Agricultural Biotechnology: Current and Future Trends and Implications for Africa

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Abstract

The agricultural biotechnology revolution is occurring in developed countries. To date, Africa lags far behind in development, use and commercialization of biotechnology. The development of human resources in both technical and policy areas is sorely needed. This paper outlines the current status of the biotechnology industry, and highlights some important issues for African policy makers to consider as they develop an agricultural biotechnology strategy for the continent.

1.0 Introduction

Experts at the United Nations anticipate the world population in 2050 to be between 7.8 billion and 12.5 billion, an enormous increase compared to approximately 5.9 billion in 1997. How will the world feed all these people? This question is particularly important in Africa, where the yearly population growth rate is 2.9%; the world's greatest. In addition, in Sub-Saharan Africa, the per capita calorie supply has actually declined since the early 1970s.

The world's population may be growing but its surface area certainly is not. Compounding the effects of population growth is the fact that most of the Earth's ideal farming land is already being utilized. Dennis Avery, Director, Center for Global Food Issues, The Hudson Institute has stated, "We have two choices. We can either secure more land for agricultural purposes, or we can increase the food output on land that we now use for farming." To avoid damaging environmentally sensitive areas, such as rain forests, methods need to be utilized to increase crop yields for land currently in use. More and more experts believe that biotechnology is an important part of the solution.

According to former US President Jimmy Carter, "By increasing crop yields, genetically modified organisms reduce the constant need to clear more land for growing food." Such yield-enhancing food biotechnology techniques are not long into the future—they are being utilized now—and they hold the key to a more secure agricultural future, particularly for developing nations. Maurice Strong, the chairman of the System Review of the Consultative Group on International Agriculture Research (a coalition of 17 international agricultural research centers) encouraged further research into biotechnology. He noted, "Agricultural research is a crucial component of this effort because transformed and sustainable agriculture is the first step on the ascent from poverty for most of the world's poor countries."

However, a very powerful anti-biotechnology lobby in Europe is making a strong case for Africa to be excluded from the biotechnology revolution which need to be counteracted and for this reason the African Perspective on the need for biotechnology needs to be fully explained. The African perspective on the need for biotechnology is different from those of Europe or USA.

The critics of biotechnology claim that Africa has no chance to benefit from biotechnology, and that Africa will only be a dumping ground or will be exploited by multinationals (Christian Aid, 1999). On the contrary, small-scale farmers in Africa have benefited by using hybrid seeds from local and multinational companies, and transgenic seeds are in effect simply an added-value improvement to these hybrids. Local farmers are benefiting from tissue-culture technologies for banana, sugar cane, pyrethrum, cassava and other crops. There is every reason to believe they will also benefit from the crop-protection transgenic technologies in the pipeline for banana, such as Black Sigatoka, the disease-resistant transgenic variety now ready for field trials. Virus- and pest-resistant transgenic sugar-cane technologies are currently being developed in countries such as Mauritius, South Africa and Egypt.

The African continent, more than any other, urgently needs agricultural biotechnology, including transgenic crops, to improve food production. Africa needs to think and operate as stakeholders, rather than the "victim mentality" created in Europe. Africa has the local germplasm, some of it well-characterized and clean, being held in genebanks in trust by international Consultative Group of International Agricultural Research (CGIAR) centres, as well as indigenous knowledge, local field ecosystems for product development, capacities and infrastructures that are required by foreign multinational companies to do successful business in Africa. The needs of Africa and Europe are different. Europe has surplus food production and has never experienced hunger, mass starvation and death on the regular scale we sadly witness in Africa. The priority of Africa is to feed her people with safe foods and to sustain agricultural production and the environment.

Africa missed the green revolution, which helped Asia and Latin America achieve self-sufficiency in food production, particularly in the case of rice, maize and wheat. Africa cannot afford to be excluded or to miss another major global 'technological revolution'. It must join the biotechnology endeavor: transgenic food production has increased from 4 to 70 million acres from 1996 to 1998 due to use of transgenic agricultural biotechnology with measurable economic gains and within sustainable agricultural production (James, 1988). It would be a much higher risk for Africa to ignore agricultural biotechnology. Africa's crop production per unit area of land is the lowest in the world. For example the production of the staple crop sweet potato is 6 tons/ha compared to the global average of 14 tons/ha. China produces on average 18 tons/ha, three times the African average. Control of viral diseases using transgenic technology has the potential to double African production.

The African continent imports at least 25% of its grain. But the use of biotechnology to increase local grain production is far preferable to this dependence on other countries, particularly as the population growth rate exceeds food production in Africa. The inability to produce adequate food forces Africa to rely on food aid from the United States, Britain and other industrialized nations when mass starvation occurs in some nations like Ethiopia and Somalia. Although biotechnology is not the only answer to this problem, Africa should certainly benefit in many ways from its use, for example in improved seed quality, pest- and disease resistance. The average maize yields in Africa is about 1.7 tons/ha compared to a global average of 4 tons/ha. Some biotechnology applications can be used to reduce this gap, for example in the case of the maize streak virus (MSV) which causes losses of 100% of the crop in many parts of Kenya and other African countries.

This paper reviews the current status of biotechnology in the industrial and developing world and highlights future developments. It provides a broad background in the science, policy and international issues of biotechnology, with a special emphasis on the issues most important to African policy makers.

2.0 What is biotechnology?

A standard definition of biotechnology is any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses. Biotechnology has been with us since the dawn of man – beer brewing and bread baking are two examples. Plant breeding, biological control of pests, and classical vaccine productions are also considered biotechnological processes.

The information encoded in the genetic structures of plants, animals and microorganisms is an immense natural resource. From the beginning of agriculture 10,000 years ago, people have been using this resource to improve domesticated plants and animals and to process and preserve food. All food sources available have evolved through natural selection. Almost every ingredient used in food production originates from a living organism, be it a plant, a microorganism or an animal. The rich genetic diversity represented by all these sources was first maximized when farmers began to save the seeds from their best crops for later sowing and to use the best animals for breeding. Therefore biotechnology has always been an intimate part of food production.

Techniques for managing genetic resources have gradually become more sophisticated. Within the past 20 years, it has become possible to add genetic modification to mankind¹s toolkit for improving the health and productivity of agricultural plants and animals. However, today, most publicity and debate is centered around “modern” biotechnology that can be broadly defined as the use of recombinant DNA technology, monoclonal antibodies and new cell and tissue culture techniques. Recombinant DNA techniques – “genetic engineering” – allows genes to be manipulated and transferred from one species to another, perhaps unrelated, species. This technique, coupled with advancements in cellular biology, has provided researchers with powerful new tools to address traditional constraints in agriculture, health and the environment.

2.1 Implications for Africa

Agricultural policy makers need to know that “biotechnology” is a set of scientific tools that can and are widely applied across disciplines. While likely to be applied, in Africa, within the agricultural field first, these techniques will impact healthcare and environmental science. Therefore, policies cannot be made in an agricultural vacuum, but need to be cognizant of the wide potential impact of biotechnology on society as a whole.

3.0 What is agricultural biotechnology?

Farmers and plant breeders have labored for centuries to improve the crops that produce our food. Traditional breeding methods include selecting and sowing the seeds from plants with beneficial characteristics, such as higher yield, better nutrition and resistance to disease. By breeding plants with these good characteristics, plant breeders combined the genetics of those plants, long before the science of genetics was understood. The tools of biotechnology allow plant breeders to select genes that produce beneficial traits and move them from one plant to another. The process is far more precise and selective.

The term agricultural biotechnology is typically used to describe a broad range of biological processes in addition to genetic engineering, such as those used in micropropagation, plant and animal health diagnostics, vaccines and biopesticides. Agricultural biotechnology integrates advanced disciplines such as biology, genetics, molecular biology, biophysics, biochemistry, chemical engineering and computer science and applies them to alter or add information to the genetic code within plants and animal cells.

In addition to a scientific definition, an agricultural biotechnology industry has developed. Industry has recognized the potential of agricultural applications of biotechnology. Investments in the research and development of these techniques are beginning to yield exciting new products. Agricultural biotechnology is expected to become an increasingly important engine of development for the agri-food industry. Consumers, farmers and the agri-food industry all stand to benefit from the use of biotechnology. Consumers can expect to find novel foods with added purity, flavor and nutrition; farmers are already enjoying new inputs, such as safer, biological fertilizers and pesticides; and the agri-food industry is discovering a wide range of new processes that add-value to the products they bring to market.

3.1 Implications for Africa

The development of an agribusiness or "life sciences" industry offers challenges and opportunities to Africans. There has been, within developed countries, a fundamental shift from "public accessed' goods to "proprietary/owned" agricultural research tools and crops. This shift will affect African scientists, farmers and consumers in ways that are not well understood. However, it seems clear that the old ways of doing business, through open access to materials and processes, is over. Africa must learn how to adapt to new partnerships and collaborations if it hopes to access biotechnology for African needs. The factors driving this change are discussed more below.

4.0 Current status of seed and agricultural biotechnology industry worldwide

The seed industry is becoming more concentrated as seed and chemical companies acquire one another. Acquisitions and joint ventures are a means to better capturing the benefits of the new biotechnology that is finally beginning to be commercialized in the crop sector. Yet the increasing dominance of a few major players, and the biotechnology and chemical patent restrictions on what competitors can do, raise questions regarding the potential for too much market power in parts of the seed and chemical industries. While the examples presented below highlight the US sector, it is important to note that the concentration of the industry may:

- Effect the ability of African scientists to access technologies
- Decrease potential international partners
- Decrease choice for different input traits for farmers

4.1 Consolidation in the seed industry

Several major players in the seed, herbicide and biotechnology complex are emerging as leading competitors, developing and marketing the early biotechnology products in the grain and oilseed industries. Monsanto is the world leader, with massive investments in biotechnology research, and with seed and biotechnology company mergers and acquisitions (M&As). Novartis, DuPont/Pioneer, Dow Agrosciences, AgrEvo (Hoescht/Schering), and Zeneca/van der Have are all involved in similar efforts.

The on-going concentration in the agricultural biotechnology industry is a result of chemical companies vertically integrating into the seed and biotechnology industries. The end-goal of such integration has been to capture profits from biotechnology innovations that, in some cases, are also complementary to their chemical technology.

Tables 1 and 2 show estimated 1997 seed company market shares in North America. Shares in 1998 are likely to be similar, though the dramatic success of Roundup Ready soybeans has increased Asgrow's market share a few points and reduced Pioneer's share. DeKalb Genetics (which first introduced Roundup Ready corn) and Novartis (which has had success with Bt corn) increased their seed corn market shares by 1 or 2 points in 1998. Ownership changes occurring in 1998 are reflected in tables 1 and 2 (Hayenga, 1998) with italics indicating companies acquired by Monsanto during this period.

Table 1. North American Seed Corn Market Shares, 1997

Company	Percent
Pioneer Hi-Bred	42
Monsanto	**14**
DeKalb (subset of Monsanto)	*10*
Asgrow (subset of Monsanto)	*4*
Novartis	9
Dow Agrosciences / Mycogen	4
Golden Harvest	4
AgrEvo / Cargill	4
Hoechst / Schering / Advanta	3
Others	20
Source: Industry Estimates	

Pioneer Hi-Bred International (now owned by DuPont) has been the leading branded seed merchandiser in the corn and soybean markets. Monsanto's purchases of Asgrow and DeKalb Genetics have resulted in a branded seed corn market share of nearly 14 percent. In addition, Monsanto's purchase of Holdens gives them significant influence over germplasm sold to other companies; Holdens' germplasm is estimated to be part of an additional 30-40 percent of branded seed sales. With Monsanto's acquisition of DeKalb, Monsanto and Pioneer combined will either own or significantly influence over 90 percent of the North American seed corn market. In addition, Monsanto has license agreements for its Roundup Ready and YieldGuard technologies with other companies. These companies account for a very high share of the soybean seed market and a smaller share of the seed corn market.

Other companies have also been involved in the restructuring of the seed industry. In 1996, Novartis combined the Ciba-Geigy (one of the first marketers of Bt corn) and Northrup King

seed businesses. Novartis then capitalized upon the Bt products of these companies in order to expand its corn seed market share from about 6 percent in 1995 to 9-10 percent in 1998. Dow Agrosciences recently acquired Mycogen. Mycogen has a 4 percent market share in corn seed. In addition, Dow Agrosciences recently acquired part of Illinois Foundation Seeds which provides foundation seed for another 11 percent of branded seed corn sales by other companies. AgrEvo recently acquired Cargill's domestic seed business, while Monsanto acquired Cargill's international seed business. The objectives of several companies, including Monsanto, Novartis, DuPont and Pioneer, is to develop seed with value-added traits for the food and feed markets, and to establish joint ventures to market the end products. These objectives will be achieved through companies like Optimum Quality Grain, Continental Grain, Cargill, and ADM.
The soybean market has long been considered the low margin part of the seed business. In the soybean seed market there is no hybridization to differentiate products, and a significant amount of farmer-saved seed. In addition, public varieties from universities provide low priced competition that has limited branded soybean seed profit margins (Kimle & Hayenga, 1993). Pioneer's entry into the soybean seed market in the early 1980s, and their very large corn market shares and strong dealer system, have resulted in their emergence as the leading soybean seed company in the late 1990s. Asgrow and DeKalb were strong competitors who were recently acquired by Monsanto. Asgrow has capitalized on the Roundup Ready soybean demand in order to capture the largest market share in 1998, partly at Pioneer's expense. After the DeKalb acquisition, Monsanto seed companies account for 23-25 percent of purchased soybean seed in 1998, up five points from 1997.

The cotton seed market has long been dominated by Delta and Pine Land (Table 2). Monsanto became a competitor when it bought Calgene and Calgene's Stoneville cotton seed subsidiary. Monsanto's recent purchase of Delta and Pine Land (not yet approved by the Justice Department) will bring its total market share near 84 percent in 1997, and 87 percent in 1998. Because of this extremely high market share, and in an apparent attempt to avoid, objections from antitrust agencies in the U.S., Monsanto recently announced that it will divest the Stoneville operations. Stoneville's market share has increased to 16 percent due to the combination of superior yielding varieties and its introduction of Buctril herbicide resistant cotton.

Table 2. Cotton Seed Market Shares

Company	1997	1998
Monsanto	**84**	**87**
Delta & Pine Land	*72*	*71*
Stoneville	*12*	*16*
Other	16	13
Source: Agricultural Marketing Service. (1997;1998). Cotton varieties planted. Washington, DC: United States Department of Agriculture.		

Consolidation is taking place throughout the global economy. The top ten agrochemical corporations accounted for 82% of all agrochemical sales in 1996.

Table 3. Top Ten Agrochemical Corporations Worldwide

Company	Estimated 1996 Seed Sales (US$ millions)	Remark
Pioneer Hi-Bred Intl. (USA)	1721	DuPont now owns Pioneer Hi-Bred
Novartis (Switzerland)	991	Formerly Ciba-Geigy and Sandoz
Limagrain (France)	552	French cooperative
Advanta (Netherlands)	493	Zeneca (UK) and VanderHave started this joint venture in 1996
Grupo Pulsar (Mexico)	400	Owns Empresas La Moderna (ELM), which controls Seminis, Inc.
Sakata (Japan)	403	Vegetable, flower, turfgrass
Takii (Japan)	396	Vegetable, flower, turfgrass, and maize, privately held company
DeKalb Plant Genetics (USA)	388	Monsanto a major shareholder, owns approx. 40%
KWS (Germany)	377	World's largest sugar beet seed company with 25% market share
Cargill (USA)	+300 (est.)	Privately held, will not release financial information

Source: RAFI (The Life Industry 1997)

4.1.1 Implications for Africa

It is clear that the global seed industry is undergoing a major structural reorganization. The impact that this will have on developed country agriculture is not well understood, let alone its impact on African agriculture. It seems clear that there will be fewer seed providers, but that competition among them will remain fierce. More importantly, basic research tools and techniques will not likely be openly and freely available, as has been the case in the past. With continued collaborations between advanced public sector institutions and the private sector in developed countries (see section below), African researchers cannot assume that technology developed in the university community will be available on an unrestricted basis either. African scientists, policy makers and administrators will have to become familiar with negotiating and complying with restricted access, irregardless of their own national laws and regulations, if they want to collaborate with industry (local or multi-national) or access technology from advanced laboratories (public or private). An alternative is to develop the technology external to collaboration with advanced laboratories. This is probably not practical, given levels of expertise and resources within Africa, and certainly is not efficient.

4.2 Current commercial status of agricultural biotechnology products

The dramatic changes in the seed, chemical, and grain industrial complex have been triggered in the last five years by the "coming of age" of agricultural biotechnology. The first significant commercial sales of biotechnology products have materialized; products like herbicide and insect resistant seed varieties in corn, soybeans and cotton (Hayenga, 1998; Kimle & Hayenga, 1993;

Carlson, Marra, & Hubbell, 1997). These sales are the tip of the iceberg, as can be seen in Appendices I and II which describe agricultural biotechnology products currently on the market and expected on the market within the next six years. It should be noted that not all these products are "transgenic", i.e. they have not all been developed using recombinant DNA techniques, but rather with other cellular advances in agricultural biotechnology. The transgenic crops on the market are broadly described in Table 4.

Table 4. Transgenic Products on the Market

Beneficial product traits	...in these crops
Bt crops are protected against insect damage and reduce pesticide use. Plants produce a protein--toxic only to certain insects--found in a common soil bacterium called *Bacillus thuringiensis*, or Bt.	corn, cotton, potatoes future: sunflower, soybean, canola, wheat, tomatoes
Herbicide tolerant crops allow farmers to apply a specific herbicide to control weeds without harm to the crop. Gives farmers greater flexibility in pest management and promotes conservation tillage.	soybean, cotton, corn, canola, rice future: wheat, sugar beet
Disease-resistant crops are armed against destructive viral plant diseases with the plant equivalent of a "vaccine".	sweet potato, cassava, rice, corn, squash, papaya future: tomatoes, banana
High-performance cooking oils are improved for processing at high temperatures, reduce need for hydrogenation and create healthier food products-lower in trans fats. The oils are either high oleic or low linoleic. In future, high stearate	Sunflower, peanut
Healthier cooking oils have reduced saturated fat.	soybean
Delayed ripening fruits and vegetables have superior flavor, color and texture, are firmer for shipping and stay fresh longer.	tomatoes future: raspberries, strawberries, cherry tomatoes, banana, pineapple
Increased-solids tomatoes have superior taste and texture for processed tomato pastes and sauces.	tomatoes
RBSTis a recombinant form of a natural hormone, bovine somatotropin, which causes cows to produce milk. rBST increases milk production by as much as 10B15 percent. It is used to treat over 30 percent of U.S. cows.	rBST (milk production)
Food enzymes, including a purer, more stable form of chymosin used to curdle milk in cheese production. It is used to make 60 percent of hard cheeses. Replaces chymosin of rennet from slaughtered calves stomachs.	chymosin (in cheese) --the *first* biotechnology product in food
Nutritionally enhanced foods will offer increased levels of nutrients, vitamins and other healthful phytochemicals. Benefits range from helping developing nations meet basic dietary requirements, to boosting disease-fighting and health-promoting foods.	Future: protein enhanced sweet potato and rice; high vitamin A canola oil; increased antioxidant fruits and vegetables.

Source: BIO Member Survey, 1997

Between 1996 and 1998, eight countries, five industrial and three developing, have contributed to more than a fifteen fold increase in the global area of transgenic crops. Adoption rates for transgenic crops are some of the highest for new technologies by agricultural industry standards. High adoption rates reflect grower satisfaction with products that offer significant benefits ranging from more flexible crop management, higher productivity and a safer environment through decreased use of conventional pesticides, which collectively contribute to a more sustainable agriculture. In 1998, the global area of transgenic crops increased by 16.8 million ha to 27.8 million ha, from 11.0 million ha in 1997. Five principal transgenic crops were grown in eight countries in 1998, three of which, Spain, France and South Africa, grew transgenic crops for the first time in 1998.

The countries listed in descending order of transgenic crop area on a global basis in 1998 are:

- USA with 20.5 million hectares representing 74 % of the global area
- Argentina with 4.3 million hectares equivalent to 15% of global area
- Canada with 2.8 million hectares representing 10 % of global area
- Australia with approximately 0.1 million ha equivalent to 1 % of global area
- Mexico, Spain, France and South Africa each with <0.1 million ha, equivalent to less than 1 % of the global area of transgenic crops in 1998 (Table 5).

The proportion of transgenic crops grown in industrial countries was 84 %, about the same as 1997 (86%) with 16 % grown in the developing countries, mostly in Argentina, and the balance in Mexico and South Africa. As in 1997, the largest increase in transgenic crops in 1998 occurred in the USA (12.4 million ha) where there was a 2.5 fold increase, followed by Argentina (2.9 million ha) with a 3.0 fold increase, and Canada (1.5 million ha) with a 2.1 fold increase. The USA continued to be the principal grower of transgenic crops in 1998 and its share of global area was the same (74 %) in 1997 and 1998. Argentina's transgenic crop area increase was the largest relative change, increasing 3.0 fold from 1.4 million ha in 1997 to 4.3 million ha in 1998; thus Argentina's global share of transgenic crop area increased from 13 % of global area in 1997 to 15 % in 1998. Canada's share of global transgenic crop area decreased marginally from 12 % in 1997 to 10 % of global area in 1998.

Table 5. Global Area of Transgenic Crops by Country. 1997-1998 (millions of ha)

Country	**1997**	**%**	**1998**	**%**
USA	8.1	74	20.5	74
Argentina	1.4	13	4.3	15
Canada	1.3	12	2.8	10
Australia	0.1	1	0.1	1
Mexico	<0.1	<1	<0.1	<1
Spain	0.0	0	<0.1	<1
France	0.0	0	<0.1	<1
South Africa	0.0	0	<0.1	<1
Total	11.0	100	27.8	100

James, 1998

The five principal transgenic crops grown in 1998 were, in descending order of area, soybean, corn/maize, cotton, canola/rapeseed, and potato. Transgenic soybean and corn continued to be ranked first and second in 1998, accounting for 52 % and 30 % of global transgenic area, respectively. Cotton and canola shared third ranking position in 1998 each occupying 9 % of global area (Table 6).

Table 6. Global Area of Transgenic Crops in 1997 and 1998 by Crop (millions of has)

Crop	1997	%	1998	%
Soybean	5.1	46	14.5	52
Corn	3.2	30	8.3	30
Cotton	1.4	13	2.5	9
Canola	1.2	11	2.4	9
Potato	<0.1	<1	<0.1	<1
Total	11.0	100	27.8	100

James, 1998

The relative ranking of the principal transgenic traits were the same in 1997 and 1998, with herbicide tolerance being by far the highest, increasing from 63 % in 1997 to 71 % in 1998. Insect resistant crops decreased from 36 % in 1997 to 28 % in 1998. Stacked genes for insect resistance and herbicide tolerance increased from <0.1 % in 1997 (<0.1 million ha) to 1 % or 0.3 million ha in 1998 with quality traits occupying less than 1 % and <0.1 million ha in both 1997 and 1998 (Table 7).

Table 7. Global Area of Transgenic Crops in 1997 and 1998 by Trait (millions of ha)

Trait	1997	%	1998	%
Herbicide Tolerance	6.9	63	19.8	71
Insect Resistance	4.0	36	7.7	28
Insect Res. & Herb. Tolerance	<0.1	<1	0.3	1
Quality Traits	<0.1	<1	<0.1	<1
Global Totals	11.0	100	27.8	100

James, 1998

In reviewing the shift in global share of transgenic crops for the respective countries, crops and traits, the major changes between 1997 and 1998 were related to the following trends:

- Growth in area of transgenic crops between 1997 and 1998 in the industrial countries continued to be significant and almost 5 times greater than in developing countries (13.9 million ha versus 2.9 million ha);
- In terms of crops, soybean contributed the most (56 %) to global growth of transgenic crops, equivalent to 9.4 million ha between 1997 and 1998, followed by corn at 30 % (5.1 million ha), canola at 7 % (1.2 million ha) and cotton at 6 % (1.1 million ha).

There were three noteworthy developments in terms of traits:

- Herbicide tolerance contributed the most (77 % or 12.9 million ha) to global growth

- Insect resistance contributed 22 % equivalent to 3.7 million ha
- Multiple or stacked traits of insect resistance and herbicide tolerance increased by 0.2 million ha in 1998 representing 1 % of global area with significant prospects for further growth in future.

Of the five major transgenic crops grown in eight countries in 1998, the two principal crops of soybean and corn represented 82 % of the global transgenic area. In 1998 herbicide tolerant soybean was the most dominant transgenic crop (52 % of global transgenic area) followed by insect resistant corn (24 %), herbicide tolerant canola (9 %), and insect resistant/herbicide tolerant cotton at 9 % and herbicide tolerant corn at 6 %.

The three major factors that influenced the change in absolute area of transgenic crops between 1997 and 1998 and the relative global share of different countries, crops and traits were:

1. The enormous increase in herbicide tolerant soybean in the USA from 3.6 million ha in 1997 to 10.2 million ha in 1998 (equivalent to 36 % of the US national soybean area) coupled with a similar increase in herbicide tolerant soybean in Argentina from 1.4 million ha in 1997 to 4.3 million ha in 1998 and equivalent to >60 % of the Argentinean national soybean area
2. The significant increase of insect resistant corn in the USA from 2.8 million ha in 1997 to 6.5 million ha in 1998, equivalent to 22 % of the US national corn area in 1998
3. The large increase of herbicide tolerant canola in Canada from 1.2 million ha in 1997 to 2.4 million ha in 1998, equivalent to 50 % of the Canadian canola area.

The combined effect of these three factors resulted in a global area in 1998 that was 16.8 million ha higher and 2.5 fold greater than 1997.

4.2.1 Future trends

There are several trends within the agricultural biotechnology sector that should be mentioned. First, within the commercial agricultural biotechnology sector, "value-added" traits are receiving an increasingly large share of resources. These value-added traits include products such as enhanced oils and vitamin A enriched canola. The industry is rapidly moving in this direction, and away from input traits such as insect and viral resistance. While these traits will remain important, they will be part of a larger package focusing on improved nutrition for the consumer.

Another trend is the development of neutraceuticals and pharmaceuticals in plants. The production of antibodies and vaccines in plants is rapidly moving forward, with significant investment in this area.

The entire field of genomics – mapping, sequencing, and analyzing the genetic make-up to determine the structure and function of every gene in a plant – is receiving significant investment in both the public and private sector. Genomic information can be used to improve useful plant traits through genetic engineering to increase food and fiber production, provide a safer and healthier environment and a sustainable source of renewable energy and chemicals. In 1998, the US government launched a publicly funded National Plant Genome Initiative with international links to other programs such as the Japanese Rice Genome Program. US industry is also investing enormous resources into genomic studies in numerous plants, including corn, soybean, wheat and rice.

4.2.2 Implications for Africa

Products produced using the new tools of modern biotechnology are commercially available in a number of countries around the world. The US is the world leader, both in terms of products for sale and research investment. There are already commercial products that could be adapted for use in Africa (insect resistant corn, for example) that could significantly increase yields. However, other commercially available crops, such as herbicide-tolerant cotton, requires access to the chemical herbicide, which may be too expensive for African farmers to use.

More importantly, the swift adaptation of the industry to consumer demand raises several important issues for African policy makers. Will the shift toward value-added traits produce products of importance to Africa (perhaps vitamin A enriched rice)? Will this shift increase potential collaboration with African scientists (who may be able to access the basic input traits more easily when industry focuses on value-added)? Or will the shift from input traits to value-added traits affect African agriculture in a negative way, with companies and advanced public sector institutions moving away from yield enhancing research and technologies?

4.3 Status of Investment in Agricultural Research and Agricultural Biotechnology – Focus on US and public/private collaboration

Investment in agricultural biotechnology has been dominated by the private sector. This investment has affected public sector research trends (Klotz-Ingram and Day-Rubenstein, 1999). In addition, in the US, collaborations between the public and private sectors have grown due to national policies developed in the mid-1980s. Before 1980, collaboration was limited because the private sector could not assume ownership of any inventions that resulted from federally-funded research. The government patent policy of 1980 (Bayh-Dole Act) granted all institutions "certainty of title" for inventions resulting from federally funded research. The Bayh-Dole Act also allowed federal laboratories to issue exclusive licenses for patents of their inventions, which are more attractive than the nonexclusive or open licenses previously granted to firms. Other legislation sought to promote greater collaboration and exchange between federal laboratories and the private sector. The 1980 Stevenson-Wydler Technology Innovation Act mandated that each federal research agency develop specific mechanisms for disseminating government innovations. The 1986 Technology Transfer Act gave government agencies additional means to foster technology transfer by authorizing Cooperative Research and Development Agreements (CRADAs). Previously, federal researchers were not permitted to collaborate directly with the private sector (Congressional Research Service, 1991). The United States Department of Agriculture's collaborations with the private sector have significantly increased over the last decade (Day-Rubenstein & Fuglie, in press). These policy changes have contributed to increased private sector involvement in agricultural R&D. Private investments in agricultural and food R&D have nearly tripled in real terms from about $1.3 billion in 1960 to $4 billion in 1996 (Fuglie *et al*., 1996).

In the US, private agricultural research investments have exceeded public sector spending since the early 1980's. Public sector expenditures in 1996 were $3.15 billion, about $800 million less than private sector expenditures. Research funding in agricultural biotechnology is even more skewed towards the private sector, with investments totally 50-70% of all funding in this area. The composition of private sector research has also changed. The share of R&D expenditures for biological and chemical inputs (plant breeding, agricultural chemicals, and veterinary pharmaceuticals) rose from 19 percent of total agricultural research spending by private firms in 1960 to 58 percent in 1996. Furthermore, private support of public sector research funds has become increasingly important. The non-governmental share of funding (industry grants, product sales, and other sources combined) had the most rapid rate of growth. Between 1978 and 1996, this funding source increased from 14 percent to 20 percent of total research expenditures at state agricultural research institutions. Research grants from industry grew from 5.1 percent to 7.5 percent during this period.

Public research policy can account for the increasing role of the private sector in agricultural research. In response to increased private sector activity, public research institutions have been directing more resources to research with a public goods component. While this research offers the greatest overall benefit to society, private returns are limited and industry has little incentive to conduct this research (Fuglie *et al*., 1996). One example of research with a strong public goods component is basic research. Although basic research has higher social rates of return than applied research, results generally cannot be appropriated. As a result, the share of private sector research expenditures devoted to basic research is only 14 percent, whereas 47 percent of public sector research funds are allocated to basic research (Table 8). It should be noted that the data for private sector research expenditure is from 1984. It is likely that today, significantly more investment is focused on basic research , especially genomics research.

Table 8: Shares Of Agricultural Research Expenditures.

	Percentage of Research Expenditures		
	Basic	**Applied**	**Development**
Public Institutions	46	47	7
Private Industry	14	44	42

Note. Public research data are for Fiscal Year 1997 from CRIS (1999); private research data are from a 1984 survey by the Agricultural Research Institute (1985).

Differing research priorities of the public and private sector can be observed specifically in plant breeding. A recent comprehensive survey of public and private plant breeding research showed that USDA's ARS concentrates most of its research on long-term pre-breeding activities, while the private sector devotes most of its resources to short-term varietal development (Frey, 1996). The Agricultural Research Service has terminated most of its research on variety development, increasingly concentrating on research areas not pursued intensely by the private sector.

Besides ensuring that the public research agenda accounts for private sector research, the USDA has also sought to strengthen research collaborations with the private sector. Joint research with the private sector (e.g., patent licensing, research consortia, contracted research, and CRADAs) can promote the use of public sector research results, while providing additional resources for public research. The USDA often uses research collaborations to bring specific inventions to the marketplace, such as biopesticides. The USDA has established more than 700 CRADAs since the beginning of the program. Likewise, changes in patent policy have increased USDA's licensing of patents to the private sector. Royalties from patent licenses have risen steadily since 1987, indicating increased licensing activity (Table 9).

Table 9: USDA Public-Private Research Activities.

Year	Active CRADAs[a] (Number)	Value Of CRADAs[b] ($ Millions)	Patents Awarded (Number)	Patent License Royalties ($ Millions)
1987	9	1.6	34	0.09
1988	48	8.7	28	0.10
1989	86	15.6	47	0.42
1990	104	18.9	42	0.57
1991	139	25.6	57	0.83
1992	160	30.0	56	1.0
1993	185	34.0	57	1.5
1994	212	61.3	40	1.4
1995	227	80.1	38	1.6
1996	258	98.9	53	2.1

[a] Number of CRADAs with the private sector. [b] Value of CRADAs includes the total value of USDA and private-sector resources committed to active CRADAs over their lifetime.

A review of ARS CRADAs from 1987-1995 shows the topics addressed by this public-private research. Using USDA's classification system, CRADAs with financial data were grouped into five main areas (Table 10). As expected, plant research was the largest category in terms of total resources because plants are a priority for both public and private researchers. Almost 35% of CRADA resources were used for post-harvest use research. Animal research was third among CRADA priorities.

Table 10: Cooperative Research And Development Agreements By Resource Allocation.

Research Categories						
Percentage of Total Resources	Natural Resources	Plant Production and Protection	Animal Production and Health	Post-harvest Use of Agriculture Commodities	Human Nutrition	General
	6.3	36.5	17.2	34.6	2.7	2.7
Note. Based on data from CRADA's initiated by ARS between 1987 and 1995. Value of research resources available for only 366 projects.						

Changes in ARS research priorities during the CRADA program suggest that closer R&D cooperation between the USDA and the private sector may have enhanced research efficiency by enabling the public sector to focus resources on public goods research (Day-Rubenstein & Fuglie, in press). Overall, the pattern of research allocation by the USDA has remained relatively stable since the CRADA program began. However, USDA research resources became increasingly focused on natural resources and human nutrition, where the private sector is unlikely to develop new technology.

Public research can also foster competition among private sector research institutions. For example, public researchers can "invent around" enabling technologies held by companies. If a critical agricultural technology is protected by a patent, public researchers may work to develop new technologies that perform similar functions. For instance, USDA conducts research on apomixis traits (Adams, 1993). Apomixis allows for asexual reproduction of seeds providing a way to circumvent the hybrid barrier. Public research can also enhance competition directly by providing competing technologies. In the past, public research fostered competition in the plant breeding industry (Ruttan, 1982). One example is the hybrid corn industry. Prior to 1984, USDA released parent lines of hybrid corn varieties that benefited small companies who relied heavily on these public sector lines (Huffman & Evenson, 1993).

4.3.1 Implications for Africa

The more complete linkage of the public and private sectors in developed countries, as demonstrated by the US example above, has profound implications for African scientists vis a vis potential collaborations with developed country institutions. African policy makers and scientist need to understand that, just because research was conducted at a university or agricultural research center, the research innovations arising from that work can no longer be expected to be freely shared. As with collaborations with industry, collaborations with advanced laboratories in the public sector, in biotechnology, will likely come with strings attached. That does not mean that technologies can’t be accessed, but that arrangements will be more formalized, with legal agreements developed to oversee the transfer of research tools, collaborations, and intellectual property developments. African scientists and administrators will have to learn new skills, such as negotiation and intellectual property management, to assure collaborators of their ability to “play” in this new game. It should be noted that these arrangements are still relatively new to donor organizations, who are also grappling with this changing environment. Many organizations are currently finding that research results supported from donor funds may not be easily employed for commercialization and/or distribution because components of the process are proprietary to certain institutions (both public and private).

4.4 Investment for developing country agriculture

Investments in developing country agriculture have been historically very low, despite the high return on investment of agricultural research. In relation to agricultural biotechnology, developing countries have invested very little in training scientists, promoting new skills in the areas of risk assessment and research management, or promoting training and development of professionals in intellectual property management and negotiation. This latter issue is very important because, in developed countries at least, most innovations resulting from biotechnology research are patented for commercial purposes (see section below on intellectual property).

This privatization of technology may lead to products that are too high-priced for poor countries. While one could envision special agreements being worked out for life-saving medicines - an AIDS vaccine, for example - or for seed varieties vital to survival, it would be unrealistic to expect private enterprise to forgo market-oriented pricing of the fruits of its research for charitable reasons. A clear-eyed scrutiny of numerous companies' research objectives leads one to conclude that, with a view to optimizing the funds ventured in research, they are concentrating on problem solutions that can be marketed primarily in the rich industrial nations, because only these countries have the buying power needed to bring the return on investment aimed for.

That is the reason why more public research is called for, and above all in the developing countries, since the results forthcoming from this source - which, incidentally, ought also to be patented (Von Wijk et al, 1993)- can be turned to use at cost-oriented prices, subsidized or even made available gratis. Although a number of countries do have an impressive national engagement in biotechnology research, a great deal more still needs to be invested (Komen and Persely, 1993)

If the gap between North and South is not to go on widening endlessly and the needs of the poor people in the poor countries are not simply to be forgotten public research geared to the specific problems of these people must be built up in the Third World and supported by international funding. Failing a substantial reinforcement of international agricultural research, more and more developing countries with their rapidly growing populations could already face serious food shortfalls in the next ten years (Action Group on Food Security, 1994).

Expanded research does not signify only expanded scientific research either. To an ever greater extent it also means research in development policy and sociology in order to improve the social parameters for technology transfers and thus pare the social transaction costs.

4.4.1 Implications for Africa

There is a tendency to view the use of biotechnology as an income-generating opportunity. While certain collaborations may be devised with potential economic payoff (biosprospecting, for example), most collaborations will not produce income generating opportunities for the African research organization, particularly if it is focused on the use of biotechnology for small-scale African farmers. It is important that policy makers realize that continued public investment in agricultural research, both in terms of human resources and infrastructure, will continue to be a critical component to the successful use of biotechnological methods for Africa.

5.0 Partnerships for strength in biotechnology transfer in Africa; case studies

Africa is experiencing considerable challenges in regard to modern biotechnology transfer and applications for improvement in production of food and cash crops, especially for small-scale resource poor farmers, who form the large propotion of the farming community. To start with, the high level requirement in human capacity expertise in issues such as National Biosafety Regulatory Agencies (NBRA), capital investment and infrastructure to develop especially transgenic crops biotechnologies and related products, which runs in billions of dollars is beyond reach for majority of African countries. In developed countries, such level of research and development (R&D) is taking place in the private sector biotechnology companies who have invested heavily and have produced some very promising products, some of which are currently in the market. In Africa, such R&D is limited or lacking especially from the private sector agriculture for transfer and application especially to small-scale farmers. Where appropriate and relatively low key technologies such as tissue culture would make an impact, the problem of reaching out or delivery system to the so called "invisible market" of many small-scale farm units of farmers, become a limiting factor to the private sector investors. The numerous small units of small-scale farmers that have to be reached out is further confounded by other logistic factors such as poor communication system, poor roads and transport network, lack of finances to support field trials and clear demonstrations to show the superiority of the technology, monitoring field trials and impact assessments, that are essential for technology diffusion. When it comes to transgenic crops, technology transfer is further hindered by unoperation and relatively unexperienced National Biosafety Committees (NBC) or lack of such committees in some countries

The key to success in Africa is through working partnerships with comparative advantages as in the case of MSV problem. Here, four institutions including the Kenya Agricultural research Institute (KARI), the University of Cape Town, the International Centre for Insect Physiology and Ecology (ICIPE) and the John Innes Centre in the United Kingdom, with funding from the Rockefeller Foundation, are collaborating in a biotechnology-transfer project brokered by the International service for Acquisition of Agri-Biotech Applications (ISAAA). Novartis in Europe has donated some technology to KARI to enhance the process of developing MSV-resistant varieties. Under this biotechnology-transfer project, researchers at KARI are studying the mechanism of MSV resistance and trying to map the genes responsible. Advanced biotechnology skills, including the use of advanced agroinoculation techniques and molecular markers, is at the core of this effort focused on production of varieties resistant to MSV in the farmer's field. A priority in Kenya is also for high-yielding drought-tolerant crop varieties to boost food production in the arid and semi-arid regions that occupy 71 per cent of the country.

Africa needs biotechnology to solve its environmental problems, and there is unlimited public demand for agricultural biotechnology products and services. In Kenya, the demand for tree seedlings reaches 14 million per year whereas the country can only supply 3 million, a clear indication of the practical need for tissue-culture and clonal techniques to curb deforestation and boost re-afforestation using various indigenous species threatened with extinction. These technologies are being successfully used in South Africa, and ISAAA has facilitated a project for transfer and application in Kenya. There are issues of intellectual property rights and patents which require hard work to develop or acquire and use various advanced agricultural biotechnology skills. This may also mean working out appropriate collaboration agreements with the private sector or with companies that already have patents.

Biotechnology in Africa is needs-based. After working in KARI for nearly a decade to help improve sweet potato production in eastern Africa using traditional breeding and agronomy methods, I made no progress. An opportunity to work in the private biotechnology sector abroad resulted in the development of a transgenic variety that is resistant to sweet-potato feathery mottle virus (SPFMV), which can reduce yields by between 20-80 per cent. Control of this disease will improve household food security for millions in the region. This project involved a collaboration between KARI, USAID, ABSP and Monsanto. The work by Kenyan scientists focus on local varieties, and there will be a smooth and sustainable transfer of the technology, which will be shared with neighbouring countries. Kenyan scientists have also been trained in gene technology for future work and impact. ISAAA has been formally requested to help in the transfer and licensing agreement. Similar projects are under way for bananas, sugar cane and tropical fruits.

6.0 Policies Driving Development of Agricultural Biotechnology: International and National

6.1 Investment Climate

The general investment climate for biotechnology is not remarkably different from the investment climate needed for other industries, and so will not be explored in any great depth. Good governance, including an effective, functioning court system and transparent decision-making processes are critical. In addition, tax codes that allow depreciation for research investment encourage private sector participation in research-intensive industries. There are two main areas that are critically important to investment in biotechnology: Intellectual Property Rights (IPR) and Regulatory Review. These are described more below, following a discussion on international commitments in these two areas.

6.2 International Agreements and Treaties Affecting Agricultural Biotechnology

Several key international agreements and ongoing international discussions may impact the development and use of biotechnology. These agreement have broadened biotechnology beyond cooperative research and technical capacity building to now include trade and larger political, cultural and economic issues. The priority that many developing countries place on capacity building in policy and regulatory areas such as agricultural IPR and biosafety (see below) have increased. The international agreements are described briefly, followed by a more in-depth focus on the two primary policy areas of interest – IPR and biosafety.

6.2.1 Convention on Biological Diversity

Perhaps the most significant international agreement to reshape the environment for international biotechnology development is the Convention on Biological Diversity (CBD) which entered into force in 1994. The CBD represents an important step in biodiversity conservation for the environmental community. It also represents an important political expression for those who felt that the system of free access to genetic resources in developing countries and the increasing extension of IPR to biotechnology innovations were unfair to developing countries, benefiting primarily the commercial sector of developed countries (Witmeyer, 1997)). In most concrete terms, the CBD altered the global system of free access to genetic resources by allowing countries to exert sovereignty over their genetic resources and to control access by these researchers and commercial firms alike. More importantly, though, the CBD highlighted the politics of equity between developed and developing countries in realizing the economic benefits of biodiversity, including, specifically, those derived from biotechnology. It did so in two ways:

1. Through an emphasis in a number of articles on the need for increased technology transfer and capacity building in biotechnology, and
2. Through references to the need to consider the potentially disadvantageous position of developing countries with respect to IPR (CBD, 1994).

The latter is dealt with in the context of both concessional terms for the use of proprietary technology by developing countries and in the equitable sharing of the economic benefits derived from IPR.

Following the establishment of the CBD and WTO (see below), developing countries have increasingly approached IPR from the perspective of equity; both seeking capacity building in IPR to increase their share of economic benefits derived from biotechnology, and, conversely, to question the fundamental application of IPR to agriculture and biotechnology from a cultural perspective. Researchers in developing countries will likely encounter IPR in collaborating with public and private institutions in developed countries regardless of the policy decisions those countries take toward IPR protection nationally. Further, as countries move towards development of policies in line with the CBD it will be important that issues such as IPR, and biosafety as discussed below, reflect cross sectoral discussion among agricultural, scientific, environmental, legal, and trade policy makers. Because of their broader impact on agriculture and research, it is disconcerting that such discussions are not generally the source of national positions or policy decisions. Recognizing that biotechnology is not just a scientific issue in the international community, it is none-the-less important that technical capacity building in biotechnology, IPR, or biosafety feed into the policy making process.

<u>6.2.2 TRIPS</u>

A second international agreement which deals with agricultural IPR is the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Also adopted in 1994, the TRIPS agreement requires protection of pharmaceuticals and genes; it does permit exclusion of living plants and animals for patentability, but requires use of a *sui generis* system such as plant breeders' rights for plants (Leskien and Flitner, 1997)). TRIPS allows countries some flexibility in the precise form and the extent of protection. Nonetheless, it promotes the fundamental idea of extending IPR to agricultural genetic resources. The response by developing countries to the TRIPS agreement has been from two directions. First, countries interested in both the potential benefit of crop-related IPR policies and in meeting the WTO deadline for implementation of the TRIPS agreement have sought technical assistance in developing and implementing national systems of plant variety protection (PVP) such as that outlined by the International Union for the Protection of New Plant Varieties (UPOV). Conversely, much has been written and expressed by developing country representatives critiquing the benefit of the TRIPS agreement for developing countries and questioning the consistency of TRIPS, and UPOV, with the CBD (Ekpere, 1999)). While it is not clear that legal conflicts between the CBD and TRIPS do actually exist (CBD/UNEP, 1996)), the political significance of such a debate carries into international biotechnology collaborations. As with the CBD, the challenge is to recognize the diverse perspectives, but to move beyond solely the political and into the specific legal and scientific issues surrounding PVP. For countries to pursue their options under TRIPS for *sui generis* systems of PVP, an understanding of legal, economic, and scientific costs and benefits of policy options will be essential. Further, the implementation of PVP will likely be the responsibility of agricultural rather than trade or legal ministries. Thus, WTO compliance, like the CBD, should involve dialog between agricultural and trade policy makers.

6.2.3 Biosafety Protocol of the CBD

Finally, the Biosafety Protocol to the CBD has been under negotiation for the last several years and reached a dramatic point in February 1999 with the failure to reach international consensus at the final negotiating session in Cartagena. The Biosafety Protocol seeks to establish international regulatory procedures for the transboundary movement of the products of biotechnology as a means of mitigating potential negative effects of biotechnology on biodiversity. Like the parent agreement, the CBD, the Biosafety Protocol goes beyond solely environmental conservation to address issues of technology transfer and capacity building for developing countries. It also shares the CBD's equity agenda of restricting trade and the economic pursuit of biotechnology development. The CBD provided for restrictions on access to genetic resources as a means of partially addressing the equity of benefits derived from commercial biotechnology, but in so doing also affected non-profit public research. Similarly, the Biosafety Protocol, while largely focused on commercial trade, will also impact technology transfer and cooperative research undertaken by international collaborative programs. In practical terms, it remains questionable whether the Biosafety Protocol will unintentionally create significant barriers to non-profit oriented technology cooperation and capacity building. While still under negotiation, an impact of the Protocol negotiations is already seen in the high priority developing countries now place on biosafety over any other area of biotechnology capacity needs (Cohen, et al, 1998).

6.3 Intellectual Property Rights

In contrast with real property (land) or physical property, which one can see, feel, and use, intellectual property (IP) is intangible. IPs are ideas and thoughts, or products of the mind. As long as these ideas or thoughts are not expressed in a tangible form, they remain protected and cannot be used by others. Only when IPs are expressed in a tangible from can they be protected. IP rights (IPRs) have been created to protect the right of individuals to enjoy their creations and discoveries. IPRs can be traced back to the fourteenth century when European monarchs granted proprietary rights to writers for their literary works.

Owners of IP are granted protection by a state under varying conditions and periods of time. This protection includes the right to: defend their rights to the property they create; prevent others from taking advantage of their ingenuity; encourage continued innovation and creativity; and assure the world a flow of useful, informative and intellectual works.

6.3.1 Forms of IPRs

Trade secret. The trade secret is any information that gives a company a competitive edge over competitors and which the company maintains as secret, away from public knowledge. Trade secrets are mainly kept and enforced through agreements between employers and employees. The protection provided by a trade secret has an indeterminable term. Examples include the base formula for Coca Cola and the instant film chemical formula for Polaroid film.

6.3.1.1 Copyright. Copyrights are often thought of as a special territory for artists, composers and writers. Copyrights were developed to protect the original works, derivative works and work for hire of these groups. Works are not protected if they are mere ideas, transient sounds or gestures; they must be in a tangible form, either visually or audibly, creating the representation of the original work. The main factor in determining copyright protection is the concept of originality; i.e. it must be an original effort and labor of a creator. Copyrights are used extensively in the fields of literature, music, drama, photography, sound recordings and even computer program source codes. They are not generally considered important in agricultural biotechnology.

6.3.1.2 Trademark. A trademark is a symbol that helps to distinguish one product or company from another, and include designs, shapes, numbers, slogans, smells, sounds or anything that helps the consumer to identify the product or company. While the classical justification for trademarks is to identify the origin or ownership of the article to which a trademark is affixed, today its primary purpose is to guarantee that a company's investment in research and development, marketing and the reputation a company has spent years creating in the eye of the consumer is not stolen by a competitor. Trademarks also maintain quality control in products. In the US, trademark law, unlike patent or copyright law, confers a perpetual right. Trademarks are important in commercial agriculture; for example, the Pioneer Hi-Bred trademark, for many farmers around the world, denotes high quality, consistent seed.

6.3.1.3 Patent. A patent is an exclusive right given to an inventor to exclude all others from making, using and/or selling the invention. Once issued, a patent gives the inventor the legal right to create a monopoly by excluding others from creating, producing, selling or importing the invention. This right is of limited duration, for a period of 20 years from the date of filing the patent application. The purpose of a patent is to promote the progress of science and the useful arts. In exchange for the right of exclusion, the inventor must disclose all details describing the invention, so that when the 20 year patent right expires, the public may have the opportunity to develop and profit from the use of the invention.

In the US, there are three main types of patents: plant patent; design patent; and utility patent or "regular patent." Plant patents are granted for newly discovered asexually propagated plants; however, outside the US, few patent offices recognize plant patents. Like a utility patent, the plant patent provides 20 years protection. Design patents, unlike a utility patent, protects ornamental characteristics. The life span of a design patent is only 14 years. The utility patent consists of the largest portion of patents issued and is most commonly used by companies and universities to protect the results of their research and development. It has a life span of 20 years from the date of filing.

Utility patents are granted provided the invention is novel (new), is non-obvious to one skilled in the field and has a utility (use). Most biotechnological inventions are filed as utility patents and not as plant patents. Using utility patents, it is possible to protect plant genes, rather than just the plant, and to control the use of the genetic material of a number of plants for multiple uses such as pharmaceutical, pest protection, herbicide resistance, oil production, etc. Patents are only enforceable in the country that issues it.

6.3.1.4 Plant Variety Protection. Plant variety protection (PVP), also referred to as Plant Breeders Rights (PBRs), allows one to protect new varieties of sexually reproducing plant varieties for a term of 20 years (25 for tree crops). It is considered a *sui generis* system, i.e. a system of rights designed to fit a particular context and need that is a unique alternative to standard IP protection. Advantages to PVP over plant patents include: the cost is much lower; the simplicity of application; the requirements for protection are less than those for patenting; and the protection is similar. Generally PVP is not sought for transformed plants, i.e. plants into which genes have been incorporated through biotechnology, but rather for plant or varieties that have been developed through traditional breeding. PVP DOES allow the saving of seed by farmers and the use of material for breeding purposes; this is often misunderstood.

<u>6.3.2 Pros and Cons to Patenting</u>

It appears that the momentum behind international agreements such as the Convention on Biological Diversity (CBD) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS), will make the introduction of IPRs in developing countries inevitable. These initiatives, driven by industrial IP concerns, have engulfed agricultural interests with a speed and intensity that has caught many in the developing world unaware.

Proponents state that IP:

- Provides incentives to create knowledge
- Encourages greater research and development within the country
- Discloses information other researchers can use to make further advances
- Encourages greater research and development investments in industrialized countries on issues of concern in developing countries
- Encourages transfer of knowledge to developing countries
- Creates a market for knowledge by providing a legal basis for technology sales and licensing

While critics state that IP:

- Increases costs of protected products and may price them beyond the reach of the poor
- Shifts bargaining power toward producers of knowledge rather than users
- Broad patents may discourage follow-on inventions and slow the overall pace of innovation
- The knowledge gap between industrial and developing countries may increase
- Industrial country firms may take advantage of indigenous knowledge and natural products without compensation to local communities

Clear evidence exists that the patent system has stimulated the development of new products and technologies (in pharmaceuticals, for example). Additional studies in Latin America have indicated that development of PVP legislation increases investments in private sector breeding. However, patents may have anti-competitive effects. Clearly, the development of a balanced system comprising the length and breadth of protection is necessary to maximize social welfare and to achieve appropriate levels of research investment and competition.

Intellectual Property systems represent a kind of contract between society and inventors and their investors. As with any such arrangement, both parties must monitor the balance of benefits and obligations to ensure that technological progress continues and that society's needs are answered. The application of the industrial patent system to biological processes and products is stimulating unprecedented debate; in the social context, as some question the appropriateness of patenting life forms; in the technical context, where there is concern that patents may be an inefficient method of protecting new biotechnologies; and, at the political level, where corporate and sovereign nation interests are juxtaposed.

6.4 New systems of IP protection?

Whatever one's view of the patent system, some broad biotechnology-related patent claims in the US provide a legitimate cause for concern. It is clearly more difficult to establish consistent technical criteria and to determine an equitable inventor–society balance for the application of IP systems to living resources than it is for inanimate objects. As with the protection of copyright, computer software, or integrated circuits in semiconductors, it may be useful to consider a *sui generis* system of IP for biotechnology. Such a system should take into account the inherent complexities of applying IP systems to life forms, the contribution of many generations of local communities in shaping those life forms, and the need to balance the interest of society as a whole for continuous innovation with the interest of the individual inventor for reward and compensation.

One of the areas that is often mentioned for new forms of IP protection is “Farmers’ Rights.” There is no doubt that farmers are the original owners and custodians of biological diversity, and have also been responsible for knowledge and innovation through generations that have resulted in agricultural biodiversity. It is unclear whether or not this warrants the development of a new system of IPR, but proponents of this system content that these rights, like the current IPR regime, are founded on innovation. But they would not resemble current IPR systems in that they are non-exclusive (and therefore non-monopolistic), are communally owned or held in trust for past and future generations of those who make up the community (and not individually owned) and are based on cumulative collective achievements (and not a single invention). It remains to be seen if such a system can be devised that encourages investment in technology development (which is the basis for the granting of a period of monopoly under current IPR regimes).

6.5 Implications for Africa

The area of Intellectual Property is controversial and complex. However, it must be remembered that, within the parameters of the Convention on Biological Diversity and Trade-Related Aspects of Intellectual Property, developing countries have international commitments that they will have to meet. If countries wish to access biotechnology products or technologies (through collaborations with industry or other public sector institutions, for example), it will become increasingly important to have IP policies and procedures in place at the national and institutional level. These policies can take into account national interests such as Farmer's Rights and compensation to indigenous people, but will have to be crafted in such a way as to promote collaboration and private sector investment while securing the greater public good.

7.0 Potential risks of biotechnology

In spite of the widely uncontested favorable potential of genetic engineering and biotechnology, the climate for them in some industrial countries remains skeptical, even to the point of rejection. Possible risks must always be taken seriously, and it is in everyone's ultimate interest to make sure that a risk/benefit assessment based on a broad - but also informed - social consensus has been undertaken before decisions are made. The current public debate on the new technologies often suffers, however, from a lack of specialized knowledge as well as from a failure to differentiate between the risks inherent in a technology and those that transcend it.

Technology-inherent risks arise when a technical action plan is designed to improve an existing situation, but then during the research or implementation phase unforeseeable problems and unwanted side effects crop up - undesirable mutations, for instance. Risks of this sort must be distinguished from those hazards that transcend technology, i.e. which emanate from its mode of application in certain circumstances. Such risks might materialize when proposed and technologically feasible improvements founder on social, economic or cultural obstacles. But to flatly demonize a technology instead of giving thought to how external conditions could be altered for the better is, in view of the dimensions of the problems to be dealt with in the developing countries, short-sighted.

7.1 Regulatory Regimes

Technology inherent risks can be mitigated by the development of regulatory processes and procedures. In both developing and developed countries, the safe application of biotechnology to problems of agricultural productivity requires an appropriate biosafety system that encompasses both policy and regulations. Developing countries seeking to use the new technology to address limitations in food and fiber production are being pressured from within as well as by outside forces to formulate biosafety systems. Countries lacking mechanisms for review and oversight of biotechnology products risk being used as a testing ground for materials deemed too risky to test in a developed country. At the same time, companies or collaborative research programs seeking to produce genetically engineered crops tailored for developing country needs are reluctant to operate in the absence of a regulatory structure.

A well-designed biosafety policy will ensure the safety of human health and the environment without restricting innovation or stifling incentives for product development. The policy should embody two basic principles:

- ♦ That the risks of introducing a genetically modified organism into the environment derive from the nature of the organisms and the environment into which it is introduced, rather than from the process by which it was developed
- ♦ That the degree of oversight applied to a GMO in the environment should be commensurate with the risk it represents.

Biosafety policy should address national priorities in agriculture, food safety and environmental protection, and should establish the scope and intent of guidelines or regulations. In addition to issues of science and technology, a well-designed biosafety policy will also address social, legal and economic issues. These aspects of agricultural biotechnology are not generally codified in regulations but merit consideration during the formulation of policy.

Biosafety regulations address the scientific and technical issues of GMOs and describe procedures and practices for safe handling of genetically engineered materials in the laboratory, greenhouse and field. Biotechnology regulations need to be compatible with existing laws; for example, rules for importing GMOS should be consistent with plant and animal quarantine statutes. Coordination is needed among various national authorities for public health, food safety, natural resources, and industry.

The regulatory structure needs to be flexible and responsive to new information relevant to risk assessment. It should be implemented in a way that will allow rules to evolve as initially identified risks are shown to be negligible or only narrowly relevant and as unanticipated risks become apparent.

<u>7.1.1 Technical Issues of Risk Assessment</u>

Scientific and technical biosafety issues associated with GMOs concern the consequences of releasing transgenic materials outside the laboratory and impacts on human health. Potential deleterious effects on natural or managed ecosystems need to be considered for small scale field tests and become even more important when transgenic crops are grown for commercial production. The primary environmental issues to be addressed concern the ability of the new crop to be invasive ("weedy"), toxicity of new compounds to non-target pests, development of resistance, and the transfer of introduced genes into new plant species. Responsible environmental risk assessment should therefore address the following questions:

1. Does the newly engineered trait confer "weediness" on the genetically modified crop? Traits such as drought or slat tolerance may confer enhanced fitness, allowing the transgenic species to invade and become established in previously unsuitable environments (like a weed that has enhanced fitness in a particular environment; hence the term "weediness"). Such spread could lead to displacement or replacement of other species occurring naturally in the ecosystem which may have deleterious effects on the environment.
2. Are transgenically expressed pesticidal or pharmaceutical compounds toxic to non-target organisms? Where plants producing these compounds are grown on a commercial scale, what are the potential short- and long-term effects on animals, microbes, and other plants in the area:
3. Will the widespread deployment of plants engineered to express pesticidal proteins hasten the development of resistance in target pest species? Insect populations can respond quickly to the selection pressure imposed by large scale and prolonged application of conventional pesticides. Use of only a few genes, such as those encoding delta endotoxins in *Bacillus thuringiensis*, to transform numerous crop species is poor pest management practice with potentially serious implications. The same argument can be raised with respect to genes for resistance to bacterial and fungal pathogens.
4. What is the potential for gene flow, in which a trait genetically engineered into a crop species in inadvertently transferred to sexually compatible specie via pollen from the transgenic

plant? Such “escape” of introduced genes could lead to the contamination of wild germplasm and a subsequent loss of genetic diversity.

5. Most importantly, for a particular GMO introduced into a particular environment, what interactions between the biology of the organisms and ecology of the site present unique concerns for biosafety?

Human health issues associated with agricultural biotechnology are primarily concerns about the safety of food and food additives. Public acceptance of the new technology will be directly lined to consumer perceptions that foods derived from bioechnology are safe to eat. Genetically engineered food products should be evaluated for potential toxicity or allergenicity of new expressed proteins, increased levels of known toxicants, or significantly altered nutritional qualities. Clear and consistent policy must be developed regarding labeling of genetically engineered foods, keeping in mind the purpose and intent of other food labeling statutes.

7.1.2 Implications for Africa

There is a strong interest and desire in Africa for the development of biosafety regulatory systems. This is certainly desirable; however, sub-Saharan Africa suffers from a lack of technical expertise to review and evaluate risks associated with GMOs. It seems reasonable, given the paucity of highly trained molecular biologists, ecologists, plant breeders, virologists, etc. that a regional approach to technical review and assessment should be explored. While the decision to allow field-testing and commercialization of a GMO would remain a national one, the technical reviews and recommendations could be handled by a regional team of experts. In addition, countries could decide to accept certain data from tests in other countries (such as toxicity feeding studies) to streamline the process and lesson the burden on African scientists and administrators.

7.2 Technology-transcending risks of biotechnology

Technology-transcending risks are not caused by a technology as such and therefore cannot be prevented by the technology. In developing countries these risks spring from both the course the global economy is taking and country-specific configurations. The most critical fears in this context have to do with socio-political concerns:

- *Aggravation of the prosperity gap* between North and South through possible substitution of tropical agricultural exports with genetically engineered products and exploitation of indigenous genetic resources without appropriate compensation.

- *Increased inequalities in the distribution of income and wealth* because the privileged classes (by dint of better education or stronger financial position) profit earlier and more from the introduction of powerful technologies than do the socially disadvantaged. This problem accompanies every innovation, of course, but the high potency of genetic engineering and biotechnology stirs fears that the negative effects on development may prove particularly severe.

In light of the magnitude of poverty-related problems throughout most of the developing world and the dwindling competitiveness of a great many poor countries (World Bank, 1994), these concerns are valid and serious.

With the new technologies it may become possible to produce in the laboratory or in temperate zones goods that have hitherto been grown exclusively in the tropics. This prospect gives rise to concerns that the resultant competitive edge could drive tropical products off the market. To take just one example, the production of vanilla aroma in the laboratory using biotechnological techniques could have existence-threatening effects on 70,000 small farmers in Madagascar alone (Wambui, 1989)

Similar but even more far-reaching consequences could materialize in connection with cocoa. Genetically improved cocoa varieties could not only result in higher yields and a concomitant drop in prices. They could also lead to the dislodging of small-hold production in the dirt-poor West African countries by plantation-scale farming in the newly industrialized economies of Asia (Zweifel, 1990)). A comparable outcome might happen with vegetable oils.

Furthermore, countries like Cuba or Mauritius, which depend on sugarcane for a decisive share of their export earnings, could find themselves extremely hard-pressed should industrial manufacture of the low-calorie protein sweetener thaumatin or similar substances come broadly to supplant sugarcane (Sasson, 1988)

7.2.1 Implications for Africa

In the perspective of economic rationality, it has to be expected that superior goods will conquer the market. Copper can serve as an example. Its price is determined by the metal's electrical conductivity. Once electric current can be conducted cheaper and better by glass or carbon fiber, for instance, copper will in due course no longer be used for this purpose - with corresponding consequences for demand and thus price. The substitution will take place even though crumbling prices may lead in countries like Zambia or Chile to mass unemployment, with all the human distress it brings.

The same market logic tells us to expect that if lab vanilla or lab sugar should prove cheaper or exhibit some other edge - healthier than the real thing, for example - over products previously imported from the South, then substitution will follow. Ultimately this process cannot be forestalled, not even by sizeable government intervention, which is not desirable anyway.

The solution to the product substitution problem must therefore lie in a concerted endeavor to diversify the production structure in vulnerable countries and not in counter-market intervention. Here a bigger allocation of funds from the international development establishment to the support of diversification efforts is urgently required. A comprehensive risk/benefit analysis of the substitution of agricultural export commodities from the tropics would also have to examine the alternative use of the land left fallow by substitution for increasing local food production, and perhaps ecologically opportune changes in how it is used as well - for afforestation, for example.

8.0 Who will benefit from agricultural biotechnology?

The developmental impact of recombinant genetics and biotechnology is only as good as the socio-political soil in which they are planted. Any technical advance, progress in genetics included, can only benefit those who understand the technology and are able to apply it. Every restriction on access, be it lack of trained personnel, poor investment climate, or poor national and institutional policies, can have the effect of aggravating income discrepancies - pronouncedly so when the technology is very potent. Unless policy reforms are introduced and reinforced with supportive measures that also enable the middle and lower strata of society to gain their share, technological innovations actually work against the development goal of breaking down inequalities.

As a collective term, “developing countries” is no longer appropriate in discussions on the social and economic effects of the sophisticated new technologies. It encompasses countries so different economically, socially and culturally, as well as in their capacity to absorb the fruits of research and technology, as to defy generalizations.

Recent studies differentiate more carefully, categorizing the developing countries on the basis of their research capacity and their institutional arrangements for stimulating biotechnological development. Further criteria include the share of agriculture in overall exports, whether a country is a net exporter or importer of agricultural products, and how agriculture is structured (importance of large-scale farming as over against small-holder farming) (Commandeur and von Roozendaal, 1993). In their analysis of the effects on agriculture in the developing countries, Commandeur and von Roozendaal come to the following conclusions:

- Countries that are both net agricultural exporters and have a weak technological potential will not be in a position to avail themselves of biotechnology. Because these countries depend chiefly on exports of their products they will be affected most negatively.

- Countries that have a weak technological potential but are net importers of food could profit short-term from lower prices on the world market. In the long term, however, this trend could adversely affect domestic food production.

- Countries with a strong technological potential and high food imports could benefit most from biotechnology, since it could be oriented towards self-sufficiency.

- Countries with a strong technological potential and high food exports could benefit from biotechnology by using it to diversify their exports.

8.1 Implications for Africa

A country's vulnerability to the new technologies is greatest where a low technological potential coincides with net exports of potentially substitutable agricultural products. This situation exists in most of Sub-Saharan Africa and the Caribbean. However, sub-Saharan Africa should not despair. It is becoming increasingly clear that governance is of paramount importance. Developing policies that encourage investment, education, collaboration, and technology access will all promote technology transfer and access to biotechnology products that can improve the health and well-being of citizens. This includes working with private industry, both locally and internationally, as they own much of the technology and have the resources to bring products to market. Sub-Shaharan Africa may also have to develop a common market to attract investment, requiring increased cooperation within Africa itself.

Agricultural biotechnology can assist Africa in meeting its food demand needs in the 21st century. Whether or not this happens will depend upon donor investment, private sector interests, and, most importantly, by the African countries themselves. The development of appropriate policies will determine whether the promise of biotechnology is fulfilled, or if it is one more technology that passes Africa by.

9.0 Remaining problems for Africa

Needless to say, Africa has many problems -- a shortage or lack of skilled manpower (especially in biotechnology), poor funding of research, lack of appropriate policies and civil strife. Nevertheless, countries like South Africa, Egypt, Zimbabwe and Kenya are taking practical steps to ensure that they can use biotechnology for sustainable development.

African countries need to avoid exploitation and to participate as stakeholders in the transgenic biotechnology business. They need the right policies and agencies, such as operational biosafety regulatory agencies, breeders' rights and an effective local and public and private sector, to interface with multinational companies that already have the technologies. Consumers need to be informed of various agricultural biotechnology packages, the use of unsuitable foreign germplasm and to avoid loss of local germplasm and to maintain local diversity. Other checks and balances are needed to avoid patenting local germplasm and innovations by multinationals, ensure rights policies and avoid unfair competition, monopoly, buying of local seed companies, and other safeguards to prevent exploitation of local consumers and companies by foreign multinationals. Field trials need to be done locally, in Africa, to establish environmental safety under tropical conditions.

The main issue is finding a balanced formula for how local institutions can participate in transgenic product development and share the benefits/risks and profits of the technology, as they own the local germplasm needed by the multinationals for sustainable commercialization. New varieties must not simply replace local ones. The removal of genes which were in the public domain into the private sector raises concern in Africa, where there is a lot of catching up to do in the field of biotechnology.

All these issues mean that Africa must strengthen its capacity to deal with various aspects of biotechnology, including issues of bio-safety, creating and sustaining genebanks, and encouraging the emergence of a local biotechnology private sector. The great potential of biotechnology to increase agriculture in Africa lies in its 'packaged technology in the seed', which ensures technology benefits without changing local cultural practices. In the past, many foreign donors funded high-input projects, which have failed to be sustainable because they have failed to address social economic issues such as changes in as cultural practice. The criticism of agribiotech products in Europe is truly based on socio-economic issues and not food safety issues, and no evidence so far justifies the opinion of some in Europe that Africa should be excluded from transgenic crops. Africans can speak for themselves.

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APPENDIX I

Agricultural Biotech Products on the Market

- **LibertyLink® Corn (Produced by AgrEvo)** - Introduced in 1997 in the United States and 1998 in Canada, LibertyLink® Corn allows growers to apply Liberty® herbicide over the top during the growing season. Liberty herbicide kills over 100 grass and breadleaf weeds fast, with no crop injury. LibertyLink® Corn hybrids are offered by seed company partners like Pioneer, Novartis, Cargill, Garst and over 100 other seed companies. Liberty® herbicide is offered by AgrEvo.
- **LibertyLink® Canola (Produced by AgrEvo)** - Introduced in 1995, LibertyLink® Canola allows growers to apply Liberty® herbicide over-the-top during the growing season. This results in weed control with no effect on crop performance or yield.
- S**tarLink Corn (Produced by ArgEvo)** - Expected to be introduced in 1998, these plants express a protein toxic to various lepidopteran pests, which allow less insecticide usage.
- **IMI-CORN® (Produced by American Cyanamid)** - Introduced in 1992, imidazolinone-tolerant and -resistant corn allows growers to apply the flexible and environmentally friendly imidazolinone herbicides to corn. Registration of LIGHTNING™ herbicide, a new imidazolinone specifically for use on IMI-CORN®, was approved by the EPA on March 31, 1997. One postemergence application of LIGHTNING™ herbicide provides both contact and residual control of broadleaf and grassy weeds resulting in maximum yield potential.
- **SMART™ Canola Seed (Produced by American Cyanamid)** - Introduced in 1995, imidazolinone-tolerant canola allows growers to apply environmentally friendly imidazolinone herbicides to canola. In Canada, registration of ODYSSEY™ herbicide, a new imidazolinone for use on imidazolinone-tolerant canola, was approved on April 4, 1997. One postemergence application of ODYSSEY™ herbicide provides both contact and residual control of hard-to-control broadleaf and grassy weeds resulting in maximum yield potential.
- **Bollgard with BXN Cotton (Produced by Calgene, LLC, unit of Monsanto)** - These cotton plants will require less chemical herbicide and insecticide to lower grower input costs and to achieve greater crop yield.
- **Laurical® (Produced by Calgene, LLC)** - A less- expensive source of high-quality raw materials for soaps, detergents and cocoa butter replacement fats. Rapeseed plants with more than 35 percent laurate in oil have been produced.
- **DeKalBt™ Insect-Protected Hybrid Corn (Produced by DeKalb Genetics Corporation)** - Approved in 1997, select DeKalb leader hybrids are now available with built-in protection against the European corn borer.
- **DeKalb Brand Roundup Ready® Corn (Developed by DeKalb Genetics Corporation)** - Approved in 1998, DeKalb offers several elite hybrids with resistance to Roundup Ultra™ herbicide.
- **DeKalb GR Hybrid Corn (Produced by DeKalb Genetics Corporation)** - Approved in 1996, DeKalb GR hybrids provide growers the added weed control benefits of over-the-top glufosinate herbicide application during the growing season.
- **FreshWorld Farms® Tomato (Produced by DNAP Holding Corporation)** - The FreshWorld Farms® tomato is a premium, fresh market tomato developed through **somaclonal variation**[3] to have superior color, taste and texture and a 10- to 14-day shelf life.
- **FreshWorld Farms Endless Summer® Tomato (Produced by DNAP Holding Corporation)** - The Endless Summer® tomato is a genetically engineered version of the FreshWorld Farms®

tomato on the market since April 1993, and shares its superior color, taste and texture. What's new is its greatly extended shelf life of more than 30 to 40 days after harvest. Company scientists used Transwitch® technology to suppress production of ethylene, the hormone that causes tomatoes and other fruits to ripen. It is the company's first whole-food product developed through recombinant DNA technology.

- **FreshWorld Farms® Sweet Mini-Peppers (Produced by DNAP Holding Corporation)** - The FreshWorld Farms® sweet mini-pepper has a novel sweet taste, deep red color and is nearly seedless. It was developed through anther culture, an advanced breeding technique that captures and stabilizes preferred characteristics such as taste, texture and low seed count.
- **FreshWorld Farms® Cherry Tomatoes (Produced by DNAP Holding Corporation)** - The FreshWorld Farms® cherry tomato is specially bred for superior taste, color and texture. It is sold through distributors and supermarket chains in the Mid-Atlantic, Northwest and Midwest regions.
- **High pH Tolerant Corn Hybrids (Produced by Garst Seed Company)** - These corn hybrids are capable of growing successfully on the severely alkaline soils that characterize the western U.S. corn belt.
- **Gray Leaf Spot Resistant Corn Hybrids (Produced by Garst Seed Company)** - Corn hybrids tolerant to the disease Cercospora spp., which attacks corn hybrids in the Central and Southeastern corn belts.
- **G-Stac™ Corn Hybrids (Produced by Garst Seed Company) -** Corn hybrids featuring "stacked" genes providing multitask capability. For example, hybrids that contain genes for the control of European corn borer (B.t.), genes for resistance to Liberty® herbicide and genes for resistance to imidazolinone herbicide all in the same corn hybrid.
- **Chymogen® (Produced by Genencor International and marketed by Chr. Hansen's) -** Chymogen is the biotechnology-produced version of an enzyme (chymosin) found in calves that makes milk curdle to produce cheese. Because it is produced through biotechnology, it is purer, more plentiful and eliminates variability in the quality and availability of calves' stomachs. It is used in approximately 60 percent of all hard cheese products made today.
- **Bollgard® Insect-Protected Cotton (Produced by Monsanto)** - Introduced in 1996, cotton with Monsanto's Bollgard gene is protected against cotton bollworms, pink bollworms and tobacco budworms.
- **NewLeaf® Insect-Protected Potato (Produced by Monsanto)** - Introduced in 1995, the NewLeaf® Potato is the first commercial crop to be protected against insect pest through biotechnology. Thanks to a gene from a variety of the B.t. bacteria, the NewLeaf® Potato is resistant to the Colorado potato beetle.
- **Posilac® Bovine Somatotropin, Recombinant Bovine Somatotropin, (rBST) (Produced by Monsanto)** - BST is a naturally occurring protein hormone in cows that induces them to produce milk. rBST improves milk production by as much as 10 to 15 percent and is now used by farmers whose herds represent over 30 percent of the nation's cows. It was approved by the FDA in 1993.
- **Roundup® Ready Cotton (Produced by Monsanto)** - Approved in 1996, Roundup Ready® cotton tolerates both topical and post-directed applications of Roundup® herbicide.
- **Roundup Ready® Soybeans (Produced by Monsanto)** - Introduced in 1996, Roundup Ready® Soybeans allow growers to apply Roundup® herbicide over-the-top during growing season. The result is dependable, superior weed control with no effect on crop performance or yield.

- **Roundup Ready® Corn (Produced by Monsanto)** - Approved in 1997 Roundup® Ready Corn allows over-the-top applications of Roundup® herbicide during the growing season for superior weed control.
- **YieldGard™ Insect-Protected Corn (Produced by Monsanto)** - The YieldGard gene provides control of the European corn borer throughout the corn plant during the season.
- **NatureGard® Hybrid Seed Corn (Produced by Mycogen)** - These corn plants express a protein toxic to European corn borer that reduces or eliminates the need for insecticides.
- **IMI-Corn (Produced by Mycogen)** - Corn hybrid that can tolerate application of imidazolinone herbicides.
- **High Oleic Sunflower (Produced by Mycogen)** - Sunflower plants modified by mutagenesis to produce sunflower oil that is low in trans- fatty acids, does not require hydrogenation and has improved temperature stability.
- **High Oleic Peanut (Produced by Mycogen)** - Peanut plants modified by mutagenesis to produce nuts in high oleic acid results in longer life for nuts, candy and peanut butter.
- **NK Knockout™ Corn, NK YieldGard™ Hybrid Corn, Attribute™ B.t. Sweetcorn (Produced by Novartis Seeds)** - Novartis seeds has produced several corn varieties that have been modified to provide natural protection against certain pests.
- **Novartis Seeds Roundup Ready® Soybeans (Produced by Novartis Seeds)**
- **High Oleic Acid Soybeans (Produced by Optimum Quality Grains, L.L.C.)** - These soybeans produce an oil that contains a higher level of oleic acid than that found in currently available soybean oil and also contains lower levels of saturated fat. The oil will fit applications that require enhanced stability without the need for chemical hydrogenation, which generates trans-fatty acids.
- **Low Linolenic Soybean Oil (Produced by Optimum Quality Grains, L.L.C.)** - With less than 3.5 percent, linoleic is an enhanced stability oil that will reduce the need for chemical hydrogenation, therefore reducing trans-fatty acids.
- **Low Saturate Soybean Oils (Produced by Optimum Quality Grains, L.L.C.)** - This oil is 50 percent less saturated fat than commodity soybean oil (vegetable oil), or approximately 8 percent total saturated fat. A 14-gram serving has just one gram of saturated fat - the same as canola oil. Zero saturated fat can be reached in many formulations when a low saturated soy is used in place of commodity soy.
- **High Oleic Sunflower Oil (Produced by Optimum Quality Grains, L.L.C.)** - As an enhanced-stability oil, high oleic sunflower oil (less than 80 percent oleic) is excellent for use as an ingredient, in cooking or as spray oil, without the need for chemical hydrogenation. New hybrids currently in production are expected to increase oleic acid content to around 85 percent.
- **Chy Max® (fermentation-derived) (Produced by Pfizer, marketed by Chr. Hansen's)** - Chy Max® is another version of chymosin, an enzyme that causes milk to coagulate. It is an advanced fermentation ingredient that is of higher purity, quality and activity than natural rennet.
- **Increased Pectin Tomatoes (Produced by Zeneca Plant Sciences)** - Tomatoes that have been genetically modified to remain firm longer and retain pectin during processing into tomato paste.

Source: BIO Member Survey

APPENDIX II

<u>Agricultural Biotechnology Products Expected on the Market Within Six Years</u>

- **Genetically Engineered Cotton Fiber (Produced by Agracetus, unit of Monsanto Company)** - This biotech product will enhance fiber performance, reduce dye-shop pollution and improve textile manufacturing efficiency.
- **LibertyLink® Soybean, Cotton, Sugar Beet and Rice (Produced by AgrEvo)** - These LibertyLink® crops will be available in Canada and/or the United States. Like LibertyLink® Corn, when used together with Liberty® herbicide, they will allow farmers greater flexibility and environmental soundness in weed control.
- **SeedLink Corn (Produced by AgrEvo)** - These plants provide a more reliable pollination control system for corn seed production. The use of the SeedLink System eliminates the need for hand or mechanical detasseling.
- **IMI™Wheat Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities, public and private laboratories and seed companies to develop wheat varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide contact and residual control of weeds common to wheat production, including ones not controlled by currently registered wheat herbicides.
- **IMI™Rice Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and public and private seed companies to develop rice varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.
- **IMI™Sugar Beet Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and seed companies to develop sugar beet varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.
- **Insect Protected Tomatoes (Produced by Calgene, LLC, unit of Monsanto Company)** - These tomato plants will require less chemical insecticides to achieve higher yields.
- **High-Stearate Oil (Produced by the Calgene, LLC, unit of Monsanto Company)** - High-stearate oil is an ingredient in margarine, shortenings and other food ingredients that would not require hydrogenation, thus reducing the expense.
- **Medium Chain Fatty Acids/Medium Chain Triglycerides (Produced by Calgene, LLC)** - This will be a less-expensive source of raw materials for high-performance lubricants, nutritional formulas and high- energy foods.
- **High Sweetness Tomato (Produced by Calgene, LLC)** - Tomato plants that produce high flavor tomatoes.
- **Genetically Engineered Fruits and Vegetables with Longer Post-Harvest Shelf Life (Produced by Agritope, Inc., a wholly owned subsidiary of Epitope, Inc.)** - Using ethylene-control technology, Agritope, Inc., has created delayed-ripening, longer-lasting tomatoes, raspberries and strawberries.
- **Virus Resistance Tomatoes (Produced by Calgene, LLC)** - These tomato plants will be resistant to infection by certain plant viruses.

- **AquaAdvantage® Salmon, Tilapia, Trout, and Flounder (Produced by A/F Protein)** - The AquaAdvantage® salmon, tilapia, trout and flounder have the capability of growing from egg to market size (8 to 10 lb.) in one to one-and-a-half years. Conventional fish breeding techniques require three years to bring a fish to market. This new salmon could make fish more plentiful, decrease overfishing of wild salmon and lower consumer costs. A/F Protein expects to introduce the AquaAdvantage® salmon within four to six years to a public for whom salmon is an increasingly popular food.
- **Ripening-Controlled Cherry Tomatoes (Produced by DNAP Holding Corporation)** - Using the same technology as in its Endless Summer™ fresh market tomato, the company has developed cherry tomatoes with longer market life, improved flavor and better harvest traits through ripening control.
- **Firmer Peppers (Produced by DNAP Holding Corporation)** - This sweet pepper has been modified using Transwitch® technology to remain firmer after harvest. Pepper plants are currently in field evaluations.
- **Sweeter Peppers (Produced by DNAP Holding Corporation)** - This pepper has been modified to be sweeter and tastier by overexpressing a gene for sweetness. Pepper plants are in early stages of seed increase and field evaluation.
- **Ripening-Controlled Bananas and Pineapples (Produced by DNAP Holding Corporation)** - Using the same ripening control technology as in its Endless Summer™ tomato, the company is developing banana and pineapple varieties with extended market life.
- **Strawberry (Produced by DNAP Holding Corporation)** - The company is improving the market life of fresh strawberries by using Transwitch® technology to keep fruit firmer after harvest and adding genes to resist disease.
- **Messanger™ (Produced by EDEN Bioscience)** - This is the first of a series of products based on the Harpin Protein technology. Harpin Proteins induce disease resistance and promote increased yield in a broad range of agriculture and horticulture crops. Harpin Proteins induce the natural disease immune system and growth pathways inherent within each plant.
- **High-Solids Potato (Produced by Monsanto)** - Monsanto has developed a higher-solids (or starch content) potato by introducing a starch- producing gene from a soil bacteria into a potato plant. With the reduction in the percentage of water in the genetically improved potato, less oil is absorbed during processing, resulting in a reduction of cooking time and costs, better-tasting french fries and an economic benefit to the processor.
- **Roundup Ready® Canola (Produced by Monsanto) -** Roundup Ready canola allows growers to apply Roundup® herbicide over-the-top of the crop during the growing season, for superior weed control with enhanced crop safety.
- **Roundup Ready® Sugar Beets (Produced by Monsanto)** - Roundup Ready sugar beets are tolerant of Roundup® herbicide and provide growers with a new weed-control option while the crop is growing.
- **NewLeaf® Plus (Produced by Monsanto)** - Insect- and virus-protected potatoes. These potatoes are protecting themselves against Colorado potato beetles and potato leaf roll virus.
- **New-Leaf® Y Insect-and Virus-Protected Potatoes (Produced by Monsanto)** - These potatoes protect themselves against the Colorado potato beetle and the potato virus Y.
- **Second-Generation Bollagard® Insect-Protected Cotton (Produced by Monsanto)** - This cotton controls insect pests, like the original Bollagard cotton, but using a different mode of action to help growers manage insect resistance concerns.
- **High-Stearate Soy Oil (Produced by Monsanto)** - This is a functional oil with healthier properties for margarines and shortenings. High-stearate oil requires no hydrogenation and contains no trans-fatty acids, which increase cholesterol.
- **B.t. Sunflower, Soybeans, Canola and Wheat (Produced by Mycogen Corp.)** - These crops will express a protein toxin providing protection against various caterpillar and beetle pests.
- **Fresh Market Tomato (Produced by Zeneca Plant Sciences)** - Zeneca is modifying the tomatoes for enhanced flavor, color and increased antioxidant vitamin content.

- **Banana (Produced by Zeneca Plant Sciences)** - Zeneca is developing an inherent resistance to Black Sigatoka and modifying ripening characteristics in bananas. This will reduce the need for chemical fungicides, as well as improve the agronomics of production and the quality to the consumer.
- **Modified Lignin in Paper Pulp Trees (Produced by Zeneca Plant Sciences under separate agreements with Shell Forestry and Nippon Paper)** - By making lignin easier to remove from cellulose - the primary ingredient in paper - papermakers can make high-quality paper with less energy and bleaching, which benefits both the paper processor and the environment.

Source: BIO Member Survey

Aawork/Agtranspap5 doc.