic tobacco resistant to Cucumber Mosaic Virus (CMV) incorporating a single coat protein construct was sown on approximately 100 acres in 1992 for commercial seed increase in 1992. In 1994/1995 a double construct (CMV and TMV [tobacco mosaic virus]) was sown for seed increase. The transgenic virus resistant tobacco, sown commercially in China since 1992, is used nationally for tobacco manufacturing. The cultivated area of transgenic tobacco is now estimated to occupy more than 2.5 million acres covering up to 30% of total national tobacco acreage in China. The area is expected to grow up to 70% of national tobacco acreage by the end of the decade. Virus resistant genetically modified tobacco is reported to result in very significant benefits which include a yield increase averaging 5-7% more leaves for processing with savings of 2-3 insecticide applications (40 to 60%) from the normal program of approximately 7 applications. Note that aphids transmit the major viruses, including CMV and TMV, that infect tobacco, hence there is significant saving on insecticides which has environmental and economic implications. Virus resistant transgenic tomato is also reported to be grown commercially in China since 1994 although there is a paucity of official data to document the details on the extent of the plantings.

The first approval for commercial sale of a food product from a genetically modified crop in an industrialized country was in the USA in May 1994 when Calgene marketed its FlavrSavr™ delayed ripening tomato. Approval for commercial sale and human consumption of the genetically modified FlavrSavr™ tomato was granted by the Food and Drug Administration (FDA) of the Government of the USA in May 1994. The sale of these tomatoes began the same month within the USA, particularly California and the Mid-West and consumer acceptance has been positive.

Whereas China has two crops, tobacco and tomato, occupying the largest acreage of transgenic crops under commercial production at this time, the USA now has 20 approvals for 7 crops. This would not have been possible in the USA without the benefits of a well organized, regulation system which has continually analyzed its experience with transgenic crops and evolved its regulation

Table 11: Global Status of Applications for the Commercialization of Transgenic Crops

Country/Crop (Status of approval)[1]	**Trait**	*(Estimated 1996 acreage)*	**Company** (Year Approved for Sale)
Argentina			
Soybean (A)	Herbicide tol. (glyphosate)	*375,000 acres*	Monsanto (1996)
Corn/maize (P)	Herbicide tol. (glufosinate)		AgrEvo
Corn/maize (P)	*Bt* insect resistance		Ciba-Geigy)
Corn/maize (P)	Herbicide tol. (phosphinothricin)		DeKalb)
Corn/maize (P)	Insect resistance *Bt*		Monsanto)
Corn/maize (P)	Insect resistance		Northrup King
Australia			
Carnation (A)	Increased vase life		Florigene (1995)
Carnation (A)	Modified flower color		Florigene (1995)
Cotton (P)	Insect resistance		Monsanto
Canada			
Canola/oilseed rape (A)	Herbicide tol. (glufosinate)	*>200,000 acres*	AgrEvo (1995)
Canola/oilseed rape (A)	Herbicide tol. (glyphosate)		Monsanto (1995)
Canola/oilseed rape (A)	Herbicide tol. (glufosinate) & pollination control		PGS (1995)
Canola/oilseed rape (A)	Herbicide tol. (imidazolinone)		Pioneer Hi-Bred (1995)
Canola/oilseed rape (A)	High lauric acid		Calgene (1996)
Corn/maize (A)	*Bt* insect resistance		Mycogen/Ciba (1996)
Corn/maize (A)	Herbicide tol. (imidazolinone)		Pioneer Hi-Bred (1996)
Potato (A)	*Bt* insect resistance		Monsanto (1996)
Flax (A)[2]	Herbicide tol. (sulfonylurea)		Univ. of Saskatch. (1995)
Soybean (A)[3]	Herbicide tol. (glyphosate)		Monsanto (1995)
China			
Tobacco (A)	Virus resistance	*>2 million acres*	n/a (1992)
Tomato (A)	Virus resistance		n/a (1994)
European Union			
Tobacco (A)	Herbicide tol. (bromoxynil)		SEITA (1995)
Canola/oilseed rape (A)[4]	Herbicide tol. (glufosinate) & Pollination control		PGS (1996)
Chicory (A)[4]	Herbicide tol. (glufosinate) & Pollination control		Bejo Zaden (1995)
Cotton oil (A)[5]	Herbicide tol. (glyphosate)		Monsanto (1996, UK only)
Soybean (A)[5]	Herbicide tol. (glyphosate)		Monsanto (1996)
Tomato (A)[5]	Delayed ripening tomato		Zeneca (1995)
Canola/rapeseed (P)	Herbicide tolerance		AgrEvo
Canola/rapeseed (P)[7]	Male sterility/Herbicide tolerance		PGS
Canola/rapeseed (P)[7]	Herbicide tolerance		AgrEvo
Corn/maize (P)	Insect resistance & herbicide tolerance		Ciba
Corn/maize (P)	Insect resistance *Bt*		Ciba
Corn/Maize (P)	Herbicide tolerance		AgrEvo
Corn/Maize (P)	Herbicide tolerance		Pioneer Hi-Bred
Corn/Maize (P)	Insect resistance		Monsanto
Soybean(P)	Herbicide tolerance		Monsanto
Tomato (P)	Delayed ripening		Zeneca
Tomato (P)[7]	Delayed ripening		Calgene
Tomato (P)[7]	Delayed ripening		Zeneca

continued...

Table 11 continued...

Japan			
Canola (P)	Herbicide tol. (glufosinate)		AgrEvo
Canola (P)	Pollination control/oil quality		PGS
Corn/maize (P)	Insect resistance		Ciba
Corn/maize (P)	Herbicide tol. (glyphosate)		Monsanto
Corn/maize (P)	Insect resistance		Northup King
Potato (P)	Insect resistance		Monsanto
Soybean (P)	Herbicide tol. (glyphosate)		Monsanto
Mexico			
Tomato (A)	FlavrSavr™ (Delayed Ripening)		Calgene (1995)
Canola (A)[5]	Herbicide Tol. (glyphosate)		Monsanto (1996)
Cotton (A)[5]	Insect resistance *Bt*		Monsanto (1996)
Potato (A)[5]	Insect resistance *Bt*		Monsanto (1996)
Soybean (A)[6]	Herbicide tol. (glyphosate)		Monsanto (1996)
USA			
Canola/oilseed rape (A)	Modified oil (ACP)		Calgene (1995)
Corn/maize (A)	*Bt* insect resistance	*470,000 acres*	Ciba-Geigy (1995)
Corn/maize (A)	Herbicide tol. (glufosinate)		AgrEvo (1996)
Corn/maize (A)	Herbicide tol. (phosphinothricin)		DeKalb (1996)
Corn/maize (A)	Insect resistance		Northrup King (1996)
Corn/maize (A)	Insect resistance *Bt*		Monsanto (1996)
Corn/maize (A)	Male sterility/herbicide tol.		PGS (1996)
Cotton (A)	Herbicide tol. (bromoxynil)		Calgene (1995)
Cotton (A)	*Bt* insect resistance (lepidoptera)	*1-2 million acres*	Monsanto (1995)
Cotton (A)	Herbicide tol. (glyphosate)	*25,000 acres*	Monsanto (1996)
Cotton (A)	Herbicide tol.		DuPont (1996)
Potato (A)	*Bt* insect resistance (coleoptera CryIIIA-Btt)		Monsanto (1995)
Potato (A)	Insect resistance		Monsanto (1996)
Soybean (A)	Herbicide tol. (glyphosate)	*>1 million acres*	Monsanto (1995)
Squash (A)	Virus resistance (WMV2/ZYMV)		Asgrow (1995)
Tomato (A)	Delayed fruit softening	*up to 10,000 acres*	Calgene (1994)
Tomato (A)	Delayed ripening (ACC synthase)		DNAP (1995)
Tomato (A)	Fruit ripening (PGL antisense)		Zeneca/Peto (1995)
Tomato (A)	Fruit ripening (ACC)		Monsanto (1995)
Tomato (A)	Fruit ripening		Agritope (1996)
Papaya (P)	Virus resistance PRSV		Cornell Univ./Hawaii Growers' Association
Soybean (P)	Herbicide tol.		AgrEvo
Squash (P)	Virus resistance		Asgrow

1 A = Approved; P = Pending; tol. = tolerance
2 For feed and fiber use only.
3 Feed use only.
4 For breeding purposes only.
5 Import of product only.
6 Feed use only, import of product only.
7 Application under food law of the UK.

system accordingly to responsibly facilitate the commercialization of transgenic crops to meet emerging and growing global needs for food, feed and fiber. Applicants seeking approval to grow a transgenic crop commercially in the USA can submit a request (official nomenclature is petition) for a specific transgenic crop to be deregulated. Approved petitions by APHIS stipulate that there is no longer any need for an APHIS review or approval for introductions of the plant into agriculture and the environment. However a petition that is approved by APHIS is not a license to commercialize a crop since food safety, pesticide or other regulatory questions may still have to be addressed by other regulatory agencies, such as EPA.

Table 12 summarizes the 20 transgenic crop products that have been deregulated in the USA, and the three that are pending approval. Of the 20 approvals for commercial production of 7 transgenic crops in the USA (Table 12) the following have been approved and will be grown for seed or commercially in 1996: tomato with delayed ripening qualities (5 approvals), also approved in Mexico; cotton with herbicide resistance (3) and insect resistance conferred by the *Bt* gene (1); soybean with herbicide resistance (1) also approved in Argentina; corn with insect resistance (3) and herbicide resistance (2), male sterility (1); canola/rapeseed with modified oil quality (1); potato with insect resistance (2); and squash with virus resistance (1). It is estimated that over 3 million acres of genetically engineered crops have been planted in the USA in 1996 for seed multiplication or as commercial crops. The largest acreages reported are 1.5 to 2 million acres of Monsanto's Bollgard™ insect resistant cotton and 1 million acres of Monsanto's Roundup Ready™ herbicide resistant soybean. It is noteworthy that all 20 transgenic crops approved for commercial production in the USA are the products of private sector companies with Monsanto being the most prominent with 7 approvals (35%), Calgene with 3 (15%) for a total of 50%, with the ten other companies listed in Table 12 each having one product approved for growing commercially.

After the USA, Canada has the most approvals for commercial production of transgenic crops with a total of 8 approvals, of which 5 are for canola, 2 for corn and 1 for potato. With the exception of one canola modified for lauric acid, the other 4 transgenic canola are all herbicide resistance, one of which also has a pollination control gene. Of the two corn approvals, one is for insect resistance and the other is for herbicide resistance. The approved transgenic potato is for insect resistance. Canada has also approved limited use of transgenic flax with herbicide resistance for feed and fiber use and herbicide resistant soybean for feed use only.

Of the other countries listed in Table 11, Argentina has approved herbicide tolerant soybean for growing commercially and Australia has approved insect resistant cotton and two carnation varieties with increased vase life and modified flowers for commercial production. To date the EU has only approved one crop, tobacco with herbicide resistance, for commercial production with limited approval for use of products from transgenic canola and chicory for breeding only and the import of herbicide tolerant soybean grain and cotton oil, and delayed ripening tomato for use in processing. One application for a herbicide tolerant and insect resistant corn and another for insect resistant corn are pending approval in the EU; the transgenic corn is likely to be the first food/feed crop to be approved by the EU for commercial production later in 1996. Mexico has approved delayed ripening tomato for commercial production, and limited approval for imported grain from herbicide resistant canola and insect resistant soybean for feed use. Finally, Japan has not approved any transgenic crops for commercial plantings and has for some time had pending approvals for use of products from the following transgenic crops: two canola varieties, one with herbicide tolerance and the other with modified oil quality and a gene for pollination control; three maize varieties, two with insect resistance and one with herbicide tolerance; potato with insect resistance; and soybean with herbicide tolerance.

Conclusions and Outlook

After an extensive and expensive long-term research and development program in biotechnology, the long-awaited transgenic crops and their derived products are finally being commercialized. Following the first commercial plantings of transgenic tobacco in China in the early 1990s and the first approval of a product from a transgenic crop for food use in the USA in 1994 (the FlavrSavr™ tomato), the last two years 1995 and 1996 have witnessed the advent of 35 transgenic crops approved for commercial production. 80% of the number of world-

Table 12: Summary of Transgenic Crops that have been Approved, or Pending Approval for Growing in the USA as Commercial Crops

Product	Company	Altered Trait	Year Approved for Sale *Name of Crop* *Estimated '96 Acreage*
Tomato	Calgene	Delayed ripening	1994 Flavr Savr™ *up to 10,000 acres*
Cotton	Monsanto	Resistance to bollworms & budworm (*Bt* toxin)	1995 *Bollgard™* *1.5 to 2.0 million acres*
Soybean	Monsanto	Resistance to herbicide glyphosate	1995 *Roundup Ready™* *1 million acres*
Corn/maize	Ciba-Geigy	Resistance to corn borer (*Bt* toxin)	1995 *Maximizer™*
Cotton	Monsanto	Resistance to herbicide glyphosate	1996 *Roundup Ready™* *25,000 acres*
Canola/Rapeseed	Calgene	Altered oil composition (high lauric acid)	1995 *Laurical™*
Cotton	Calgene	Resistance to herbicide bromoxynil	1995 *BXN Cotton™*
Potato	Monsanto	Resistance to Colorado potato beetle (*Bt* toxin)	1995 *New Leaf™*
Squash	Asgrow	Resistance to viruses	1995 *Freedom II™*
Tomato	DNA Plant Technology	Delayed ripening	1995 *Endless Summer™*
Tomato	Monsanto	Delayed ripening	1995
Tomato	Zeneca/Peto Seed	Thicker skin, altered pectin	1995
Corn/maize	DeKalb	Resistance to herbicide glufosinate	1996
Corn/maize	AgrEvo	Resistance to herbicide glufosinate	1996 *Liberty Link™*
Corn/maize	Plant Genetic Systems	Male sterility	1996
Corn/maize	Monsanto	Resistance to corn borer (*Bt* toxin)	1996 *YieldGard™*
Corn/maize	Northup King	Resistance to corn borer (*Bt* toxin)	1996
Cotton	Dupont	Resistance to herbicide sulfonylurea	1996
Tomato	Agritope	Altered ripening	1996
Potato	Monsanto	Insect resistance	1996
Squash	Asgrow	Virus resistance	Pending *(Freedom II™)*
Papaya	CU/HGA[1]	Virus resistance	Pending
Soybean	AgrEvo	Resistance to herbicide	Pending

[1] Cornell University/Hawaii Growers' Association.

wide approvals have been in the USA and Canada with the balance from China, Australia, Latin America and only one approved for the countries of the European Union. In the imminent future the principal crops that will benefit from early commercialization of transgenic technology will be tobacco, corn, tomato, canola, cotton, potato, soybean, and squash. An assessment of the benefits that will derive from specific traits incorporated in commercial transgenic crops indicates that significant benefits have already accrued from the use of virus resistance in tobacco in China, where yields have increased coincidentally with decreased dependency on insecticides to control the insect vectors that spread the specific viruses. As the USA Canada and the other countries commercialize transgenic crops in 1996 and beyond, significant benefits will accrue from:

- improved and more efficient weed control in crops, particularly corn, canola, cotton, soybean and tobacco;
- decreased losses from selected insect pests of corn, potato, and cotton and a decrease in the need for insecticides, particularly for pests controlled by the *Bt* gene, which is the most prevalent gene used in transgenic crops to control important lepidopteran insect pests;
- decrease in post-harvest losses in tomatoes with better shelf life and marketing flexibility;
- improved nutrition from quality changes such as modified oil in crops such as canola;
- decreased losses to viruses in vegetable crops such as squash which will also require less insecticides to control the insect vectors for viruses; and
- improved control of pollination that will allow more effective production of hybrid seed.

Biotic stresses in crop production due to insects, diseases and weeds are estimated to reduce global crop production by 14%, 12% and 10% respectively, for a total of 36% (James, 1981; James *et al.*, 1991; James, 1996). Given that approximately two-thirds of the genes incorporated in the newly commercialized transgenic crops confer either herbicide tolerance, insect resistance or disease resistance, it follows that the potential impact of biotechnology in the near term on global food production will be substantial. In addition to decreasing losses in food production from more effective crop protection of biotic stresses, the use of biotechnology-based pest and disease resistance can lead to substantial substitution of conventional pesticides, improved pest control and monetary savings in pesticides. The global pesticide market was estimated at $27.8 billion in 1994 (James, 1996) and the largest potential for improved control and substitution of conventional pesticides is in the insecticide market, which globally was $8.1 billion in 1994; in the near term pests that can be controlled by *Bt* and insect vectors that spread viruses in crops offer the best opportunities. Similarly, more effective and flexible weed control can not only reduce losses due to weeds but also contribute to less erosion through facilitating no-till or low-till practices which can also contribute to more sustainable cropping systems which are particularly important for marginal areas.

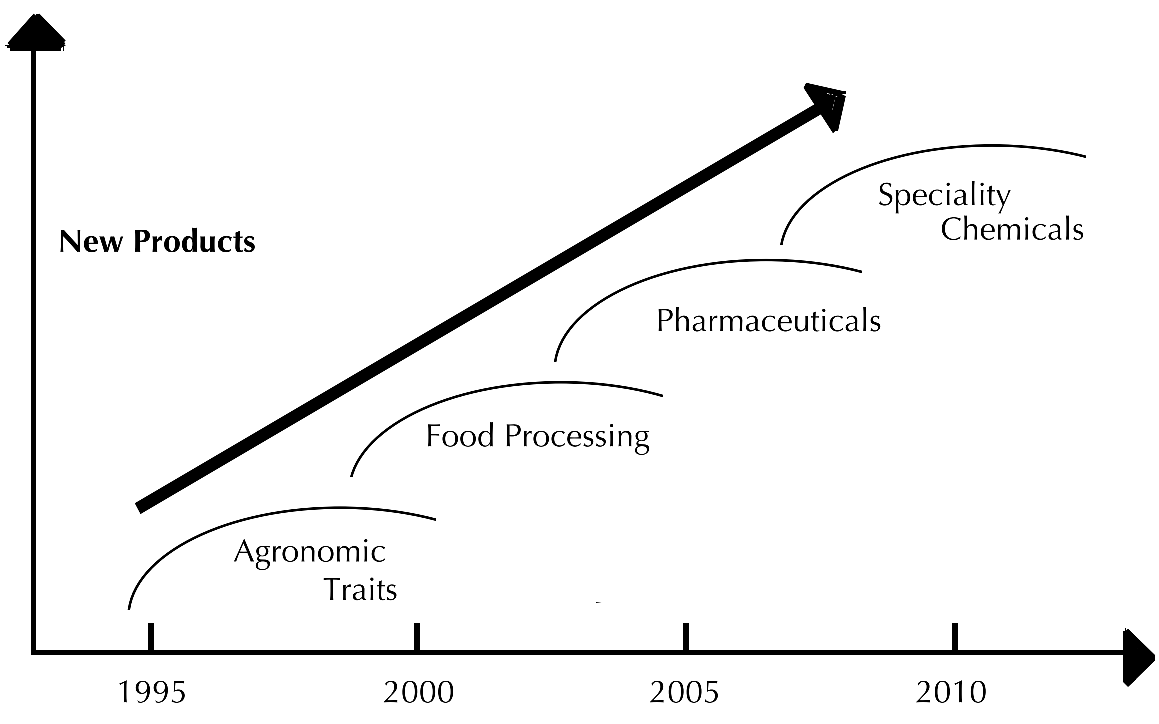
Thus, multiple benefits can accrue which can increase food feed and fiber production globally and at the same time contribute to sustainability and a safer environment through more effective and less dependent use of conventional pesticides. Post-harvest losses are estimated to reduce food availability substantially, particularly in developing countries with poor farm to market roads, inadequate transportation and insufficient and unreliable refrigerated storage facilities. The introduction of delayed ripening genes in tomatoes should reduce post-harvest losses substantially and the same or similar genes could be incorporated in many other perishable fruits and vegetables of high value. The use of seed as a vehicle to deliver the new biotechnologies represents a powerful mechanism that allows controlled distribution of proprietary applications. Unlike the semidwarf wheat and rice which required inputs of fertilizer and water to realize increased productivity, most of the new generation of biotechnology-based genes, such as delayed ripening and virus and pest resistance genes, do not require additional inputs to increase productivity; this has extremely important implications in relation to equitable distribution of benefits to large and small farmers who are the end users of the new technologies.

The seed industry will be required to play a critical, central and increasingly important role because most of the increased food production will have to be generated from crops. Total world consumption of seed has been fairly stable at approximately 118 million tons annually since 1980. However Asia experienced significant growth in seed consumption between 1980 and 1990 (Rabobank, 1994) when consumption of agricultural seed (including farm-saved seed) increased from 32.6 million tons in 1980 to 38.4 million tons in 1990; this is equivalent to an 18% increase at a time when all other regions in the world experienced static or declining consumption. Asia currently consumes approximately one third of global seed consumption, and growth in seed consumption in Asia is expected to continue in the coming decades to meet the burgeoning population of the continent. The incorporation of high value biotechnology applications in seed provides the industry with a new opportunity to enhance the benefits to farmers from superior seed capable of higher and more stable yields.

To-date, biotechnology has established a credible record and the development and implementation of appropriate biosafety regulations has served an important function. A consequence of employing appropriate guidelines is that the management of the science, since its genesis 25 years ago, has increasingly gained the confidence of scientists, regulators, policy makers, politicians and the lay public. The guidelines have, for example, allowed any issues related to genetically modified organisms or pathogens to be identified and studied during the containment stage so that solutions can be employed before the organisms are used in a transgenic crop field trial (McCammon and Medley, 1990). The same care and attention needs to be applied at the deployment stage during large scale adoption because this is often the time when new constraints and opportunities become evident. Thus, prudent monitoring of transgenic crops deployed on large acreages for the first time is important and this should be achieved without incurring unnecessary delays on the adoption of the technology that can deliver important benefits to many in the near-term. Biotechnology has already made significant progress in overcoming some of the regulatory constraints and public perceptions about the new science but these continue to be a principal constraint in some countries, and harmonization of regulations should continue to be a major goal. Other challenges include issues in relation to the enforcement of intellectual property rights, and marketing of products derived from transgenic crops. The deployment of genes for the control of mutable pests and diseases will continue to be a significant issue and the large scale deployment of *Bt* in several principal crops will be a major challenge in terms of the management and durability of *Bt* resistance. However, the technology is also becoming more robust with improved and different genes becoming increasingly available to overcome a single constraint, such as the alternate control for important pests, such as cotton bollworm with an RNA HaSV virus (Anonymous, 1996), thereby decreasing the risk associated with dependency on one or few mechanisms or genes such as *Bt* (for extensive discussion on *Bt* technology, see Krattiger and Raman, 1996).

In summary, the future looks optimistic because biotechnology is starting to deliver its the essential products that can, in conjunction with conventional technology, increase food, feed and fiber production to meet the growing demands of a burgeoning global population which will reach 11 billion by 2050. Figure 10 summarizes the different generations of biotechnology products that can be exploited through crops (Fraley, 1994), during the next two decades. The first generation is the current agronomic traits such as herbicide tolerance, pest and disease resistance, delayed ripening genes for reducing post-harvest and improved quality and pollination control. For this

Figure 10: Crop Biotechnology Products for the Future



Source: Fraley (1994).

generation of products the value of the global market in transgenic crops is projected at between $2 billion and $3 billion dollars for the year 2000 increasing to $6 billion in 2005. The next generation are genes that can enhance food processing through higher and improved quantities of starch, sucrose and fatty acids and the production of flavors, coloring materials and preservatives for the food industry which will have to meet more demanding standards in response to public demand.

Exploratory work on the production of foreign proteins, vaccines and pharmaceuticals in plants is already underway. Crops offer a significant biological renewable resource with potential for producing pharmaceuticals in natural bioreactors. The options range from producing high value pharmaceutical products in seeds, to using the natural latex vascular system of a rubber tree to generate and tap products such as insulin. Transgenic rubber trees have already been produced and a mature rubber tree can produce a significant quantity of latex, 200ml of latex per tapping, and a tree can be tapped every other day of the year without interruption (ISAAA, 1996). It is projected that these pharmaceutical products could come on stream in the early years of the next century which is only 5 to 10 years from now. Finally, towards the end of the first decade of the next century we may expect speciality chemicals to be increasingly produced in crops. For the last three decades speciality chemicals have been derived from petroleum-based products that are becoming depleted because they are a nonrenewable resource. Genetic engineering will significantly increase our capacity to produce monomers and polymers and sustainability considerations, associated with a global movement to place more reliance on production of materials from renewable resources, will provide crops with a significant comparative advantage.

The range of possibilities that the applications of biotechnology offer to crops is enormous but in the near term the most important contribution that biotechnology can make is to increase the quantity and quality of global food, feed and fiber. It is evident that plant biotechnology can now deliver transgenic crops that can contribute to higher productivity and to more sustainable cropping systems that are essential in order to utilize natural resources responsibly and safeguard the environment. Equitable distribution of benefits from biotechnology will require global access and adoption of the technology and the support and participation of all the players involved. These range from the lay public who determine public perception and as consumers are the ultimate beneficiaries, to farmers who are the end users, to the policy makers who promulgate legislation, and the private sector which is the major investor and source of the new biotechnology applications and products. The challenge is for the public and private sector, in both industrial and developing countries, to work together in new, equitable and creative partnerships towards common and mutually beneficial goals to ensure food security and a better quality of life in tomorrow's world.

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