Universidade de Aveiro Secção Autónoma das Ciências Sociais, Jurídicas e Políticas
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Mariza Fernandes Pinheiro

Agricultura Biotecnológica na China: Um Objectivo Nacional

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Dissertação apresentada à Universidade de Aveiro para cumprimento dos requisitos necessários à obtenção do grau de Mestre em Estudos Chineses, realizada sob a orientação científica do Professor Richard Louis Edmonds, Professor Catedrático Visitante do Departamento de Geografia da Universidade de Londres e Membro Associado do Centro de Estudos Asiáticos da Universidade de Chicago

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palavras-chave

Agricultura biotecnológica, China, políticas, estratégias.

resumo

O presente trabalho propõe-se investigar as políticas de desenvolvimento de agricultura biotecnológica chinesa. Objectivos de investigação, estratégias, prioridades, comercialização e a organização institucional para o desenvolvimento da agricultura biotecnológica são examinados. Incluída está também uma descrição da avaliação dos regulamentos sobre a biosegurança na China, bem como a construção da capacidade de investigação e o investimento público – um dos maiores esforços de investimento público em agricultura biotecnológica no mundo. O objectivo deste trabalho é obter um maior entendimento dos principais processos políticos relacionados com agricultura biotecnológica, para poder identificar potenciais temas para subsequente investigação.

keywords

Agricultural biotechnology, China, policies, strategies

abstract

This dissertation researches China's agricultural biotechnology development policies. Research goals, strategies, priorities, commercialization, and China's organizational framework for agricultural biotechnology development are examined. Included is a description of the evaluation of China's biosafety regulations as well as China's research capacity building and public investment – one of the largest public research efforts on agricultural biotechnology in the world. The goal of this dissertation is to have a better understanding of the main features of policy and policy processes surrounding agricultural biotechnology to identify potential issues for subsequent research.

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Introduction

Introduction

During the past decade, China accelerated its investments in agricultural biotechnology research and developed the largest plant biotechnology capacity outside of North America. It is often forgotten that China was the first country to grow a transgenic crop commercially – tobacco. After having 1.6 million hectares planted with GM tobacco in 1996, China discontinued growing GM tobacco due to concerns that tobacco processors, mostly from the U.S., would ban Chinese imports of tobacco because it was genetically modified.

In a rapidly growing area of GM plants, China has become the fourth largest grower of GM crops after the United States, Argentina, and Canada.

In developing countries with a high population pressure, genetically modified organisms (GMOs) might be a ready way to solve food security and this can be a reason for hasty adoption, though this promise is not being fulfilled by industry. Food shortage is particularly imminent for China, which houses one-fifth of the world population.

In 1995, the scientist Lester Brown shocked the Chinese government, and received much criticism, with his prediction that the People's Republic would face critical food shortages in the future. In China the average area of farmland per capita is only one-third of the world average. Many experts say that high yield and disease resistant genetically modified (GM) crops may help developing nations like China and India feed their growing populations. GM foods might thus provide an attractive solution to the Chinese government.

China has enthusiastically pursued genetically modified products in its drive to be self-sufficient in food supplies for its 1.3 billion people. Proponents contend that genetically altering crops to resist pests, drought or other adverse conditions may be the only way to ensure food security in the developing world, particularly in densely populated Asia. But the technique of splicing genes from one organism into another has also provoked fears of unforeseen hazards to health and the environment. Although, the country has not seen the level of heated debate that has raged in Europe and elsewhere over their safety.

Two 21st century megatrends – China's likely emergence as an economic colossus and the global rise of commercial life science – are coming together. For this nexus yield a world-class biotech industry will probably take a decade or more: turning science into commerce requires a commercial infrastructure with lots of venture capitalists, strong patent protections, and vibrant stock exchanges – the product of a daunting process of legal and cultural change that China has only just begun. Whatever the future will bring, the Chinese government is stepping up its efforts to control the biotechnological sector.

China is fast applying the latest life science techniques learned from the West to aggressively pursue genome research. It is establishing its own centres of technical excellence to build a scientific base to compete directly with the US and Europe. With a plentiful supply of smart young scientists at home and lots of interest abroad, biotechnology is on the brink of a boom in China. Potential profits aside, achievements in the field will help put to rest perennial fears in China about food security. They also will place the country amongst a vanguard of innovators in an industry that is changing the world as fundamentally as the communications revolution has in the past decade. In the view of foreign scientists, Beijing is playing a clever hand, maximizing the opportunities open to them.

China considers agricultural biotechnology a strategically significant tool to improve its national food security, raise agricultural productivity, and create a competitive position in international agricultural markets. China also intends to position itself as a world leader in biotechnology research. This objective also addresses the perception that policy makers have of the risk associated with the dependence of national food security on imported technologies. Despite the growing debate worldwide on GM crops, China has developed agricultural biotechnology decisively since the mid-1980s. China was the first country to commercialize a GM crop and was the fifth country in terms of GM crop area in 2003. China has about 20 genetically modified plants that are in the pipeline for commercialization.

This work will show that China's efforts in promoting biotechnology research have increased over time. Most efforts have been made to improve research capacity, increase the stock of knowledge and technology, and promote commercialization of the biotechnology significantly needed by farmers (i.e., Bt cotton). Research capacity in terms of both quantity and quality has improved significantly. The share of professional staff holding a PhD degree in biotechnology research is the highest in China's agricultural research system. On the other hand, human capacity may need further improvement if

China intends to establish an internationally competitive biotechnology research program and to achieve the overall goal of promoting agricultural biotechnology in China.

A remarkable event has been the growth of government investments in agricultural biotechnology research. In contrast to stagnating expenditures on agricultural research in general, investments in agricultural biotechnology have increased significantly since the early 1980s. In spite of the fact that the number of researchers increased rapidly over the past 15 years, investment measured as expenditure per scientist more than doubled.

Examination of the research focuses of agricultural biotechnology research reveals that the food security objective and the current farmers' demands for specific traits and crops have been incorporated into priority setting. Moreover, the current priority setting of investments in agricultural biotechnology research has led to investment in favor of the commodities in which China does not have relative comparative advantage in the international market such as grain, cotton and oil crops, which implies that China is targeting its GMO products at the domestic market. However, the impact of the current priority setting on poverty is not clear.

The rise of China in the 21st Century to coincide with the Biology Century is not only of symbolic importance but also holds great promise not just for China but for the biotechnology industry as a whole. After the breakthroughs of biotechnology in recent times, and the dotcom crash of recent years, thus diverting venture funds elsewhere to other growth industries, the stage is set for biotechnology to boom. Therefore, the growth of biotechnology in China is like biotechnology itself, multifaceted, multidisciplinary and multiplier, making the economy expand in explosive terms. The country has an excellent set of comparative advantages when compared to other countries. China is a country that is a paradise and heaven for the development of biotechnology. It has the market, it has the talents, the resources, and the great biotechnological research and development work that have actually gone on for thousands of years already. China, with its own remarkable achievements in recent years is where the biotechnological researchers and "scientrepreneurs'" dream come true.

There are other important questions that require attention, and that are going to be made throughout this study. Should China continue to investment only its own resources in biotechnology or can China rely more on imported technology? Can China define the appropriate mix and trade-offs between domestic and imported technologies? What are the implications of the current biotechnology development on the income and welfare of the poor? How can China incorporate the objective of poverty alleviation into the priority setting of biotechnology research? Does China need to continue expanding its biotechnology at the sub-national level? How can biotechnology programs at different levels (and within the same level) be coordinated to maximize the efficiency of the research investment?

This study will be divided into two Parts, which will then be divided into Chapters.

Part I attempts to summarize the concept of agricultural biotechnology worldwide. The study of agricultural biotechnology in China is better understood when looking at the general environment that surrounds it. It explores the frontiers of agricultural biotechnology and places it in the broader context of the production, conservation and management goals that researchers are addressing. Most of the controversies surrounding biotechnology focus on transgenic crops, but these innovations represent only a tiny fraction of the technical possibilities offered by biotechnology in crops. Genetic engineering is both a more precise extension of breeding tools that have been used for decades and a radical departure from conventional methods. It is the ability of genetic engineering to move genes across species barriers that gives it its tremendous power and that makes it so controversial. Part I is divided in four chapters.

Chapter I introduces the definition of biotechnology and agricultural biotechnology in a scientific context.

Chapter II reviews the risks and benefits associated with transgenic crops. Scientists have determined that the transgenic products currently on the market are safe to eat, although they recommend ongoing monitoring and that newer, more complex products may need additional food safety procedures. The potential environmental impacts of transgenic crops provoke greater disagreement among scientists. They generally agree on the types of hazard that exist, but they disagree on their likelihood and severity. Thus far, none of the major environmental hazards potentially associated with transgenic crops has developed in the field. Scientists agree that transgenic crops must be evaluated on a case-by-case basis taking into consideration the crop, the trait and the agro-ecosystem in which it is to be released. Scientists also agree that regulation should be science-based, but that judgement and dialogue are essential elements in any science-based regulatory framework.

The scientific evidence concerning the environmental and health impacts of genetic engineering is still emerging. Scientists generally agree that the transgenic crops currently being grown and the foods derived from them are safe to eat, although little is known about their long-term effects. There is less scientific agreements on the environmental impacts of transgenic crops. Scientists generally agree on the nature of the potential environmental risks, although they differ regarding their likelihood and consequences. There is strong consensus among scientists concerning the need for a case-by-case evaluation that considers the potential benefits and risks of individual genetically modified organisms (GMOs) compared with alternative technologies.

Chapter III makes a brief overview of role of agricultural biotechnology in promoting food security and poverty and hunger alleviation worldwide and in China. The Green Revolution, which lifted millions of people out of poverty, came about through an international program of public-sector agricultural research specifically aimed at creating and transferring technologies to the developing world as free public goods. The Gene Revolution, by contrast, is currently being driven primarily by the private sector, which naturally focuses on developing products of large commercial markets. This raises serious questions about the type of research that is being performed and the likelihood that the poor will benefit.

Chapter IV reviews the global status of agricultural biotechnology, from 1996 to 2003, according to data reported by Clive James and other researchers.

Part II analyzes agricultural biotechnology in China and it is divided in four chapters. Chapter I traces a historical overview of technology and biotechnology in China. Chapter II makes an analysis of China’s agricultural biotechnology development and strategies. The nation’s public-dominated research system that has been given a clear mandate to emphasize food security also has given China’s researchers a strong incentive to produce GM crops that increase yields and prevent pest outbreaks. The information on the scope of new plant biotechnologies produced by China illustrates the differences in their research priorities when compared to different parts of the world, differences that may reflect the fact that China’s research is done by the public sector while in other countries much of the work is being done by the private sector.

Chapter III recalls China’s agricultural biotechnology research institutions and administrative system. The statistics on biotechnology research investment and human capacity will be based on a survey of 29 of China's leading plant biotechnology research institutes, a sample that includes information on more than 80 percent of the plant biotechnology programs in China.

Chapter III also tracks the record that the nation has achieved in the extension of Bt cotton, the case of one of the earliest and the largest episodes of the commercialization of plant biotechnology in China. The determinants of adoption and the effect that the new technology has had on production, the environment, and the health of farmers are analyzed.

The institutional framework for supporting agricultural biotechnology research program is complex both at the national and local levels. However the current institutional arrangements show that the coordination among institutions and consolidation of agricultural biotechnology programs are taking place and have become essential for China to create a stronger and more effective biotechnology research program in the future.

Chapter IV gives an overview of biosafety management and regulation in China. It looks at the politics of biosafety regulation in China and policy processes around GM crops. What implications are associated with them? In China, biosafety decision-making is one key area where agricultural biotechnology policy is defended and contested. The chapter looks at how regulatory decisions about imports of GM soybeans have used scientific arguments strategically to defend China's nascent biotech industry and the country's room for manoeuvre in relation to agricultural trade and food security policy choices.

This study tries to go beyond describing China's agricultural biotechnology research, policies, administration and infrastructure. It tries to understand the causes and consequences of agricultural biotechnology policies undertaken by the Chinese Government. Why is agricultural biotechnology a national goal? Is food security concerns the main reason for the development of agricultural biotechnology in China, or is China positioning itself to be the world leader in agricultural biotechnology in coming years? What should be the role of China's emergence as an agricultural biotechnology trading nation, and its rising strength in plant biotechnology research, production and commercialization?

In order to better understand China's role of agricultural biotechnology worldwide at the moment, this work will rely on different and diverse sources and data, which are by no means comprehensive in their overview of Chinese interest and importance in agricultural biotechnology. It is, therefore, my objective to present and to analyze as much information on this topic as possible in order to understand the reason why agricultural biotechnology is of major importance for the Chinese policymakers, in particular, and the Chinese population, in general. In short, this work will try to establish why agricultural biotechnology has become for the Chinese a national goal.

PART I
Agricultural Biotechnology in the World: An Overview

Chapter I
Scientific Context of Biotechnology

1 - Definitions of Biotechnology and Agricultural Biotechnology

Biotechnology is far too diverse and diffuse for any brief definition to be completely satisfactory. Biotechnology, broadly defined, includes any technique that uses living organisms, or parts of such organisms, to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. It ranges from traditional biotechnology to the most advanced modern biotechnology. Biotechnology is not a separate science but rather a mix of disciplines (genetics, molecular biology, biochemistry, embryology, and cell biology) converted into productive processes by linking them with such practical disciplines as chemical engineering, information technology, and robotics. Modern biotechnology should be seen as an integration of new techniques with the well-established approaches of traditional biotechnology such as plant and animal breeding, food production, fermentation products and processes, and production of pharmaceuticals and fertilizers (Doyle and Persley, 1996).

The key components of modern biotechnology are listed below:

- Genomics: The molecular characterization of all genes in a species.
- Bioinformatics: The assembly of data from genomic analysis into accessible forms, involving the application of information technology to analyze and manage large data sets resulting from gene sequencing or related techniques.
- Transformation: The introduction of one or more genes conferring potentially useful traits into plants, livestock, fish and tree species.
- Genetically improved organism.
- Genetically modified organism (GMO).
- Living modified organism (LMO).
- Molecular breeding: Identification and evaluation of useful traits in breeding programs by the use of marker-assisted selection (MAS).
- Diagnostics: The use of molecular characterization to provide more accurate and quicker identification of pathogens.
- Vaccine technology: The use of modern immunology to develop recombinant deoxyribonucleic acid (rDNA) vaccines for improved control of livestock and fish diseases.

Cohen (1999) quoted in FAO (2004) proposes another definition of biotechnology. In this definition, biotechnologies are the products arising from cellular or molecular biology and the resulting techniques coming from these disciplines for improving the genetic makeup and agronomic management of crops and animals. These techniques include fermentation, microbial inoculation of plants, plant cell and tissue culture, enzyme technologies, embryo transfer, protoplast fusions, hybridoma or monoclonal antibody technology and recombinant DNA (rDNA) technologies. This definition allows for a focus on products arising from the research continuum between traditional and modern biotechnology. The artificial segregation between modern and traditional biotechnologies will certainly disappear, as laboratories world-wide incorporate modern biotechnology techniques into their daily research operations.

Biotechnology also can be defined as the application of our knowledge and understanding of biology to meet practical needs. By this definition, biotechnology is as old as the growing of crops and the making of cheese and wines. Today’s biotechnology is largely identified with applications in medicine, and agriculture based on our knowledge of the genetic code of life. Various terms have been used to describe this form of biotechnology including genetic engineering, genetic transformation, transgenic technology, recombinant DNA (deoxyribonucleic acid) technology, and genetic modification technology (National Academy of Sciences, 2000).

According to the Convention on Biological Diversity (CBD), biotechnology means “any technological application that uses biological systems, living organisms, or derivates thereof, to make or modify products or processes for specific use”. Interpreted in the broad sense, the definition covers many of the tools and techniques that are commonplace today in agriculture and food production. Interpreted in a narrow sense, biotechnology mainly covers technological applications involving reproductive biology, or, secondly, the manipulation, or use, of the genetic material of living organisms for specific uses. This definition covers a wide range of diverse technologies including, for example, the use of molecular DNA (deoxyribonucleic acid) markers, gene manipulation and gene transfer, vegetative, reproduction (crops and forest trees), embryo transfer and freezing (livestock) and triploidization (fish).

Agricultural Biotechnology is that area of biotechnology involving applications to agriculture. In the broadest sense, traditional biotechnology has been used for thousands of years, since the advent of the first agricultural practices, for the improvement of plants, animals, and microorganisms (Persley *et al.*, 1999).

2 – The History of Biotechnology

For thousands of years humankind has been taking advantage of the activities of micro-organisms to produce foodstuffs and drinks without understanding the microbial processes (fermentation). The ancient Egyptians applied mouldy bread to infected wounds for its antibiotic effect – today we turn that the mould into penicillin. Also, the fermentation of fruits and grains to make wine, beer and spirits has been going on all over the world for thousands of years.

To understand why biotechnology is becoming a major influence at this time, it is useful to review a number of significant advances in modern biotechnology over the past two decades. A chronology of the development of modern biotechnology is given in Table 1.

Table1 – The evolution of the science of genetics, leading to modern biotechnology.

1866	Mendel postulates a set of rules to explain the inheritance of biological characteristics in living organisms.
1900	Mendelian law rediscovered after independent experimental evidence confirms Mendel's basic principles.
1903	Sutton postulates that genes are located on chromosomes.
1910	Morgan's experiments prove genes are located on chromosomes.
1911	Johannsen devises the term "gene", and distinguishes genotypes (determined by genetic composition) and phenotypes (influenced by environment).
1922	Morgan and colleagues develop gene mapping techniques and prepare gene map of fruit fly chromosomes, ultimately containing over 2000 genes.
1944	Avery, MacLeod and McCarty demonstrated that genes are composed of DNA rather than protein.
1952	Hershey and Chase confirm role of DNA as the basic genetic material.
1953	Watson and Crick discover the double-helix structure of DNA.
1960	Genetic code deciphered.
1971	Cohen and Boyer develop initial techniques for rDNA technology, to allow transfer of genetic material from one organism to another.
1973	First gene (for insulin production) cloned, using rDNA technology.
1974	First expression in bacteria of a gene cloned from a different species.
1976	First new biotechnology firm established to exploit rDNA technology (Genentech in USA).
1980	USA Supreme Court rules that microorganisms can be patented under existing law (Diamond v. Chakrabarty).
1982	First rDNA animal vaccine approved for sale in Europe (colibacillosis).
	First rDNA pharmaceutical (insulin) approved for sale in USA and UK.
	First successful transfer of a gene from one animal species to another (a transgenic mouse carrying the gene for rat growth hormone).
	First transgenic plant produced, using an agrobacterium transformation system.
1983	First successful transfer of a plant gene from one species to another.
1985	US Patent Office extends patent protection to genetically engineered plants.
1986	Transgenic pigs produced carrying the gene for human growth hormone.
1987	First field trials in USA of transgenic plants (tomatoes with a gene for insect resistance).
	First field trials in USA of genetically engineered microorganism.
1988	US Patent Office extends patent protection to genetically engineered animals.
	First GMO approved. Human genome mapping project initiated.
1989	Plant genome mapping projects (for cereals and *Arabidopsis*) initiated.
2000	Plant genome mapping projects for rice and Arabidopsis completed, and about 44 million hectares of land planted to GMO crops.

DNA = deoxyribonucleic acid, GMO = genetically modified organism, rDNA = recombinant DNA, UK = United Kingdom, USA = United States of America.
Source: Asian Development Bank (ADB), 2001.

Genetic improvement as we know it today is the result of a lengthy process of research and scientific discoveries that occurred throughout the 20th Century. Though plant breeding existed for thousands of years, it became a scientific endeover only after Gregor Mendel formulated his laws on inheritance in 1866. Mendel's basic discovery was that each heritable property in any living organism is determined by a physical factor contained within the cell of the organism.

In the 1930s and 1940s, several new methods of chromosome and gene manipulation were discovered, such as the use of colchicines to achieve a doubling in chromosome number, commercial exploitation of hybrid vigor in maize and other crops, use of chemicals such as nitrogen mustard and ethyl methane sulphonate to induce mutations and techniques like tissue culture and embryo rescue to get viable hybrids from distantly related species (Swaminathan, 2000).

In 1953 James Watson and Francis Crick discovered the double helix structure of DNA (deoxyribonucleic acid), the chemical substance of hereditary. DNA is the molecular blueprint for life and codes for the proteins that perform the functions of cells. DNA consists of a series of molecules called bases that join together to form a linear strand. DNA contains four types of bases termed adenine (A), thymine (T), guanine (G) and cytosine (C). The order in which these bases occur on the DNA strand determines what information is carried by that strand. This information is divided into regions that are called genes. Each gene codes for a specific protein. The technique allows molecular biologists to "decode" the information held in an organism's DNA.

This triggered explosive progress in every field of genetics. From the discovery fifty years ago of the structure of DNA, scientists soon came to realize they could take segments of DNA that carried information for specific traits – genes – and move them into another organism. In 1972, the collaboration of Hubert Boyer and Stanley Cohen resulted in the first isolation and transfer of a gene from one organism to a single – celled bacterium where it would express the gene and manufacture a protein. Their discoveries led to the first direct use of biotechnology – the production of synthetic insulin to treat people with diabetes – and the start of what is often called modern biotechnology (Babinard, 2001).

By the late 1970s, both human growth hormone and human insulin had been produced in bacteria and in 1980 the first patent for a genetically modified microorganism was granted in the US (Manning, 2000).

The first microorganism patented granted in the US and the granting of the Cohen-Boyer process patent for their genetic transfer technique in the 1980 generated a rapidly growing interest in biotechnology and in its commercial applications (Babinard, 2001). This was rapidly followed by the development of GM plants and their patenting in 1985. The first genetically modified animal was patented in 1988 (Manning, 2000). The first wave of agricultural biotechnology products initiated in the early 1990s has benefited farmers and producers by providing agronomic traits that make it easier to grow crops while reducing production costs. The products are primarily modified to include pest or herbicide resistance genes. Biotechnology is also being applied with some success in the livestock sector (Babinard, 2001).

3 – Techniques of Genetically Modified Organisms (GMOs)

3.1 – Recombinant DNA Technology

Deoxyribonucleic acid (DNA) and its sister compound ribonucleic acid (RNA) are vital components of many biotechnological applications. The molecular biology revolution that has occurred in the last twenty years and created so many new biotechnological opportunities is fundamentally based on the ability to precisely manipulate DNA (Johnson-Green, 2002).

The prime role of DNA is to act as a reservoir of genetic information. This is possible because of the following structural features of DNA:

- DNA is a double helix made up of two antiparallel strands.
- Each strand is made up of a backbone of deoxyribose monosaccharides linked covalently through phosphate bridges.
- Each deoxyribose unit is linked covalently to a base consisting of either adenine (A), guanine (G), cytosine (C), or thymine (T).
- Two antiparallel strands, through hydrogen bonding between adjacent base pairs, can form a stable double helix.
- Hydrogen bonds from between complementary base pairs (C-G and A-T).

- Three linear bases on a strand code for a specific amino acid – this allows a linear sequence of bases on a strand of DNA to code for a linear sequence of amino acids on a polypeptide. Each group of three bases is a codon (Johnson-Green, 2002).

The gene is the basic functional unit of inheritance and each gene consists of a DNA molecule which enables an organism to make a particular protein together with the "molecular switches" that determine when and where each gene is active. The DNA sequence (genetic code) of each gene specifies the protein to be made when the gene is active (Robinson *et al.*, 2000).

Genetic modification allows selected individual genes discovered in one organism to be inserted directly into another. This can be a related or unrelated species. Since the way particular genes function is similar in most organisms, genes or part of genes from one organism can generally be transferred to any other organism. The transferred gene is called the transgene. Genetic modification can be used to promote a desirable crop character or to suppress an undesirable trait. The technology is also sometimes called gene technology, recombinant DNA technology or genetic engineering. Practical and functional methods have now been developed to modify most of our major crops (Nuffield Council on Bioethics, 2003). Furthermore, in the development of gene technology, DNA can be isolated from an organism and its sequence (genetic code) determined. DNA molecules can be chemically synthesized and can be copied in a test tube or by using bacteria as "DNA factories" to multiply specific DNA molecules. In this way, individual genes can be identified and new combinations of genetic material can be made. The order of the four constituent bases that make up DNA (its sequence) determines what product the gene will make in a cell, but the chemical and physical properties of DNA are essentially the same in all organisms. This common feature of DNA makes it possible to transfer genes from one organism to another. There is significant overlap in genes across a wide range of organisms; for example, bacteria, fungi, plants and animals all contain the same basic set of genes responsible for cell synthesis and function (Robinson *et al.*, 2000).

The major breakthrough in the development of recombinant DNA technology was the ability to clone genes. This refers to the process of isolating a specific gene from an organism's genome (the entire set of genetic information in an organism).

In general terms, genes are usually cloned by inserting fragments of a genome into a vector. A vector is an agent that can be used to move DNA segments from one organism to another.

Plasmids, small circular double-stranded DNA molecules that are capable of replication within their host cell, are commonly used as vectors. Once a plasmid vector has been inserted into a cell, the cell that contains the desired gene can be located and separated from cells that contain other fragments of DNA.

Gene cloning allows careful study of a gene's sequence and properties, and it also allows the gene to be transferred to a wide variety of organisms. Thus, a gene isolated from a bacterium can be transferred to another bacterium, a plant, or an animal. In some cases, gene transfer is relatively easy; in others (e.g., inserting a gene into a multicellular animal), it is much more challenging and complex. A defining feature of molecular biotechnology is the ability to transfer specific genes from organism to organism without the restrictions of incompatibility that otherwise apply (e.g., animals will breed successfully only with animals of the same species) (Johnson-Green, 2002).

The basic techniques of gene cloning were developed in the mid-1970s. A product of direct gene transfer is considered to be recombinant, because its genome now consists of DNA from different organisms. The transfer process is known as genetic engineering, and in the popular media, the products are known as genetically modified organisms (GMOs). GMOs are often described as "transgenic"; that is, they contain genetic material from another organism.

3.2 – Comparing Traditional Breeding with Modern Biotechnology

Around ten to twelve thousands years ago humans began to cultivate plants and herd animals for food. They probably also began to breed these crops and animals. Over succeeding generations, the nutritional qualities of various plants and animals were stabilised and improved. Continued cross breeding and selection, conducted mainly by farmers for desirable traits in plants and animals, have resulted in slow improvement in domestic species (Abdalla *et al.*, 2003)

Conventional plant breeding involves cross-hybridization between two parents and selection of the best offspring for further breeding. In this process, large blocks of genetic material (i.e. thousands of genes) are mixed, generating numerous new combinations of genes. Over several successive generations, plant breeders are able to introduce and stabilize new genes, such as those providing disease resistance from a wild relative, into existing varieties and then gradually remove most of the unwanted new genes that were also transferred in the first cross (Robinson *et al.*, 2000).

In the mid-1970s, plant scientists were quick to see the potential of recombinant DNA technology to revolutionize plant breeding.

Conventional plant breeding is often understood as the selection of particular individuals from a great variety of naturally occurring types of plants. This activity tends to be seen as natural. Many would also view the systematic interbreeding of naturally occurring types of plants in the same vein. However, plant breeders also create plants which would not be achievable by judicious interbreeding, using techniques such as wide-crossing. This has led to completely new varieties such as Triticale (a hybrid between wheat and rye). Another technique, mutation breeding, involves the exposure of plants and seeds to radiation or chemical substances. These procedures have been, and still are being used to produce many important staple crops around the world. Thus, it is important to note that the deliberate alteration of plants as they occur in nature has been practised and accepted for several decades. In this context, genetic modification can be seen as a new means to achieve the same end; it is certainly used in that way. It differs from conventional plant breeding in that it can allow for much faster and more precise ways of producing improved crops (Nuffield Council on Bioethics, 2003).

The application of recombinant DNA technology to facilitate genetic exchange in crops has several advantages over traditional breeding methods. The exchange is far more precise because only a single (or at most, a few), specific gene that has been identified as providing a useful trait is being transferred to the recipient plant. As a result, there is no inclusion of ancillary, unwanted traits that need to be eliminated in subsequent generations, as often happens with traditional plant breeding (Persley *et al.*, 1999).

Application of recombinant DNA technology to plant breeding also allows more rapid development of varieties containing new and desirable traits. Further, the specific gene being transferred is known so the genetic change taking place to bring about a desired trait also is known, which often is not the case with traditional breeding methods where the fundamental basis of the trait being introduced may not be known at all. Finally, the ability to transfer genes from any other plant or other organism into a chosen recipient means that the entire span of genetic capabilities available among all biological organisms has the potential to be genetically transferred or used in any other organism. This markedly expands the range of useful traits that ultimately can be applied to the development of new crop varieties (Persley *et al.*, 1999). Therefore, the major advantage of the transgenic approach over traditional approaches is that theoretically any organism can be a source of transferred genetic material.

Genes can be transferred from distantly related plants, from bacteria, fungi, or viruses, and even from animals. Furthermore, the potential exists for exquisite control over the activity of transferred genes, in terms of the amount and the timing of gene expression (Johnson-Green, 2002).

In nature, there are a few instances where genetic material is transferred from one organism to another – usually by a form of infection. One of the most common methods used to insert genes into a plant exploits the natural ability of the gall forming soil bacterium, *Agrobacterium tumefaciens*, to incorporate its DNA into a host plant (Robinson *et al.*, 2000).

Agrobacterium naturally infects a wide range of plants and it does so by inserting some of its own DNA directly into the DNA of the plant. By taking out the undesired traits associated with *Agrobacterium* infection and inserting a gene(s) of interest into the *Agrobacterium* DNA that will ultimately be incorporated into the plant's DNA where they are inserted into chromosomes to become a permanent part of the genome (any desired gene can be transferred into a plant's DNA following bacterial infection). The cells containing the new gene subsequently can be identified and grown using plant cell culture technology into a whole plant that now contains the new transgene incorporated into its DNA (Persley *et al.*, 1999).

3.3 – Transgenic Plants

Genetic modification of plants involves the targeted introduction of a small number of selected genes (usually two) into an existing plant variety to affect its performance. This will normally involve the target gene, which will improve the plant, plus a selectable marker gene to allow scientists to rapidly identify and isolate those cells that have taken up the target gene. To date, the marker genes most commonly used produce a characteristic, such as herbicide or antibiotic resistance, to allow positive selection of the GM cells. New marker genes are presently being developed that do not involve antibiotic or herbicide resistance and are only manifested in the laboratory. In some crops, it is also possible to delete the marker gene after the genetic modification has been achieved. Both the target and marker genes will have controlling elements (promoters and terminators) that are the "molecular switches" to control when the genes are turned on and off and to specify the tissues where the genes will be active. The controlling elements from plant virus genes have been found to be effective in plants and are often used to switch on the introduced genes (Robinson *et al.*, 2000).

Although several methods of plant transformation have been used, only two are relevant today to the transformation of food crops. These are the biolistics or "gene gun" and *Agrobacterium*. Since both these methods have been patented, we can expect that other methods will continue to be developed in order to circumvent these patents. Both methods have advantages and disadvantages, depending on the application and the crop (Nuffield Council on Bioethics, 1999).

In the biolistics or "gene gun" method, gold or tungsten micro-particles are coated with transgene constructs and fired into target cells or tissues. Initially the projectiles were propelled by gunpowder. Later versions of the "gene gun" have used compressed helium gas or electro-volatilized water propulsion (Nuffield Council on Bioethics, 1999 and Widhom, 2001). One or more copies of the transgene construct are integrated into the chromosomes of the target cells. Such methods initially required a sophisticated laboratory environment. However, portable hand-held guns have recently been developed to make the technology more widely available (Nuffield Council on Bioethics, 1999).

The other commonly used method utilizes the natural genetic engineer, a bacterium, *Agrobacterium tumefaciens,* which can transfer a defined piece of its own DNA into plant cells at wound sites. Normally the DNA placed in the plant cells by *A. tumefaciens* carries genes to make plant growth hormones, causing abnormal tissue growth to produce galls, resulting in the so-called crown gall disease (Widhom, 2001). The attenuated strains used as carriers or vectors by plant genetic engineers have had their plant gall-inducing ability removed. The modified vector is then transformed to carry the engineered gene constructs before being introduced into a host plant cell. The new genes then integrate into the host

DNA of the plant (Nuffield Council on Bioethics, 1999). It was initially assumed that *A. tumefaciens* could only transfer DNA to dicotyledonous plants such as tobacco and grapes since crown gall disease was not found on monocotyledonous crops such as cereals. However, recent research has shown that *A. tumefaciens* can insert genes into cereals such as rice (Widhom, 2001).

This method has the advantage that it is relatively simple and can be applied by any laboratory with suitable tissue culture facilities. Occasionally, DNA from the bacteria may get transferred in addition to the transgene and it is possible that the carrier itself may persist in or on transformed plants for up to a year after transformation. These technical difficulties have been criticised as the inadvertent transfer of genetic material and the introduction of live-engineered bacteria into the environment (Nuffield Council on Bioethics, 1999).

The use of *A. tumefaciens* has an important advantage over biolistics. The bombardment procedure often inserts multiple gene copies that can be rearranged in undesirable ways while the *A. tumefaciens* system in more likely to result in the insertion of one copy of the correct, full-length DNA fragment since the bacterium has the ability to direct the specific fragment to the plant nucleous (Widhom, 2001).

All plant transformation methods in use today suffer from the fact that the transgene(s) cannot be directed to any particular point on the host chromosomes. Incorporation into the host DNA is more or less at random. Since the location of the transgene in the host's DNA can affect the efficiency with which it is expressed, it is often necessary for the researcher to produce many individual transgenic plants to ensure that an effective breeding group or line with the desired characteristics can be selected from them. These plants will then be bred conventionally (Nuffield Council on Bioethics, 1999).

The most widely used transgenic pest-protected plants express insecticidal proteins derived from the bacterium *Bacillus thuringiensis* (Bt). Bt is a naturally occurring soil-borne bacterium found worldwide. Bt forms asexual reproductive cells, called spores, which enable it to survive in adverse conditions. During the process of spore formation, Bt also produces unique crystal-like or "Cry" proteins. When eaten by a susceptible insect during its feeding stage of development (as larvae), the crystal acts as poison. The insect's digestive enzymes activate the toxin. The "Cry" proteins bind to specific receptors on the intestinal lining and rupture the cells. Insects stop feeding within two hours of a first bite and if enough toxin is eaten, die within two or three days (Nelson, 2001).

A unique feature of Bt as a pesticide is that a specific “Cry” protein is toxic only to specific groups of insects and has no effect on mammals. These characteristics make various Bt insecticides very desirable generally and crucial to the organic food industry (Nelson, 2001).

3.3.1 – Introduced Traits by Genetic Engineering

Most commonly, the improvement of plants aims to increase the yield or quality of crops. Yield is influenced by many factors including pests, diseases, soil conditions, or abiotic stresses which stem from unfavourable climatic conditions. Significant improvements can often be achieved by means of irrigation, the application of insecticides or pesticides and the addition of fertiliser. However, most of these interventions are expensive, particularly for small-scale farmers in developing countries. The use of genetic modification provides plant breeders with new opportunities to produce crops that are protected from environmental stresses and attacks from pathogens and insects. The following list gives examples of traits that researchers aim to develop by means of genetic modification. Some of these are still in early stages of development, while others have been achieved more recently in the laboratory setting. A few are in field trials, or can already be found in crops used by farmers. In some cases the traits can be arrived at by conventional breeding, while others are achievable only by genetic modification.

- **Herbicide tolerance crops** The mostly wide adopted bioengineered crops have been those with herbicide-tolerant traits. These crops were developed to survive the application of specific herbicides that previously would have destroyed the crop along with the targeted weeds, and provide farmers a broader variety of herbicide options for effective weed control. A transgene confers tolerance to a specific herbicide. This trait allows farmers to apply a herbicide which acts on a wide range of weeds while not affecting the modified crop. The most common herbicide tolerant crops are crops resistant to glyphosate, an herbicide effective on many species of grasses, broadleaf weeds, and sedges. Glyphosate tolerance has been incorporated into soybeans, corn, canola, and cotton. Other GE herbicide-tolerant crops include corn that is resistant to glufosinate-ammonium, and cotton that is resistant to bromoxynil. The adoption of most herbicide-tolerant crops has been particularly rapid and are mainly grown in developed countries with the primary aim of reducing applications of herbicides (Fernandez-Cornejo *et al.*, 2002 and Nuffield Council on Bioethics, 1999). According to proponents of HRCs, this technology represents an innovation that enables farmers to simplify their weed management requirements, by reducing herbicide use to post-emergence situations using a single, broad-spectrum herbicide that breaks down relatively rapidly in the soil. Herbicide candidates with such characteristics include glyphosate, bromoxynil, sulfonylurea and imidazolinones, among others. However, in actuality the use of herbicide-resistant crops is likely to increase herbicide use as well as production costs. It is also likely to cause serious environmental problems (Altieri, 1999).

- **Insect/pest resistance crops** Crops inserted with insect-resistant traits have also been widely adopted. Bt crops containing the gene from a soil bacterium, *Bacillus thuringiensis*, are the only insect-resistant crops commercially available. The bacteria produce a protein that is toxic when ingested by certain Lepidopteran insects (insects that go through a caterpillar stage). The Bt technology is a novel approach to controlling insects because the insecticide is produced throughout the plant over its entire life. Therefore, the insecticide is more effective than conventional and biological insecticides because it cannot be washed off by rain or broken down by other environmental factors. Bt has been built into several crops, including corn and cotton. Bt corn provides protection mainly from the European corn borer. Bt cotton is primarily effective in controlling the tobacco budworm, the bollworm, and the pink bollworm (Fernandez-Cornejo *et al.*, 2002).
- **Bacterial, fungal and viral resistance** Plants suffer from many diseases; some are physiological, caused by drought stress, mineral deprivation, and other environmental causes, but infectious agents (pathogens) also cause disease, reducing the amount of harvestable food by about 15% globally. In declining order of importance, fungi, viruses, and bacteria are the pathogens responsible for infectious plant disease, and fungi are responsible for most post-harvest food spoilage. Here a transgene makes crops resistant to biotic stresses such as plant pathogens which often reduce yields substantially. Examples of crops in which

these traits are being introduced include coffee, bananas, cassava, potato, sweet potato, beans, wheat, papaya, squash and melon. In some cases the transgenes used are genes which occur naturally in the same species (Nuffield Council on Bioethics, 1999).

- **Abiotic stress resistance** In the past, plant breeders mainly concentrated on increasing yield, and rarely ventured to increase crop stress tolerance. However, plant scientists have become increasingly aware that abiotic stresses have strong effects on yield. Increasing stress tolerance of staple food crops is an important goal for both traditional plant breeders and biotechnologists. The most serious abiotic stress in most parts of the world is water availability. Dry or saline soil seriously affects growth of crops. Dry soil is linked to climate, but saline soil is often exacerbated by agricultural practices. Excessive irrigation, for example, can lead to saline soil, because irrigation water always contains a certain level of ions; when the soil dries, these ions become more concentrated and interfere with crop water uptake (Johnson-Green, 2002). The ability of some plants to survive in harsh climatic or soil conditions is sometimes associated with specific groups of genes. These genes can be isolated and introduced into crops. Such applications promise to be particularly valuable for developing countries, where abiotic stresses such as drought, heat, frost and acidic or salty soils are common. Research on crops such as cotton, coffee, rice, wheat, potato, *Brassica*, tomato and barley varieties is currently in different stages of completion (Nuffield Council on Bioethics, 1999).
- **Micronutrient enrichment** In aiming to prevent malnutrition, transgenes could play a vital role in the provision of vitamins or minerals. GM crops could help to provide people with essential micronutrients through consumption of their main staple crop. Research in this area is currently being undertaken in rice, cassava, millet and potato (Nuffield Council on Bioethics, 2003). Recent research in Switzerland, funded by the Rockefeller Foundation, shows the potential of modern biotechnology to address developing country micronutrient malnutrition problems. A gene that enhances vitamin A production was inserted into rice using a gene from a daffodil, and in a separate experiment, the bioavailability of iron for human consumption was also increased by introduction of a gene from a French bean. The potential of these advances is enormous. More than 2 billion people are anemic due

to iron deficiency. In developing countries, 180 million children die annually from diseases linked to vitamin A deficiency, especially in Asia, where poor children are weaned on rice gruel (McCalla and Brown, 2000).

Chapter II
Risks and Benefits of Agricultural Biotechnology

1 – Risks and Benefits of Agricultural Biotechnology

As with any science and technology, biotechnology can bring with it benefits and risks. It is the risks of agricultural biotechnology that have received widespread publicity in the media even though biotechnology has also been applied to health and industrial sectors. Environmental non-government organizations (NGOs) have been particularly vocal in taking issue with the new technologies derived from or incorporating GMOs. As a consequence, in the public debate biotechnology has become synonymous with GMOs, although they are only one of the many products of biotechnology.

A number of food-related crises in recent years have made consumers particularly sensitive about food safety issues. Health and food safety concerns are again at the forefront in Europe following additional cases of mad cow disease (bovine spongiform encephalopathy) and the banning throughout the European Union of blood and bone meal in feed for all animals. These crises have not been caused by GMOs, but by the intensification of agriculture and food production, a fact that appears to have escaped public attention. In Europe in particular, demands have been made for informative food labeling so that consumers may, if they wish, avoid genetically modified foods. The anti-GMO movement reveals profound mistrust of developments in science and technology and of the forces seen to be driving them (ADB, 2001).

Opposition to biotechnology and specifically to genetic engineering is derived from several viewpoints. They include fears of high-tech farming destroying the livelihood of smallholders, concerns about artificially created products competing with and destroying the marketability of “natural” products, and the presumption of environmental threat. Many critics fear that biotechnology is a scientists’ obsession which is being exploited to bring quick profits to the few even though it can do great harm to the many. Those who hold such views are profoundly concerned that the increased application of biotechnology will harm not only ourselves but even generations of the future. These concerns are genuine and cannot be ignored (Serageldin, 2000).

In considering the potential risks and benefits of modern biotechnology, it is useful to distinguish technology-inherent and technology-transcending risks. This distinction is of utmost importance in any attempt to reason out the risks arising from biotechnology. Whether this new technology promises to be the key technological paradigm in the fight for food security and reducing poverty depends on how its risks are perceived, disentangled, and accordingly addressed (Leisinger, 2000). Technology-inherent risks are those where the technology itself has potential risks to human health, ecology, and the environment. Technology-transcending risks include those that are not specific to the technology but where its use may have risks. For biotechnology these include the risk of increasing the poverty gap within and between societies, reducing biodiversity, and antitrust and international trade issues (Persley, 2000).

2 - Technology Inherent Risks

For genetically improved organisms, the risks classified as inherent in the technology are frequently summarized as biosafety risks. Most countries with biotechnological-based industries have sophisticated legislation in place intended to ensure the safe transfer, handling, use, and disposal of such organisms and their products. But even with the best procedures and regulations in place, some risks will remain. Risks—calculable risks—must be taken, otherwise technological progress becomes impossible. There is always the possibility, no matter how slim, that something could go wrong (Leisinger, 2000).

Especially in the discussion about genetic engineering, concerns have been expressed that the direct change in an organism's genome causes new, unforeseeable and unwarrantable large risks for humans and environment. Since human knowledge is limited the possible existence of such unknown risks cannot be ruled out with absolute certainty neither in the case of genetic engineering nor in the case of any other technology. However, at current knowledge it can be stated that genetically modified plants are not *per se* more dangerous than conventionally bread ones. Risk assessment can therefore not be conducted for genetic engineering in general or biotechnology as a whole, but has to be performed specifically for each single technology product under respective local frame conditions.

2.1 - Risks to Human Health

Some commentators take the view that possible risks of GM crops for human health have not yet been sufficiently examined. In a common, but controversial, interpretation of what is known as the "precautionary principle", critics argue that GM crops should not be used anywhere unless there is a guarantee that no risk will arise.

Some of the debate about GM crops concerns the marker genes co-introduced with the transgenes. Several exotic markers have been used as research tools, for instance, GUS, a gene encoding ß-glucuronidase, can be identified in stained material by a blue colour. However, in practical plant improvement programs, markers have been largely restricted to proteins providing resistance to herbicides or antibiotics. Putative transformants can be sprayed with, or grown on, media containing the appropriate chemical. Transformed plants are identified as those that survive. Critics of GM technology argue that even if marker genes are avoided, the resulting lines are still likely to contain small segments of non-coding, non-native DNA, which initially flanked the construct in the vector. The presence, size and any possible function of such inserts are always considered in the UK regulatory approval process.

Markers are used only to make the detection of transgenic plants easier. Removal of marker genes from such plants is technically possible but extremely difficult, although methods are being developed to do just this. However, in situations where the presence of the transgene itself can be detected easily or when efficiencies in transgenic production become high enough, then the use of markers can be dispensed with. Efficiencies as high as 5% are now being obtained and, at these rates, it is feasible to screen directly for the unique DNA sequence that describes any gene. It is likely, therefore, that selectable markers (which include genes that confer antibiotic resistance) will cease to be an issue with the next generation of transgenic releases (Nuffield Council on Bioethics, 1999).

Since the advent of GM technology, researchers have used antibiotic resistance genes as selective markers for the process of genetic modification. Bengtsson (1997) quoted in Robinson (1999) maintained that as some crop varieties will be transformed many times, antibiotic resistance genes will accumulate, and it is therefore sensible to remove them as plant breeders will soon encounter difficulties in locating new, harmless antibiotic marker genes.

The concern has been raised that the widespread use of such genes in plants could increase the antibiotic resistance of human pathogens. Kanamycin, one of the most commonly used resistance markers for plant transformation, is still used for the treatment of the following human infections: bone, respiratory tract, skin, soft-tissue, and abdominal infections, complicated urinary tract infections, endocarditis, septicemia, and enterococcalinfections.

Scientists now have the means to remove these marker genes before a crop plant is developed for commercial use. Developers should continue to move rapidly to remove all such markers from transgenic plants and to utilize alternative markers for the selection of new varieties. No definitive evidence exists that these antibiotic resistance genes cause harm to humans, but because of public concerns, all those involved in the development of transgenic plants should move quickly to eliminate these markers (National Academy of Sciences, 2000).

Other principal concerns are that transgenic foods will be toxic or allergenic. Genetically improved crops and food, and the risk of allergens associated with them, are now a concern throughout the world, especially in industrial countries. More than 90 percent of food allergens that occur in 2 percent of adults and 4 percent of children are associated with eight food groups. Allergenicity of genetically improved foods can be raised in crops and foods either by raising the level of endogenous allergen or by introducing a new allergen. Assessment of the risk of allergens is a challenge (Persley, 2000).

Franck-Oberaspach and Keller (1997) quoted in Robinson (1999) reviewed the consequences of classical and biotechnological resistance breeding for food toxicology and allergenicity. They reported on many classes of actual and putative toxins and allergens, concluding that several naturally occurring defence substances found in plants are highly toxic to mammals, but also indicating that food safety can be severely influenced by natural pathogens and their products. It is interesting how little we yet know about the toxicity of non-engineered foods. Known toxins and allergens can be screened for in advance however to reduce the chances of releasing potentially dangerous foods. Careful labelling of products would be informative for customers with allergies and for those averse to buying a product derived from a transgenic crop.

Based on data like the one presented above, the International Life Sciences Institute (ILSI) has developed a decision tree that provides framework for risk assessment (Lehrer 2000). It uses the following criterion: that an introduced protein in a food is not a concern if there is (1) no history of common allergenicity, (2) no similar amino acid sequence to known allergens, (3) rapid digestion of the protein, and (4) the protein is expressed at low levels. Protocols enable assembly of the data to judge food against this criterion. It is also important to inform consumers of any potential risk. A key concern of consumers is being able to identify where allergens are found. Therefore, consumers want to know where the potential for food allergens exists. Any protein added to food should be assessed for potential allergenicity, whether it is added by genetic engineering or by manufacturing. There are several related areas of concern with regard to potential human health risks of genetically improved foods: toxicity, carcinogenicity, food intolerances; the risk of the use of gene markers for antibiotic resistance; other macromolecules aside from protein that could be potential allergens; and nutritional value. Methods of testing and evaluating risks of toxicity and carcinogenicity are well established for food. The question remains as to whether developing countries can implement and use currently available technologies and protocols to assess food allergens and other health risks. The techniques are well established, and should be readily implementable by trained professionals.

There is one documented case where genetic modification involving transfer of a gene from the Brazil nut to soybean also led to transfer of allergenicity. Blood serum from people known to be allergic to Brazil nuts was tested for the appropriate antibody response to the transferred gene. Seven out of nine individuals showed a positive response. This adverse result alerted the company and the work was discontinued so the product was not even submitted to the regulatory authorities. The potential allergenicity of proteins expressed by novel genes is now a routine part of safety assessment procedures and that there are many databases of known allergens that could help identify proteins that may be problematic if inserted into food products.

When an application to market a GM variety for cultivation in the EU is submitted, information on likely toxic or allergenic effects must be included in the application. Continued care is needed in this area, and if there is any reason to suspect an allergenicity problem, then the appropriate health network can be alerted. It should be noted that the EU Novel Food Regulations specifically require that products must be clearly labelled if they contain genes that may result in toxicity or allergenicity, particularly if such genes would not normally be expected to occur in the food (Nuffield Council on Bioethics, 1999).

Although no clear cases of harmful effects on human health have been documented from new genetically improved food, that does not mean that risks do not exist and they should be assessed on a case by case (Persley, 2000).

2.2 - Environmental Risks

The potential impact of GM crops on the environment has received much attention in recent years from the scientific community. Altieri (2000) and others have argued that the transmission of genetic material from GMOs could have adverse effects on the environment as well as on crop production. On the environmental risk, one of the major concerns is the possible transmission of transgenes to the wild relatives of the GM crop through crossbreeding. Of particular concern is the potential development of "superweeds" as a result of wild plants acquiring the genes that are responsible for herbicide resistance over time. This could result in these species outcompeting wild species and causing a reduction in biodiversity. Also, control of these "superweeds" would come at a higher cost to the farmer and might have a negative impact on farm productivity.

There are also concerns that pesticide resistant crops could have negative effects on non-target insect species. For example, there have been claims that, in North America, windblown pollen from Bt corn fields landing on surrounding vegetation could kill the larvae of Monarch butterflies feeding on milkweed (Losey, Rayor and Carter 1999 quoted in Abdalla *et al.*, 2003). However, being relatively heavy, corn pollens do not disperse widely and the possible impact of Bt crops on nontarget species is generally recognised as being far less than the impact of conventional area spraying of pesticides that can affect a wider spectrum of insects. Based on a two year study, Sears et al. (2001) quoted in Abdalla *et al.* (2003) concluded that the impact of Bt corn pollen on Monarch butterfly populations is negligible.

In the case of vertical gene transfer – i.e. the out-crossing of genes of transgenic crops into wild relatives by pollen – the risk can, however, be greater in developing countries than in industrialised countries. This is because of the fact that in developing regions are the centres of genetic diversity of most domesticated crops. While in temperate regions only few wild relatives of agronomically important species occur, there are far more sexually compatible partners in the natural environment of tropical regions, so that a vertical gene-transfer is more likely. Findings from risk studies that are carried out in industrialised countries cannot simply be transferred to countries of the South. This shows clearly that in developing countries great care has to be taken in defining appropriate rules for biosafety as well as in the establishment of effective structures for their implementation. This applies just the same for the area of food-safety.

Such rules have to fulfil mainly two criteria. Firstly a responsible, locally adapted handling of the technology needs to be ensured; secondly limitations for technical advancement should not be too tight. The identification of risk must not automatically mean to relinquish the technology. Risks have to be judged realistically and always be set in relation to the potential benefit of a technology which includes possible benefits to the environment.

The support of establishing and enforcing suitable mechanisms for regulation within partnering countries also represents an important starting point for developmental co-operation. The development of a regulatory structure is as important as the qualification of specialists and the strengthening of national institutions and structures to ensure the enforcement by operational control and regulatory processes (GTZ, 1999).

3 - Technology Transcending Risks

Technology-transcending risks, as opposed to technology-inherent risks, emanate from the political and social context in which a technology is used (Leisinger, 2000). In other words, technology transcending risks include problems that can be triggered by the technology but have its cause in the social, economical and political frame conditions. It has to be clear that technology alone is an inadequate instrument for removing social grievances.

3.1 – Socioeconomic Risks

In developing countries, these risks spring from both the course the global economy takes and country-specific political and social circumstances. The most critical risks have to do with three issues: aggravation of the prosperity gap between industrial and developing countries, growth in the disparity in income and wealth distribution within poor societies, and loss of biodiversity.

Modern biotechnology research and development (R&D) has been conducted in an institutional and economic environment that differs significantly from the development of the earlier Green Revolution technologies. While the latter were essentially the prerogative of public research institutions and philanthropic foundations, developments in biotechnology have been driven essentially as a competitive, commercial endeavour in which powerful private sector actors compete (ADB, 2001).

The major socioeconomic risk of agricultural biotechnology stems from the fact that the research, development, commercialization, and distribution of new biotechnological products have been carried out mainly in developed countries by a few, large, multinational companies. These companies have focused on temperate crops for large farmers in developed countries. Undertaking R&D on Asia's basic food crops for small farmers in rainfed and marginal areas is of little interest because they see limited returns from such investments. Furthermore, in rural family farms the frame conditions for acceptance of technologies are often less favourable. For example, poor households generally have less access to information and extension services that are crucial for the adoption of technical innovations; temporary financial limitations at the time of sowing can also aggravate the acceptance of technologies by small holdings with little resources even if the technology is generally profitable. Adequate access to agricultural extension service and credits as well as a well functioning seed market by which the technology reaches farmers are important prerequisites, so that unintended aspects of distribution within a country can be prevented. National technology politics must also not be restricted to research but has to explicitly include the area of technology distribution and application.

If this trend continues, modern biotechnology will aggravate the income disparity between developed and developing countries, and between large and small farmers. Unless countries have policies in place to ensure that small farmers have access to delivery systems, extension services, productive resources, markets, and infrastructure, there is a risk that the introduction of agricultural biotechnology could lead to increased inequality of income and wealth. In such cases, larger farmers are likely to capture most of the benefits through early adoption of the technology, expanded production, and reduced unit costs (Persley, 2000).

3.2 – Risk of Loss of Biodiversity

The reduction of biodiversity is a technology transcending risk. The reduction of biological diversity due to the destruction of tropical forests, conversion of more land to agriculture, overfishing, and the other practices to feed a growing world population is more significant than any potential loss of biodiversity due to the adoption of genetically modified crop varieties. This is not an issue restricted to transgenic crops. Farmers have adopted new commercially developed varieties in the past and will continue to do so when they perceive this to be to their advantage (Persley *et al.*, 1999).

To slow the continuing loss of biodiversity, the main tasks are the preservation of tropical forests, mangroves and other wetlands, rivers, lakes, and coral reefs. The fact that farmers replace traditional varieties with superior varieties does not necessarily result in a loss of biodiversity. Varieties that are under pressure of substitution also can be conserved through in vivo and in vitro strategies. Improved governance and international support are necessary to limit loss of biodiversity. Actually or potentially useful biological resources should not be lost simply because we do not know or appreciate them at present (Leisinger, 1999).

A trend throughout most agricultural history is the ever-increasing production of fewer crop species in what is called monoculture. Monoculture is the practice of planting large acreages with a single type of crop. Limiting production to just one or a few crops has the effect of reducing the crop diversity of our farmland. This trend has been due to demands of the marketplace and the specialization of farming production systems. A factor that has prevented some farmers from continuous monoculture production of certain crop plants such as corn has been the need for crop rotation for insect and/or disease control. More effective insect or disease control through biotechnology can make it easier and more economical for farmers to grow the same crop year after year.

According to the dominant paradigm of production, diversity goes against productivity, which creates an imperative for uniformity and monocultures. Agricultural biotechnology promotes intensification of monocultures, and is thus more likely to erode the environment than to heal it. Monocultures are ecologically unstable – this alone should be enough to prevent them being viewed as essential to production.

Agricultural biodiversity is the basis of economic life for two-thirds of the world's population – those people who live in rural economies in the Third World. Biodiversity is the means of livelihood and the means of production of the poor who have no access to other assets or means of production (Shiva, 2000).

As food industry becomes more concentrated and integrated, uniformity is the result, and the globalization of consumption patterns, by creating monocultures and destroying diversity, has a devastating effect on the poorest on the planet. First, they are pushed into deeper poverty by being forced to "compete" with globally powerful forces to gain access to the local biological resources. Secondly, their economic alternatives outside the global market are destroyed (Shiva, 2000).

4 - Benefits

The major potential benefits from the current generation of transgenic crops include increases in productivity and higher yields. Herbicide tolerant and insect resistant crops may lower chemical use in agricultural production. Results from a number of studies (reported in US Department of Agriculture 2001) show significant increases in the net returns to US farmers growing these crops. Depending on the crop variety and location, the increases in returns stemmed from combinations of reductions in the use of chemical inputs and farm fuel and, in many instances, increases in yield. Balanced against these cost savings, growers have usually faced higher seed costs, with the need to purchase new seed each season (Abdalla et al., 2003).

Reductions in the use of chemicals in agriculture also have favorable impacts on human health and the environment. For example, Huang, Hu, Pray, Qiao and Rozelle (2001) estimated the impact of Bt cotton in China. China approved Bt cotton for cultivation in 1998. Two competing sets of Bt cotton varieties were approved for cultivation in different provinces. Thus, the two sets of varieties are not allowed to compete with each other. The first one is a set of varieties produced by the Chinese Academy of Agricultural Sciences. The second is a set of cotton varieties produced and introduced into China by a joint venture between Monsanto Corporation and a Chinese partner. Estimations from these researchers indicate that Bt cotton in general has a significant advantage over conventional cotton. In the surveys conducted in 1999 and 2000, the authors reported that, on average, growers using Bt cotton reduced pesticide usefrom 55 to 16 kg of formulated product per hectare. In addition, Bt cotton adopters reduced the number of insecticide sprays per crop from 20 to 7. In addition to a 70% pesticide reduction, the authors also noted the almost complete elimination of highly toxic organochlorine and organophosphate insecticides. Preliminary evidence in this study suggests that the use of Bt cotton resulted in a significant positive effect on farmers' health. The authors noted that 30% of farmers who used conventional cotton varieties reported health problems associated with spraying compared with only 9% who used Bt cotton. The authors concluded that the evidence is quite clear that Bt cotton reduces pesticide use and is likely to be beneficial to health and the environment.

Reductions in chemical applications also benefit the environment in other ways. By reducing the need for conventional tillage necessary for weed control, herbicide tolerant GM crops could be grown with minimum or no tillage. This would result in reductions in farm fuel consumption. Besides lower costs to farmers, reductions in fuel use would generate environmental benefits in terms of reductions in greenhouse gas emissions.

There are many potential benefits for poor people in developing countries. Biotechnology may help achieve the productivity gains needed to feed a growing global population, introduce resistance to pests and diseases without costly purchased inputs, heighten crops' tolerance to adverse weather and soil conditions, improve the nutritional value of some foods, and enhance the durability of products during harvesting or shipping. New crop varieties and biocontrol agents may reduce reliance on pesticides, thereby reducing farmers' crop protection costs and benefiting both the environment and public health. Biotechnology may offer cost-effective solutions to micronutrient malnutrition, such as vitamin A and iron-rich crops (Pinstrup-Andersen and Cohen, 2000). An example of this is the development of "golden rice", a crop that has been genetically modified to produce vitamin A, which is necessary to reduce the incidence of blindness (due to vitamin A deficiency) in children for whom rice makes up a disproportionate part of the diet.

The application of biotechnology in agriculture offers a wide range of potential benefits, yet many of these benefits will not be realized unless a number of important policy issues are resolved. Policies must ensure that a development-friendly environment exists and that technological progress is oriented toward the needs of the poor, particularly smallholders. All serious analyses admit concerns with regard to human health, environmental safety, and intellectual property rights (IPR), but the majority conclude that—with a proper regulatory regimen enforced—benefits are likely to greatly outstrip concerns, so that ethically there should be every effort to realize these benefits. Continued research on all aspects of genetic engineering and biotechnology is necessary to maximize benefits and minimize risks. Whatever helps to address public concerns and regain public confidence for genetic engineering and biotechnology must be done, because in the end, in pluralistic democratic societies, it is social acceptance that makes success feasible (Leisinger, 2000).

5 - Summary

Whether the European public becomes as accepting of GM foods as the American public will depend on changed perceptions of the risks to human health and the environment. Such changes will hinge on reliable communication of information from scientists, policy makers, industry and the press. It might require that there is more public participation in agricultural research planning in the future. Thus, clear thinking, scientific information, and realistic views to minimize the risks and maximize the benefits are needed.

Biotechnology could give us a future where perennial crops have in-built resistance to pests and diseases, fix their own nitrogen, and give higher yields. However, this calls for a cautious case-by-case approach to address legitimate concerns for the biosafety of each product or process prior to its release. The possible effects on biodiversity, the environment and food safety need to be evaluated, and the extent to which the benefits of the product or process outweigh its risks assessed. The evaluation process should also take into consideration experience gained by national regulatory authorities in clearing such products. Careful monitoring of the post-release effects of these products and processes is also essential to ensure their continued safety to human beings, animals and the environment.

Chapter III
Role of Agricultural Biotechnology

1 – The Green Revolution

The Green Revolution occurred during the 1960s and 70s, it was a planned international effort funded by the Rockefeller Foundation, the Ford Foundation and many developing country governments. Its purpose was to eliminate hunger by improving crop performance. This was central to agricultural development debates in the 1960s and 1970s and was the basis for the foundation of the International Agricultural Research Centres who were to spearhead a publicly/philanthropically funded drive to increase food production in the developing world.

Beginning in the 1960s, advances in classical crop breeding and farm management techniques resulted in massive growth in cereal crop production, and came to be known as the Green Revolution. The Green Revolution was driven by a need to increase land productivity in areas with growing land scarcity and/or high cost land. Increased production was also achieved through a considerable amount of investment in agricultural research and infrastructure development, particularly in irrigation.

The Green Revolution of the 1960s and 1970s introduced higher-yielding varieties (HYVs) of staple food crops, new tilling methods and increased use of chemical inputs. Along with these technical innovations, modernizers promoted commercial, export-based agriculture using loans, technical advisors, aid programs, tax incentives, advertising and military support. Despite these innovations, overall food production more than kept pace with population growth. These food production increases were achieved largely by the cultivation of high-yielding varieties (HYVs) of rice and wheat, accompanied by expansion of irrigated areas, increases in fertilizer and pesticide use, and greater availability of credit.

The scientific basis for the Green Revolution stemmed from national and international research programs that led to the development and distribution of new HYVs, particularly of rice and wheat (Asian Development Bank, 2001).

The key elements in improving food security in Asia from 1970-95 were government policies reflecting a belief that investments in increasing agricultural productivity were a prerequisite to economic development. These national policies were supported by political leaders in Asia and by both the public and private sectors of the international community. This mix of supportive public policies, scientific discoveries, and public and private investments in rural Asia, particularly in irrigation, credit, and inputs, led to substantial reductions in poverty and improved food security throughout Asia over the past 30 years. Increased agricultural productivity, rapid industrial growth, and expansion of the nonfarm rural economy have all contributed to almost a tripling of per capita gross domestic product across Asia since 1970 (Pinstrup-Andersen and Cohen, 2000).

In other words, the Green Revolution of the 1960s and 1970s helped many developing countries such as India and China become agriculturally self-sufficient, net exporters of food in the last three decades. The increased productivity has been accompanied by a subsequent increase in personal income and stimulus to national economies.

Despite these successes, problems remain. The intensification of agriculture and the reliance on irrigation and chemical inputs has led to environmental degradation, increased salinity, and pesticide misuse. Deforestation, overgrazing, and overfishing also threaten the sustainable use of natural resources.

What is more, the Green Revolution technologies had little impact on the millions of smallholders living in rainfed and marginal areas, where poverty is concentrated. Furthermore, the Green Revolution has already run its course in much of Asia. Wheat and rice yields in the major growing areas of Asia have been stagnant or declining for the past decade, while population continues to increase (Asian Development Bank, 2001).

The much heralded Green Revolution was an example of the failure of new technology applied to farming to reduce hunger. Using the technology, developing countries significantly increased crop yields, but they nevertheless failed to eliminate hunger, because they failed to address the root social and economic causes of hunger. Furthermore, the Green Revolution exacerbated poverty and social inequality. If favored larger, wealthier farmers who could afford the new high yielding crop varieties and the chemical fertilizers, pesticides, and irrigation systems that accompanied them. Left behind were poorer farmers unable to afford such inputs. In the meantime, the heavy use of chemical fertilizers and pesticides generated resistant pests and degraded the fertility of the soil, undermining the very basis for future production (Kucinich, 2001).

The key question that arises nowadays is whether the use of recombinant crops will accentuate the positive or negative aspects of the Green Revolution**.** It led to enormous increases in agricultural productivity, but at the cost of increased economic disparity among farmers and increased reliance on technology and chemicals supplied by corporations from industrialized nations. Because most recombinant crops have been developed by corporate interests that are relatively uninterested in creating crops that are specifically tailored to agricultural problems in Asia, biotechnology may have a relatively small impact on this part of the world. However, increased western support of agricultural research in Asian countries could lead to the development of transgenic crops targeted to specific agricultural problems in the developing world.

During the next 25 years, Asia will need a Second Green Revolution, commonly denominated Biorevolution or Doubly Green Revolution. Conway (1997) pointed out that the next technology-driven revolution must be doubly green—it must increase food production at a faster rate than in recent years without significantly damaging the environment. It must also increase incomes and increase access to food by the poor. The major differences between the Green Revolution and Biorevolution can be characterized the following features:

(i) Potentially many crops (particularly high value and specialty crops), will be affected as well as livestock and aquaculture.

(ii) Potentially all areas, both irrigated and rainfed, will benefit from biotechnology R&D.

(iii) Technology development and dissemination will substantially involve the private sector with the public sector playing the role of facilitator and regulator.

(iv) Many processes and products will be patentable and protectable.

(v) Capital costs of research will be high.

(vi) Molecular and cell biology expertise will be required in addition to expertise in conventional plant breeding and other agricultural sciences (ADB, 2001).

Nevertheless, some of these issues are embedded with controversy and ambiguity among researchers, policymakers, government leaders and especially in public opinion within some of the European countries.

2 – Poverty Alleviation and Food Security

In 2000, the world's population was about 6 billion. It is expected to increase to 9 billion by 2050; 97% of this population increase will occur in the developing countries, with Asia being by far the most populous continent (James, 1996). About 1.2 billion people, or one of every five humans, live in a state of absolute poverty, on the equivalent of US$1/day or less (World Bank, 1999).

About 800 million people are food insecure (FAO, 1999), and 160 million preschool children suffer from energy-protein malnutrition, which results in the death of over 5 million children under the age of five each year (ACC/SCN, IFPRI, 1999). A much larger number of people suffer from deficiencies of micronutrients such as iron and vitamin A. Today, for example, iron deficiency anaemia affects an estimated 1.5 billion to 2.1 billion people, primarily women and children; over 200 million people are considered to be vitamin A deficient; and iodine deficiency disorders affects between 740 million and 1500 million (Scoones, 2002). Food insecurity and malnutrition result in serious public health problems and lost human potential in developing countries.

Most, perhaps 75 % of this nutritionally at-risk population live in rural agricultural regions in developing countries.

Small-scale farmers in developing countries are faced with many problems and constraints. Pre-and post-harvest crop losses due to insects, diseases, weeds, and droughts result in low and fluctuating yields, as well as risks and fluctuations in incomes and food availability. Low soil fertility and lack of access to reasonably priced plant nutrients, along with acid, salinated, and waterlogged soils and other abiotic factors, contribute to low yields, production risks, and degradation of natural resources as poor farmers try to eke out a living. They are often forced to clear forest or farm ever more marginal land to cultivate crops. Poor infrastructure and poorly functioning markets for inputs and outputs together with lack of access to credit and technical assistance add to the impediments facing these farmers (Pinstrup-Andersen and Cohen, 2000).

Family income is probably the single most important determinant of adequacy of access to food. The World Food Summit in 2002 reaffirmed a commitment made by the international community five years earlier to halve the number of hungry people by the year 2015. That goal will not be met unless agricultural productivity and personal income can be improved in the world's poorest regions (Chassy, 2003).

The concept of "food security" has been defined in various ways. In the 1970s, food security was used to refer to the availability of foodstuff in sufficient quantity at a global level. During the course of the 1980s and 1990s, academics and non-government organizations (NGOs) pointed out the inadequacy of food security approaches rooted in promoting global production levels and a country's access to world markets for food alone. They emphasised instead that food security approaches should guarantee livelihoods which would generate sufficient food at the household level (Yamin, 2003).

At the 1996 Rome World Food Summit (WFS), the UN Food and Agricultural Organisation (FAO) produced a new definition. The FAO definition of food security is "food that is available at all times, that all persons have means of access to it, that it is nutritionally adequate in terms of quantity, quality and variety and it is acceptable within the given culture". Although this definition tried to remedy earlier deficiencies, it is by no means universally accepted (Yamin, 2003).

Because land and water for agriculture are diminishing resources, there is no option but to produce more food and other agricultural comodities from less arable land, and irrigation water. The need for more food has to be met through higher yields per units of land, water, energy and time.

On a global basis the amount of cultivable land has decreased from 0.44 ha per capita in 1961 to 0.26 ha in 1997 and is expected to fall further to 0.15 ha per capita by the year 2050. Given the rate of expansion of arable land is now below 0.2% per annum and continuing to fall, increasing productivity, through increasing production per unit area of land, represents the only significant means for increasing food, feed and fiber production (James, 1997).

Abiotic stresses and non-sustainable agricultural practices have led to decreased productivity of agricultural land; this has been due to several factors including wind and water erosion, salinization, overgrazing and overintensification.

With increasing population pressure in developing countries it has become paramount to find ways of increasing productivity on existing agricultural lands if food security is to improve and environmental damage is to be minimised. Advances in agricultural biotechnology are widely considered to have a key role in fulfilling these objectives (Abdalla *et al.*, 2003). Equally important is the recognition of the need to evolve and practice a sustainable system of agriculture that will increase productivity, conserve natural resources and protect the environment. As such, agricultural biotechnology is a potential means to enhance crop productivity in a environmentally sustainable way.

It is often assumed that world food shortages can be eliminated by increasing food and agricultural production through the application of modern technology. However, when a new agricultural technology enters a system characterized by unequal power relationships, it brings greater profits only to those who already have some combination of land, finance resources, credit worthiness and political influence.

Although developing countries are gene-rich in terms of plant genetic resources relevant to developing agriculture on a sustainable basis they are widely recognised to be resource poor in terms of technological and institutional capabilities when compared with developed countries. Such imbalances are part of the wider, on-going disparities between developed and developing countries in terms of economic, political and military power. Thus notwithstanding the fact that the World Food Summit Declaration states that the “primary responsibility” for attaining food security rests with individual governments, the ability of developing countries, acting alone, to achieve food security goals unaided is compromised by many factors (Yamin, 2003).

Hunger persists today despite the fact that increases in food production during the past 35 years have outstripped the world’s population growth by 16%. Indeed, the United Nations Food and Agriculture Organization recently stated that growth in agriculture will continue to outstrip world population growth. The Institute for Food Policy notes that there is no relationship between the prevalence of hunger in a given country and its population (Kucinich, 2001).

Hunger is a much more complicated phenomenon that can be rectified by expanding agricultural production, although, in most instances, expanding agricultural output is a necessary condition. This is true because issues concerning hunger reach the heart of the nation’s political economies. The key obstacle to alleviating hunger is that the rural poor population in most developing countries, who depend and live primarily on local agricultural production, exercise little control over the prices they receive and the productive resources they need for efficient production. When the control of resources is in the hands of the actual farmers and tenants rather than in the hands of absentee landlords, the farmers are likely to make efficient use of their land. When farmers own land and work for themselves, they have the motivation to work hard to make the land more productive (Gebremedhin, 1997).

Most farmers are poor, with small land holdings. Productivity is low and agriculture is subject to water, wind, and temperatures stresses. As such they are the farming systems most likely to be adversely affected by global warming. Increasing smallholder agricultural productivity in these areas will not only increase food supplies, but also will increase smallholder incomes food access, reduce malnutrition, and improve living standards of the poor (McCalla and Brown, 2000).

Accordingly to Robinson (1999), it is a commonly held view that transformation of agriculture is a moral imperative for reducing poverty and hunger and promoting equity in many of the world's poorer countries. It is Malthusian preoccupations, feeding a human population of ten billion in the foreseeable future, which represent the ethical justification for employing such biotechnology. This presupposes that food shortage as such is the principal cause of hunger, and ignores to some extent the reasons for poverty, inequitable distribution of food, land tenure inequity, overpopulation, poor health, poor education etc. In theory, cultivation of transgenic crops could, through intensification of agriculture, contribute to increased agricultural production and therefore alleviate human hunger, while promoting environmental conservation.

To increase food production by at least 40% within the next 25 years, Asian countries not only have to move toward the best technological frontier (to push farmer's yields to the optimum level), but keep moving the technological frontier itself. As long as product safety, environmental and ethical concerns, and intellectual property issues are adequately addressed, modern agricultural biotechnology has the potential to significantly increase the quantity and potential to significantly increase the quantity and quality of the food supply for developing countries (Asian Development Bank, 2001).

Modern plant breeding may help to achieve productivity gains, introduce resistance to pests and diseases, reduce pesticide use, improve crop tolerance for abiotic stress, improve the nutritional value of some foods, and enhance the durability of products during harvesting and shipping. Biotechnology may offer cost-effective solutions to vitamin and mineral deficiencies by developing rice varieties that contain vitamin A and minerals. Raising productivity could increase smallholders' incomes, reduce poverty, increase food access, reduce malnutrition, and improve the livelihoods of the poor. In the PRC, cotton farmers that have adopted insect-resistant, transgenic Bt cotton have reduced their use of highly toxic insecticides. That in turn has reduced farmers' crop protection costs and benefited both the environment and public health. A real problem is how to provide adequate incentives for crop breeders to focus on crops and adaptations to difficult environments, which are of greater interest to poor farmers. Public funding and the involvement of international organizations will be crucial to such research (Asian Development Bank, 2001).

As mentioned above, the most critical areas in the world for bringing economic prosperity and stability are the developing countries. It is the developing countries which have a high population density and few arable land and, consequently, the severest problems of food security.

Increasing food production has always been the highest agricultural priority in China because of the huge population of the country. Demand for food production will increase by at least 60 percent to keep pace with population growth, which is estimated to reach 1.6 billion by the year 2030.This rapid population increase and vast urbanization will eventually result in loss of valuable farmland and other natural resources. The only viable approach to increasing food production, therefore, is to increase the productivity of existing farmland.

As China's population increases, the amount of land and water available for agriculture will become increasingly scarce in per capita terms. Population pressure may also lead to growing environmental degradation, including erosion and salinization, and may reduce the amount of land suitable for cultivation. The breeding of higher yielding varieties and varieties resistant to environmental stresses may compensate for the decline in cultivated land. However, it is also important to protect the resource base through measures to control erosion, control water, and enhance soil fertility. In the pre-reform period, the government was able to mobilize agricultural labor in slack seasons for environmental improvement projects such as upgrading irrigation systems, salinization control, reforestation, and terracing. Since the shift to the individual household farming system, it has become more difficult to mobilize rural labor for such projects. Government investment in projects for upgrading or maintaining the agricultural resource base thus becomes increasingly important (Lin, 1998).

Chinese scientists, for many years, have been making great efforts to improve the crop yield by traditional breeding techniques which have contributed significantly to agricultural production. Starting 1983, with the development of transgenic techniques, more and more transgenic plants have been developed and agricultural biotechnology has become a powerful tool for improving agriculture production.

But China has relatively long history of promoting and developing biotechnology spanning several decades. It has seen in biotechnology the potential to deliver development gains through the application of hi-tech science to the industrialisation and modernisation of agriculture. Agricultural biotechnology potentially has a key part to play in China’s agricultural rural development. With high levels of rural poverty, declining yields from many key crops and damaging levels of pesticide use, technologies that promise to reduce reliance on chemical inputs and boost yields are a welcome development. Because of this, China has sought to promote biotechnology development through strong state-funded research programs. In China’s case, against a background of ambitious science programs in Europe and North America (in the form of EURIKA and the Strategic Defence Initiative respectively), four top scientists made a proposal to Premier Deng Xiaoping, in which the development of biotechnology featured highly, which he approved in March 1986 (Newell, 2003).

Being one of the most populated and one of the largest agricultural countries in the world, Chinese local and central governments have taken food security for the people as a major national concern. Food self-sufficiency has been and will continue to be the central goal of China’s agricultural policy. The Ninth Five-year Plan for 1996-2000 and the National Long Term Economic Plan both call for continued agricultural production growth, annual farmer income growth of four percent, maintenance of “near” food self-sufficiency, and elimination of absolute poverty (Huang *et al.*, 2000).

Together with food security, poverty alleviation has been a priority of both local and central Chinese authorities for the last decades. According to government poverty statistics, the number of people under the poverty line in the rural area declined from 260 million in 1978 to 89 million in 1984. The incidence of poverty (the share of the poor in the total population) declined from 32.9 percent to 11.0 percent during the period. Much of the credit for the early reduction in poverty is attributed to the rapid rural economic growth that resulted from better incentives and the government’s rural reform program. However, the adequacy of financial resources for the poverty area's development is a challenge for officials charged with running China’s poor area development. While total funds for poor areas increased in nominal terms over time, real investment in the poor areas declined in the late 1980s and early 1990s.

With the poor increasingly located in the more remote areas, the change in lending strategy from the household to economic entities, the inadequacy of financial resources, and slower growth of the rural economy, the progress achieved since the early 1980s has slowed. There were about 42 million people still living below the official poverty line in 1998, or approximately 5 percent of the rural population.

The government originally set a goal of eliminating absolute poverty for the remaining 42 million people by the end of this century. To achieve the above, the program called for increased funding for the poor areas, particularly for the 592 poor counties that are designated by the central government. However, the increase of funds for the poor areas has not been realized since 1994. Indeed, the real investment in the poor area declined by 33 percent between 1993 and 1996. Although the investment in poor areas rose in 1997, it was still lower than the level of funding allocated in the first year (1994) of the 8-7 program’s push to eliminate poverty. For a more comprehensive review of poverty policy.

Although tremendous progress was made in addressing China’s poverty problem in 1980s due to general rural economic growth and government commitment to poverty alleviation, the progress has slowed down since the early 1990s. There were about 34 million rural people (3.7 percent of rural population) under the government poverty line in 1999. If applying the World Bank’s poverty standard (1$ per day), the number of the poor rised to 106 million in 1999. The majority of today's poor live in marginal areas that are cut off from the economic mainstream. As argued by several studies from World Bank and ADB, the nexus between agricultural productivity growth, poverty reduction, and environmental sustainability is arguably strong in many developing countries. Without agricultural productivity growth in fragile environments and marginal areas, poverty incidence may worsen and environmental degradation will increase. Agricultural research will be the major source of productivity increases.

If agricultural productivity in developing countries is to advance rapidly to meet growing food demand, biotechnology apparently has the potential to play a large role in this achievement (Penn, 2003). Biotech proponents argue that genetic engineering is the solution to the problem because it will increase crop yields to feed a growing population.

The company Monsanto ran an advertising campaign announcing that "Worrying about starving future generations won't feed them. Food biotechnology will". What is different, now, is that the idea of GM crops being a "magic bullet" is no longer regarded as credible, even by the biotechnology industry. Monsanto's UK Director of Corporate Affairs is recently reported to have said that "Nobody has ever claimed that GM is the answer to world hunger". Instead, proponents now argue that GM crops have the potential to help increase food security, and only if the correct policies are pursued. However, the view that GM crops have pro-poor potential challenges arguments that GM crops in general will not contribute to food security. Several prominent development charities, such as Oxfam, Christian Aid and Action Aid, have published reports arguing that GM crops may, in fact, exacerbate food insecurity, even if they increase the amount of food that is produced. They argue that GM crops would not reach the poorest farmers, who therefore would be even less able to obtain or retain food than they are now. Even if GM crops might help in exceptional cases, their overall effect might therefore be to increase food insecurity. This focus on the specifics – specific countries, policies and crops – sounds quite reasonable. One can agree that it is impossible to sustain the old sweeping claim that GM crops will feed the world (Huang *et al.*, 2001a).

Undoubtedly, most current GM crops serve the interests of large-scale farmers. However, a "second generation" of GM crops has the potential to benefit some of the world's poorest people. For instance, scientists using GM techniques are researching how to make staple foods more nutritious, and how crops can be made to grow in drought-prone areas. The case of "golden rice", which is commonly treated as an example of a potentially pro-poor GM technology, is a strain of rice genetically modified to contain increased levels of ß-carotene, a substance that our bodies can convert into vitamin A. It was developed non-commercially – part funded by the Rockefeller Foundation – in the hope that it would alleviate the serious problem of vitamin A deficiency in areas of Asia where rice dominates the diets of poor people. Golden Rice is well-known because it has become a two-faced totem in debates about GM crops and food security: for proponents, it typifies the promise of genetic engineering; for critics, its promises are a hoax.

Chapter IV
The Status of Global Agricultural Biotechnology

1 – The Global Area of Transgenic Crops

There was an insignificant area planted in GM crops before 1992. China was the first country to commercialize transgenic crops in the early 1990s with the introduction of virus resistance tobacco, which was later followed by a virus resistant tomato. In 1994, Calgene obtained the first approval in the USA to commercialize a genetically modified food product, when the company marketed its Flavr Savr ™ delayed ripening tomato (James, 1997).

After two decades of intensive and expensive research and development in agricultural biotechnology, the commercial cultivation of transgenic plant varieties has commenced in 1996 (Persley *et al.*, 1999). According to James (2002), the rapid adoption in many countries of transgenic crops during the "initial six-year period", i.e.; from 1996 to 2001 reflects the substantial multiple benefits realized by both large and small farmers in industrial and developing countries that have grown transgenic crops commercially. James (2002) also advocates that the most compelling case for biotechnology, and more specifically GM crops, are their capability to contribute to increasing crop productivity and thus contribute to global food, feed and fiber security; conserving biodiversity, as a land saving technology capable of higher productivity; more efficient use of external inputs and thus a more sustainable agriculture and environment; increasing stability of production to lessen suffering during famines due to abiotic and biotic stresses; to the improvement of economic and social benefits and the alleviation of abject poverty in developing countries.

According to James (2003), for the seventh consecutive year, farmers around the world continued to plant biotech crops at a double digit growth rate of 15% compared with 12% in 2002. The estimated global area of GM crops for 2003 was 67.7 million hectares (Table 2 and Figure 1). The increase in area between 2002 and 2003 of 15% is equivalent to 9 million hectares, this increase includes a provisional conservative estimate of 3 million hectares of biotech soybeans in Brazil, which officially approved planting of biotech soybeans for the first time in 2003. The final planted area in Brazil could be significantly higher.

Seven million farmers in 18 countries – more than 85% resource-poor farmers in the developing world –planted GM crops, up from 6 million in 16 countries in 2002. As shown in Table 3 and Figure 1, in 2003 almost one third of the global transgenic crop area was grown in developing countries, up from one-quarter in 2002 (James, 2003).

Table 2 - Global area of transgenic crops, 1996 to 2003 (million hectares).

Year	Hectares (million)
1996	1.7
1997	11.0
1998	27.8
1999	39.9
2000	44.2
2001	52.6
2002	58.7
2003	67.7

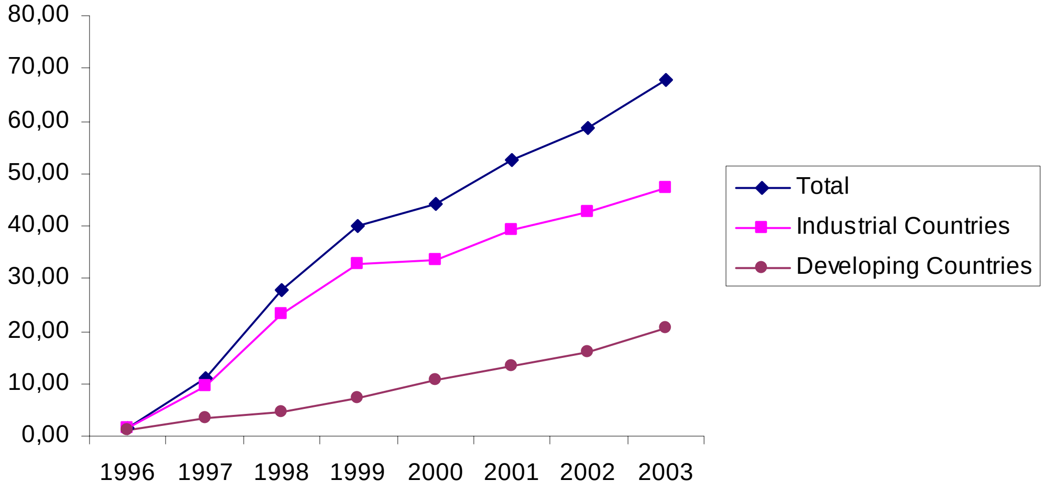
Source: Adapted from James (2002, 2003).

Table 3 - Global area of transgenic crops in 2002 and 2003: industrial and developing countries (million hectares).

	2002	%	2003	%	+/-	%
Industrial Countries	42.7	73	47.7	70	+5.0	+12
Developing Countries	16.0	27	20.0	30	+4.0	+25
Total	58.7	100	67.7	100	+9.0	+15

Source: Adapted from James (2002, 2003).

Figure 1 - Global area of transgenic crops, 1996 to 2003 (million hectares). Global area of transgenic crops, 1996 to 2003: industrial and developing countries (million hectares)



Source: Adapted from James (2002, 2003).

2 – Distribution of Transgenic Crops, by Country

Accordingly to James (2003), the number of countries responsible for 99% of the global transgenic crop area expanded to six in 2003, up from four in 2002. Two new countries, Brazil and the Philippines, joined the expanding global group of countries that are growing GM crops. The USA grew 42.8 million hectares (63% of global total), followed by Argentina with 13.9 million hectares (21%), Canada 4.4 million hectares (6%), Brazil 3 million hectares (4%), China 2.8 million hectares (4%) and South Africa 0.4 million hectares (1%). Brazil and South Africa joined the USA, Argentina, Canada and China as the leading growers of biotech crops. Of the six leading GM crop countries, China and South Africa experienced the greatest annual increase, with both countries planting one-third more biotech hectares than in 2002 (table 4).

The USA grew 42.8 million hectares of biotech crops, up 10% from 2002, and accounted for 63 percent of the global total of transgenic crops. The continued growth was a result of significant acreage gains in biotech corn varieties and continued increases in herbicide-tolerant soybeans.

Despite the continuing economic constraints in Argentina, and soybean adoption rates already close to 100% in 2002, its GM crop area grew at 3% with strong growth in Bt maize. Canada’s GM crop area grew at a significant 26% between 2002 and 2003 to reach 4.4 million hectares with increases totaling almost 1 million hectares in the three crops, canola, maize and soybean. Brazil, planting GM soybeans for the first time in 2003, contributed 4% of the global total at 3 million hectares. This is a conservative provisional estimate as only half of the area was planted at the time of James (2003) report. The final area could be significantly higher. China grew 2.8 million hectares of Bt cotton (58% of the national cotton crop) in 2003, an increase of 33% above 2002 and 4% of the total global area of biotech crops. South Africa planted approximately 0.4 million hectares of transgenic crops in 2003, up 33% from 2002 and 1% of the global total of GM crops. The increase is from gains in biotech white and yellow maize, cotton and soybeans.

While GM crop hectarage in Australia decreased slightly due to the continuing drought that resulted in significantly reduced planting overall, farmers still planted a total area to cotton at approximately one third of normal plantings. In its second year of GM crops production, India doubled its Bt cotton area. Romania and Uruguay also reported significant growth, exceeding 50,000 hectares of GM crops for the first time, whilst countries that introduced GM crops for the first time in 2002, such as Colombia and Honduras reported modest growth.

Spain remained the only country in the European Union to plant significant hectarage of biotech crops, with an increase of Bt maize area by one third to reach over 6% of the national maize crop in 2003. Elsewhere in Europe, Germany continued to grow a small area of Bt maize, and Bulgaria continued to grow a few thousand hectares of herbicide-tolerant maize.

Mexico grew about 62 million hectares of Bt cotton and approximately 10 million hectares of herbicide-tolerant soybeans. The Philippines grew biotech crops for the first time in 2003 with about 20 million hectares of Bt maize – the first biotech food/feed crop to be grown in Asia. Reports from Indonesia indicate farmers planted a small area of Bt cotton. The global area of transgenic crops from 1996 to 2003, by country, is shown in Table 5 and Figure 2.

Table 4 - Global area of transgenic crops in 2002 and 2003: by country (million hectares).

	2002	%	2003	%	+/-	%
USA	39.0	66	42.8	63	+3.8	+10
Argentina	13.5	23	13.9	21	+0.4	+3
Canada	3.5	6	4.4	6	+0.9	+26
Brazil	--	--	3.0	4	--	--
China	2.1	4	2.8	4	+0.7	+33
South Africa	0.3	1	0.4	1	+0.1	+33
Australia	0.1	<1	0.1	<1	0	0
India	<0.1	<1	0.1	<1	<0.1	--
Romania	<0.1	<1	<0.1	<1	<0.1	--
Uruguay	<0.1	<1	<0.1	<1	<0.1	
Spain	<0.1	<1	--	--	--	--
Mexico	<0.1	<1	--	--	--	--
Philippines	--	--	--	--	--	--
Colombia	<0.1	<1	--	--	--	--
Bulgaria	<0.1	<1	--	--	--	--
Honduras	<0.1	<1	--	--	--	--
Germany	<0.1	<1	--	--	--	--
Indonesia	<0.1	<1	--	--	--	--
Total	58.7	100	67.7	100	+9	+15

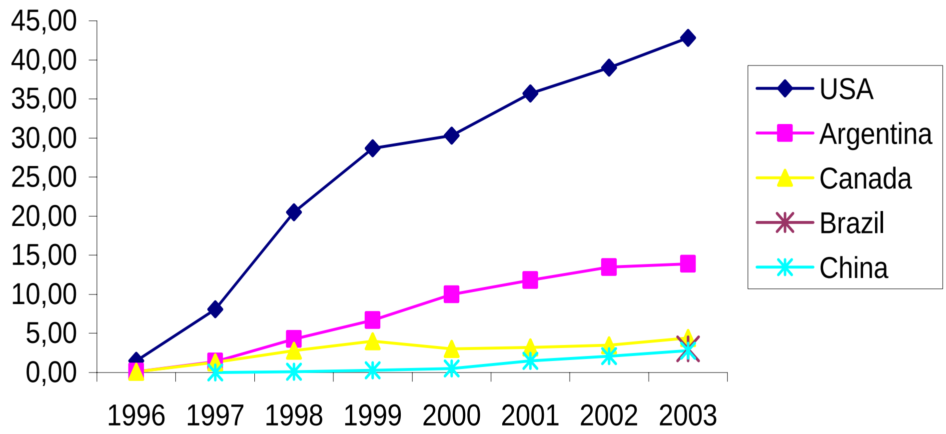
Source: Adapted from James (2002, 2003)

Table 5 - Global area of transgenic crops, 1996 to 2003: by country (million hectares).

	1996	1997	1998	1999	2000	2001	2002	2003
USA	1.5	8.1	20.5	28.7	30.3	35.7	39.0	42.8
Argentina	0.1	1.4	4.3	6.7	10.0	11.8	13.5	13.9
Canada	0.1	1.3	2.8	4.0	3.0	3.2	3.5	4.4
Brazil	--	--	--	--	--	--	--	3.0
China	--	0.0	<0.1	0.3	0.5	1.5	2.1	2.8
South Africa	--	--	<0.1	0.1	0.2	0.2	0.3	0.4
Australia	<0.1	0.1	0.1	0.1	0.2	0.2	0.1	0.1
India	--	--	--	--	--	--	<0.1	0.1
Romania	--	--	--	<0.1	<0.1	<0.1	<0.1	<0.1
Spain	--	--	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Uruguay	--	--	--	--	<0.1	<0.1	<0.1	<0.1
Mexico	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Bulgaria	--	--	--	--	<0.1	<0.1	<0.1	<0.1
Indonesia	--	--	--	--	--	<0.1	<0.1	<0.1
Colombia	--	--	--	--	--	--	<0.1	<0.1
Honduras	--	--	--	--	--	--	<0.1	<0.1
Germany	--	--	--	--	<0.1	<0.1	<0.1	<0.1
Philippines	--	--	--	--	--	--	--	<0.1
Total	1.7	11.0	27.8	39.9	44.2	52.6	58.7	67.7

Source: Adapted from James (2003).

Figure 2 - Global area of transgenic crops, 1996 to 2003: by country (million hectares).



Source: Adapted from James (2002, 2003).

3 – Sowing of Transgenic Crops, by Crop Type

The sown area of four major global transgenic crops is illustrated in Table 6 and Figure 3 for the period 1996 to 2003. It clearly shows the dominance of transgenic soybean (herbicide tolerant).

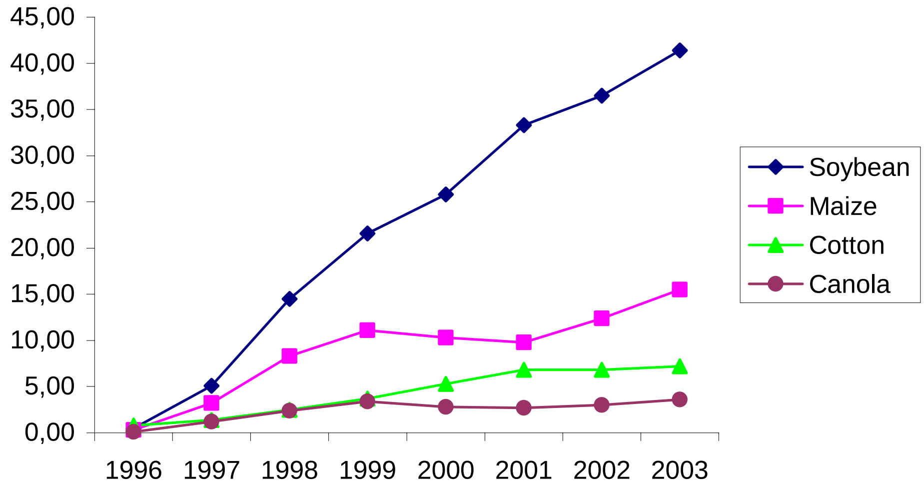
As shown in Table 7, globally, in 2003, growth continued in all four commercialized GM crops: GM soybean occupied 41.4 million hectares (61% of global GM area), up from 36.5 million hectares in 2002; GM maize was planted on 15.5 million hectares (23% of global GM area), up substantially from 12.4 million hectares in 2002, with the highest growth rate for all crops at 25% - this follows a 27% growth rate in GM maize in 2002; transgenic cotton was grown on 7.2 million hectares (11% of global GM area) compared with 6.8 million hectares in 2002; and GM canola occupied 3.6 million hectares (5% of global GM area), up from 3.0 million hectares in 2002 (James, 2003).

Table 6 - Global area of transgenic crops in 2002 and 2003: by crop (million hectares).

	1996	1997	1998	1999	2000	2001	2002	2003
Soybean	0.5	5.1	14.5	21.6	25.8	33.3	36.5	41.4
Maize	0.3	3.2	8.3	11.1	10.3	9.8	12.4	15.5
Cotton	0.8	1.4	2.5	3.7	5.3	6.8	6.8	7.2
Canola	0.1	1.2	2.4	3.4	2.8	2.7	3.0	3.6
Squash	--	--	0.0	<0.1	<0.1	<0.1	<0.1	<0.1
Papaya	--	--	0.0	<0.1	<0.1	<0.1	<0.1	<0.1
Potato	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	--	--
Total	1.7	11	27.8	39.9	44.2	52.6	58.7	67.7

Source: James (2003).

Figure 3 - Global area of transgenic crops, 1996 to 2003: by crop (million hectares).



Source: Adapted from James (2002, 2003).

Table 7 - Global area of transgenic crops in 2002 and 2003: by crop (million hectares).

Crop	2002	%	2003	%	+/-	%
Soybean	36.5	62	41.4	61	+4.9	+13
Maize	12.4	21	15.5	23	+3.1	+25
Cotton	6.8	12	7.2	11	+0.4	+6
Canola	3.0	5	3.6	5	+0.6	+20
Total	58.7	100	67.7	100	+9	+15

Source: Adapted from James (2002, 2003).

4 – The Distribution of Transgenic Crops, by Modification Traits

During the eight-year period 1996 to 2003, herbicide tolerance has consistently been the dominant trait followed by insect resistance (Table 8 and Figure 4).

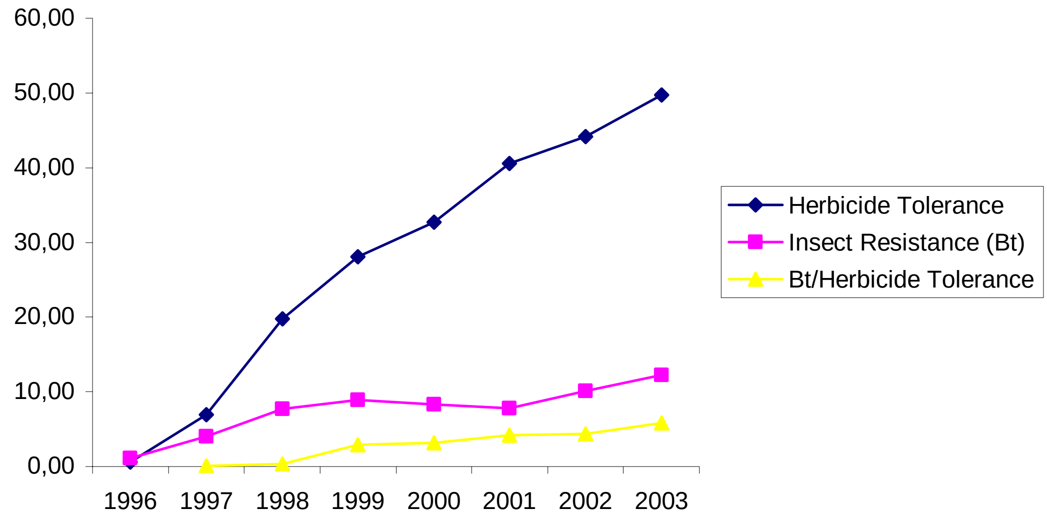
In 2003, herbicide tolerance, deployed in soybean, maize, canola and cotton occupied 73% or 49.7 million hectares of the global GM 67.7 million hectares, with 12.2 million hectares (18%) planted to Bt crops. Stacked genes for herbicide tolerance and insect resistance deployed in both cotton and maize continued to grow and occupied 8% or 5.8 million hectares, up from 4.4 million hectares in 2002 (Table 9). The two dominant GM crop/trait combinations in 2003 were: herbicide tolerant soybean occupying 41.4 million hectares or 61% of the global total and grown in seven countries; and Bt maize, occupying 9.1 million hectares, equivalent to 13% of global transgenic area and grown in nine countries. Whereas the largest increase in Bt maize was in the US, growth was witnessed in all seven countries growing Bt maize. Notably, South Africa grew 84,000 hectares of Bt white maize for food in 2003, a substantial 14 fold increase from when it was first introduced in 2001. Bt/herbicide tolerant maize and cotton both increased substantially, reflecting a continuing trend for stacked genes to occupy an increasing percentage of the area planted to GM crops on a global basis (James, 2003).

Table 8 - Global area of transgenic crops, 1996 to 2003: by trait (million hectares).

	1996	1997	1998	1999	2000	2001	2002	2003
Herbicide Tolerance	0.6	6.9	19.8	28.1	32.7	40.6	44.2	49.7
Insect Resistance (Bt)	1.1	4.0	7.7	8.9	8.3	7.8	10.1	12.2
Bt/Herbicide Tolerance	--	<0.1	0.3	2.9	3.2	4.2	4.4	5.8
Virus resistance/Others	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Total	1.7	11	27.8	39.9	44.2	52.6	58.7	67.7

Source: James (2003).

Figure 4 - Global area of transgenic crops, 1996 to 2003: by trait (million hectares).



Source: Adapted from James (2002, 2003).

Table 9 - Global area of transgenic crops in 2002 and 2003: by trait (million hectares).

Trait	2002	%	2003	%	+/-	%
Herbicide tolerance	44.2	75	49.7	73	+5.5	+12
Insect resistance (Bt)	10.1	17	12.2	18	+2.1	+21
Bt/Herbicide tolerance	4.4	8	5.8	8	+1.4	+32
Virus resistance/Other	<0.1	<1	<0.1	<1	<0.1	--
Total	58.7	100	67.7	100	+9	+15

Source: Adapted from James (2002, 2003).

5 – The Global Value of GM Crops

James (2003) predicts that within the next five years 10 million farmers in 25 or more countries will plant 100 million hectares of transgenic crops. In 2003, the global market value of GM crops is estimated to be $4.50 billion to $4.75 billion ($4.0 billion in 2002). As of 2003, this represents 15% of the $31 billion global crop protection market, and 13% of the $30 billion global commercial seed market. The market value of the global transgenic crop market is based on the sale price of transgenic seed plus any technology fees that apply. The global market value of the GM crop is expected to increase from approximately $4.5 billion in 2003 to $5 billion or more by 2005

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PART II
Agricultural Biotechnology in China

Chapter I
Historical and Current Status of Technology and Biotechnology in China

1 - Historical and Current Status of Technology and Biotechnology in China

1.1 - Pre-1949

Traditional forms of biotechnology have existed in China since its earliest history. According to legend, Shen Nong, a mythical king, introduced China to grain cultivation and crop rotation, and invented a transparent stomach covering in order to observe the effects of herbal medicines on the digestive tract. During the late Neolithic period, the Chinese were already adept at alcohol fermentation, as evidenced by the discovery of wine cups and containers from the Longshan culture and of winery ruins in Henan Province. Records from the eleventh century B.C. show that the importance of temperature and water quality to grain fermentation was understood. By the end of the Zhou Dynasty in 221 B.C., the Chinese were producing bean curd, soy sauce, and vinegar by methods still used today. The process of flax maceration by anaerobic bacteria is alluded to in a verse from the *Book of Songs*, China's earliest collection of poetry (200 B.C.), while the rotation of bean crops is described in writings from A.D. 500. As early as the sixth century, the Chinese understood that rabies could be spread by mad dogs. During the Sui Dynasty (581-618), a vaccine against smallpox was developed, and by the Ming Dynasty (1368-1644), it was widely available to the masses (Hamer and Kung, 1989).

Despite this early inventiveness, China's science and technology, including biotechnology and medicine, failed to go through the explosive changes that altered Western science in the seventeenth to nineteenth centuries. As noted by Joseph Needham in his epic *Science and Civilization in China* (Cambridge: Cambridge University Press, 1961), China never underwent a scientific revolution; there are no Chinese equivalents to Locke, Newton, or Darwin. Consequently, the fundamental concept of testing hypotheses by experimentation was still unknown in China when the door to the west was reluctantly opened to traders and missionaries during the sixteenth and seventeenth centuries (Hamer and Kung, 1989).

China's defeat by the gunboats of European imperialism in the Opium War (1840-1842) ushered in the "half feudal, half colonial" period of the late nineteenth and early twentieth centuries, when China flirted with Western technology. Many students, including Sun Yatsen, went to Japan, Europe, and the United States for training. However, except for the brief Hundred Days Reform of 1898, efforts to modernize China’s science and education systems were suppressed by the government (Hamer and Kung, 1989).

In 1911, the fall of the last emperor and establishment of the Republic marked a turning point in China’s science policy. Under the influence of Sun Yatsen, a physician and firm believer in science, learned societies were formed, scientific journals began publication, science departments were established at several universities, and students were once again abroad. An important development was the founding of the Central Academy of Sciences and the Beijing Academy of Sciences, which were later combined to form the Chinese Academy of Sciences (CAS) (Hamer and Kung, 1989).

1.2 - 1949-1959

China’s efforts to build a scientific establishment were stymied, however, by political unrest, and were completely halted by the war with Japan (1937-1945) and by the subsequent civil war between the Nationalists and the Communists. After the Communist Party’s victory in 1949, China began restructuring its scientific research and educational institutions. Following the example of the Soviet Union, basic research was assigned to Chinese Academy of Sciences (CAS), applied research to various state ministries such as agriculture and public health, and education to the universities. An important issue confronting most developing countries is how to develop agriculture rapidly, both to meet the increased food demand brought on by explosive population growth and also to support urban industrialization (Hamer and Kung, 1989).

In this context, China's achievements have been remarkable. However, along the way China also has made many mistakes, for which it has paid a high price. At the founding of the People's Republic of China in 1949, 89% of the population resided in rural areas. At that time heavy industry was a major characteristic of the economic structures of developed countries. China's technological buildup started in the early fifties and heavily relied on the supports provided by the Soviet Union. To enhance national prestige, the government in 1952 adopted a Stalinist development strategy oriented toward heavy industry. The goal was to build, as rapidly as possible, the capacity to produce capital goods and military materials. Agriculture, in effect, was treated as a supporting sector (Lin, 1998). In addition, the strategy was part of China's ambition to catch up with the developed world and regain its glory in a short time. In China's first Five-year Plan of 1953-1958, the Soviet Union helped China with 156 major industrial projects. These projects were almost exclusively in the heavy industry, especially electricity, steel, and heavy equipment manufacturing. In addition, China imported 426 sets of equipment and 122 single technologies and production lines from Soviet Union, Eastern European countries and several western countries (Chen, 1997). These imported technologies laid the foundation of China's modern industry, their impacts can still be felt even today. As a result, China's economic structure was changed swiftly.

In 1949, the share of heavy industry in gross national output was only 7.9%, by 1962 when the second Five-year Plan ended, the figure became 35.5%. Inside the industrial sector, the share of heavy industry was 26.4% in 1949, but became 53.5% in 1962 (Chen, 1997). However, the heavy-industry development strategy was not free of flaws. In fact, it has been criticized by some authors as the most important factor that has retarded China's economic development. To be sure, with a weak industrial base and few national savings, this strategy had to be aided by distorted price signals, the most significant being the suppression of agricultural prices in order to maintain a low wage workforce (Yao, 2001). Unfortunately, capital was extremely scarce and the voluntary savings rate far too low to finance the high rate of investment in heavy industry sought through this development strategy. To facilitate rapid capital expansion, a policy of low wages for industrial workers evolved alongside the development strategy oriented toward heavy-industry. The assumption was that through low wages, state-owned enterprises would be able to create large profits and reinvest them for infrastructure and capital construction. The practice of establishing low prices for energy, transportation, and other raw materials, such as cotton, was instituted for the same reason. To implement its low-wage policy, the government needed to provide the urban population with inexpensive food and other necessities, including housing, medical care, and clothing. The government instituted a restrictive food rationing system in 1953, which remained in place until the early 1990s. During the same year, to secure a low-priced supply of food for urban rationing, a low-price, compulsory grain procurement policy was imposed in rural areas. The domestic grain trade was virtually monopolized by the state. The industrial development strategy resulted in greater demand for agricultural products because of the increased numbers of urban workers, the need to expand agricultural exports to earn foreign exchange for importing industrial equipment, and the increased industrial demand for raw material. Under those conditions, agricultural stagnation and poor harvests would not only affect the food supply, but would also have an almost immediate and direct adverse impact on industrial expansion.

Reluctant to divert resources from industry to agriculture, the government pursued a new agricultural development strategy that relied on mass mobilization of rural labor to work on labor-intensive projects, such as irrigation, flood control, and land reclamation, and to raise unit yields in agriculture through traditional methods, such as closer planting, more careful weeding, and the use of more organic fertilizer. The government believed that collectivized agriculture was the farming institution that would make all of this possible (Lin, 1998). The 1959-61 crisis made the government more realistic and for a number of years immediately afterward the government gave priority to agriculture in its development strategy. Government policy started to emphasize modern inputs. China's irrigated area increased gradually from 30.55 million hectares (29.7% percent of cultivated area) in 1962 to 44.97 million hectares (45.2% percent of cultivated area) in 1978, but as Table 10 in the annex shows, most of this increase came from the spread of powered irrigation rather than the construction of labor-intensive canals and dams. The utilization of chemical fertilizer accelerated as well, rising from a very modest 4.6 kg/ha in 1962 to 58.9 kg/ha in 1978. Equally impressive was the expansion in the utilization of electricity, a 17.5-fold increase between 1962 and 1978.

1.3 - 1960-1978

The fast development of the 1950s ended up with the Great Leap-forward movement launched in 1958 and the subsequent famine that took at least 20 million lives in just 3 years (Lin, 1990 quoted in Lin, 1998). In the subsequent 18 years, China was in the abyss of political movements, economic stagnation, treachery, fractional fights, and ultimately human degradation. In the early 1970s after the frenzy of the Cultural Revolution abated, the government under the leadership of the late Premier Zhou Enlai tried to continue China's modernization process by proposing to achieve Four Modernizations (agriculture, industry, science, and military) by the end of the century. Encouraged by this aim, there was a new wave of technological importation. This time, the source countries were exclusively western countries. In the period of 1972-1976, 5.14

billion US dollars were spent to equip new factories all with imported equipment. The emphasis in this period was heavy chemical industry. In 1977, the new party chairman, Hua Guofeng, an honest but close-minded party functionary, proposed several new grand plans to catch up with the western world, and a new wave of heavy-industry development was launched. In 1978, the total investment was 50.1 billion yuan, a 31% increase over 1977; in addition, many technological import contracts were signed in a hasty way, as a result, foreign reserve had nearly 10 billion US dollar deficit in that year (Chen, 1997). This wave has been subsequently called "Foreign Leap-forward" and was stopped quickly after Deng Xiaoping controlled the government in 1979 (Yao, 2001).

China was still in the throes of the Cultural Revolution in the 1970s, and thus, Chinese scientists had little chance to participate in the development of modern biotechnology. But in the last years of this decade, China chose economic reform and development over political ideology by emphasizing the Four Modernizations of agriculture, industry, national defense, and science and technology, last of this period making biotechnology the top priority in the high technology field. Funding for biological research was increased more than 25-fold during this period, and new mechanisms were introduced to allocate these monies by competitive, peer-reviewed grants. At that time, China’s investment in biotechnology, as a percentage of its gross national product, was comparable to that in many Western countries.

The most noteworthy change was the establishment of an agricultural research and extension system for modern varieties. As a matter of fact, agricultural research is an area that the Chinese government can view with pride. The Chinese Academy of Agricultural Sciences was founded in Beijing in 1957; concurrently, each of the 29 provinces in the mainland established its own academy of agricultural sciences. However, this institution was initially at an embryonic stage, which developed especially in the 1980s, assuming a major role in the biotechnological development nationwide. Each national and provincial academy consists of several independent research institutes. Most prefectures also founded prefectural research institutes. In addition, agricultural research was conducted in a few research institutes of the Chinese Academy of Sciences and in some universities (Lin, 1998).

After the 1960s, China’s research institutions grew rapidly, producing a steady flow of new varieties and other technologies. China’s farmers used semi-dwarf seed varieties several years before the release of Green Revolution technology elsewhere in the world. China was the first country to develop and extend the use of hybrid rice. Chinese-bred corn, wheat, and sweet potatoes were comparable to the best in the world in the pre-reform era (Stone, 1988 quoted in Huang *et al.*, 2000a).

Several research institutes within CAAS (the Chinese Academy of Agricultural Sciences) and CAS (the Chinese Academy of Sciences) as well as in public universities, initiated their first agricultural biotechnology research programs in the early 1970s. The research focus of biotechnology in the 1970s was on cell engineering, such as tissue culture, anther culture, and cell fusion etc. This research covered many crops, including rice, wheat, maize, cotton, vegetables and others.

This agricultural research system fell apart during the Cultural Revolution, from 1966 to 1976. The Chinese Academy of Agricultural Sciences and many provincial and prefectural academies were reorganized, and many research scientists were sent in small groups to work on farms. They were sent to the countryside or factories for reeducation, and most research institutes were either closed or converted to production facilities. Between 1966 and 1976, the Cultural Revolution did its best to erase all forms of scientific innovation in China. A rare exception was the Shanghai Institute of Biochemistry, which carried out work on the synthesis of insulin and transfer ribonucleic acid (tRNA) during this period. The agricultural research system was restored after the end of the Cultural Revolution, and at that time many countries also established their own agricultural research institutes. The agricultural research institutes were funded by government budgets at their corresponding levels. The Ministry of Agriculture and the State Science and Technology Commission, however, also provided grants to research projects at lower level institutes (Lin, 1998). The government also made a major effort to attract scientists who had left the country during the war, particularly nuclear physicists and doctors, by promising them the opportunity to help build a new Chinese society. These promises were soon broken as China embarked on a series of vicious antirightist campaigns in which scientists, as members of the intellectual class, were castigated as “evil cow snakes” and “foreign devil lovers”. The situation was exacerbated by the split with the Soviet Union, China’s main provider of technological and scientific training in the 1950s (Lin, 1998).

1.4 - 1979-1999

Since the late 1970s, China's attitude toward the United States and other developed countries also underwent a major shift from strict isolationism to ever increasing contact and cooperation. Since 1978, in the biological sciences alone, China has sent more than 2000 students and researchers to the United States for advanced training. In addition, many joint research and training programs in China are currently being supported by American and other foreign academic institutions, private foundations, commercial enterprises, and government agencies. Such cooperative ventures have the potential to provide a rapid and efficient mechanism for Chinese scientists to obtain the training and technology needed to perform advanced biotechnology research.

Since China's leadership initiated the economic reforms in 1978, the economy has grown steadily. The annual growth rate of China's GDP averaged approximately 9.5 percent between 1979 and 1995 (see Table 11 in annex). China's foreign trade expanded even more rapidly than its overall economic growth, except during the most recent three-year period. Even when the Asian financial crisis plagued the region in the late 1990s, China's economy continued to grow, albeit at a somewhat more moderate rate than during the pre-crisis period (Huang *et al.*, 2000a).

China's GDP grew at 7.8 percent in 1998 and 8.3 percent in the first quarter of 1999 (compared to the first quarter of 1998). From a technological point of view, China's economy has the potential to maintain a dynamic GDP growth rate of 8 to10 percent annually in the coming decades (Lin, Shen, and Zhao, 1996 quoted in Huang *et al.*, 2000a). China set a priority on science and technology (S&T) more than twenty years ago. Endeavours to build strength in this area have resulted in rapid improvements, marked by the quadrupling of Gross National Product since 1978.

During the Sixth 5-Year Plan (1981-1985), funds were allocated to support biotechnology research in the fields of agriculture, food processing, and pharmaceutical production; and in 1983, the China National Center for Biotechnology Development (CNCBD) was established to coordinate these activities. During the Seventh 5-Year Plan (1986-1990), the level and scope of biotechnology funding have been greatly increased. In March 1986, the State Council Leading Group on Science and Technology published a pivotal document, often referred to as the "863 Plan", describing China's high technology development program and making biotechnology its top priority. That same year, the National Natural Science Foundation of China (NSFC) was founded to support basic research. In 1988, the State Science and Technology Commission (SSTC) published its second white paper on science and technology, which reinforced biotechnology as China's number one priority for high technology development. These events set the stage for the current mechanisms for determining biotechnology research priorities, administration, and funding.

2 – China's Research and Development System

China has traditionally had one of the strongest research systems in the world, including the largest number of agricultural scientists of any country in the developing world. Since the 1950s, China's researchers have successfully produced a steady flow of new varieties and other technologies. Farmers used semi-dwarf varieties developed in China several years before the release of Green Revolution technology elsewhere. China was the first country to develop and extend an F-1 variety of hybrid rice. Chinese-bred corn, wheat, and sweet potatoes technologies were comparable to the best varieties in the world in the pre-reform era (Stone, 1988 quoted in Jin *et al.*, 1998).

Variety improvement has been the core of China's agricultural research program from the very beginning. In the early 1950s, emphasis was given to the selection and promotion of the best local varieties. New varieties of rice, wheat, cotton, maize, and other crops were also imported from abroad. A major breakthrough in rice breeding occurred in 1964 when China began full-scale distribution of fertilizer-responsive, lodging-resistant dwarf rice varieties with high yield potential. This breakthrough occurred two years earlier than International Rice Research Institute's (IRRI) release of IR-8, the variety that launched the Green Revolution in rice elsewhere in Asia. At about the same time, hybrid maize and sorghum, improved cotton varieties, and new varieties of other crops were also released and promoted. These high yielding varieties were rapidly adopted (Lin, 1998).

A second major breakthrough in rice breeding occurred in 1976, when China became the first country to commercialize the production of hybrid rice. The innovative breeding and commercial development of hybrid rice has been heralded by some as the most important achievement in rice breeding in the 1970s. By 1979, high yielding varieties covered 80% of the rice area, 85% of the wheat area, 60% of the soybean area, 75% of the cotton area, 70% of the peanut area, and 45% of the rapeseed area (Lin, 1998).

China's agricultural scientists and the government support system developed and disseminated technology throughout the People's Republic period. By the early 1980s, China's research and development system for agriculture was at its peak. It had just made several major breakthroughs. Its level of national funding had been increasing. In part as a consequence of past investments, throughout the reform era, breeders turned out a constant stream of varieties. Since 1982, rice farmers in China have used about 400 "major" varieties each year (Huang *et al.*, 2000a).

Rice farmers in each province use around 25 major varieties per year. In the case of wheat, because there is no single dominant variety like hybrid rice (for which several varieties make up a large proportion of the nation's sown area), the total number of varieties per year nationally and the number per province are expected to be larger. In fact, wheat and maize breeders enjoyed less success. Wheat farmers in each province use around 23 varieties each year; maize farmers, on average, use 13 varieties. There are even fewer major soybean varieties in China both in total and on a per province basis. One reason may be that the research system has not traditionally centered its attention on the crop. Additionally, China is the center of origin for soybeans and there are many more small, traditional varieties that are still being grown (Huang *et al.*, 2000a).

Chinese farmers adopt new varieties with great regularity. The rate of turnover of varieties of major rice, wheat, maize, and soybeans in China is very impressive. Between the early 1980s and 1995, China's farmers turned their varieties over at a rate that ranged from about 13 to 45 percent. Maize farmers turned their varieties over the fastest, averaging more than 33 percent per year. This means that every three years farmers on average replace all of the varieties in their fields. Rice and wheat farmers adopt varieties at a somewhat slower rate, changing their varieties every 4 to 5 years. Soybean farmers adopt varieties at the slowest rate, changing their varieties every 6 years. Again, this might be consistent with the fact that the research system has not traditionally centered its attention on soybean (Huang *et al.*, 2000a).

In addition to producing genetic material itself, China also has drawn heavily on the international research system for genetic material, especially for rice. The International Rice Research Institute's material comprises a large share of China's rice germplasm.

Nationwide, we can trace around 20 percent of the germplasm to IRRI varieties. The proportion varies greatly over time (from 16 to 25 percent) and also varies by province, reaching more than 40 percent in Hunan Province, one of China's largest rice growing provinces, in the late 1980s. Although the national use of wheat and maize materials from the CG system (varietal contribution by Consultant Group for International Agricultural Research, CGIAR), mostly from CIMMYT, is lower (4 percent on nation average), there does exist great variability among provinces, and in some provinces material from the CG system (i.e. especially those in CIMMYT's mandate area, for example, Yunnan province for wheat or Guangxi Province for maize) makes up around half of the germplasm (Huang *et al.*, 2000a).

In summary, China's research system has created a lot of new technology and it has succeeded in getting farmers to adopt it at a rapid pace. The technology embodies significant levels of yield-increasing material that may prove to be an important determinant of productivity. The national research effort also is aided by the international agricultural research system. The rate of adoption of the highest yielding material, however, is much slower. China's yields and output certainly have grown due to increased use of inputs (Huang *et al.*, 2000a and Jin *et al.*, 2002).

Although China has spent the last 50 years building the most successful agricultural research system in the developing world—employing more than 70,000 scientists—research in modern plant biotechnology did not begin until the mid-1980s. Scientists now apply advanced biotechnology tools to the field of plant science, regularly working on the synthesis, isolation, and cloning of new genes and the transformations of plants with these genes. With the initiation of a research program on rice functional genomics in 1997, China's researchers began using AC/DS transposons and T-DNA insertion methods to create rice mutagenesis pools. Biotechnologists also have initiated functional genomics research for *Arabidopsis*. Some surveys of China's laboratories identified over 50 plant species and more than 120 functional genes that scientists are using in plant genetic engineering, making China a global leader in the field (Huang *et al.*, 2002a).

There are over 100 laboratories in China involved in transgenic plants research. By 2000, there were 18 GM crops generated by Chinese research institutes, four of them have been approved for commercialization since 1997. GM varieties in crops such as rice, maize, wheat, soybean, peanut and others are either in the research pipeline or are ready for commercialization (Huang *et al.*, 2002a).

An interest in biotechnology also builds on strong traditions of agricultural research in China, and the Green Revolution narratives have been particularly important in this aspect. Technology has been a key source of growth alongside institutional and price reforms, although perhaps in recent times it has received less attention by comparison with the emphasis placed on market reforms. It is often forgotten that China was the first nation to extend semi-dwarf rice varieties and drought and pest resistant wheat cultivars in the 1950s. These were followed by hybrid maize in the 1960s and the very first hybrid rice cultivars in the 1970s. Hybrids from the prestigious Hunan [now China] Hybrid Rice Research Institute covered half the area of cultivated rice by 1990. Nevertheless, strong arguments have been made that, while research has been key to maintaining total factor productivity in agriculture, returns in recent years have been declining. Such a case leads to an emphasis on new, more promising areas of research, given limitations in traditional avenues. Research institutes are also very crop oriented. The model of research is one of getting winning new varieties out to farmers, and biotechnology can be seen as an extension of this through yield increases and a variety focused approach. Some fear that one consequence of this is that rather less emphasis is perhaps placed on integrated farming systems or livelihoods-based approaches (Keeley, 2003a).

2.1 – Total Factor Productivity (TFP)

Although China's ability to feed itself during the last 45 years was highly acclaimed, really remarkable achievements in Chinese agriculture did not occur until the reform began in 1979 (see Table 12 in annex). As mentioned before, this growth has mainly come from institutional changes, the mobilization of inputs, intensity of farming, and growth in productivity from technological changes. Therefore, major elements of the reform included the replacement of the collective team system with the household responsibility system, the expansion of rural product and factor markets, and the liberalization of agricultural prices, except for grain and cotton. Among those reforms, the change to the household system had the largest impact on productivity (Lin, 1998).

Accordingly to Lin and Li (1995) quoted in Lin (1998), between 1979, when this institutional change began, and 1984, when it was complete, we see the largest annual growth rate in agriculture's TFP as well as in total grain output and per capita grain output. However, the impact of this institutional change on agricultural production was a one-time effect that had run its course by 1984. Although growth since 1984 in TFP has remained substantially higher than in the pre-reform period, annual growth of grain output has declined significantly. The average annual growth rate of 1.55% from 1984-96 was even lower than the average annual growth rate of 2.41% in the pre-reform period of 1952-78. As a result, during 1984-96, the annual growth rate of grain output per capita was 0.14%, the lowest since 1952. The poor performance in grain production resulted mainly from continuous government intervention in grain production and marketing. As the government liberalized the prices and marketing of most other agricultural products, the production of grain became less profitable than other products and farmers did not have adequate incentives to increase grain output.

Recent studies on agricultural TFP further confirm that agricultural productivity growth has mainly come from technology, including both the expansion of HYVs and improvement in farming system. Technology contributed half of the increase in rice yield between 1975- 1992. More than 50 percent of the growth of grain production and nearly 40 percent of cash crop output between 1978 and 1992 can be attributed to agricultural research. The major outputs of agricultural research – improved varieties and hybrids – have come from national, provincial, and prefectural institutes as well as from agricultural universities (Huang *et al.*, 2001a).

Research efforts and the application of new technologies are expected to contribute significantly to growth in agricultural output. The yield profile in Figure 5 in annex, which measures changes in land productivity, provides indirect evidence of the contribution of research and technologies to grain production. In an empirical study that directly measured the contribution of research to production, Fan and Pardey (1997) quoted in Lin (1998), found that 20% of the growth in agricultural output from 1965 to 1993 was attributable to research-induced technological change. Another empirical study, focused on rice production from 1970-90, also confirmed the primacy of technological change in explaining yield improvements. However, when we look at total factor productivity (TFP) instead of land productivity and examine the productivity profile for the entire period from

1952 to 1996 (instead of just a subperiod), we see a quite different picture. Studies by Fan (1997) and Wen (1993) quoted in Lin (1998) show that the TFP throughout the 1960s and 1970s was lower than that in the 1950s and did not rise above the 1952 level until the beginning of the agricultural reform in 1979.

2.2 – China's Research Performance and Funding Trends

China's research effort has succeeded by almost every indicator in many different sectors. Fan (1991) quoted in Jin *et al.* (1998) has demonstrated the positive effect of technology on the value of the output of the agriculture sector in the early reform era. More recent work has demonstrated that the contribution of research to the increase in yields and production of rice, wheat, maize, and cash crops exceeds that of any other factor in the early and late reform eras (Huang and Rozelle, 1996; Huang and Rozelle, 1997; Rozelle and Huang, 1997 quoted in Jin *et al.*, 1998). Research on the rates of return of agricultural research spending also have generated estimated levels that range between 70 and 108 percent, high for investments even in China's capital short economy.

Despite the contributions of research to the national food supply, farmer incomes, and efforts of leaders to meet the nation's food security goals, sectoral officials have had trouble maintaining access to enough fiscal resources to keep agricultural research investment from falling—although the direction of research investment is currently the subject of intense debate.

Budget pressures, the nation's "urban first" mentality, and poor intellectual property rights, in part, account for the inability of China to maintain a robust and growing agricultural research system. Despite the rapid growth of the economy, China's record on tax collection has left governments at all levels, but especially the national government and poorer provinces, short of fiscal resources. Faced with hard budget constraints, one response of budget managers has been to slash even well-functioning public services. Cuts to agriculture-oriented public agencies, may be even greater, given the well-known bias of policy makers against the rural sector and for urbanites. Weak intellectual property rights, as typified by the lack of plant breeding rights before 1997, have exacerbated the problem, since agricultural research institutes have been unable or unwilling to make up funds by marketing their products or selling their technology (Rozelle, Pray, and Huang, 1997 quoted in Jin *et al.*, 1998).

Chapter II
China's Agricultural Biotechnology Development Strategies and Policies

1 - China's Agricultural Biotechnology Development Strategies and Policies

China's leaders have paid great attention to agricultural biotechnology, as discussed above. Traditionally, biotech development has been conceived of strongly consistent with the national interest as defined by the leaders of China.

Chinese leaders have made clear their strong support for biotechnology and urged that China should position herself to take advantage of the potential biotech revolution. In his Government Work Report delivered to the National Peoples' Congress in March 1999, then Chinese Premier Zhu Rongji said "We should work vigorously to develop agriculture through science and technology, information technology and other high and new technologies, accelerate the work of breed selection and improvement and spread the use of advanced, applicable techniques which can increase production and income" (Ma, 1999 quoted in Newell, 2003).

In response to *Science* Editor Ellis Rubenstein's question about concerns in the West regarding GMOs and criticisms of biotechnology, Jiang Zemin stated that "We are also very much concerned about these... I think it is important to uphold the principle of freedom of science. But advances in science must serve, no harm humankind. The Chinese government is now mulling over new rules and regulations to guide, promote regulate, and guarantee a healthy development of science. I believe biotechnology, especially gene research, will bring good to humanity" (Rubenstein, 2000 quoted in Huang and Wang, 2003). These statements reflects China's position on biotechnology development: promoting the technology but showing appropriate precaution for biosafety, the environment, food safety, and the commercialization of biotechnology.

In the early days, China's vision included shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice especially for the welfare of the poor. More recently, however Chinese biotech policy has expressed a greater degree of uncertainty about the future of the technology, despite continuing levels of high investment in the sector. There is less consensus now than was the case even a year or two ago about the political and economic costs associated with following a strongly promotional position on biotech and no new crops have been commercialized since 1999 (Newell, 2003).

This shift results in part from strategic choices about the need to export food to European publics sceptical about the safety of GM crops. The size of the European market means that its policies strongly affect global food and feed production, commodity prices and trade patterns, and therefore influence the policies of many other countries. The impacts of the EU moratorium have included a rapid change in the patterns of transatlantic trade in commodities like soya and maize, as European buyers sought supplies of non-GM grain from formally GM-free countries such as Brazil instead of traditional suppliers in the United States (Newell, 2003 and Glover, 2003). This signal was received loud and clear when Chinese soy sauce was rejected by the UK because it contained GM ingredients from the US. This was said to be "the most direct cause for the new labelling restrictions in China".

Ever since it was announced in 1999 the European Union's *de facto* moratorium on new approvals for the production and import of GMOs, the politics of biotechnology in China have notably changed with regard to the commercialization of GM crops. China appeared poised to commercialize GM varieties of food crops such as maize and rice. However when the European moratorium began, the commercialization of GM food crops in China was unofficially and indefinitely put on hold (Glover, 2003).

The move towards process-based regulations suggests that China has started to follow a precautionary position that places its overall approach closer to the European model of biosafety regulation than to that of the US.

The discussion below makes clear that protection of Chinese producers and promotion of China's own biotechnology enterprises are also key factors in this shift of position. This helps to explain the restrictions on foreign investment that other commentators have taken as evidence of a "cooling" towards the technology. Overall it would appear that the combination of global market imperatives and domestic commercial considerations make what Huang and Wang refer to as a "wait and see" strategy the only viable and strategically sensible option to adopt, allowing China to keep open all options about its future agricultural development (Huang and Wang, 2003).

China can be considered to be pursuing a dual strategy in which it seeks to consolidate its position as a global contender in GMO production, but is also keen to open market channels to Europe and elsewhere where there is demand for non-GM produce. There has been some discussion, for example, of the suitability of China aping Brazil's strategy of seeking to export GMOs from some areas and GM-free produce from other parts of the country. The Ministry of Agriculture has floated the possibility of developing the North-East into the world's largest producer of non-genetically modified soybeans over the next five years. This dual strategy would mean that China would push forward fast on GM foods which offer high yield and resistance to disease while promoting GM-free areas for crops for sale to rich markets where many consumers still reject the idea of genetically modified.

2 - The Role of the Private and Public Sectors

The private sector dominates the worldwide research in the field of agricultural biotechnology. Although exact data about international research expenses is not available, it is estimated that private companies account for about 75 percent in this area worldwide, with increasing tendency. Few trans-national companies from industrialized countries dominate biotechnology research and the degree of concentration on the markets for the respective technology products is growing (GTZ, 1999). However, China's experience with biotechnology has been very different from other countries. Unlike the rest of the world, in which most plant biotechnology research is financed privately, China's government funds almost all of its plant biotechnology research. Ministry of Science and Technology has increased plant biotechnology project funding in the sample institutes from $8 million in 1986 to $48 million in 1999. After a number of adjustments, China's total investment in plant biotechnology in 1999 was estimated to be $112 million. Expenditures of this level demonstrate the seriousness of China's commitment to plant biotechnology (Huang *et al.*, 2002a).

Since the "Biotechnology Revolution" is being led by private companies, there is little reason to believe the products that emerge are destined to feed the billions on the planet or to protect the environment. Because the private sector is motivated by incentives such as profits, timely return to stockholders, and market share, it is not surprising that the genetic manipulation funded by the private sector would emphasize investments and product attributes that would differ from that of a more complete public agenda. Put more formally, one would expect the private sector to invest in low exclusion goods such as seed-chemical-machinery "packages" or value-added foods and neglect high exclusion goods, such as protection of biodiversity or the improvement of minor traditional crops in the developing world. Private investments can thus be expected to focus on high-return and high-value crops, on labor-saving technologies, and the needs of capital intensive farming in order to feed those who can pay, and not on the needs of the smallholder farmers in the developing world nor environmental conservation (Batie and Ervin, 2000). Thus, there is a role for the public sector, which is significant in the Chinese case. The nation's public-dominated research system has given China's researchers a strong incentive to produce GM crops that increase yields and prevent pest outbreaks. In industrialized countries, 45% of field trials are for herbicide tolerance and improving product quality; only 19% are for insect resistance. In China, more than 90% of field trials target insect and disease resistance (Huang *et al.*, 2002a).

This means that the profile of biotechnology products emerging from research is very different from most other developed and developing country settings. China has not so far, for example, concentrated on the herbicide-resistant crops that have been a priority of multinational corporations. The emphasis has been more on producing new seeds that lower input costs for farmers, rather than tie them into particular proprietary chemicals. In the case of Bt cotton some farmers have already made significant savings. Also, there has been more emphasis on non-transgenic techniques of less interest to the private sector, because they are less likely to result in patentable products: marker-assisted selection, for example. Meanwhile, crops are being developed with a "pro-poor focus", including stress tolerant crops suited for dry, low-fertility or saline settings (Keeley, 2003b).

In 1997, the release of Bt cotton began China's first large-scale commercial experience with a product of the nation's biotechnology research program. (In the early 1990s, virus-resistant tobacco variety had been commercialized before being removed from production because of pressure from an international tobacco importer). Response by China's poor farmers to the introduction of Bt cotton eliminates any doubt that GM crops can play a role in poor countries. A survey of agricultural producers in China demonstrates that *Bacillus thuringiensis* cotton adoption increases production efficiency and improves farmer health (Bt cotton in China will be discussed in more detail later on). China increased its Bt cotton area for the fifth consecutive year from 2.1 million hectares in 2002 to 2.8 million hectares in 2003, equivalent to 58% of the total cotton area of 4.8 million hectares in 2003 (James, 2003). Currently, Bt cotton in China is the world's most widespread transgenic crop program for small farmers (Huang *et al.*, 2002a).

3 - Institutional and Policy Measures

The goals of biotechnology development have been defined in several dimensions in China. From the point of view of users of biotechnology, the government defines the goals of biotechnology development as improving the nation's food security, promoting sustainable agricultural development, increasing farmer income, reducing pesticide use and improving the environment and human health, and raising its competitive positions in international agricultural markets along with other public agricultural development programs. From the point of view of the technology itself, the most frequent statement of the development goal of biotechnology in China is to create a modern, market responsive, and internationally competitive biotechnology research and development system (Huang *et al.*, 2001a).

An ambitious scheme to promote biotechnology research was started in the beginning of the "Seventh Five-year Plan" (1986-1990) when the first comprehensive National Biotechnology Development Policy Outline was issued. The Outline was prepared by more than 200 scientists and officials under the leadership of the Ministry of Science and Technology (MOST), the State Development and Planning Commission (SDPC), and the State Economic Commission in 1985 and revised in 1986. Although the State Council issued this Outline two years later (in 1988), it has been used as policy guideline in developing modern biotechnology programs in China since 1986. The Outline defines the goals and objectives of biotechnology development in agriculture, medicine, chemistry, environment, and food processing. The Outline also provides policy measures and research priorities in each field of agriculture, medicine, chemistry, environment, and food processing.

A number of high profile technology programs were launched thereafter (see Table 13 in the annex). Some of the most significant programs include the "863 High-tech Plan" and the "973 Plan", both discussed below, the Initiative of National Key Laboratories on Biotechnology, Special Foundation for Transgenic Plants, Key Science Engineering Program, Special Foundation for Hightech Industrialization, Bridge Plan, and so on (see

Table 13 in annex). Based on the Outline, each biotechnology program develops its own guideline that specifies the research priorities within its program for a certain period (usually 5 years), and also annually. In each program there is an expert committee with members from Chinese Academy of Agricultural Sciences (CAAS), Chinese Academy of Sciences (CAS), leading universities and several other government organizations that formulate program guidelines. Therefore in the whole policy making procedure for biotechnology research, the scientists play a very important role in setting priorities (Huang *et al.*, 2001a).

3.1 - Key Government Biotechnology Development Programs

3.1.1 - The 863 Plan

The 863 Plan, also called National High-Tech Research and Development Plan, was approved in March 1986. The 863 Plan supports a large number of applied as well as basic research projects with a 10 billion yuan budget (equivalent to US$ 3 billion, based on the official exchange rate of 3.4 in 1985, or US$ 1.2 billion, based on the official exchange rate of 8.27 in 2000) over 15 years to promote high technology research and development (R&D) in China. Biotechnology is one of seven supporting areas, with a budget of 1.3 billion RMB yuan in 1986-2000, with 50% of this budget focused on agricultural biotechnology (Huang and Wang, 2003).

One of the key bodies through which MOST operates is the 863 program. This program concentrates on applied science and was started in March 1986 after a group of four scientists persuaded Deng Xiaoping that major investment in science and technology research and development was vital if the Four Modernizations were to be realized, and China were not to fall far behind the West. The importance of this change, and of top level endorsement, cannot be underestimated; while nuclear science and the science underpinning heavy industry were key parts of the ideology of the new Chinese state, scientists have not had an easy ride in modern China. Only 15 years before 863 was formed, for instance, scientists were being labelled as class enemies and being sent to the countryside for political re-education. Nevertheless since 1986 a vision of a biotech future has been an integral part of China's plans for modernization (Keeley, 2003a).

Funds allocated to the 863 program have been very significant. The first 15 years of the program coincided with the 7th, 8th and 9th Five Year Plans, during which time 11 billion yuan (US $ 1.3m) was allocated, with 1.4 billion going on biotechnology. 863 has now been extended to coincide with the 10th Five Year Plan. For this period 15 billion yuan (US $ 1.8m) has been allocated, with 3 billion RMB going to biotechnology and 50 per cent of that to agriculture. There have also been significant strategic overseas sources of finance, such as the Rockefeller Rice Biotechnology Program noted earlier, from which China has benefited (Keeley, 2003a).

There has been a clear nationalist edge to China’s biotech program, and this can be seen in relation to the pride associated with achievements like decoding of the rice genome, and also in the way that Biocentury – the company promoted by 863 to commercialize Bt cotton – and the Biotechnology Research Institute present their biotech achievements; their promotional material.

3.1.2 - The 973 Plan

973 Plan was initiated in March 1997. This plan is similar to the 863 Plan. The 973 plan was established to support basic science and technology research. Life sciences, with biotechnology as priority, constitute one of the key supporting areas (Huang *et al.*, 2001b).

The National Basic Sciences Initiative, also called the 973 Plan, with a total budget of 2.5 billion yuan (US$ 302 million, converted at the1997-2002 average exchange rate) in the period of 1997-2002, was another high-tech research plan initiated in March 1997. This plan is complementary to the 863 and many other national initiatives on high-tech development, as it exclusively supports basic research. Life science, with biotechnology as a priority, constitutes one of the key programs under this plan (Huang and Wang, 2003).

3.1.3 - Natural Science Foundation of China (NSFC)

The Natural Science Foundation of China (NSFC) was founded in 1986 expressly to support basic research in China. The NSFC promotes basic research in all science and technology sectors and carries out the SSTC’s plans for basic research. NSFC gives grants for basic research only. 1993 Figures for NSFC show total allocation of yuan 240 million (US$ 28 million), of which about one third was devoted to life sciences. The largest fraction, 14 percent, was devoted to clinical medical sciences (Kahaner, 1996).

3.1.4 - Special Foundation of Transgenic Plants Research and Commercialization (SFTPRC)

A new program aimed at strengthening the national research and industrialization of China's agricultural biotechnology, the Special Foundation of Transgenic Plants Research and Commercialization (SFTPRC), was initiated in 1999 by the Ministry of Science and Technology. This new program is a unique foundation to promote both research and commercialization of transgenic plants. Only those projects that are jointly submitted by research institutes and companies are eligible to receive funding from about half of the programs under SFTPRC. The foundation also requires a significant financial commitment from companies to commercialize technology generated by a project, a reflection of China's aim to accelerate the diffusion of biotechnology. The total budget of SFTPRC during its first five years (1999-2003) was 500 million yuan (about US$ 60 million) (Huang *et al.*, 2001b).

3.1.5 - Key Science Engineering Program (KSEP)

Concurrently, the Ministry of Science and Technology and the State Development and Planning Commission jointly sponsored the Key Science Engineering Program (KSEP), a national program to promote the fundamental construction for research in the late 1990s. As an example, one extremely large biotechnology project on crop germplasm and quality improvement through biotechnology received 140 million RMB yuan (US$ 17 million) from KSEP in 2000. Moreover, the State Council passed a new Agricultural Science and Technology (S&T) Development Compendium in 2001. The compendium reemphasizes the importance of agricultural biotechnology in improving the nation's agricultural productivity, food security, and farmers' income, and has led to a new decision to further increase the research budget for the development of biotechnology. The proposed biotechnology development budget for the Tenth Five-year Plan (2001-2005) is far more than all prior budgets over the past 15 years (Huang *et al.*, 2001b).

Chapter III
China's Agricultural Biotechnology Research Institutions and Administrative System

1 - China's Agricultural Biotechnology Research Institutions and Administrative System

As discussed above, biotechnology and GM crops have appealed to Chinese policymakers for a number of reasons. How these arguments were made and how this has worked in institutional terms are important questions. The primary role of the public sector in deciding to pursue biotechnology, guiding investment and vigorously promoting the new technology is central to the Chinese story. Policies related to biotechnology in terms of development strategies, research priorities, the approval and allocation of budgets, and biosafety management are formulated by several supra-ministries and agencies. The supra-ministries and agencies include the Ministry of Science and Technology (MOST), State Development Planning Commission (SDPC), the Ministry of Agriculture (MOA), and the Ministry of Public Health (MPH), among others (see Figure 6 in annex) (Huang *et al.*, 2001a; Huang *et al.*, 2001b and Keeley, 2003a).

1.1 - Ministry of Sciences and Technology (MOST)

At the national level, the most important of these is the Ministry of Science and Technology (MOST). MOST funds scientific research in a number of ways including through support to a series of National Key Laboratories and a system of competitive tendering for biotech research grants. It also develops science and technology policy, therefore it proposes R&D legislation, and implements legislated policies. MOST also supervises, coordinates, and evaluates biotechnology R&D plans, projects and budgets – including some competitive grants which it administers. MOST has always had a key role together with Ministry of Agriculture (MOA) in writing the research part of the five-year plans, the route through which most financial support to agricultural research is allocated (Huang *et al.*, 2001a; Huang *et al.*, 2001b and Keeley, 2003a).

Four departments and centers under MOST administer its biotechnology programs (see Figure 7 in the annex). They are the National Center for Biological Engineering Development (in charge of High-Tech R&D, including biotechnology), the Department of Rural & Social Development (especially the Biotechnology Division under this department, in charge of research program development), the Department of Infrastructure (especially

Base Construction Division in charge of physical capacity building), and China's Center for Rural Development (in charge of commercialization of agricultural high-tech program).

Four giant high-tech and biotechnology programs, are run by MOST and SDPC. They are the "863 Plan, the "973 Plan, the Special Foundation for Transgenic Plants, and the Key Science Engineering Program (discussed in Chapter II) (see Figure 8 and Table 13 in annex).

1.2 - State Development Planning Commission (SDPC)

SDPC makes annual, five-year and long-term plans and ultimately determines national level financial budgets for all ministries. SDPC authorizes the Ministry of Finance (MOF) to transmit such funds to MOST for onward transmission to the various ministries (and their research institutes) and the Chinese Academy of Science (CAS). The principle institution under SDPC in charge of biotechnology is the Department of High Technology (DHT, Figure 7, in the annex). Under DHT, there are several divisions responsible for different aspects of advanced technologies. The Agricultural Division specializes in agricultural biotechnology and together with MOST co-manages one of the major agricultural biotechnology programs in China, namely the Key Scientific Engineering Program (KSEP). The other division (Industrialization Division) was established recently to promoting the commercialization and extension of biotechnology in both agricultural and non-agricultural areas through a large and unique program, called the High-tech Industrialization Program (HTIP, Figures 7 and 8, in annex, and see Table 13 in annex) (Huang *et al.*, 2001a and Huang *et al.*, 2001b).

1.3 - Ministry of Agriculture (MOA)

MOA contains a Science, Technology and Education Department that coordinates national level biotechnology research within the Ministry's research system and attempts to coordinate R&D between national and sub-national levels and provide some guidance to lower jurisdiction institutes, but local institutions have considerable autonomy. Activities of research institutes that lie outside the domain of MOA are largely uncoordinated with

MOA R&D. Coordination between institutes at local levels is generally weak – which contributes to unnecessary and inefficient duplication of efforts.

MOA contributes to agricultural biotechnology research programs mainly through its involvement in formulation of overall agricultural biotechnology research and development plans (i.e., five-year and long-term plans; R&D legislation) and implementation of legislation and policies. This activity is coordinated by MOST. Only one Foundation was set in the late 1990s and run by the MOA, this is the China Agricultural Sciences and Education Foundation (CASEF). The budget of this Foundation is nothing, however, when compared with the biotechnology programs administered by MOST and SDPC. Moreover, biotechnology is only a small component of CASEF. The debate on which ministry is the appropriate institution to manage agricultural research programs in general, and agricultural biotechnology in particular, has been going for while. This debate has generally been resolved in favour of MOST. This may be explained by the fact that agricultural research institutes directly under MOA account for only 8 percent of total agricultural research staff and 12 percent of the total agricultural research budget in 1999. Most of research is conducted at provincial (39 percent of the budget) and prefectural (35 percent of the budget) research institutes. Some agricultural research is also conducted at universities (8 percent of budget) and at CAS and other ministries (8 percent of budget in 1999) (Huang and Hu, 2001).

While MOST is responsible for management of biosafety in general, MOA is in charge of the formulation and implementation of biosafety regulations on agricultural biotechnology in particular. Several divisions within MOA are involved in agricultural biosafety management. The Office of Agricultural Genetic Engineering Safety Administration (OAGESA) and the Biosafety Division of Agricultural Genetic Engineering (BDAGE) under the Center of Science and Technology Development (CSTD) and the Planning Division under the Department of Science and Education are jointly responsible for the biosafety management. OAGESA and BDAGE focus mainly on biosafety assessment applications for GMOs and implementation of biosafety regulations. The Planning Division is responsible for the approval of GMOs release and making decisions on biosafety issues (Huang *et al.*, 2001a).

1.4 - Other Ministries and Agencies

Currently, there are about 150 laboratories at national and local level located in more than 50 research institutes and universities across the country working on agricultural (plant and animal) biotechnology (see Figures 6 and 7 in annex). Laboratories that were evaluated and selected as National Key Laboratory (NKL) have been equipped with advanced instrumentation and also received extra operating funds to strengthen the biotechnology research program at the recipient laboratory. Both SDPC and MOA administrated the laboratory selection program. NKLs are denominated "Open Laboratories" because of the mandate that they should train and allow usage of both domestic and foreign guest researchers (Huang *et al.*, 2001b).

The laboratories are open to investigators from outside institutions and are intended to serve as national training centers. In general, these key laboratories have been established at the most advanced biotechnology research centers in China: Peking University, Fudan University, Beijing Institute of Virology, Beijing Institute of Biophysics, Shanghai Institute of Biochemistry, Shanghai Institute of Plant Physiology, and Shanghai Institute of Cell Biology (Hamer and Kung, 1989).

The value of the key laboratories as training centers is dubious since, in general, visiting scientists from distant provinces are unable to apply their new knowledge after returning to their home institutions that lack adequate facilities. On the other hand, the program has allowed some of China's best biology research centers to make great improvements in their facilities and equipment. An example is the Laboratory of Genetic Engineering at Fudan University. Rather than building a new facility, this key laboratory was integrated with existing laboratories of the university's Institute of Genetics, and the money was spent on new instrumentation. This allows visiting investigators maximum contact with well-trained university scientists and, at the same time, permits access by scientists to highly sophisticated laboratory instruments (Hamer and Kung, 1989).

Over the last 2 decades, China established 30 National Key Laboratories (NKL). Among these NKLs, twelve NKLs are exclusively working on and 3 NKLs have major activities on agricultural biotechnology. Besides NKLs, there are ministerial and provincial biotechnology laboratories and programs.

At the nation level, the MOA, Chinese Academy of Sciences (CAS), State Forestry Bureau (SFB), and Ministry of Education (MOE) are the major authorities responsible for agricultural biotechnology research (see Figure 6 in annex). Under MOA, there are 3 large academies, Chinese Academy of Agricultural Sciences (CAAS, about 8000 research and supporting staff), Chinese Academy of Tropical Agriculture (CATA), and Chinese Academy of Fisheries (CAFi). Among 37 institutes in CAAS, there are 12 institutes and 2 National Key Laboratories (NKL) and 5 ministerial laboratories that conduct biotechnology research programs. CAFi and CATA also have several biotechnology laboratories or programs, and each has one NKL in biotechnology.

Agricultural biotechnology research is also undertaken by national institutes outside the MOA system. These include 7 research institutes and 4 NKLs under CAS, research institutes within the Chinese Academy of Forestry (CAFo) under the State Forest Bureau, and universities under the Ministry of Education (MOE). There are 7 NKLs located in 7 leading universities conducted agricultural biotechnology or agriculturally related basic biotechnology research. Other public biotechnology research efforts on agriculturally related topics include agro-chemical (e.g. fertilizer) research by institutes in the State Petro-Chemical Industrial Bureau (Huang *et al.*, 2001a and Huang *et al.*, 2001b).

Agricultural biotech research at the provincial level follows a similar institutional framework to that at the national level (see Figure 6 in annex). Each province has its own provincial academy of agricultural sciences, and at least one agricultural university. Each academy or university at provincial level normally has 1-2 institutes or laboratories focused their works on agricultural biotechnology. Local biotechnology research is financed by both local government (core funding and research projects) and central government (research projects only) (Huang *et al.*, 2001a). At provincial level funds come directly from Provincial Science and Technology Commissions; indeed provincial level Academies of Agricultural Science are under the STCs, rather than agricultural bureaux.

Summarizing, the institutional framework of agricultural biotechnology program in China is very complex, having a large number of participating institutions engaged in agricultural biotechnology. However, multiple sources of funding (MOST, SDPC, MOA, local and province), combined with the large number of biotechnology research institutes and laboratories, and the lack of coordination and collaboration among research institutes both at the national and the provincial level, have led to large overlaps of the agricultural biotechnology research programs and has contributed to unnecessary and inefficient duplication of efforts, particularly at the local level (Huang *et al.*, 2001b).

2 – Agricultural Biotechnology Research Indicators

2.1 - Human Resources

High quality researchers and support staff are invaluable elements for any successful biotechnology program. In order to build and maintain a strong biotechnology industry (production and research), China must inevitably lure back many of its students who went away to the U.S., Europe and Japan for advanced training.

Although moving towards prosperity, China faces some circumstantial and self-imposed difficulties in convincing these now well trained professionals to return to its own research institutions and biotechnology companies. The government policy of trying to wean research institutions off government support may be premature and could possibly serve to discourage returning scientists. Money will be one problem. While desiring the return of its overseas students, the government is also trying to save money by forcing institutions into "self-sufficiency". In the end though, these laboratories will become "dependent" on earning harder to obtain funds from sources such as international grants and joint or contracted projects with private companies. Though there has been the creation of at least one Singapore-based investment fund that speculates on the industry's long term prospects, local private investment hasn't materialized to any great extent, yet to compete with inflation of more than 10% and often in the teens, local investors are looking for quicker ways to get return on their investment. This uncertain funding period will probably discourage those who have comfortable jobs from returning. Circumstantially, China's still developing infrastructure and under equipped research facilities also serve to discourage students from leaving their properly equipped laboratories located in countries which offer a better standard of living (Kahaner, 1996).

This is not to say that China has not taken some steps to attract its foreign-trained professionals. On the contrary, China now offers all returning PhD's ranking positions, at least associate professorships, and relatively spacious 2-3 bedroom apartments in research institution apartment buildings.

Unfortunately this encouragement program is not without potential problems. First, a large number of returning students may place an unprecedented stress on the research institution's physical and organizational resources that might undermine the benefits of the talent and knowledge, which they bring to China. Second, the current meagre research budgets allotted by local biotechnology companies cannot absorb these returning scientists. Concurrently, many better-paying positions for these well educated bi-lingual individuals in non-biotechnology industries may siphon off some of the returnees. Lastly, the increased competition for a relatively fixed amount of funding will increase the already considerable amount of time wasted searching for funding.

There are already several bright spots in Chinese biotechnology, often centred on returning scientists. One such is Yang Huanming, who trained in Europe and America before returning to start the Beijing Genomics Institute. As well as leading China's contribution to the human genome sequence and working with Danish partners on the pig genome, the institute announced completion of a detailed map of the rice genome. It is also involved in the International HapMap Project, a five-country initiative launched in October 2002, to follow up the Human Genome Project with a large-scale study of human genetic variation and its relation to disease (*The Economist* – Science & Technology, 2002).

Similarly, the National Engineering Research Centre for Beijing Biochip Technology is headed by Cheng Jing, an engineer and molecular biologist trained in Britain and America. Dr Cheng is one of China's most entrepreneurial academics, having already spun out some of the centre's technology to Chinese and American start-ups. He was working on two diagnostic chips, for infectious disease and tissue transplantation, in trials at Beijing hospitals (*The Economist* – Science & Technology, 2002).

Another hotspot is the Chinese National Human Genome Centre in Shanghai. Here, the focus is on studying the genetics of diseases that particularly afflict the Chinese population, such as hepatocellular carcinoma, a form of liver cancer. Stem-cell research is in the works at a handful of centres. Most of China's stem-cell scientists are focused on adult cells, and half a dozen stem-cell banks have already sprung up. But some researchers are working in the more controversial area of embryonic stem cells. Among them is Sheng Huizhen, at Shanghai Second Medical University, who is trying to generate stem cells by transferring nuclei from human skin cells into rabbit eggs (*The Economist* – Science & Technology, 2002).

Dr Sheng's experiments are strictly academic; she wants to understand better the early stages of cellular reprogramming, work that requires thousands of eggs that are unavailable from human sources. After more than a decade at America's National Institutes of Health, she decided to return to China, as increasing restrictions made this line of research difficult. These are interesting times indeed, with academics returning to China for the intellectual freedom they cannot find in the West (*The Economist* – Science & Technology, 2002).

For all these scientific strengths, the expansion of Chinese biotechnology is held back by several problems. One is funding. Biotechnology is not cheap: long development times and scientific uncertainty mean that it takes lots of money to develop a successful product. At the moment, most Chinese biotechnology is bankrolled by the government, although private money is beginning to trickle in (*The Economist* – Science & Technology, 2002).

On the whole, biotech entrepreneurs such as Dr Cheng would rather have private money than deal with the strings that inevitably come with public funds. So far, private investors in China are far less sophisticated than their foreign counterparts. Zhao Guoping, director of Shanghai's genomics centre, has seen plenty of millionaires beat a path to his door, only to turn back when they hear how risky biotechnology can be. Some investors from Taiwan, Singapore and Hong Kong have taken the plunge. But venture-capital groups from Europe and America are holding off until they can be assured of a way to recoup their investment, preferably by floating any resultant company on the stockmarket, or selling it to a larger firm (The Economist – Science & Technology, 2002).

China’s public agricultural research system, the largest in terms of research numbers in the world, employs more than 130,000 staff (Huang and Hu, 2001). China’s agricultural biotechnology research system probably is also one of the largest in the world. Table 14 in annex shows the number and composition of plant biotechnology research staff in a recent study conducted by the authors. The total researchers in 29 plant biotechnology research institutes reached 1657 in 1999 (see Table 14 in annex). For China as a whole, Huang *et al.* (2001b) estimate that the number of researchers in plant biotechnology could be over 2000.

Results from 22 institutes with complete information show that the number of total staff involved in biotechnology doubled within 13 years increasing from 641 in 1986 to

1205 in 1999 (see Table 14 in annex). Of total professional staff, 484 were involved in research directly, whereas 207 were in management positions. Total professional staff increased 142% since 1986. The total number of professional staff in all the 29 plant biotechnology institutes reached 691 in 1999. Among total staff, almost 60 percent was professional (i.e., researchers and research managers) (Huang *et al*, 2001b).

The share of the professional staff has been rising over time (see Table 14 in annex). Professional staff increased by 142 percent within the same period. The most significant growth was in the late 1980s, reflecting the large movements of several biotechnology promotion initiatives by the government in the second half of the 1980s (see Table 14 in annex) (Huang *et al*, 2001b).

Similar to other agricultural research program in China, plant biotechnology research primarily is built around the research institutes (see Table 14 in annex). In the 29 institutes surveyed in the study made by Huang *et al*. (2001b) in 1999, there where 633 researchers employed at research institutes. Total staff in universities sum 166. Of total research staff in universities, 72 were researchers, 52 managers, and 42 support staff. In contrast there were 1491 personnel in institutes, of which 633 were researchers, 212 management and 646 were support staff. It is interesting to note that the total personnel in universities represented 5 percent of the total universities' research staff and about 4 percent of all the agricultural research system.

A significant improvement occurred in human capacity in biotechnology research in China. In 1986 there were only 5 researchers holding a PhD degree (see Table 15 in annex). The number of researchers with a PhD reached 141 in 1999 for 22 institutes and 203 for 29 institutes. Within professional staff, the share of researchers holding PhD degrees increased from 2 percent in 1986 to about 20 percent in 1999. The share of professional staff holding a PhD degree is expected to keep rising in the future as the ability to conduct PhD educational programs in biotechnology has been strengthened in several of the surveyed institutes. The percentage of professional researchers with PhD degree in universities is much higher than that in research institutes. Among 124 professional staff in universities, 58 held PhD degrees in 1999, accounting for 47 percent of the total. In research institutes, researchers with PhD degree represented 17 percent of total staff in 1999. The percent of PhD degree holding staff varied widely between institutes and universities. The large number of biotechnology research institutes and wide variation of human capacity within institutes will be a challenge for China to consolidate its national biotechnology research programs for any given amount of research budget in the future (Huang *et al*, 2001b).

While the share of researchers with a PhD degree in biotechnology is still low in comparison to leading biotechnology countries, it is interesting to note that this share is much higher than that in the Chinese agricultural research system in general. In the national agricultural research system, researchers holding a PhD degree accounted for only 1.1 percent of the total professional staff in 1999 (Huang and Hu, 2001).

Another unique characteristic of biotechnology research in China is that the share of female researchers relative to the total professional staff is higher than in the rest of the agricultural research system. In plant biotechnology, the professional female researchers accounted for about 33 percent of the total (see Table 16 in annex). In contrast, the percent of female researchers in the rest of the agricultural research system was about 30 percent of the total in 1999. The different working environment compared to non-biotechnology research may explain the relatively larger share of females in biotechnology research. Agricultural research in the rest of the Chinese research system involves extensive field activities in which the female researchers may have less comparative advantage than male researchers due to cultural and social constraints of Chinese society (Huang *et al*, 2001b).

2.2 - Financial Resources

Accordingly to the study conducted by Huang *et al.* (2001b) in 1999, a significant growth in biotechnology research investment was observed in China during the 1990s (see Table 17 in annex). Biotechnology research investment was insignificant during the early 1980s in China. For 22 of the institutes surveyed in their study, total investment in plant biotechnology research reached 16 million yuan in 1986 when China formally started its 863 Plan. By 1990, investments in biotechnology grew to 27.7 million yuan, representing an increase of 73 percent over 1986 or roughly a 20 percent annual growth rate. Strong growth during this period was mainly due to the increasing research project budgets and equipment expenses. Investments in biotechnology reached 92.8 million yuan in 1999 for 22 institutes surveyed. Total investments increase to 130.8 million yuan if information for all 29 institutes is included.

The growth rate of biotechnology research investment slowed down to 4 percent in 1990-95. The slow-down of investment growth was expected as large investments in biotechnology equipment were nearly completed during the early 1990s. On the other hand, the growth in research project budgets was still remarkable. The annual growth rate of research project budgets remained as high as 10 percent in 1990-95. Several large biotechnology programs (or programs with a biotechnology component) were initiated since the mid-1990s. These include the "973" Plan, Special Foundation of Transgenic Plants, and Key Science Engineering Program, and the Bridge Plan. With the implementation of these programs, biotechnology research investment increased dramatically from 32.7 million yuan in 1995 to 92.8 million yuan in 1999 for the 22 institutes studied. This increase represented an annual growth of about 30 percent. Based on our estimates, total investments in plant biotechnology research reached 140 million yuan in 1999 for the 29 institutes surveyed (Huang *et al*, 2001b).

The main source of investments in biotechnology research in China is the national government. Donor agencies contributed between 1.5 percent in 1986 to 6.9 percent of the total plant biotechnology budget for 22 institutes studied in 1999 (see Table 17 in annex). Funds from competitive grants supporting research projects accounted for two thirds of the total budget. The increasing share of competitive grants reflects the change in priority from capacity building to an increase in specific research projects (Huang *et al*, 2001b).

Of the total investment in plant biotechnology research in the sampled institutes, 28 percent (or 36.7 million yuan) was allocated to research in universities, whereas the remaining 72 percent (94.1 million yuan) to research institutes in 1999 (see Table 17 in annex). Because the share of researchers in universities represents about 10 percent of the total, this implies that the research expenditure per scientist is much higher in the universities than in the research institutes. This pattern of investment is expected, as the share of the researchers with a PhD degree is higher in the universities than in research institutes (Huang *et al*, 2001b).

Among the total budget, payments for personnel accounted between 36 percent in 1986 to 18 percent in 1999 (see Table 18 in annex). If information for all 29 institutes is included the percent expenditures on personnel reaches 21 percent. This share is much lower than in developed countries where they normally reach half of the total budget (Huang and Hu, 2001). The lower share of personnel costs may partially reflect a lower level of human resources but may also point to a relatively lower cost of conducting biotechnology research in China. As the level of private sector investments in agricultural R&D increases in China (Huang and Hu, 2001), public biotechnology research programs may face the challenge of keeping its best professional staff from moving to the private sector, particularly if the salary and incentive system for public agricultural research is not improved in the future.

Operating expenditures have increased from 3 million in 1986 to 44 million yuan in 1999. If all 29 institutes sampled in the survey are included this figure increases to 56.2 million yuan. The increase from 3 to 44 million yuan represents an increase from 23 to 52 percent in 1986 and 1999 respectively. Conversely, capital expenditures have increased from 5.5 million yuan in 1986 to 21.5 million yuan in 1999. However, the increase in capital expenditures represents a decrease of the capital's share of the total budget from 42 % in 1986 to 27% in 1999 (Huang *et al*, 2001b).

While both research investments and the number of researchers increased in the past 15 years, the former has grown much faster than the latter, and thus research expenditures per researcher increased rapidly. Expenditure per professional staff doubled from 46 thousand yuan in 1986 (at constant 1999 price) to 115 thousand yuan in 1999 (see Table 19 in annex). Expenditure per staff member has tripled from 20.6 thousand yuan in 1986 to 66.0 in 1999. If information from 29 institutes is included the increase in expenditures changes slightly. Huang *et al.* (2001b) personal communications with scientists and leaders of the 29 biotechnology institutes surveyed in 1999 reveal that, while most of them are satisfied with rising research budgets, many of them are still concerned with the low level of research expenditures per staff member and the fragmentation of biotechnology research projects over many research institutes.

3 - Agricultural Biotechnology Research Focus

3.1 - Priorities for Agricultural Biotechnology Research

Table 20 in annex summarizes research priorities of plant biotechnology identified in various Biotechnology Development Outlines for the past 15 years in China. In the selection of major crops to be included in the biotechnology programs, cotton, rice, wheat, maize, soybean, potato, and rapeseed have been consistently listed as priority crops for research funding from the national biotechnology programs since the mid-1980s. Total area sown to crops listed as priorities was over 100 million hectares, accounting for more than two-third of the total crop area sown in China in the 1990s (Huang *et al*, 2001b and Huang and Wang, 2003).

Cotton has been consistently selected as a top priority crop not only because of its importance due to area sown and its contributions to the textile industry and trade, but also because of the serious problems with the associated rapid increase in pesticide applications to control insects (i.e., bollworm and aphids) (Huang and Wang, 2003).

Rice, wheat and maize are the three most important crops in China. Each accounts for about 20 percent of the total area planted. Production and market stability of these three crops are primary concern of the Chinese government as they are central to China's food security. National food security, particularly related to grains, has been a central goal of China's agricultural and food policy and has been incorporated into biotechnology research priority setting. Grain crops have been prioritized not only for biotechnology and non-biotechnology research programs, but also for irrigation investment and other government support programs in agriculture (Huang and Wang, 2003).

Genetic traits viewed as priorities may be transferred into target crops. Priority traits include those related to insect and disease resistance, stress tolerance, and quality improvement (see Table 20 in annex). Pest resistance traits have top priority over all traits.

Although input decreasing or output enhancing have been the main priority of Chinese agricultural biotechnology research, quality improvement traits have recently been included as priority traits in response to increased market demand for quality foods. Quality improvements have been targeted particularly to rice and wheat, as consumer income rises in China. Having quality improvement traits as a priority is associated with recent government structural change policies in agriculture that emphasizes the production of better quality food. In addition, stress tolerance traits — particularly resistance to drought — are gaining attention particularly with the growing concern over water shortages in northern China. Northern China is a major wheat and soybean production region with significant implications to China's future food security and trade.

Tables 21 through 25 (in annex) provide lists of all the plant biotechnology products approved for field trial, environmental releases, and commercialization. Interviews with the scientists involved in biotechnology research programs indicate that most cases approved for various stages of bio-safety assessment presented in Tables 21 through 25 (in annex) are in general consistent with the biotechnology development China's priority setting framework as presented in Table 20 in annex. It is worth noting that among the cases from domestically generated biotechnology that were approved for environmental release from 1997 to July 1999, approximately 85 percent were from the 29 institutes in which they conducted their survey for this study. In addition, of the 26 cases approved for commercialization so far, twenty three cases came from the institutes sampled in their study and 3 were from Monsanto (Bt cotton) (Huang *et al*, 2001b).

Table 21 in annex presents the available plant events in China up to 1999. A plant event is the specific combination of a genetic transformation construct and a plant host. This list also includes the stage in which each plant event is in the biosafety approval process. There are 18 crops with events that have entered the biosafety approval process. There are 39 events, of which 9 are for insect resistance, 20 for disease resistance, 2 for herbicide resistance, 5 for agronomic or quality modification, and 3 for stacked insect or disease resistance and quality modification (Huang *et al*, 2001b).

Accordingly to Huang *et al*. (2001b), in 1997 there were 57 applications for field trial, environmental release, and commercialization (see Table 22 in annex). Of these China approved 46 requests for agricultural biotechnology products. The total number of approved cases for field trials, environmental release or commercialization reached 251 in 1999. Of the 251 approved cases, 92 where approved for field trials, 74 for environmental release and 33 for commercialization. Up to July 1999, 44 cases have been approved for field trials in China (see Table 23 in annex). Of the 44 cases approved for field trials 21 are for resistance to insects, 15 resistant to disease, 7 with an altered agronomic characteristic, and 1 with a stacked herbicide resistance and altered agronomic response. Rice has the most approved cases with 21, followed by cotton with 10, tomato with 3, maize and tobacco with 2. Table 24 in annex presents the cases approved for environmental release in China. 51 cases have been approved, of which are for resistance to insects, 17 for resistance to disease, 6 are for a modified agronomic characteristic or response, and 3 are for herbicide resistance. Cotton has the highest number of approved cases for environmental disease with 14, followed by rice with 10, potato with 8, tomato and tobacco with 10, and maize with 4, and sweet pepper and poplar with 2. Among the approved releases for commercialization (see Table 25 in annex) sixteen approvals were granted to Bt cotton (varieties developed by CAAS and by Monsanto), 5 to tomatoes with resistance to insects or improved shelf-life, a petunia with altered flower color, and sweet pepper resistant to diseases.

3.2 - Plant Biotechnology Products in the Research Continuum

There are over 120 different genes and more than 50 different plant varieties that have been used in plant genetic engineering in China since the middle 1980s. Plant biotechnology research has emphasized the development of new varieties for major crops seemed as high priority by the Chinese government such as cotton, rice, wheat, maize, soybean, potato and rapeseed. Genetic traits viewed as priorities may be transferred into target crops. Priority traits include those related to insect and disease resistance, stress tolerance, and quality improvement (Huang *et al.*, 2001b). Pest resistance traits have top priority over all traits. Recently, quality improvement traits have been included as priority traits in response to increased market demand for quality foods. In addition, stress tolerance traits - particularly resistance to drought - are gaining attention with the growing concern over water shortages in northern China.

The main achievements include: newer research focuses on the isolation and cloning of new disease - and insect-resistance genes, including the genes conferring resistance to cotton bollworm (Bt, CpTI), rice stem borer (Bt), rice bacterial blight (Xa22 and Xa24), rice plant hopper, wheat powdery mildew (Pm20), wheat yellow mosaic virus, and potato bacterial wilt (cecropin B). These genes have been applied in plant genetic engineering since the late 1990s. Significant progress has also been made in the functional genomics of arabidopsis and in plant bioreactors, especially in utilizing transgenic plant to produce oral vaccines (Huang and Wang, 2003).

3.2.1 - Transgenic plants resistant to insects

• **Cotton**: The Biotechnology Research Institute (BRI) of the Chinese Academy of Agricultural Sciences (CAAS) has developed insect-resistant Bt cotton. The Bt gene's modification and plant vector construction technique was granted a patent in China in 1998. The Bt gene was introduced into major cotton varieties using the Chinese-developed pollen tube pathway (Guo and Cui, 1998 and 2000 quoted in Huang *et al.,* 2001b). Five transgenic, open-pollinated varieties and one transgenic hybrid Bt cotton variety have been registered with the new plant variety registration authorities. Bt cotton has been approved for commercialization in 9 provinces since 1997. The area planted to Bt cotton reached around 700,000 hectares, nearly equally shared by Chinese and Monsanto Bt varieties (Bt cotton will be discussed with more detail later on).

• **Rice**: Several research institutes and universities have been working on transgenic rice resistant to insects since the early 1990s. Transgenic hybrid and conventional Bt rice varieties, resistant to rice stem borer and leaf roller were approved for environmental release in 1997 and 1998. An additional transgenic rice variety that expressed resistance to rice plant hopper has been tested in field trials. Through anther culture, the CpTi gene and the Bar gene were successfully introduced into rice, which expressed resistance to rice stem borer and herbicide (NCBED, 2000; Zhu, 2000 quoted in Huang *et al.*, 2001b).

More efforts have been put on the GM rice sector. Numerous research institutes and universities have been working on transgenic rice resistant to insects since the early 1990s. Transgenic hybrid and conventional Bt rice varieties, resistant to rice stem borer and leaf roller were approved for environmental release in 1997 and 1998. The transgenic rice variety that expressed resistance to rice plant hopper has been tested in field trials. Through the anther culture, the CpTi gene and the Bar gene were successfully introduced into rice, which expressed resistance to rice stem borer and herbicide (NCBED, 2000; Zhu, 2000 quoted in Huang *et al.,* 2001b).

Transgenic rice with Xa21, Xa7 and CpTi genes resistant to bacteria blight or rice blast where developed by the Institute of Genetics of CAS, BRI, and China Central Agricultural University. These transgenic rice plants have been approved for environmental release since 1997 (NCBED, 2000 quoted in Huang *et al.,* 2001b). Significant progress has also been made with transgenic plants expressing drought and salinity tolerance in rice. Transgenic rice expressing drought and salinity tolerance has been in field trials since 1998. Genetically modified nitrogen fixing bacteria for rice was approved for commercialization in 2000. Technically, the commercialization of various GM rice is ready. However, the commercializing GM rice production has not yet been approved as the policy makers' concern on food safety, rice trade (China exports rice though the amount traded is small compared to its consumption) and its implication for the commercialization of other GM food crops such as soybean, wheat and maize.

• **Maize**: A transgenic Bt maize resistant to maize stem borer was developed by the China Agricultural University, which was approved for environmental release in 1997 (OGESA, 1999 quoted in Huang *et al.*, 2001b).

• **Soybean**: The Jinlin Academy of Agricultural Sciences recently developed a transgenic Bt soybean that expresses resistance to the soybean moth. The transgenic lines Jilin 27 and Heilong 35 have already been approved for field trials and environmental release in 1997 (NCBED, 2000 quoted in Huang *et al.*, 2001b).

• **Others**: Transgenic tobacco, papaya, poplar tree, and a few others now are either in the stages of field trials or environmental releases (OGESA, 1999; Wu, Sun, and Yao, 2000 quoted in Huang *et al.*, 2001b). Research in transgenic wheat resistant to insect (i.e., aphids) is in the research pipeline.

3.2.2 - Transgenic plant resistant to disease

• **Cotton**: BRI of CAAS made a breakthrough in plant disease resistance by developing cotton resistant to fungal diseases. Glucanase, glucoxidase and chitnase genes were introduced into major cotton varieties. Transgenic cotton lines with enhanced resistance to V*erticillium* and *Fusarium* were approved for environmental release in 1999 (BRI, 2000 quoted in Huang *et al.*, 2001b).

• **Rice**: Transgenic rice with Xa21, Xa7 and CpTi genes resistant to bacteria blight or rice blast where developed by the Institute of Genetics of CAS, BRI, and China Central Agricultural University. These transgenic rice plants have been approved for environmental release since 1997 (Zai and Zhu, 1999; NCBED, 2000 quoted in Huang *et al.*, 2001b).

• **Potato**: Synthesized cecropin polypeptide genes and transgenic potato lines resistant to bacterial wilt were developed by BRI in the mid-1990s. These genetically modified potato lines resistant to bacterial wilt were approved for environmental release in Beijing and Sichuan province in 1997 (Jia and Tang, 1998 quoted in Huang *et al.*, 2001b).

3.2.3 - Other plant biotechnologies

According to Huang *et al.* (2001b), significant progress has been made with transgenic plants expressing drought and salinity tolerance in rice and wheat. Transgenic rice expressing drought and salinity tolerance has been in field trials since 1998. Genetically modified nitrogen fixing bacteria for rice and maize, as well as phytase for feed additives, were approved for commercialization in 2000. In addition to plant genetic engineering, tissue culture techniques have also have been often applied in horticulture, to produce virus free potatoes and strawberries. Several adopted rice and sugar beet varieties were developed by anther culture. Progress has also been made in molecular marker assisted selection of plant varieties. For example, a new soybean line with high yield and resistance to cyst nematode disease was produced in 1998. In microbial research, several valuable insecticidal genes were isolated and cloned.

4 - Bt Cotton in China

4.1 - Adoption of Bt Cotton in China

Cotton is an important economic and fibre crop, grown in 70 countries in the world. Over 180 million people are associated with the fibre industry that produces 20 to 30 billion dollars worth of raw cotton. Although great progress has been made in the field of improvement of cotton with conventional breeding methodology, it is time-consuming and commercialization of new cotton varieties often takes 6 to 10 years. Compatibility limitations narrow the gene pool available for this process. A number of these shortcomings may be overcome by plant biotechnology. For example, control can be exerted over selection of the gene(s) and its expression. The gene pool can be expanded to all living organisms (plants, animals, bacteria and fungi). As technology is refined, custommade synthetic genes will become another source for desired traits. Thus, cotton biotechnology can be significantly applied for the improvement of cotton (Zhang *et al.*, 2000).

China produces more cotton than any country in the world despite the fact that both India and the USA have larger areas of cotton. In 2001/02, China grew 4.8 million hectares of cotton with a high yield of 1,103 kg of lint per hectare to produce 5.3 million metric tons (MT), equivalent to 25% of world cotton production. China also consumes more cotton than any other country (5.4 million MT, equivalent to 27% of world consumption) and imported 100,000 MT compared with 50,000 MT of exports in 2000/01 (ISAAA, 2004).

The adoption rates for Bt cotton in China (Pray *et al.*, 2002) indicate that Bt cotton quickly escalated (Table 26) from less than 1% (<0.1 million hectares) in 1997, to 2% (0.1 million hectares) in 1998, 11% (0.4 million hectares) in 1999, 22% (0.9 million hectares) in 2000, and 31% (1.5 million hectares) in 2001. The initial 500,000 small farmers who adopted Bt cotton in 1998 derived significant and multiple benefits from the technology. Because farmers who adopted Bt cotton in 1998 were very satisfied with the experience, they were keen to continue the practice in 1999 and were joined by 1 million other small cotton farmers, which in turn led to the planting of 400,000 hectares of Bt cotton in 1999. This was equivalent to 11% of the Chinese national cotton area of 3.7 million hectares in 1999. The number of cotton farmers in China fluctuates annually, depending on the planted area of the cotton crop which ranged from 3.7 million hectares in 1999, to 4.8 million hectares in 2001 (Table 26). The estimated number of Bt cotton farmers in China has increased from a few thousand at its introduction in 1997 to 0.5 million in 1998, to 1.5 million in 1999, to 2.7-3 million in 2000, and 4 to 5 million in 2001.

Table 26 – Production of Bt Cotton in China, 1997-2001.

Year	Cotton Area Ha Millions	Bt Cotton Area Ha Millions	Bt Cotton % of Area	Number of Cotton Farmers (Millions)	Number of Bt Cotton Farmers (Millions)
1997	4.5	<0.1	1	10.8	<0.1
1998	4.5	0.1	2	10.7	0.5
1999	3.7	0.4	11	8.5	1.5
2000	4.0	0.9	22	9.0	2.7 to 3.0
2001	4.8	1.5	31	13.0	4.0 to 5.0

Source: Pray *et al.* (2002).

Bt cotton now occupies about one third of the total cotton area in China. It is widely adopted in the Yellow River Valley where some provinces like Hebei are almost exclusively Bt cotton, 80% in Shandong, about 30% adoption in Anhui and Henan, and even small areas in the Northwest province of Xinjiang where bollworm infestation is much lower, and where cotton is grown under irrigation (see Figure 9 in annex). Estimates of adoption are probably conservative, particularly for the last two years, when farmers have become increasingly aware of the value of Bt cotton, and save/sell more of their own seed and acquire it through many more formal and informal channels (Pray *et al.*, 2002).

Cotton is of superior importance to the Chinese textile industry, which is the largest in the world. This industry employs nine million workers, and its contribution to China's export volume comprises about 25 per cent of the total. Currently China is the biggest cotton producer in the world; about 50 million farming households grow cotton (Zhang *et al.*, 2000). Although cotton only occupies between two and three per cent of the total cultivated area, it renders seven to ten per cent of the total value of agriculture. However, since the end of the 1980s, cotton production has decreased due to a decline in both yield and coverage area. The decline in yield of 15 to 30 per cent has mainly been caused by bollworm infestation. In 1992 and 1993, outbreaks of bollworm infestation in China caused direct economic losses of about US$ 630 million (Song, 1999). According to Jia (1998), quoted in ISAAA (2004), the loss was even higher, valued at the national level in 10 billion RMB equivalent to US$1.2 billion (calculated at the official exchange rate of 8.27 RMB = US$1.00). Furthermore, farmers were discouraged from growing cotton. As a result, the national growing area decreased by 10–15%, and there is a tendency for cotton production to move from relatively favourable areas towards marginal regions (Zhang *et al.*, 2000).

4.2 - Pest Control in China

The growing use of farm chemicals, especially chemical fertilizers and pesticides was a major factor in the rising production and productivity of China's post-transition farm sector. Various kinds of pesticides have been used on a large scale to protect crops from damage inflicted by insects and diseases in China since the 1950s (Stone, 1988). Particularly after the spread of modern, semi-dwarf, high-yielding varieties in the 1960s and 1970s, China's producers began using increasingly higher levels of pesticides to offset and avoid damage inflicted by insect and diseases (Huang *et al.*, 2002c)

Initially, farmers used chlorinated hydrocarbons (such as DDT) until they were banned for environmental and health reasons in the early 1980s (Stone, 1988). In the mid-1980s, farmers began to use organophosphates, but in the case of cotton, pests developed resistance. In the early 1990s, farmers began to use pyrethroids, which were more effective and safer than organophosphates. However, as in the case of other pesticides, China's bollworms rapidly began to develop resistance to pyrethroids in the mid-1990s. At this time, farmers resorted to cocktails of organophosphates, pyrethroids and whatever else they could obtain (including DDT, although the use of cholorinated hydrocarbons is illegal) with less and less impact on the pests (Pray *et al.*, 2002; Huang and Pray, 2002 and Huang *et al.*, 2002d).

With rising pest pressure and increasingly ineffective pesticides, the use of pesticides by cotton farmers in China has risen sharply. Farmers use more pesticide per hectare on cotton than on any other field crop in China (Huang *et al.*, 2002a). In aggregate, cotton farmers use more pesticide than farmers of any other crop except rice (as the sown area of rice is many times more than that of cotton). Per hectare pesticide cost reached US$101 in 1995 for cotton, much higher than that for rice, wheat or maize, and many times more than the level applied by most other farmers in the world. Cotton production consumes nearly US$500 million in pesticides annually (Huang *et al.*, 2002b).

The nation's farmers apply more chemical pesticides on their crops than producers in almost any country in the world. Their annual applications have increased in recent years, rising from 211,000 metric tons (mt) of active ingredients in 1985 to 340,000 mt in 1996. Without doubt, pesticides have played a major role in increasing the output and productivity of China's farming sector. Their use, however, has created many negative externalities. The use, overuse and misuse of pesticides in China have led to poisonings of farmers and their families, degradation of rural land and water, and increased levels of dangerous chemicals in China's food (Huang *et al.,* 2001d).

Almost $ 50 million is spent each year on chemical pesticides to control cotton insect pests, a significant proportion of it being toxic organosulphur and organophosphorus insecticides such as endosulfan and pyrethroid. The more environmentally friendly synthetic pyrethrin insecticides have been effective in the past, but there are growing fears that development of resistance by the insects may soon make pyrethroids ineffective. This, together with the increasing public concern about the use of toxic chemicals and their impact on the environment, has led to a flurry of interest in more environmentally acceptable insecticides and the development of more insect-tolerant cotton varieties (Zhang *et al.*, 2000).

Both the active ingredients and the formulated pesticides are mainly produced by Chinese companies. Foreign suppliers have been limited by Chinese regulations to approximately 20% of the market. The pesticides are distributed to farmers by government input supply organizations and the extension service. The government extension service not only supplies the technology but also does scouting for pests and provides advice to farmers about when to spray and what to spray. At present the Chinese pesticide market is probably the largest in the world based on quantity used, and China competes with the United States for the highest-value market (Hossain *et al.*, 2004).

More pesticide is applied per hectare to cotton than to any other major field crop, although the amount used is less than for most vegetable crops (Hossain *et al.*, 2004).

Recognizing the negative externalities of excessive pesticide use, China's government has made an effort to regulate pesticide production, marketing and application since the 1970s (Huang *et al.*, 2002c). Initially, agricultural leaders banned the use of chlorinated hydrocarbons such as DDT, endosulfan, and BHC in 1983 to eliminate their impacts on the environment and their longer-term health risks. However, the government did not ban the use of some very dangerous organophosphate pesticides. Through the extension system the government has tried to promote integrated pest management practices with the goals of reducing pesticide use and using pesticides more effectively. Nevertheless, pesticide use continues to grow rapidly (Hossain *et al.*, 2004 and Huang *et al.*, 2001d).

After the government banned the use of chlorinated hydrocarbons in the early 1980s, organophosphates were the main type of pesticide used to control bollworm. However, bollworms that were resistant to most organophosphates evolved and farmers had to shift to a new type of pesticide called pyrethroids. These pesticides were effective for a while against bollworm and had the added advantage of being relatively safe for the farmers that applied them. However, by the mid 1990s bollworms had developed resistance to the pyrethroids, too (Hossain *et al.*, 2004).

The Ministry of Agriculture also began a campaign to teach farmers about the safe use and management of pesticides. However, as experience has shown, the promulgation of rules and regulations does not guarantee improvements in the quality of pesticide products on the market or their proper and safe use. A vast majority of farmers have not changed the way that they handle and apply pesticides in recent years. Moreover, despite legal and regulatory bans, farmers in our sample still used highly hazardous pesticides in 2000 (Huang *et al.*, 2001d and Huang *et al.*, 2002c).

China's leaders also invested in and promoted alternative ways to control pests, many of which hold promise for reducing pollution. The research system greatly expanded host-plant resistance technology in food and fiber crops in the 1970s and 1980s. Although the record of IPM has been mixed, improvement of host-plant resistance in new varieties has helped in reducing pesticide use without reducing crop yields (Huang *et al.*, 2001d).

China's pest problems have led the nation's scientists to seek new pesticides, to breed cotton varieties for resistance to pests, and to develop integrated pest management programs to control the pests. Consequently, when the possibility of incorporating genes for resistance to the pests came closer to reality, China's scientists started working on the problem. With funding primarily from government research sources, a group of public research institutes led by the Chinese Academy of Agricultural Sciences (CAAS) developed *Bacillus thuringiensis* (Bt) cotton varieties using a modified Bt fusion gene (Cry1ab and Cry 1Ac), representing an entirely new technique for controlling pests. The gene was transformed into major Chinese cotton varieties using China's own methods (pollen-tube pathways). Researchers tested the varieties for their impact on the environment and then released them for commercial use in 1997 (Pray *et al.*, 2001; Huang and Pray, 2002; Pray *et al.*, 2002 and Huang *et al.*, 2002d). Both the Chinese Academy of Agricultural Sciences and a joint venture between Monsanto, Delta, and Pineland and the Hebei Provincial Seed Company developed varieties of Bt cotton for farmers (Hossain *et al.*, 2004).

Farmers found that Bt cotton gave much better protection against bollworm than chemical pesticides—it increased yields while reducing the costs of insect control, thereby increasing the farmers' net income. As a result, farmers have adopted it rapidly (Hossain *et al.*, 2004).

4.3 - Development of Bt Cotton in China

Bt cotton has been at the heart of China's biotech program for some time. It is advertised as one of the clearest achievements in promotional material for the 863 program and in special glossy volumes documenting history, plans and achievements. The case for insect-resistant cotton was made mostly strongly after the extremely severe 1992 bollworm outbreak. This was a key opportunity for China's biotechnology community. With yield losses of 100,000 tons in the Yangtse cotton zone and 1.5m tons in the Yellow River area, valued at 10 billion yuan (US $ 1.2 billion) for north China according to Jia and Peng (2002) quoted in Keeley (2003a), Bt cotton clearly had much to offer. It became an important priority, however, not only to learn from foreign corporations, but to develop the technology at home and also commercialize it through a Chinese enterprise. In many ways the Bt cotton story in China can be read as a nationalistic battle between Biocentury, the Chinese company with Chinese technology, and Monsanto, the US multinational, operating through joint-ventures with foreign technology.

In 1991 the Biotechnology Research Center of the China Academy of Agricultural Sciences' (CAAS) initiated a major research program to develop cotton varieties that would contain a gene that would produce a *Bacillus thuringiensis* (Bt) toxin which would control cotton bollworm. After 1-1.5 years of the project CAAS developed and patented a new Bt gene. The gene was inserted into commercial cotton varieties using a process developed by Chinese scientists. The first successful genetically engineered cotton plant was produced in China in 1993 (Pray *et al.*, 2001).

In 1995 CAAS started testing these varieties in experimental fields regulated by the Ministry of Agriculture. The first Bt varieties were given to farmers for commercial planting on a small scale the next year (Pray *et al.*, 2001).

By 1996 a total of 10 transgenic Bt cotton varieties had been developed and a total of 17 field trials were conducted occupying 650 hectares (ISAAA, 2004).

In 1997 the Biosafety Committee of the Ministry of Agriculture the commercialization of the first Bt cotton. The commercial plantings of the CAAS Bt cottons feature a modified Bt fusion gene, Cry1Ab/Cry1Ac, planted in the four provinces of Anhui, Shangdong, Shanxi, and Hubei. The cowpea trypsin gene, CpTi with a different mechanism of resistance compared to Bt, has also been incorporated as a stacked gene with Bt in some varieties.

The introduction of commercial cotton varieties producing CryIA insecticidal proteins is expected to reduce environmental pollution from synthetic insecticides, increase worker safety, and improve grower profitability. Thus, Chinese breeders and farmers have more interest in the breeding and commercialization of transgenic Bt cotton.

Once the Bt gene was inserted into the elite Chinese developed cotton varieties, scientists embarked on a series of tests to demonstrate the usability of the genetically modified cotton. Researchers conducted initial experiments in the laboratory and then in restricted access greenhouses. Lastly, they ran small and large scale field trials.

Two methods were selected for breeding Bt cotton in China. First, Bt genes were directly inserted into elite Chinese cotton varieties by pollen pathway method or *Agrobacterium*-mediated transformation method. This method was selected by about 8 institutes, and has bred some elite varieties or bred lines, such as Jingmian - GK-1 and GK-12. The second method is cross breeding. Once transgenic Bt cotton plants were obtained, scientists undertook a cross and back-cross program to introduce the *Bt* toxin genes into genotypes of the current major Chinese varieties developed by Cotton Research Institute of CAAS. This method has been selected by most of institutes and universities, and more than 10 varieties (such as CCRI 30, CCRI 31 and CCRI 32) or lines have been bred and are being commercialized (Zhang *et al.*, 2000).

By 1999, the CAAS single gene Bt cottons, and the stacked Bt/CpTi cottons, designed to provide more durable resistance, were planted in nine provinces compared with four in 1998. It is estimated that at least 750,000 small farmers grew CAAS Bt cottons in 1999, most of which carried the single Bt gene. The single Bt cottons were planted in the nine provinces of Shangdong, Shanxi, Anhui, Jiangsu, Hubei, Henan, Hebei, Xinagjiang, and Lianoning (see Figure 9 in annex). The CAAS cotton with stacked genes was planted in the four provinces of Shangdong, Shanxi, Anhui, and Hubei in 1999 (see Figure 9 in annex).

In 2002, CAAS has permission from the Biosafety Committee to sell 22 Bt cotton varieties in all provinces of China (Pray *et al.*, 2002 and ISAAA, 2004). Governmental institutions have also developed new Bt cotton varieties by backcrossing the CAAS and other Bt varieties with their own locally adapted germplasm and these are being distributed and sold in many provinces (ISAAA, 2004). The Biosafety Committee has approved the sale of five Delta and Pineland Bt varieties in four provinces (Hebei, Shandong, Henan and Anhui – see Figure 9 in annex). Many other varieties from national institutes (such as the Cotton Research Institute, Anyang) and from provincial institutes are being grown, but some of these local varieties do not go through the official approval procedure set by the Chinese Biosafety Committee (Pray *et al.*, 2002).

Up to data, nine new varieties and at least 20 breed lines with the Bt gene have been bred by Chinese scientists, and ten Bt cotton varieties CCRI 29, CCRI 30, CCRI 31, CCRI 32, CCRI 38, Jiza 66, Jimian 26, GK-1, GK-12 and NewCotton 33B were allowed to be planted in China. One of these, NewCotton 33B directly came from Delta and Pine Land Co, USA. The transgenic line, GK-321, carrying both insecticide genes Bt and CpTI in one cotton plant, that has the fine characters of yield and fibre quality, was planted on 400 hectares in 1999. GK-321 was bred by the Biotechnology Center of CAAS and Jiangsu Academy of Agricultural Sciences, and will be commercialized in 2000 (Zhang *et al.*, 2000).

Once the commercial release had been approved, a restricted area of 200 hectares was planted in 1994. In 1997, the fourth year of commercial release, over 20,000 hectares of Bt cotton were planted, and in 1998 about 100,000 hectares were planted in China. In 1999, about 350,000 hectares or 8% of the total cotton area was growing transgenic Bt cotton. Of these, 20.330, 10.330, 6700, 4700 and 4700 hectares of Bt cotton were planted in Hebei, Shandong, Henan, Anhui and Shanxi Provinces (see Figure 9 in annex), respectively, which are the major areas for transgenic cotton. Each year, the demand for Bt cotton cottonseed greatly outstrips supply (Zhang *et al.*, 2000).

The CAAS Bt cotton is being carefully monitored to develop the most effective means for achieving durable resistance within the context of a Bt management strategy. The Institute of Plant Protection has regularly sampled bollworms since 1997. Results indicate that field performance of Bt cotton is superior to non-Bt cotton with no indication that resistance to Bt is developing. The multiple cropping system and the spatial distribution of Bt cotton planted on small farms in China surrounded by alternate host crops contribute to a natural "refuge". Jia (1998), quoted in ISAAA (2004), projects that the current cotton may provide adequate levels of resistance for up to 8 or 9 years from introduction in 1997, during which alternative strategies of control are being developed and implemented. One of the current alternative strategies being employed is the use of the Bt gene in conjunction with the CpTi gene, which encodes for an insecticidal protein with an independent mode of action from Bt. This strategy is being employed to provide better control and to delay resistance development.

Delta and Pineland (DLP) began formal research on cotton in China in 1995 in partnership with the CAAS Cotton Research Institute in Henan Province. It tested a number of different U.S. varieties and a number of different Bt genes. In November 1996 Monsanto, DPL and the Singapore Economic Development Authority developed a joint venture with the Hebei provincial seed company to produce and market GE cotton seed through a new company called Ji Dai. After testing a number of different varieties, they decided that the American transgenic variety 33B controlled cotton bollworm, out-yielded both GE and conventional varieties, and had good fiber quality. The Chinese biosafety committee approved it for commercial use in Hebei province in 1997. Commercial seed production started that year on 10,000 ha and Ji Dai built a state of the art seed production facility in Shijiazhuang, Hebei in 1997 (Pray *et al.*, 2001 and Zhang *et al.*, 2000).

Commercial production of 33B started in 1998 in Hebei. In 1999, 33B production was still allowed only in Hebei, but it was also being grown in neighboring provinces through farmer to farmer seed distribution and through seed traders. In 1999, Monsanto-DPL (MDP) had two new varieties of Bt cotton approved for Anhui Province (Pray *et al.*, 2001 and Zhang *et al.*, 2000).

4.3.1 - Chinese Academy of Agricultural Sciences (CAAS) Bt Cotton versus Monsanto Bt Cotton

There are two developers and suppliers of Bt cotton in China. The first is the public sector Chinese Academy of Agricultural Sciences (CAAS) in collaboration with provincial academies and seed distribution organizations, and the second is Monsanto/Delta Pine Land from the international private sector (ISAAA, 2004).

At least one third of the Bt cotton in China is marketed by companies that were formed by state research institutes. The most important of these is Biocentury which markets the varieties with the gene constructs developed by the Biotechnology Research Institute (BRI) in the Chinese Academy of Agricultural Sciences in Beijing. BRI is one of the most prestigious National Key Laboratories based at the huge Chinese Academy of Agricultural Sciences campus close to the high-tech Zhongguancun area in the north of Beijing. It was founded in 1986 at the same time as 863. While Biocentury is notionally a private company, it has clearly been fostered in its development at all stages by MOST and MOA. BRI retain a major stakeholding, and several senior scientists from the institute who played key roles in developing Bt cotton have important positions on the board. It could be argued to be the developmental, or even the entrepreneurial, state in action (Keeley, 2003a).

The setting up of Biocentury in 1998 can in many ways be seen as a key achievement of the 863 program started 12 years earlier, and particularly of the Bt cotton program begun with 863 support in 1991. The company has moved quickly to establish a significant market share, and is soon to be stock-market listed.

There has been explicit policy support for Biocentury, which echoes the experience elsewhere of nurturing fledgling companies in strategic sectors. A key form of support, alongside this type of endorsement, is funding. Biocentury was founded with start-up investment of several tens of million RMB from Dongfang Mingzhu, a southern Chinese holding company; this was matched by state investment from MOST through the 863 system, and some investment from the Biotechnology Research Institute who have a one-third share in the company. In 2000 the company got important support from the Technical Innovation Fund for Small and Medium Scientific And Technological Enterprises. Later the same year the company secured State Development and Planning Commission support for a project for commercialization of Bt and CPTI cotton (Keeley, 2003a).

Total investment in 2003 was 100m RMB (US $ 12m). Profits at present are divided between the key scientist, the state research institute and the larger company, as follows: 13.5 per cent of gross sales go to the institute; there are also gene license fee payments and variety payments; BRI are guaranteed an annual bottom line payment of half a million RMB, regardless of company performance; and 80 per cent of the profits are retained by the company. What is clear is that, whatever the profit sharing arrangements, the link to the state and the sense of continuing to be fostered as a national corporation is very strong. However, Biocentury is in other respects being encouraged to operate like a private corporation. One aspect of this is the granting of property rights over important technologies, another example of policy support for the company. The company has been granted patents on gene construction modification, and on their novel plant vector construction technique– the pollen tube pathway. Stock-market listing could also be presented as another example of privatization (Keeley, 2003a).

The second supplier of Bt cotton in China is Monsanto/Delta PineLand whose product is based on the variety 33B, which carries the Cry1A(c) gene.

The biotech multinational with the most significant presence in China is Monsanto: they have the biggest public profile, and they are the only multinational actually selling GM seed to Chinese farmers.

For cotton Monsanto first approached the Cotton Research Institute in Anyang, Henan, and began a joint research program to look at cooperating to produce Bt cotton. According to one informant in the company, Monsanto carried out 100 trials at CRI in 1995, but these talks in the end came to nothing. In 1996 it began a partnership with Hebei Provincial Seed Company to produce seed in Hebei province. The result was a joint-venture known as Jidai. The joint-venture was approved by the provincial governor which led to accusations that Monsanto was operating in China ignoring the central Ministry of Agriculture, even though at that time there were no restrictions on provinces forming joint-ventures under US $ 30 m. Following this new regulations were issued in 1997 requiring central permission for new joint-ventures. Monsanto and Delta and Pineland initially had a 66 per cent share of Jidai, this was also restricted to 49 per cent in the 1997 regulations. According to the MOA this was because the Chinese partners were not seeing enough of the benefits of the partnership. A director of Biocentury argued, however, that because of Monsanto's high technical fee and the fact they get the majority of this, they still get most of the profit from the joint-venture. The Chinese arguments around the technical fee interestingly echo the international discourse against biotechnology that argues the central problem is one of control and risk of dependence on expensive technologies (Keeley, 2003a).

Monsanto's entry into the Chinese market has created great debate and controversy among Chinese agricultural policy makers and scientists. Some of them argue that the central government should protect the market by re-establishing monopoly seed production and distribution, whereas others consider competition as helpful to the transformation of CAAS in particular and economic development in general (Song, 1999).

Monsanto introduces the foundation seed including its Bt technology, but seed production, processing and distribution are all operated locally by JiDai. Obviously, JiDai as a partly government-owned seed company has access to the entire government seed system, extension service, and marketing system. It uses county government seed companies as its sales stations and employs the local government officials and extension workers as salespersons. There are more than 5000 retailers in most of the cotton growing counties in Hebei, comprising a complete marketing network. Contracts between Monsanto and JiDai, and between JiDai and the salespersons, determine that the latter are obliged to distribute Monsanto's Bt cottonseed exclusively. Furthermore, since these retailers are local officials, they are allowed to use government intervention measures in the distribution of seeds to guarantee that farmers fulfil their quota (Song, 1999).

Jidai has gradually become the base for Monsanto's operations across the north China cotton zone, in the Yellow River watershed, concentrating on Shandong province in addition to Hebei, and presumably for Henan province where Monsanto was finally granted permission to sell after many failed attempts to get biosafety approval. Following the success of Jidai a second joint-venture followed, based in Hefei in Anhui province, together with Anhui Provincial Seed Company, again Monsanto own 49 per cent. This joint-venture known as Andai at the moment only sells in Anhui, but it would be the base for the wider Yangtse River cotton zone, were permission to be granted for Jiangsu and Hubei provinces (Keeley, 2003a).

Breakdown of cotton sales is notoriously complicated. Monsanto, for example, complain that they are presented as having sales in official statistics in provinces where they are not formally even allowed to sell. In Hebei province – Monsanto's biggest success story and a province where Bt cotton may be as much as 99 per cent – one Monsanto manager put the breakdown for of the cotton grown as: 15 per cent Monsanto, 15 per cent Biocentury, 30 per cent farmer saved seed, 30 per cent counterfeit, 10 per cent others. In Shandong the share of the market is smaller. In Anhui it's higher at 15 or 20 per cent. In Henan the market is dominated by the Cotton Research Institute (Keeley, 2003a).

Despite the complexity, Biocentury has several advantages over Monsanto. One is that links at the local level, particularly with research institutes, allow them access to well adapted local germplasm, something Monsanto – formally at least – cannot get.

Biocentury has other things in its favour. One key factor is that Biocentury seed is substantially cheaper than that of Jidai or Andai (the two joint-ventures Monsanto operates through). In 2002 Biocentury were selling in Hebei at around 38 RMB per kg, whereas Jidai seed was 45 RMB. According to the manager of Jidai profit margins between the two companies are very different: 'Our margins are not high. We have to keep up sales to reach our balance point. Biocentury can be very profitable at sales of 100,000 kg; we need to hit the one million mark.' He went on: 'Biocentury has no tech fee, or that's a grey area. Our technical fee is the major constraint on our profitability. We also spend more than Biocentury on quality assurance. Our fixed costs are also high. We don't understand their fixed costs' (Keeley, 2003a).

However, in Song's (1999) view, Monsanto has advantage over Biocentury. CAAS had difficulty selling its Bt cotton in 1998 because of the government seed companies, which have regional monopolies on cotton seed sales and were not interested in distributing it. In Hebei province, Monsanto successfully entered the market by gaining access to local government systems and by using the government's monopoly in seed production and distribution. To achieve this goal, Monsanto could rely on its superior financial resources, its marketing knowledge, and efficient management, which in the end gave it a competitive edge over CAAS.

In sum, there are then several ways in which the Chinese state can be seen to manage multinationals – by not allowing them to buy up Chinese seed companies in key sectors, by restricting them to a joint-venture model, and by not allowing the foreign partner to have a majority share. There are other ways in which MNCs can be seen to be controlled; these include strategic use of biosafety regulations, limiting breeding programs, and granting plant variety protection on a strategic basis.

Regulation, and particularly risk assessment processes, have been one way that the expansion of Monsanto in China has been contained; certainly company employees will state this, though Chinese officials or researchers will not – unsurprisingly – acknowledge it (Keeley, 2003a).

4.4 – Data and Surveys

Detailed and rigorous surveys have been conducted by an able team of Chinese and US members to assess the impact of Bt cotton in China. Surveys were conducted in 1999 (Huang *et al.* 2002d, Pray *et al.* 2001), 2000 and 2001, and the five years of experience (1997 to 2001) with Bt cotton in China (Pray *et al.* 2002).

Annual surveys conducted by Pray *et al.* (2002) are the only practical means of generating an informative database to characterize adoption and assess the impact of Bt cotton on production. The surveys were initiated in 1999 involving 283 farmers in Hebei and Shandong provinces, expanded to include Henan Province in 2000, and further expanded to include Anuhui and Jiangsu in 2001 (see Figure 9 in annex). In several of these provinces cotton can suffer significant damage from bollworm and in provinces such as Hebei and Shandong adoption rates for Bt cotton quickly soared to 97% and 80% respectively in 2000, following their introduction in 1997 (see Figure 9 in annex) (ISAAA, 2004).

The counties where the survey was conducted were selected so that the researchers could compare Monsanto's Bt cotton variety, CAAS Bt varieties, and conventional cotton. Hebei had to be included because it is the only province in which Monsanto varieties have been approved for commercial use. Within Hebei Province, Xinji County was chosen because that is the only place where the newest CAAS genetically engineered variety is grown. They chose the counties in Shandong Province because the CAAS Bt cotton variety GK-12 and some non-Bt cotton varieties were grown there. After the counties had been selected, villages were chosen randomly. Within the selected villages, farmers were randomly selected from the villages' lists of farmers, and these farmers were interviewed (Pray *et al.* 2002; Huang *et al.*, 2002d and Huang and Pray, 2002).

In the second year they included Henan Province so that they could assess the efficiency of Bt cotton by comparing it to the conventional cotton varieties that were still being grown there. Henan is in the same Yellow River cotton growing region as Hebei and Shandong, and has similar agronomic and climatic characteristics. In 2001 they added Anhui and Jiangsu provinces because Bt cotton had now spread further south. As in 1999, counties were selected so that they would contain both Bt and non-Bt cotton producers. In the second phase of sample selection, villages and farmers were selected randomly. In 2000 and 2001 they also continued to survey the same villages in Hebei and Shandong that were surveyed in 1999. The total number of farmers interviewed increased to about 400 in 2000 and 366 in 2001 (Pray *et al.* 2002; Huang *et al.*, 2002d and Huang and Pray, 2002).

4.4.1 - Impact on Yield

Data in Table 27 show that Bt cotton variety yields are higher than those of non-Bt varieties (Pray *et al.*, 2002 and Huang *et al.*, 2002d).

Taking into account all farms in the survey in 2001, Bt varieties yielded about 10% more than non-Bt varieties – 3,481 kg/hectare versus 3,138 kg/hectare, a difference of 343 kg/hectare in favor of Bt cotton. This difference is somewhat higher than the 8% yield advantage reported for 1999. Yield advantage is also an important contributor to the overall economic advantage of Bt cotton. Because Bt is omnipotent throughout the season, and is more effective than sprays, Bt cotton provides superior control resulting in higher yields, even compared to the most intensive of insecticide spray programs (ISAAA, 2004 and Pray *et al.*, 2002).

Table 27 – Yield of Bt and non-Bt cotton in provinces sampled, 1999-2001.

	Number of plots			Yield (Kg ha^{-1})		
Location/type	**1999**	**2000**	**2001**	**1999**	**2000**	**2001**
Hebei						
Bt	124	120	91	3197	3244	3510
Non-Bt	0	0	0	na	na	na
Shandong						
Bt	213	238	114	3472	3191	3842
Non-Bt	45	0	0	3186	na	na
Henan						
Bt		136	116		2237	2811
Non-Bt		122	42		1901	2634
Anhui						
Bt			130			3380
Non-Bt			105			3151
Jiangsu						
Bt			91			4051
Non-Bt			29			3820
All samples						
Bt	337	494	542	3371	2941	3481
Non-Bt	45	122	176	3186	1901	3138

Cotton production in Henan was seriously affected by flood in 2000, which lowered the yield. Counties included in the surveys are: Xinji (1999-2001) and Shenzhou (1999-2000) of Hebei province; Lingshan (1999-2001), Xiajin (1999-2000) and Lingxian (1999-2000) of Shandong province; Taikang and Fugou of Henan province (2000-01); Dongzhi, Wangjiang and Susong of Anhui province (2001); and Sheyang and Rudong of Jiangsu province (2001).

Source: Pray *et al.* (2002) and Huang *et al.* (2002d).

4.4.2 - Impact on Insecticide Use

Data in Table 28 indicate that in all three years, insecticide usage was reduced substantially on Bt cotton compared with non-Bt varieties. The average saving in formulated insecticide was 43.8 kg/ha equivalent to a 67% reduction in insecticides. At a national level this translates to a reduction of 20,000 tons of formulated insecticide in 1999 and 78,000 tons in 2001. Expressed in terms of reduction of the number of sprays at the farm level in 1999, the number of insecticide sprays decreased from 20 sprays for non-Bt to 7 sprays for Bt – equivalent to a two-thirds reduction, a saving of 13 sprays. In 2000 the reduction in number of sprays were 12 (21 sprays reduced to 9), and 14 sprays (28 sprays reduced to 14) in 2001 (ISAAA, 2004).

Table 28 – Insecticide Use on Bt and Non-Bt Cotton in China, 1991-2001. Kg/ha of Formulated Product

	1999	**2000**	**2001**	**Average**
Non-Bt	60.7	48.5	87.5	65.5
Bt	11.8	20.5	32.9	21.7
Non-Bt - Bt	48.9	28.0	54.6	43.8

Source: Pray *et al.* (2002).

In 2001, China used an estimated 16,000 tons of cotton insecticides (a.i) valued at $285 million at the farm level, down by more than 10 %, compared with 2000, which coincided with an almost 10% increase in Bt cotton adoption from 22% in 2000 to 31% in 2001. The cost savings, discussed later, associated with reduced volume of insecticides and the labor savings from reduced number of sprays is substantial and is the major element contributing to the overall substantial and is the major element contributing to the overall economic advantage of Bt cotton in China (ISAAA, 2004).

When comparing pesticide use on Bt cotton to that of non-Bt cotton in Table 29, data demonstrates that Bt cotton varieties exhibit reduced pesticide usage. For the provinces that adopted Bt cotton first - Hebei and Shandong - Table 29 shows that pesticide usage has remained low. In the provinces of Henan and Anhui, where Bt cotton was recently introduced commercially, the mean application of pesticides has been dramatically reduced when compared to non-Bt cotton. Only in Jiangsu, where red spider mites are the main pest rather than bollworms, was the difference in pesticide use small between Bt and non-Bt cotton - only 7 kilograms per hectare. This suggests that the spread of Bt cotton may be reduced as it moves away from the regions in which bollworms have historically been the major pest - Hebei and Shandong. As a consequence, the economic benefits from producing Bt cotton are not as great, especially with higher Bt seed prices. In Henan, bollworm problems are as important as in Hebei; however, farmers can only buy inferior varieties of Bt cotton. There is a virtual monopoly on seed production and sales by the Provincial Seed Company supplying varieties from the local research institutes. In addition, China's Biosafety Committee has refused to allow the 33B or 90B varieties to be grown in the Province. Thus, farmers have to grow illegal 33B and CAAS varieties supplied by private seed traders or local Bt varieties that have not been approved by the Biosafety Committee. Part of the problem for the Henan varieties is that the level of Bt expression is reduced by midseason (Huang *et al.*, 2002d and Pray *et al.*, 2002).

When looking solely at pesticide use per hectare on Bt cotton, sample does show some increase over time. In those provinces for which we have data for all three surveyed years, results on pesticide use per hectare is mixed. In the Hebei province, for example, pesticide usage increased between 1999 and 2001. In Shandong, however, after pesticide use per hectare increased between 1999 and 2000, it decreased in 2001. Precise assessment of impacts of Bt cotton on pesticide usage calls for a more methodologically oriented estimation (Huang *et al.*, 2002d and Pray *et al.*, 2002).

Table 29 – Pesticide application (Kg/ha) on Bt and non-Bt cotton, 1999-2001.

Year	Location	Bt cotton	Non-Bt cotton
1999	All samples	11.8	60.7
	Hebei	5.7	
	Shandong	15.3	60.7
2000	All samples	20.5	48.5
	Hebei	15.5	
	Shandong	24.5	
	Henan	18.0	48.5
2001	All samples	32.9	87.5
	Hebei	19.6	
	Shandong	21.2	
	Henan	15.2	35.9
	Anhui	62.6	119.0
	Jiangsu	41.0	47.9

Source: Huang *et al.* (2002d) and Pray *et al.* (2002).

4.4.3 - Health Benefits Associated with Bt Cotton

According to the survey data (Pray *et al.*, 2002) the reduction in insecticide usage on Bt cotton compared with non-Bt cotton, was associated with a decrease in the percentage of farmers reporting that they had become sick from spraying insecticides. The information in Table 30 shows that in 1999, 22% of farmers growing non-Bt cotton reported ill-effects, compared with 5% for Bt cotton – a fourfold decrease in favor of Bt cotton. Similarly, in 2000 there was a fourfold decrease from 29% poisonings for non-Bt cotton to 7% for Bt cotton. The difference was much lower in 2001 with non-Bt farmers reporting a 12% incidence of poisoning compared with 8% for Bt, 33% less poisonings for Bt cotton farmers. For the three year period 1999 to 2001 there was a consistent and significant decrease in the percentage of Bt cotton farmers suffering from pesticide poisonings, compared with non-Bt cotton farmers. In China, insecticides are applied to cotton with back-pack sprayers that are either hand or motor-powered. Given the demanding field conditions, avoidance of exposure to insecticides is difficult and the significant decrease in insecticide usage of 78,000 tons of formulated product in 2001 is a major achievement, not only in terms of health, but also in terms of the environment.

Table 30 – Percentage of Bt and Non-Bt Cotton Farmers Suffering from Pesticide Poisonings in China, 1999-2001.

	1999	**2000**	**2001**
Non-Bt	22	29	12
Bt	5	7	8
Non-Bt - Bt	17	22	4

Source: Pray *et al.* (2002).

The linkages between Bt cotton adoption, reduction of pesticide use, and reduced poisoning incidence are further strengthened by the evidence presented in Tables 31 and 32. Table 31 categorizes the pesticides used by chemical type. The use of organophosphates showed the greatest decline. A number of organophosphates are rated highly for acute toxicity—category I in the Chinese and international systems, which rate pesticides from I to IV according to acute toxicity. Table 32 shows the toxicity levels and the numbers of users reporting poisonings for the insecticides that had caused the most poisonings during the preceding five years. Five of the top six pesticides, ranked by number of farmers reporting poisonings, were organophosphates. Furthermore, the most popular pyrethroid pesticide, cypremethrin, is a category II pesticide. It is not surprising, then, that a decline the amount of organophosphates used would result in a reduction in poisonings (Hossain *et al.*, 2004).

Table 31 – Average Quantities (Kg/ha) of Framers' Pesticides Use by Type of Pesticide, 2000.

	Average Quantity (Kg/ha)		
	Bt varieties (n=377)	Non-Bt varieties (n=90)	Decline in Use (%)
Organochlorines	1.6	3.9	58
Organophosphates	8.8	21.0	58
Amino-formicdacid esters	0.3	0.4	25
Pyrethroids	5.2	13.0	60
Organosulfates	2.8	6.0	53
Other insecticides	0.8	1.2	32
Fungicide	0.1	0.3	62
Herbicide	0.8	1.2	32
TOTAL	20.5	48.0	57

Source: Hossain *et al.* (2004)

Table 32 – Type and Toxicity Levels of Pesticides Causing Farmer Poisonings, 1995-2000.

	Category Toxicity	Poisoning Cases
Organophosphates		
Chlordimeform	I	94
Parathion-methyl	I	65
Acephate	I	19
Carbofuran (furadan)	I	9
Phorate	I	9
Parathion	III	8
Monocrotophos	I	5
Pyrethroids		
Cypermethrin	II	12
Killingthrin 39	III	6

Source: Hossain *et al.* (2004)

4.4.4 - Economic Advantage of Bt cotton

The data (Table 33) indicate that the overall economic advantage of Bt cotton, compared with non-Bt cotton ranges from $357/hectare in 1999 to $550 in 2000, to $502 in 2001, with an average of $470/hectare. It is noteworthy that in all 3 years, farmers growing non-Bt cotton were actually making a loss when labor is costed, whilst Bt farmers were enjoying substantial profits. To put economic advantage into context, in 1999 cotton farmers with an average per capita income of $250/annum were generating additional income of approximately $350/hectare equivalent to additional income of $140 for the average 0.4 hectare planting of Bt cotton. Considering that Chinese cotton farmers are small resource-poor producers, the Chinese experience with Bt cotton supports the thesis in the 2001 UNDP Human Development Report, that technology can contribute to the alleviation of poverty. In terms of distribution of benefits, the data clearly show that in 1999, 80 to 85% of total benefits accrued to farmers with a small percentage (15% to 20%) to the developers of the technology.

Table 33 – Net Revenue (US$/ha) of Bt and Non-Bt Cotton Farmers in China, 1999-2001 (US$/ha).

	1999	2000	2001	Average
Bt	351	367	277	332
Non-Bt	-6	-183	-225	-138
Bt – Non-Bt	357	550	502	470

Source: Pray *et al.* (2002).

Taking all 3 years into account, savings on insecticides both in terms of lower cost for the reduced amount of product used and the substantial labor savings from reducing the number of sprays by one-half to two-thirds, is the major contributor to decreased production costs. The increase in yield of Bt cotton leads to increased revenue, which is offset by the higher price of Bt seed. For example, for 2001, labor savings, which are probably largely related to reduced number of insecticide sprays, provided savings of approximately $300, pesticide reduction approximately $100 savings, and increased yield $100 for a net economic advantage of $500/hectare. The additional cost of the Bt seed was approximately $60/hectare, whereas cost for fertilizer was higher for non-Bt cotton. Some critics voiced concern that Bt cotton would increase the supply of cotton and would result in losses rather than profits for Bt cotton farmers. Increased supply of cotton was associated with a significant price decrease of approximately 30% between 2000 and 2001 (4.42-4.45 yuan/kg to 3.02-3.04 yuan/kg). Despite this decrease in price, Bt cotton farmers still increased their income by approximately $500/hectare compared to non-Bt cotton farmers (ISAAA, 2004).

At a national level, the economic benefits of Bt cotton in China in 2001, based on adopted area of Bt cotton (Table 26) and net revenue/hectare (Table 33) was approximately $140 million in 1999, $495 million in 2000, and $750 million in 2001 (Table 34). Of this return of $1.4 billion over three years, about half, $700 million, can be attributed to the Bt cotton developed by the Chinese public sector (CAAS) which has invested R&D expenditures of the order of $100 million plus, annually on biotechnology for all crops, including cotton. This represents an excellent level of return on R&D investments for the Chinese Government and should provide the incentive to implement its intent to quadruple its R&D budget in crop biotechnology to $450 million by 2005. Bt cotton has also been an excellent investment for resource-poor small Bt cotton farmers in China who captured 80 to 85% of the total benefits in 1999. This represents a very high level of return for resource-poor small Bt cotton farmers who now suffer from less insecticide poisonings. It also represents an excellent investment for China as a nation, and for consumers who benefit from more affordable prices for cotton and a safer environment.

Table 34 – National Economic Benefits Associated with Bt Cotton in China.

Year	Benefits ($ Millions)
1999	140
2000	495
2001	750
Total	1,385

Source: Compiled by Clive James, based on data from Pray *et al.* (2002).

Chapter IV
Biosafety Management and Regulations in China

1 – Biosafety Management and Regulations in China

It is widely recognized that biotechnology is one of the most innovative technologies developed in the 20th century with an even more promising future in the 21st century. Biotechnology is currently a hot topic in both academic and political circles for its implications on food security, economic growth and income distribution, human health, the environment, and agricultural trade. Genetic modification techniques are at the center of this focus and have spurred worldwide debate on biosafety issues. Many regard these new techniques as a potential threat to human life, to existing plant and animal species, and to the environment. These concerns have resulted in government regulations in some countries that have tightened monitoring, supervision, and control of research and commercialization of genetically modified (GM) varieties, especially GM foods.

In the late 1990s, six European Union (EU) member nations (Austria, France, Germany, Greece, Italy, and Luxembourg) banned imports of transgenic corn and rapeseed that were approved by the European Union. In late 1998, the EU imposed a five-year de facto moratorium on approving new transgenic varieties, which effectively prohibits most US corn exports to Europe. In May 2003, the United States, Argentina, and Canada filed a World Trade Organization (WTO) dispute against the EU over its moratorium (Marchant *et al.*, 2002).

Japan also has strict regulations for biotech food imports. In 2000, Japanese legislation was introduced to prevent imports of food products that contain transgenic varieties not yet approved in Japan. Japan's biotech testing focuses on transgenic products approved for commercialization abroad but not yet approved in Japan (e.g., StarLink corn is not approved for any use in Japan). In Japan, foods found containing unapproved transgenic varieties must be reexported, destroyed, or diverted to nonfood use (Marchant *et al.*, 2002).

As in many other countries, Chinese policy-makers are concerned about environmental and food safety, in response to the debate on the potential risks of GMOs recently raised by the Chinese media. The debate in China has involved scientists, government officials and newspaper reporters: responses and reactions vary among stakeholders and change over time as more information becomes available on biotechnology. A consensus seems to be growing in China that the most important task a scientist or biotechnologist can do is to reduce the potential negative effects and demonstrate the safety of GMOs.

As a consequence of this consensus, research budgets allocated to biosafety management and the study of biosafety have increased. Since 1999/2000, nearly all biotechnology research programs have expanded their scope into biosafety issues particularly for the following programs: “863”, “973” and the Special Foundation for Transgenic Plants Research and Commercialization. A number of national institutes under the Ministry of Agriculture, the Ministry of Public Health and the State Environmental Protection Authority have launched various biosafety programs, including capacity building for biosafety management and risk assessment, research studies on environmental safety and food safety, detection technology for GMOs and GMO products, and monitoring of international practices (Huang and Wang, 2003).

The development of more comprehensive and science-based safety assessment are reasons for the recent adjustment of China’s GMO’s commercialization. Concern over the impacts of GMO development on agricultural trade is another important factor. Issues such as labelling of GM products and possible trade barriers resulting from biotechnology concerns in countries that follow precautionary and preventive policies do have impacts on the current (short run) pace of GMO commercialization in China as agricultural trade is an important contributor to the aggregate Chinese economy and trade (Huang and Wang, 2003).

It appears that international trade concerns may have been one of the important factors, but not the dominant factor, in recent agricultural biotechnology policy processes. The critical event here appears to have been the EU’s decision to ban Chinese soy sauce imports produced with GM soybeans imported from the United States. Additionally, the recent decision by Thailand, the world’s leading rice exporter, to halt further development of GM rice may also have been significant. It is unclear whether public attitudes towards GMOs in Europe are now softening, or whether policies may soon change, hence, a “wait and see” tactic in the short run in China is probable (Huang and Wang, 2003).

The hesitations and ambiguities around GMOs gravitate around the issue of biosafety.

According to Gopo (2001), biosafety is the safe development of biotechnology products and their safe application resulting from the existence of effective mechanisms for the safeguard of human and animal health, safe agricultural production, safe industrial production, safeguard of the natural plant and animal species, (flora and fauna) and the environment from negative consequences from the practice and applications of biotechnology and its products. Biosafety then deals with the safe uses and applications of GMO and their products for the safeguard from the negative consequences on human and animal health and on the environment.

For Glover (2003), biosafety is understood to refer to the management of the risks associated with the contained use and environmental release of GMOs. Therefore, the concept of biosafety can be seen to be based implicitly on the concept of "risk", and in particular the assumption that the environmental and human health risks associated with GMOs can be identified, evaluated and controlled by science.

For Levidow *et al.* (1996) quoted in Newell (2002), risk assessment is the process by which the state defines the problems for which it accepts responsibility. Implied by it is a social contract that specifies the terms under which state and society agree to accept the costs, risks and benefits of a given technological choice, even if it is unclear how far society is involved in making that choice.

In this sense, risk management and evaluation is both a means and an end of regulation. It implies a process whereby choices can be made and justified about acceptable risks associated with new technologies. It can both minimise side-effects from the production process and overcome the legitimacy problems of an industrial process. The choice of risk and the approach to assessing those risks are of course contested and politicised, as they imply different degrees of regulation and oversight. For example, existing regulation can appear to be adequate and competent for the task of managing risks associated with biotechnology, because only those risks that can be accurately measured or plausibly known are identified as relevant. Not only does a focus on particular risks imply a level of technical competence, but the forms of expertise that are thought to be relevant in formulating assessments help to determine who is in a position to participate in regulatory choices.

Since risk assessment is central to any biosafety system, its principles and strategies are a matter of much debate. The term "risk" is defined as the multiplicative product between likelihood and magnitude of a specific unwanted effect. This definition implies that risk can be identified and quantified mathematically. But risk also has a subjective dimension, because it relates to what we feel, accept or fear. Unfortunately, the concept of risk is burdened with negative associations and can be easily instrumentalized. Even the term “risk assessment” per se suggests that a risk exists and that the intention is to analyze and assess its impact. Any debate on assessment procedures, therefore, requires an agreement on what is perceived as a risk in principle. A few statements may outline the direction (de Kathen, 2000):

- A priori, no scenario results in a zero-risk situation. The fact that we ignore a certain risk or that we are used to it does not change the likelihood or the magnitude of the potential damage.
- Risk is commonly associated with “doing” or “modifying”, that is, something dynamic. In turn, “not doing” anything, that is, the static reference situation, is often implicitly regarded as safe. This is an inappropriate assumption; risk assessment needs to consider realistic alternative scenarios.
- In the public, the concept of risk is often confused with probability. For example, a horizontal gene transfer as such is not a risk. It occurs with a certain probability and the mere fact that it occurs is an important scientific finding, describing a feature of any genetic material (transgenic or not).

A very important point should be noted here: those who favored a strong precautionary principle in the Cartagena Protocol did so in order to remove the decision-process from an invisible scientific arena into a transparent public space. Yet the same transparency should be applicable vice versa i.e., it should be crystal-clear on what basis decisions are made. For instance, the factual moratorium – by the EU-council of Ministers of Environment in June 1999 – on the commercialization of GMOs in Europe is not the result of a negative risk assessment but politically motivated.

Limited resources also require priority setting. Biosafety assessment procedures have not been applied to non-GMOs, but such organisms may pose risks to the environment and human health, too. In fact, many of the risks of non-GMOs are identified, and the potential harm is almost quantified, but there is no feedback mechanism. It would be wrong to hypothesize that there is no risk associated with GMOs.

In 1992, the Convention on Biological Diversity (CBD) took place with the main objectives of working for the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. When developing the Convention, the negotiators recognized that biotechnology can make a contribution towards achieving the objectives of the Convention, if developed and used with adequate safety measures for the environment and human health. The Contracting Parties agreed to consider the need to develop appropriate procedures to address the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. The Biosafety Protocol is the result of that process.

The full name of the Biosafety Protocol is "the Cartagena Protocol on Biosafety to the Convention on Biological Diversity." Cartagena is the name of the city in Colombia where the Biosafety Protocol was originally scheduled to be concluded and adopted in February 1999. However, due to a number of outstanding issues, the Protocol was finalized and adopted a year later on 29th January 2000 in Montreal, Canada.

Biosafety is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. For the purposes of the Biosafety Protocol, this is based on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage. While developed countries that are at the center of the global biotechnology industry have established domestic biosafety regimes, many developing countries are only now starting to establish their own national systems. The term “biosafety” has thus been coined to describe the regulation, elimination, or control of the risks associated with the use and release of such organisms.

A special, but not infrequent situation arises, however, when lack of scientific certainty or consensus prevails. It is for such circumstances that the legal concept of precaution has been developed in the 1970s. It has subsequently increasingly been reflected in international treaties, as well as national law, and has become known as the precautionary principle (Mackenzie *et al.*, 2003).

Its most commonly referred to formulation is that contained in Principle 15 of the Rio Declaration, adopted by States at the UN Conference on Environment and Development in 1992 – the single most important non-binding international instrument adopted by States after the Stockholm Declaration of 1972 (Mackenzie *et al.*, 2003).

In short, the precautionary principle holds that uncertainty regarding serious potential environmental harm is not a valid ground for refraining from preventive measures.

In this sense, the principle's chief characteristic is to operate as enabling action, and authorizing preventive measures, in circumstances of scientific uncertainty (Mackenzie *et al.*, 2003).

Whether and to what extent there is scientific uncertainty is therefore critical in the context of precautionary action. There is no internationally agreed definition of "scientific uncertainty", nor are there internationally agreed general rules or guidelines to determine its occurrence. Those matters are thus dealt with – sometimes differently – in each international instrument incorporating precautionary measures (Mackenzie *et al.*, 2003).

2 - The Cartagena Protocol on Biosafety

The Protocol's general coverage includes the transboundary movement, transit, handling and use of all GMOs (referred to as "living modified organisms" (LMOs) in the Protocol) that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health\ (Mackenzie *et al.*, 2003). The central procedural mechanism set out in the Protocol to regulate transboundary movement of living modified organisms is advance informed agreement (AIA). Risk assessment is the central component of the AIA procedure. The AIA procedure essentially requires that before the first transboundary movement of a GMO subject to the AIA procedure, the Party of import is notified of the proposed transboundary movement and is given an opportunity to decide, within 270 days, whether or not the import shall be allowed and upon what conditions. This decision must be based upon a risk assessment, carried out in a scientifically sound manner, in accordance with Annex III of the Protocol and taking into account recognised risk assessment techniques (La Vina, 2003 and Cosbey and Burgiel, 2000). The purpose of this procedure is to ensure that importing countries have both the opportunity and the capacity to assess risks that may be associated with the LMOs before agreeing to its import.

For the agricultural and other products within its domain, the Protocol divides LMOs into three classes: (1) those intended for release into the environment; (2) those for food, feed, and processing; and (3) those in transit and for contained use.

As discussed above, the Protocol promotes biosafety by establishing rules and procedures for the safe transfer, handling, and use of LMOs, with specific focus on transboundary movements of LMOs. It features a set of procedures including one for LMOs that are to be intentionally introduced into the environment (AIA procedure), and one for LMOs that are intended to be used directly as food or feed or for processing (LMOs-FFP).

LMOs intended for direct use as food or feed, or processing (LMOs-FFP) represent a large category of agricultural commodities. The Protocol, instead of using the AIA procedure, establishes a more simplified procedure for the transboundary movement of LMOs-FFP. Under this procedure, A Party must inform other Parties through the Biosafety Clearing-House, within 15 days, of its decision regarding domestic use of LMOs that may be subject to transboundary movement (CBD, no year).

The Protocol established a Biosafety Clearing-House (BCH) as part of the clearing-house mechanism of the Convention, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist Parties to implement the Protocol (CBD, no year).

In order to reinforce the information sharing on biosafety and implement the obligation for the establishment of biosafety information clearing-house under, SEPA has organized the experts to develop “the web site of biosafety information in China”. The system design for the web site and the application for domain name have been completed and submitted to SEPA for review. The information contents in the web site include: “The Cartagena Protocol on Biosafety”, the national focal points, the competent national authority, the policies and regulations on biosafety, the technical guidelines for biosafety, the databases of contained use, field trial and commercialization of GMOs, the database of transboundary LMOs, the list of biosafety experts, the biosafety news, and other biosafety web sites (Wang *et al.*, no year).

The major players in the negotiations included five negotiating groups, they include the Miami Group, the Like-Minded Group, the European Union, the Compromised Group and the Central and Eastern European bloc of Countries (CEE).

At the end of the spectrum, the Miami Group represents the major agricultural exporting countries, Australia, Argentina, Canada, Chile, Uruguay, and the U.S., which have a particularly high stake in the free flow of agricultural commodities, argued that the Protocol should protect free trade in products of modern biotechnology (Smith, 2000).

The group's positions included limiting the scope of the Protocol by excluding commodities from the Cartagena Protocol's stringent requirements for LMOs intended to be released into the environment. One of the Miami Group's goals was to allow commodities intended for food, feed, and processing to operate under a simplified procedure, so that they would be subject to expedited import approvals. They also wanted LMOs in transit and those destined for contained use to be excluded from the scope of the agreement, since those products do not have an adverse effect on the environment. The exclusion of human pharmaceuticals produced through biotechnology was also an issue (Smith, 2000).

Another critical issue for the Miami Group was the preservation of countries' rights and obligations under other international agreements, especially the World Trade Organization's (WTO) agreements, already signed by most parties to the Protocol negotiations. As major agricultural exporters, Miami Group countries fought for a "savings clause" in the pact to clarify that the Protocol would not take precedence over other existing trade agreements. (In international agreements, a "savings clause" is an explicit statement that the rights and obligations of countries under existing international agreements are protected) (Smith, 2000).

The Like-Minded Group emerged from the G-77/China (a developing country negotiating coalition) to distinguish itself from the three developing countries in the Miami Group. The largest negotiating group (measured by the number of countries, population and biodiversity), the Like-Minded Group included countries ranging from those with no domestic regulatory structures, legislation or biotechnology industries to those with fairly developed systems (Cosbey and Burgiel, 2000). China interacts closely with the "like-minded" group of which she is a part. Although China has differences of opinion with the group, on issues around the conditions in which it is acceptable to block the trade in GMOs for example, it continues to align itself most closely with this grouping across a spectrum of substantive issues. Indeed, Cai Lijie from SEPA, (State Environmental Protection Administration) was head of the Chinese delegation and spokesperson for the Like-Minded Group at different points in the international negotiations. He is credited with maintaining a firm stance on issues such as the relationship between the Protocol and the WTO and the importance of adopting the precautionary principle in the agreement in the face of intense pressure from the Miami group (Newell, 2003).

China is a signatory to the Cartagena Protocol on Biosafety, even though China has not yet ratified the agreement. China's ratification has been slowed by a tussle between SEPA and the Ministry of Agriculture over the extent of their mandates and responsibilities for overseeing the different elements of the Protocol. While SEPA is pushing for early ratification of the Protocol, MOA is seeking overall control over the implementation of the agreement as a condition for accepting early ratification. Ultimately, however, the final decision on ratification of the agreement will be made by the State Council, which sits above the other agencies involved in policy (Newell, 2003).

They took positions almost diametrically opposed to the Miami Group. They supported a strong Protocol, in light of the unknown effects of LMOs on the environment and human health, and given the need to protect countries without adequate regulatory or institutional capacity to effectively handle LMO imports.

The Like-Minded Group called for a comprehensive scope, including LMO–FFPs (LMO intended for direct use as food or feed or for processing), arguing that seeds and other LMO products intended for consumption might actually be planted in many developing countries. They also argued for comprehensive identification and documentation requirements on LMO imports. The Like-Minded Group supported a strong statement of the precautionary principle, and was the prime backer of tough and concrete text on liability and redress.

The EU bloc took many positions in opposition to the Miami Group. It was no surprise, given the strong anti-biotechnology campaigns waged in the EU, that this bloc supported a much more restrictive Protocol. Still in the throes of U.K.-led hysteria about bioengineered food, EU policy makers have reacted by restricting this technology, and would like to see the same approaches adopted on the international level. Thus, in the Protocol negotiations, the EU bloc supported a stringent Protocol based on the precautionary principle, whose scope would cover commodities (Smith, 2000).

On scope, the EU had pushed for inclusion of LMO-FFPs (LMO intended for direct use as food or feed or for processing), while acknowledging that they might merit special treatment under the AIA procedure. They also supported alternative considerations for contained use, transit and pharmaceuticals for humans. On these issues their position generally fell somewhere between those of the Miami Group and the Like-Minded Group. The EU also supported visible identification and documentation for LMOs, given the EU desire to identify GM products through labelling. The EU objected to the inclusion of a savings clause, arguing that it would threaten decisions to deny LMO imports on environmental grounds. The EU instead supported the inclusion of a non-discrimination provision, stating that countries would not discriminate among domestically produced LMOs and those being imported (Cosbey and Burgiel, 2000).

A Compromise Group also emerged at Cartagena (consisting of Japan, Mexico, Norway, Singapore, South Korea, Switzerland, and in the final stages New Zealand). Its objective was to be to bridge gaps between the other negotiating blocs by elaborating compromise stances. In this respect, the role of the Compromise Group was to prove critical in the final discussions in Montreal. (Newell and Mackenzie, 2000).

The Group did have joint positions supporting a comprehensive scope and the precautionary principle, although they acknowledged internal difference about the savings clause. The group's inclusion of countries with high levels of biodiversity as well as those with advanced biotech industries provided additional cache for addressing the range of concerns of developed and developing countries (Cosbey and Burgiel, 2000).

The fifth negotiating bloc was formed of the countries of Central and Eastern Europe**.** These five groups were flanked by the Biotechnology Industry Organisation on the one hand, representing agricultural, food and pharmaceutical companies promoting the goals of the Miami group on trade, and an international coalition of consumer and green groups on the other, supporting the Like- Minded Group and maintaining pressure on the EU (Newell and Mackenzie, 2000).

The Miami Group insisted that risk assessments and decision-making on imports of LMOs should be based on "sound science" and should conform to WTO requirements. These include those under the Agreement on Sanitary and Phytosanitary Measures which require that measures which restrict trade on sanitary or phytosanitary grounds must be based on risk assessment and sufficient scientific evidence. In addition, the Miami Group insisted that the precautionary principle need not be expressly written into the operative provisions of the Protocol, since, as no actual threats to biodiversity or human health from LMOs had been proved, the Protocol was in itself a precautionary instrument. By contrast, while agreeing to the need for risk assessment, the Like-Minded Group and the EU argued that it was precisely the lack of scientific certainty and consensus around possible impacts of LMOs which necessitated the inclusion of the precautionary principle in the operative provisions of the Protocol on AIA. In addition, the fact that a particular LMO may have different effects in different ecosystems had to be taken into account (Newell and Mackenzie, 2000).

3 - National Biosafety Framework of China

As a result of the debate outlined above, there have been increasing policy discussions on how to regulate the application of genetic modification techniques at the national level and a number of national regulatory frameworks have been established. As activities involving the technology expanded, and in particular as actual and potential commercial use increased, the scope of national regulations tended to expand. Designing frameworks for GMO regulations has not been easy, as the main challenge was perceived to be establishing an appropriate balance between potentially important technological benefits and appropriate environmental and human health safeguards. But as the debate evolved, the role of law as a “provider” of biosafety, i.e. as the provider of mechanisms to ensure the safe handling, transfer and use of genetically modified organisms, increasingly came to the fore (Mackenzie *et al.*, 2003).

The challenges of biosafety, in particular in the context of the transboundary movement of GMOs, made an international regime a prerequisite for an efficient regulatory system: biosafety cannot be achieved without a coordinated approach between countries. This is why the Protocol has been negotiated.

A National Biosafety Framework (NBF) is a combination of policy, legal, administrative and technical instruments that is developed to address safety for the environment and human health in the context of developing and applying modern biotechnology. These frameworks often focus on GMOs. Although National Biosafety Frameworks vary from country to country, they often contain a number of common components, such as; a policy on biosafety, which is often part of a broader national policy on biotechnology; a regulatory regime for biosafety, which usually consists of a law or act in combination with implementing regulations; a system to handle notifications or requests for authorisations for certain activities, such as field test releases of GMOs in the environment. The system typically provides for administrative handling, risk assessment, decision making and public participation; systems for monitoring and enforcement;

systems for public awareness and participation, i.e. a system to inform stakeholders about and involve them in the development and implementation of the national biosafety framework (UNEP-GEF, no year).

To implement the relevant obligations of Convention on Biological Diversity and help developing countries strengthen their capacity building for biosafety management, United Nations Environment Program (UNEP) has selected in 1997 18 countries in the world for pilot projects for formulating their national biosafety framework by using the funds from Global Environment Facility (GEF) (the UNEP-GEF Biosafety Pilot enabling Activity). China was one of the 18 countries selected for this pilot project. The project was led by the State Environmental Protection Administration (SEPA) of China and implemented by 8 relevant government departments. The project was initiated at the end of 1997. The final version of the National Biosafety Framework of China (NBFC) was produced in the middle of October 1999. The NBFC brought forward the frameworks of policies and regulations for national biosafety management, established the framework of technical guidelines for risk assessment and management of LMOs and specified the priority demands and actions for capacity building of national biosafety management (UNEP-GEF, no year).

The NBFC was formulated before the adoption of the Cartagena Protocol on Biosafety. The policies brought forward in the NBFC were general outlines but not specific strategies ready for implementation. China has been a member of WTO and the Protocol came into force on 11 September 2003 (UNEP-GEF, no year).

Given these developments, it was necessary to modify some contents of the policy framework in the NBFC, to evaluate the biotechnology development status in China based on the requirements of the Protocol and needs of national biosafety management, to analyze the influence of the Protocol on biotechnological industry and the environment in China, to analyze the influence of the articles of WTO on the trade of LMOs and the management of biosafety, to further put forward the strategy on implementation of the Protocol and the measures to strengthen the management of environmental release and transboundary movement of LMOs. The above mentioned measures not only will be very significant for the protection of biodiversity, human health and environment, but also necessary for China to better implement the Protocol and offer reference to biosafety management in the world (UNEP-GEF, no year).

The People's Republic of China is a strategically important country in the field of genetically modified organisms, since research and application have both progressed fairly far. The demands on China in terms of assessing the risks in dealing with genetically modified organisms are particularly onerous, since China is one of the countries with the greatest biodiversity in the world, and is the centre of origin of many important genetic resources. Legislation on biosafety, taking into account the standards of the Cartagena Protocol on Biosafety and the pertinent EU regulations were not introduced until 2001, however. Illegal release of such plants is common, and GMO activities are far from transparent. In this sense, the Chinese Government has signed the Cartagena Protocol and is preparing to ratify it. In line with this protocol, relevant legislation and policies were and must be developed at national level (GTZ, no year).

In 2002, UNEP and GEF approved the implementation of the framework and contributed some 1 million US dollars to the project, which targets the improvement of China's legal system on biosafety and its capacity of risk assessment on GMOs among others. Over the past year, the project has achieved substantial results, including the completion of a report on the current status of research on transgenic plants and animals and risk assessment, said Xue Dayuan, chief of the project's expert group.

According to the NBFC, the Chinese government has set some theoretical principles in biosafety, which include, for example (Huang *et al.*, 2001a):

Equal attention should be paid to both biotechnology R&D and to safety management. The government actively supports and encourages biotechnology R&D through preferential policy measures, at the same time it pays great attention to biosafety issues. Promotion of biotechnology and its related industries must guarantee human health and environmental safety;

Safety issues are another priority. Based on the particular biotechnology product, negative ecological and environmental effects and potential dangers to human health in the period of experimental research, field trials, environmental release, commercialization and processing, storage, utilization and waste treatment etc should be prevented. Therefore, prevention is fundamental;

There also should be cooperative management between related ministries. Biotechnology products are associated with many fields, such as agriculture, forestry, pharmaceuticals and health, and food processing etc. Biosafety management involves not only human health and ecological and environmental protection, but also export and import management and international trade activities. Therefore, the cooperation among related ministries and agencies is necessary;

Management should be based on fair and scientific principles. Biosafety assessment must be based on science, the related manipulation techniques, monitoring processes, monitoring methods and results must be up to scientific standards. According to regulations, all released biotechnology products should be monitored regularly and corresponding safety measures should be adopted regarding monitoring data and results. A system of national biosafety assessment standards and monitoring of technology should be established;

Consumers also have the right to know the facts about the products of biotechnology. The public should be aware of similarities and differences between biotechnological and traditional products. The consumers have choice as to whether to use new genetically modified products or not;

Assessment should be on a case by case basis. Genetic information exchange during processes of genetic manipulation is complex, so specific analysis and assessment must be taken for every particular product. Based on requited information, appropriate safety measures should be taken according to the progress of genetic engineering. On the other hand, these scientific measures will be gradually improved and perfected with the development of technology, accumulation of experience, public opinion and acceptance.

4 - Consumer Acceptance of Biotechnology

The GM food safety debate seems to have been initiated by the commercialization of GM crops and has since become more heated. This debate has important implications for the development of this new technology, which is viewed as a major approach in the fight against global hunger. Also, it is widely recognized that consumer acceptance will ultimately determine whether GM foods can survive and expand in the marketplace, and will conclude this debate to some extent, at least with regard to policymaking.

A survey conducted by Chern and Rickertsen (2002), quoted in Zhong *et al.* (2002), of consumer acceptance of GM foods in Japan, Norway, Taiwan, and the United States showed wide differences in consumer acceptance across countries. For example, although

Norwegian consumers seemed better informed about GM issues, and a higher percentage of them viewed GM foods as - very safe - Norwegian consumers tended to accept GM foods much less than US consumers. In Japan and Taiwan there was also a large difference in consumers' willingness to pay for GM foods. Although Japanese consumers were most the skeptical in this survey, Taiwanese consumers seemed to have similar attitudes as those in the United States. These survey results may imply that consumer attitudes are strongly influenced by cultural and institutional factors.

Focusing on Asia, consumer surveys conducted in China, Indonesia, and the Philippines suggest that most Asian consumers have a positive attitude toward GM foods (Asian Food Information Center, 2002, 2003 quoted in Zhong *et al.*, 2002). Results indicated that about two thirds of consumers not only accepted GM foods but also believed that they would personally benefit from consuming GM foods. This finding is consistent with previous observations in Taiwan. However, this survey does not reveal Asian consumers' knowledge of GM foods.

An additional survey conducted by Xuan and Zhou (2002), quoted in Zhong *et al.* (2002), in China sought to identify consumers' awareness of GM foods. Results from questionnaires showed that only about 5% of Chinese consumers think that they know the issues concerning GM foods well, while 63% know - a little - and the rest (32%) know nothing. Additional, survey results indicated that about half of consumers did not know whether GM foods are safe for humans or the environment; 37% and 29% respectively believed they are harmful to human health and the environment in the long run. These findings are very negative. The authors suggested that the results be considered with caution, because the survey was conducted through the mail among individuals known to the investigators.

Acceptance of biotechnology by Chinese consumers carries with it enormous potential benefit to firms wishing to market biotechnology products. Consumer attitudes are heavily influenced by the government due to its control over the news media. A 1999 Environics International survey of consumers in 10 countries found that China had the highest consumer acceptance of biotechnology products of all the countries surveyed including the US, Canada, Japan, Russia, India, and four European countries. In a survey of 600 Asian consumers, including 200 Chinese citizens, 66 percent believed they would personally benefit from food biotechnology during the next five years, 55 percent believed they had eaten biotechnology foods recently and of those that had, 96 percent were satisfied with biotechnology products being available in their market and took no action to avoid them. When asked to spontaneously list advantages and disadvantages of biotechnology, five times more advantages were given than disadvantages. This survey also found that only 23 percent of respondents would prefer more information being included on food labels but when asked what information they would like to see, not one respondent mentioned genetically modified ingredients. In general, concerns over possible negative side effects were expressed in a desire for more information and demonstrated a balanced and open-minded approach (Asian Food Information Centre, 2003 quoted in Loppacher and Kerr, 2004). Of course, these are very small samples of the Chinese population and caution must be exercised in generalising the results.

Some exceptions to this positive view of biotechnology, however, appear to be emerging. Discussion of GM crops is increasing in the media. In January of 2000 the China Consumer Association issued a statement calling for labelling of genetically modified food products. The government has also begun to regulate the market. While the effects of this new legislation is not yet clear, it is apparent that China is stepping back somewhat from its unfaltering support for biotechnology (Canadian Trade Commissioner Service 2002). Due to the state control of the media, if the government position on biotechnology changes, consumer attitudes will almost surely change as well, producing a far less predicable commercial environment for biotechnology products (Loppacher and Kerr, 2004).

5 - Institutional Setting

In general, biosafety management in China is implemented at 3 levels: national, ministries and research institutes. The Ministry of Science and Technology (MOST) represents the national level and is responsible for the general management of biosafety. Recently, a new division for biosafety management has been set up within the National Center of Biological Engineering Development (see Figure 10 in annex). It is responsible for the administration of new regulations, for promoting academic exchange on biosafety, and coordinating different ministries involved with biosafety issues.

At the ministry level, the Ministry of Agriculture (MOA) is in charge of the formulation and implementation of biosafety regulations for agricultural biotechnology. Within the MOA, the Office of Agricultural Genetic Engineering Safety Administration (OAGESA) under the Department of Science and Education is responsible for the implementation of regulations (see Figure 10 in annex). The Biosafety Committee on Agricultural Biological Engineering (BCABE) composed of officials from MOA and scientists from different disciplines including agronomy, biotechnology, plant protection, animal science, microbiology, environmental protection and toxicology, nominated by the MOA, is responsible for the biosafety assessment of experimental research, field trials, environmental release and commercialization of GMOs. The Ministry of Public Health is responsible for the food safety management of biotechnology products. The Appraisal Committee consisting of food health, nutrition and toxicology experts, nominated by MPH, is responsible for reviewing and assessing GM food since it has been designated as a New Resource Food. The State Environmental Protection Agency and MOA assume responsibility for environmental safety.

While the Ministry of Science and Technology is mainly responsible for biotechnology research, the Ministry of Agriculture is the primary institution in charge of the formulation and implementation of biosafety regulations on agricultural biotechnology applications and their commercialization, particularly after 2000 (Huang and Wang, 2003).

The MOA is not however the only ministry with responsibility for biosafety. Since April 2002 there has been a coordinating body under the State Council bringing together seven different ministries with biosafety responsibility. However, building joined-up government is difficult, and some argue this Allied Ministerial Meeting has “no strong power to manage since it is bringing so many together, like the UN” (Keeley, 2003a).

In order to incorporate representation of stakeholders from different ministries, the State Council established an Allied Ministerial Meeting comprised of leaders from the MOA, the SDPC, the MOST, the Ministry of Public Health, the Ministry of Foreign Economy and Trade (MOFET), the Inspection and Quarantine Agency and the State Environmental Protection Authority (SEPA). This Allied Ministerial Meeting coordinates key issues related to biosafety of agricultural GMOs, examines and approves the applications for GMO commercialization, determines the list of GMOs for labelling and import or export policies for agricultural GMOs.

However, routine work and daily operations are handled by the Office of Agricultural Genetic Engineering Biosafety Administration (OGEBA). The National Agricultural GMO Biosafety Committee (BC) is the major player in the process of biosafety management. Currently, the Committee is comprised of 56 members. They meet twice each year to evaluate all biosafety assessment applications related to experimental research, field trials, environmental release and commercialization of agricultural GMOs. They provide approval or disapproval of recommendations to OGEBA based on the results of their biosafety assessments. OGEBA is responsible for the final approval of decisions.

The other unique aspect is that China's National Agricultural GMO Biosafety Committee plays a critical role in the biosafety decision-making process. As most of its 56 current members (29 for GM plants, 9 for recombined microorganisms for plant, 12 for transgenic animals and recombined microorganisms for animals, and 6 for GM aquatic organisms) are experts from various research institutes within the public sector. Their GMO biosafety assessment provides key information for decision makers on whether OGEBA should approve or disapprove GMO application cases. However, the weakness of this approach is the time constraint from BC members who often are leading scientists in various disciplines. There has been concern about the problem of heavy burdens on a few key individual scientists and also that there are too many biotechnologists on the Biosafety Committee (Huang and Wang, 2003).

Clear differences exist between China's technical biosafety committee and the corresponding biosafety review committees in Kenya, Brazil, and India. China's CS is the only one of this group that rests entirely within a ministry of agriculture rather than a ministry of science and technology (as in Kenya and Brazil) or chaired by an environment ministry (as with GEAC in India). The CS has consequently been less prone to paralysis over issues of scientific uncertainty in the biosafety area. Through 1999 the CS gave 26 separate commercial production approvals for GM crops, including multiple varieties of cotton, green pepper, tomato, petunia, and rice (Paarlberg, 2000).

The Ministry of Public Health (MPH) is responsible for food safety management of biotechnology products. The Appraisal Committee consisting of food health, nutrition and toxicology experts, nominated by MPH, is responsible for reviewing and assessing GM foods as they have been designated a Novel Food. The State Environmental Protection Authority (SEPA) participates in GMO biosafety management through the Allied

Ministerial Meeting and through their members on the National Agricultural GMO Biosafety Committee. While SEPA has taken the responsibility of international Biosafety Protocol and most of international activities, particular the activities implemented by UNEP, SEPA's focus on biotechnology in China is limited to biodiversity.

Comparing China to the US and the EU, China has several unique elements with regard to the institutional setting of agricultural GMO biosafety management. The Ministry of Agriculture in China appears to have more power than its counterparts in the US and the European Union. The leaders in the State Council of the previous government believe that the MOA is more familiar with, and has more expertise in agriculture and agricultural GMOs than any other ministry. Moreover, because MOA in China is also in charge of pesticide use and its environmental assessment in agricultural production, the national leaders such consider MOA as a major player in China's agricultural biosafety management (Huang and Wang, 2003).

The State Environmental Protection Administration (SEPA) is the only part of the Chinese government not satisfied with current GM crop biosafety policies (Paarlberg, 2000). SEPA argue that this institutional setting might result in less attention being paid to the environmental risks of GMOs, or even involve a potential conflict of interests as the MOA is primarily responsible for agricultural production, with many biotechnologies developed under MOA's own research system (Huang and Wang, 2003). SEPA would prefer a biosafety policy toward GM crops not so heavily dominated by molecular biologists and agricultural production scientists from MOA and the Chinese Academy of Agricultural Sciences (Paarlberg, 2000).

Another significant challenge is managing the large and extremely complex agricultural biotechnology effort in China. Lack of coordination between the numerous divisions administrating the program and between individual researchers has contributed to unnecessary and inefficient duplication of efforts, particularly at the local level. This results in fewer, more expensive technology advances.

6 - Biosafety Regulations

Concerns have been expressed by Chinese policy-makers, insofar as over the last decades, some administrative departments under the State Council have promulgated several regulations relevant to biosafety management according to their administrative responsibility, including:

- The Safety Administration Regulation of Genetic Engineering, issued by the Ministry of Science and Technology, and promulgated by the former State Commission on Science and Technology on 24th December, 1993, which was in fact not enforced and will not be enforced. This regulation consisted of general principles, safety categories, risk evaluation, application and approval, safety control measures, and legal responsibilities.
- Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering, issued by the Ministry of Agriculture on 10th July, 1996, which was not enforced and cancelled after the promulgation of the Safety Administration Regulation on Agricultural LMOs in May, 2001. This regulation in many aspects is similar to the US's GMO biosafety regulations. Labelling was not part of this regulation. Nor was any restriction imposed on imports or exports of GMO products. The regulation also did not regulate processed food products that use GMOs as inputs.
- Biosafety Regulation on LMOs in Agriculture, issued by the State Council on 9th May, 2001; The objective of the regulation is to strengthen biosafety management of LMOs in agriculture, protect human health and safety of biological organisms, protect the environment and promote the development of biotechnology in agriculture. The scope of the regulation is the research, experiment, production, process, deal, import, export of LMOs in agriculture. The competent authority is the Ministry of Agriculture. Its main mechanisms are the system of risk assessment, the system of labelling, the procedure of ratification;
- Administration Regulation on Safety Assessment of Agricultural LMOs, issued by the Ministry of Agriculture on 11th July, 2001. The objective, scope, and competent authority are the same as above. The procedures of risk assessment, application and ratification, monitoring, and supervision are stipulated;

- Administration Regulation on Safety of the Importation of Agricultural LMOs, issued by the Ministry of Agriculture on 11th July, 2001. The objective and competent authority are the same as above. The scope of the regulation is import of LMOs in agriculture. Procedures for the application and ratification of LMOs in agriculture for the purposes of research, experiment, production, and process are stipulated;
- Regulation on the Labelling of Agricultural LMOs, issued by the Ministry of Agriculture on 11th July, 2001. The objective and competent authority is the same as above. The scope of the regulation is labelling in the circumstance of placing on the market and import of LMOs.

In May 2001, the State Council decreed a new and general rule of Regulation on Safety Administration of Agricultural GMOs to replace an early regulation issued by the Ministry of Sciences and Technologies in 1993. The new regulation established four basic management systems aimed at the safety management of agricultural GMOs (Wang *et al.*, no year):

1. A joint meeting system on the safety management of agricultural GMOs was established under State Council. The meeting is composed of responsible officials from MOA, MOST, SEPA, Ministry of Public Health (MOPH), State Inspection and Quarantine Administration (SIQA), and relevant departments. The important issues on agricultural GMOs are discussed and coordinated on the meeting.
2. The management of agricultural GMOs was implemented in line with their safety level. That is that agricultural GMOs will be divided into four safety levels from level I (the most safety), II, III, to IV (the lowest safety), according to their potential risk to the human, animals, plants and microorganisms.
3. Safety assessment system of agricultural GMOs was established. The activities concerning the GMOs which are intended to conduct intermediate trial, environmental release and commercialization need to make safety assessment and to obtain the approval from the competent department.
4. Label system of agricultural GMOs was established. The species which are written into the "The List of Agricultural GMOs" need to be labelled by manufacturers and distributors before they are placed into marketplace.

In addition, The Regulation also included the provisions related to the research and experiment, the production and processing, the operation, the import and export, the supervision and inspection of agricultural GMOs.

On January 5, 2002, the Chinese MOA issued implementing regulations for transgenic products - specific regulations as a follow-up to the prior Biosafety Administration Regulations on Agricultural Transgenic Products. These implementing regulations consisted of three separate implementing documents: (a) Biosafety Evaluation and Administration Regulations on Agricultural Transgenic Products; (b) Import Safety Administration Regulations on Agricultural Transgenic Products; and (c) Labelling Administration Regulations on Agricultural Transgenic Products (Marchant *et al.*, 2002).

These new regulations placed restrictions on Chinese imports of transgenic products, including those imported from the United States (e.g., biotech soybeans). March 20, 2002 was set as the effective date for implementing these regulations. Specific rules included in these implementing regulations specified that (Marchant *et al.*, 2002):

1. The Chinese Ministry of Agriculture's approval process can take up to 270 days to grant safety certificates that are needed for importing transgenic products through China's customs inspections;

2. Each shipment of biotech products imported into China needs a single or separate safety certificate accompanying each shipment;

3. Transgenic products imported into China require test results or data obtained from in-country field experiments within the exporting country (or a third country) to prove that products are safe for human consumption and do not impose biosafety risks to other plants, animals, or the environment;

4. There is a zero threshold level (based on qualitative test results) for transgenic content in foods. Food products that contain transgenic content must be labelled;

5. The newly announced labelling regulations are applied to the following imported transgenic products: soybean seeds, soybeans, soybean flour, soybean meal, soybean oil, corn seeds, corn, corn oil, corn meal, rapeseed seeds, rapeseeds, rapeseed oil, rapeseed meal, cotton seeds, tomato seeds, fresh tomatoes, and tomato ketchup (tomato jam).

There were several important changes to existing procedures included in these guidelines, and also details of regulatory responsibilities after commercialization. These included the addition of an extra pre-production trial stage prior to commercial approval, new processing regulations for GM products, labelling requirements for products marketed in both domestic and international markets, new export and import regulations for GMOs and GMO products, and local and provincial level GMO monitoring guidelines. Meantime, the MPH also promulgated its first regulation on GMO food hygiene in April 2002 and take effect after July 2002 (Huang and Wang, 2003).

By the late 2002, the system of biosafety regulation in China has clearly become progressively more elaborate and sophisticated. Many provinces have established provincial biosafety management offices under provincial agricultural bureaus. These biosafety management offices collect local statistics on and monitor the performance of research and commercialization of agricultural biotechnology in their provinces, and assess and approve (or refuse) all applications of GM related research, field trials and commercialization in their provinces. Only those cases that have been approved by the provincial biosafety management offices can be submitted to the National Biosafety Committee for further assessment (Huang and Wang, 2003).

The Chinese government hopes that these regulations will ensure the biotechnology products grown in China for both domestic consumption and for international trade will not pose risks to human health or the environment. These regulations have already been responsible for delaying several attempts to commercialize new varieties of crops such as rice and corn. In general, it appears that China is beginning to put in place increasingly stringent regulations on GM foods in particular. While widespread support and favourable policies have been granted for non-food GM products (such as cotton), both domestic and international food safety concerns have begun to influence the government’s regulations and policies regarding GM foods. Some Chinese scientists argue that this more cautious approach is justified given that the next generation of GM crops includes staple foods such as rice which could be consumed by billions of people around the world and whose safety now rests in China’s hands (Loppacher and Kerr, 2004).

7 - Trade and Biotechnology in China

China has had to dramatically alter its trading practices, regulations, tariff system, non-tariff trade barriers, market structure and domestic legislation in order to be in compliance with their WTO accession agreement. While China has made considerable progress in moving toward compliance with the WTO's trade regime, the process has been difficult and may result in a considerable number of trade disputes. The Chinese government still frequently changes major policies affecting trade with little to no notice given to other members of the WTO. Even after these policies are made public, they are often vague and full of ambiguities. Rapid and unilateral shifts in trade policy and domestic policies that affect international commerce runs contrary to the WTO and will lead to complaints from China's trading partners.

Many of the most restrictive policies faced by firms wishing to export to China are a direct result of the pressure the government faces to provide strong domestic protection. While Chinese economic reforms have reduced the role of government, there is still a widespread expectation that the government should intervene when firms face financial difficulties. When China joined the WTO, they had to agree to reduce or eliminate a wide range of trade barriers. This has led many analysts to believe that the motivation for some of these new and confusing regulations is a way to circumvent China's WTO commitments and provide protection for their local industries. These technical and "scientific" barriers to trade have already been used to deny exporters of biotechnology access to the European Union market and many believe it is reasonable to assume that China sees it as a way to skirt around their obligations to open their markets to foreign competition. China has also been accused of making less stringent trade regulations for domestically manufactured products than regulations for their foreign counterparts, a particularly contentious issue in biotechnology trade and which runs counter to China's "National Treatment" commitments under the WTO.

China enters into trade to acquire the technology it needs to develop. It does not want the foreign exchange acquired through the exports frittered away on the importation of consumer goods. Instead, foreign exchange should be used to acquire technology. This difference in philosophy leads China to be more interventionist in their trade regime than those of developed market economies. It also leads to potential disputes at the WTO. Further, China's experience with trade regimes signed with western powers over the last three hundred years has not been particularly positive, starting with "unequal treaties" arising from the Opium Wars of the 19th century. This leads China to view the WTO from a jaded perspective. One cannot expect China to voluntarily play by the rules, but rather to attempt to circumvent them when it does not suit China's interests.

7.1 - Impact of China's 2001-2002 Biotechnology Regulations on Imports

Recent changes to the regulatory framework regarding biotechnology have become contentious trade issues. These regulations, ostensively designed to deal with safety issues, were first promulgated in 1993. The State Science and Technology Commission of China, the Ministry of Agriculture, and the Ministry of Health, all issued regulations regarding biosafety matters. These regulations were modified, clarified and enhanced in 2002 when the Ministry of Agriculture issued three documents for managing biosafety, the Biosafety Evaluation Regulation for Agricultural GMOs, Import Regulation for Agricultural GMOs, and Labelling Regulation for Agricultural GMOs. The effects of the Biosafety Evaluation Regulation was discussed above and applies to all products that will be produced in China, including imports of intermediate goods containing GM material. If imports that will be used in the production chain are deemed as having a moderately high degree of risk, the restrictions that the product will face will be quite stringent. These import regulations have had, and will continue to have, the largest effect on the trade of biotechnology products. These new regulations have been met with strong opposition from China's trading partners, especially the US, who view them as protectionist rather than science-based. In addition to being coupled with the Labelling Regulation, these regulations require companies exporting products to China to apply for safety certificates stating that their products are harmless to humans, animals and the environment. It has been estimated that it will take at least 270 days, in addition to any delays that may be caused by having to wait for the crops to be grown for evaluation purposes.

7.1.1 - The case of US soybeans

In December 2001 China joined the WTO, and many argue that the Chinese labelling rules were introduced so that China could not be accused of doing this afterwards to restrict trade. The rules introduced a labelling threshold that on paper is the strictest in the world at 0 per cent. After this was announced there was a long running dispute centred on imports of soybeans, principally from the United States. China initially imposed a moratorium on imports of GM soybeans unless they were labelled. Then in December 2002 it issued interim rules which were extended until September 2003, and again until

April 2004. This ruling allows GM soybeans to continue to be imported while safety assessment is carried out. Such a ruling buys time for Chinese administrators while still allowing the possibility of a declaration that GM soybeans are not safe at some point in the future. The multinational corporations of course oppose China's strategy arguing that environmental and food safety studies of imported GM crops have taken place elsewhere to an adequate standard. China has also been able to use the 270 day ruling under the Cartagena Protocol on Biosafety to say that GMO imports can be held for this period of time while a safety assessment is carried out (Keeley, 2003c). But in a world of international trade agreements China needs to formulate policies that do not incur trade sanctions, or infringe trade rules, and its decisions for the most part need to be justified as fitting with the sound science criteria that are the basis for exemptions and exclusions in the sub agreements to WTO such as the Sanitary and Phytosanitary and Technical Barriers to Trade agreements (Keeley, 2003c).

Similar observations can also be made in relation to the decision-making process over whether or not to allow the import of GM soybeans. Here the regulation story emphasises the international dimension. China imported 14m metric tons of soybeans in 2001 (from the US, Argentina and Brazil) and most of these were Round-up Ready, the herbicide resistant GM variety. For US soybeans exports China is the single largest market importing US $ 1 billion in 2001. Most of this soya is used for feed or for processing. In 2001 China lost 10 m RMB (US $ 1.2m) of soy sauce exports to Korea, and it has also faced the threat of lost markets in the European Union due to consumer rejection of GM products. These experiences appeared to have a very important effect. They made it clear that a commitment to GM may not be in China's interests in terms of international trade. As this argument took hold it appeared to result in a complete re-evaluation of China's commitment to biotechnology, and whereas a few years earlier there had been a glut of articles on China's GM revolution, suddenly the international press began to report that China was cooling on biotechnology (Keeley, 2003c).

Following China's imposition of a temporary moratorium on GM soybean imports while regulations were developed, President Bush made a high-level visit in February 2002 to persuade the government to keep trading channels open while regulations on biosafety were recast. Following rounds of negotiation in China, US Agriculture Secretary Ann Veneman and US Trade Representative Robert Zoellick announced in early March that the US and China had reached an agreement. This agreement indicated that China would temporarily allow imports of agricultural transgenic products that had completed the safety review process within an exporting country (e.g., the United States). On March 10, 2002, immediately before the effective date set by the implementing regulations, China's Ministry of Agriculture issued a temporary measure permitting all exporting traders to ship transgenic soybeans into China using temporary import certificates through December 20, 2002, according to the Temporary Administration Procedure of Import of Agricultural Transgenic Products. Each temporary import certificate granted by the Chinese Ministry of Agriculture was good for 10 shipments (Marchant *et al.*, 2002).

Before the termination date of these temporary import regulations (December 20, 2002), the Chinese Ministry of Agriculture announced an extension to September 20, 2003. On July 17, 2003, the Chinese MOA announced that the temporary import regulations would be further extended to April 20, 2004 (MOA, 2003). However, after September 2002, each tentative import certificate issued by the Chinese government is good for only one shipment of biotech soybeans, in contrast to the 10 shipments approved earlier (Marchant *et al.*, 2002).

8 - China's Stance on Biotechnology Development – For or Against?

While the government of China provides considerable financial support for the biotechnology industry and makes extensive claims about the benefits biotechnology will bring to their society, when it comes to regulations, the commitment is less firm and increasingly opaque. The President of Monsanto in China, the firm that holds the only foreign GM licence, John L. Killmer states that, "[China has] one foot on the accelerator, which is funding biotech research and development, and they have one foot on the regulatory brake". The lack of clear and consistent direction from the government creates an extremely risky business environment for those wishing to export GM products to China or to invest in biotechnology related activities, including research (Loppacher and Kerr, 2004).

The Chinese government's failure to provide clarity regarding the future direction of regulatory policy has made foreign governments, particularly those in the European Union, extremely nervous that insufficient care will be taken in the design and enforcement of regulations to assure the food safety and environmental concerns of consumers and others in the European Union. As a result, they have been pressuring the Chinese government for stricter safety protocols. The government has not yet been able to find a good balance between ensuring their products are safe, satisfying international concerns and encouraging the industry to grow. If the balance cannot be found, not only will the public firms suffer considerably, meaning ongoing subsidies, the lack of certainty will discourage private domestic and foreign investment.

While the apparent acceptance of biotechnology products in China is a significant advantage at present, there is uncertainty over its long-term continuance. Although the limited information available suggests that Chinese consumers have a high level of awareness, they also have little accurate knowledge of GM foods. As Chinese consumers have not been exposed to the debates regarding the safety of biotechnology, their views could easily be shifted if there were to be negative media coverage in the future.

The Chinese government has put regulations in place that restrict foreign investment in an attempt to ensure that what they perceive as a vital future industry remains under domestic control. The cost may be loss of opportunity for technology transfers.

As shown by the evidence above, China will play an important role in international biotechnology trade, but it will not be without controversy or conflict. The Chinese government continues to invest heavily in biotechnology development and if they are going to be successful, they must secure international markets for their products. One necessary component of successful trade relationships will include allowing biotechnology products, such as GMOs, into the Chinese market as a sign of goodwill. The new safety regulations that China has put in place are clearly a barrier to trade, whether intended or not. The Chinese government has proved, however, that they are willing to compromise to accommodate the needs of foreign producers and to avoid disrupting trade beyond what is absolutely necessary.

Long term acceptance of biotechnology products in China, both domestic and foreign, has still not been determined. No one knows (likely including the government itself) what the next move will be in terms of regulations for products such as GMOs. China's government needs to take a firm stand rather than trying to sit on the fence. If they decide to support it wholeheartedly, biotechnology producers, such as the US, will become strong international allies. If, on the other hand, China decides that the health and environmental risks are too high and put stringent safety regulations in place, not only will it serve as a significant trade barrier, the effect on their domestic industry will likely be detrimental.

If China chooses to embrace biotechnology, their head start in the market will prove to be an important advantage. China is already the fourth (albeit a distant fourth) largest grower of transgenic plants in the world. They certainly have the potential to at least retain their competitive advantage, if not increase it significantly. As mentioned earlier, China has some issues with compliance to the WTO that need to be resolved if they are to reap all the benefits of their commitments.

In general, China has had to develop biosafety regulations both for domestic and international purposes. Locally, to deal with the challenge of how to regulate its own GM products (and imported GM seed), and internationally, in response to the global trade in GMOs, and changing agricultural contexts following entry into WTO. The argument is that China has practised biosafety and devised and implemented regulations quite strategically. And why not – the US is after all a powerful actor on the international stage prepared to use any means to support its trading interests and those of its key corporations. China is new to this and it has to get smart. Being ultra-transparent or kowtowing to US demands in relation to process may only result in them being rolled over either in terms of subsided US exports, or US GM seeds. But approaching biosafety in this way carries with it dilemmas Keeley, 2003c).

China however seems to use biosafety in its own way to frame the biotechnology debate in a way it finds useful, that is it wants biotech, but only on certain terms, and risk assessment and regulation are important ways of asserting this. But this approach is also precarious. Other voices in China can also show limits to the sound science approach, or push for consistent and thorough risk assessment. This can challenge the room for manoeuvre of some of the core networks of actors trying to shape and guide the path of biotechnology in line with China's basic policy of supporting biotechnology as a key industry and key tool in Chinese development as set out in the mid-1980s with the formation of the 863 committee. The next section looks at how processes and practise of biosafety have been contested looking first at the theme of Bt cotton biosafety assessment and then at research into the potential impacts of GM food crops (Keeley, 2003c).

Conclusion

Conclusion

In an ever-increasing demand for food and food security in developed and developing countries agricultural biotechnology has become increasingly important. As such, the Chinese government has come to view agricultural biotechnology essentially as a tool to help improve the nation's food source, raise agricultural productivity, increase farmer's incomes, foster sustainable development, and improve its competitive position in international markets. In order to meet such objectives, the Chinese government has made considerable resources available to the sector and actively promoted its development since the mid 1980s.

To ensure food security for its 1.3 billion people, Beijing has injected large sums of public money into agricultural biotechnology research for some decades now. And what is more, China's plan appears to have two sides: push forward fast on GM foods which offer high yield, and resistance disease, while promoting GM-free areas for crops for sale to rich export markets, where many consumers still reject the idea of genetically modified food.

However, the considerable scientific success of the biotechnology sector in China has lead to a rapidly growing increase in support in recent years by policy makers, investors and the public in general. In the second half of the 1990s, biotechnology spending more than doubled from the equivalent of US $40 million to US $112 million per year. The Chinese government has also promised to increase research budgets by 400 percent over the five-year period between 2002 and 2007. Even though China is a developing country, its total expenditures on agricultural research and development comprises an estimated 10 percent of global public expenditure. There are currently nearly 400 major biotechnology laboratories aided by the government and more than 20,000 research and technical personnel working in the industry. This research effort has yielded a wide array of genetically modified (GM) varieties that have gone through field trials, been cleared for environmental release and have been put into commercial production.

Genetic modification has had a number of objectives (or combinations of objectives): insect resistance, bacterial-fungus resistance, virus resistance, salt tolerance, drought resistance, nutrition enrichment, quality improvement or yield increase. China has the fourth highest commercial acreage of transgenic crops, behind the U.S., Canada and Argentina. In China, six crops have been issued licences that permit commercial production. Two licences were granted for different varieties of insect resistant cotton. In 2000, GM cotton was planted on 700,000 hectares in China. Two licences were also granted to tomato varieties, one that is modified to delay ripening and one that is virus resistant. Colour-altered petunias and virus resistant sweet peppers have also been licensed. Monsanto, which is based in the US, holds the only license that has been issued to a foreign company for their variety of GM cotton.

There are still a large number of modified plants that have not yet been commercialized but are in field trials or have been cleared for environmental release. As of 1999, these included: two new varieties of insect resistant cotton; three varieties of disease resistant cotton; insect, disease and herbicide resistant rice; salt tolerant rice; improved quality and virus resistant wheat; improved quality and insect resistant maize; herbicide resistant soybeans; disease resistant potatoes; disease resistant rapeseed; virus resistant tobacco; virus resistant peanuts; virus resistant cabbage; cold tolerant and multi-virus resistant tomatoes; virus resistant melons; virus resistant papayas; insect resistant poplar trees; and bacterial resistant pogostemun.

As discussed briefly above, and as this dissertation has shown, China has made major investments in plant biotechnology and the government investments have paid off in benefits for small farmers. Bt varieties of cotton reduced the costs of production, increased the income, and possibly improved the health of poor farmers in China. The economic benefits from the government cotton varieties were far higher than the current cost of all plant biotech research in China. This suggests that the large increases in biotech research approved for the new five-year plan will have a high rate of return. Evidences show that the Chinese government is going to continue funding and improving its research capacity, especially in the basic sciences, so that when biotechnology finally does realize its potential, China will be well placed to reap its benefits.

Therefore, China will eventually seek to expand her industrial base beyond electronics and computers, since biotechnology has an obvious appeal. The field is so young and undeveloped that Western companies have not scooped up all the market niches. Thus, China offers more of an opportunity to develop biotechnology products than anywhere else in the world, including the US. But perhaps the most important consideration is also the simplest: China has a population of over one billion, nearly one-fifth of the global population, and it is a developing country. For these reasons, China is an important test case for the successful application of biotechnology to meeting economic development goals and basic human needs in developing countries. In this crucial way, Chinese biotechnology goals can and should diverge from those of developed countries.

However, research in biotechnology is extremely high costs and the Chinese government must decide if it is going to continue to bear almost the entire burden for funding the nation's biotechnology research. Currently, there is almost no domestic private sector funding of plant biotechnology. China has options for increasing private research but many of the options are constrained by poor intellectual property rights, underdeveloped seed markets, and prohibitive regulations of private firms. The government creates some of these constraints; others are a function of underdeveloped institutions and would take a significant amount of time to develop.

Many issues, however, face China's policy makers and research administrators. China has recently put into place a system of regulation and biosafety. But it is new, small, under-funded, and has not proven its ability to produce and enforce effective regulation.

China's leaders are also struggling with issues of consumer safety and acceptance, both within their own country and in the countries that import the farm commodities that China produces. Almost nothing is known about how the average Chinese consumer will react if they learn that their food was produced with genetically modified varieties. There is little knowledge in China about the production of their foods. For example, almost no one is aware that large amounts of the nation's imported soy oil are from herbicide-resistant soybean varieties grown in the U.S. and elsewhere. Although most of the production of China's major staple crops is consumed locally, leaders still worry about the impact of the use of transgenic varieties on exports. In recent years, China was the second largest exporter of maize and has begun to ship increasing quantities of rice into world markets. There are worries that the commercialization of transgenics could harm some of the markets, since countries like Japan and South Korea have begun to express concerns and increase regulations on the imports of genetically modified crops. It was these worries that led officials to stop farmers from using GM tobacco.

It has been discussed in this study that China's beefing up of its investment in biotech research is clear evidence that this is a temporary state of affairs and that policymakers are biding their time, when the right moment arrives they will move ahead and capitalize on China's years of investment in a range of transgenic. China's amber light is important in the international struggle over the future of GM crops most obviously being currently played out between the US and the EU. China is for some an indicator of the state of play, and China's current apparent lukewarm attitude to the idea of widespread commercialization of GM food crops reflects the generally difficult situation that proponents of GM find themselves in internationally.

This work has pinpointed several reasons to explain the real reason why China has not commercialized GM food crops. Some argue that, as discussed above, the principal concern is loss of export markets to key trading partners with large numbers of consumers rejecting GM products. Another is that, in the context of trade liberalization, China will be unable to compete with – principally US imports – of a few key crops, and that this will have serious implications for the livelihoods of certain sections of the Chinese farming population and certain geographical areas. An additional argument is that while China may have the technologies in place, in terms of commercialization, Chinese seed and biotech firms are not nearly ready to compete with the big multinational corporations.

The rapid pace of social change, the growth of new industries and the rapid spread of the market economy are a product of a conscious policy of opening to the outside world, perhaps reflected most strongly in the recent accession to WTO. Change has been styled by Chinese policy-makers, particularly since Deng, but with clear earlier antecedents, as a process of modernization. Embracing science and technology to catch-up with the West and escape backwardness, and in the case of agricultural biotechnology to improve the livelihoods of a still huge rural farming population, have been central to this vision of development.

As part of its modernization drive China has invested in and developed new technologies rapidly. To some extent this ability to effectively channel resources reflects traditions of planning and mobilization that are still strongly routed in present day politics and bureaucracy. At the same time, however, China has had to construct new science-policy cultures to deal with these new technologies and the risks associated with them. The strengths and weaknesses of these cultures, their ability to regulate effectively, to handle risk and uncertainty, and to earn public trust will increasingly be key questions in China.

There is a sense, as has been illustrated in this work that, in relation to regulation of Bt cotton and food crops, that while regulators are smart at defending China's interests in some respects, particularly in relation to foreign corporations or imports, in others there may be problems, for example, they may not be thinking carefully enough about environmental impacts. Moreover, fears that foreign companies may start to patent genetic material obtained from native Chinese products are now behind stepped-up efforts to police biotechnology, showing how nationalism is shaping views on how to commercialize the science. Recent efforts to restrict access to China's biotech market have prompted complaints from foreign industry executives, who say government protectionism is stifling investment and export opportunities.

Although China is still struggling with issues of consumer safety and acceptance, many competing factors are putting pressures on policy makers to decide whether or not continuing commercializing transgenic crops. The demand of producers (for productivity-enhancing technology) and consumers (for cost savings), the current size and rate of increase of research investments, and past success in developing technologies suggest that products from China's plant biotechnology industry will one day become widespread inside China.

Finally, the size of the China's research investment, the rise of its human capital and its past success at developing both biotechnology tools and GM plants suggest that China's plant biotechnology industry may one day become an exporter of biotechnology research methods and commodities. Opportunities for contract research; the sales of genes, markers and other tools; and exporting GM varieties are expanding in both industrialized and developing countries. China has advantages such as a large group of well-trained scientists, low cost research, limited regulation, and large collections of germplasm. In addition some seed companies have experience doing contract seed production for export and many pesticide firms have developed markets throughout the world for generic pesticides. China has the disadvantage of having almost no commercial biotech industry, a fragmented seed industry of small firms, public researchers with little experience working with corporations, and a weak intellectual property rights regime. The competition for China will primarily be from the private sector and the public sector in other countries--the private life science giants, small private biotech firms in industrialized countries, and universities in the U.S and other industrialized countries. Because of the lack of capital and experience in global competition, China may have trouble competing in the most lucrative markets. However, the multi-national life science companies likely will be willing to leave smaller crops and smaller countries to China and the plant biotechnology industries of other developing countries or small companies.

China's future in the biotechnology industry is still a blank page in the history books, waiting to be written. It is certainly in a position to benefit from the opportunities that biotechnology may provide such as increased food security, domestic production and rural incomes, decrease environmental degradation and the economic, social and political benefits that would accompany increased international trade. While China has laid the foundation as an important player in the industry, they have also begun to lay the foundation for stifling their carefully constructed industry by imposing drastic safety regulations on GMOs. The government needs to carefully examine what these arguably non-science based rules could do not only to the domestic biotechnology industry but to the Chinese economy as a whole. China is now in the unique position of being ready to go in whatever direction it chooses, it just must choose what direction that is.

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Annexs

Annexs

Table 10 – Use of modern inputs, China, 1952-95.

Year	Irrigation			Tractor-plowed area		Chemical fertilizer		Electricity (M KWh)
	Total irrigated area (M ha)	Irrigated area in total cultivated area (%)	Powered irrigation in irrigated area (%)	Total area (M ha)	Share in sown area (%)	Total amount (M t)	Per hectare (Kg/ha)	
1952	19.96	18.5	1.6	0.14	0.1	0.08	0.5	50
1957	27.34	24.4	4.4	2.64	2.4	0.37	2.3	140
1962	30.55	29.7	19.9	8.28	8.1	0.63	4.6	1,610
1965	33.06	31.5	24.5	15.58	15.0	1.94	12.4	3,710
1978	44.97	45.2	55.4	40.67	40.9	8.84	58.9	25,310
1984	44.64	46.1	56.4	34.91	30.9	17.40	120.6	46,400
1995	49.28	51.9	65.6	n.a.	n.a.	35.94	239.7	71,200

Source: Lin (1998)

Table 11 – Annual Growth Rates (%) of China's Economy, 1970-98.

	Pre-reform	Reform period		
	1970-78	1979-84	1985-95	1996-98
Gross Domestic Product	4.9	8.5	9.7	8.7
Agriculture	2.7	7.1	4.0	4.0
Industry	6.8	8.2	12.8	10.7
Service	na	11.6	9.7	7.9
Foreign Trade	20.5	14.3	15.2	5.0
Import	21.7	12.7	13.4	10.8
Export	19.4	15.9	17.2	2.0
Population	1.8	1.4	1.4	1.0
GDP per capita	3.1	7.1	8.3	7.7

Source: Huang *et al.* (2001a)

Table 12 – Average annual growth rate of total factor productivity (TFP), grain, gross domestic product (GDP), and consumption, China.

Period	Agricultural TFP*	Grain		GDP	Consumption level index		
		Total	Per capita		National	Urban	Rural
1952-96	1.51	2.52	0.77	7.7	4.5	4.7	4.0
1952-78	-0.25	2.41	0.40	6.1	2.2	2.9	1.8
1978-84	5.10	4.95	3.70	9.3	7.7	4.5	9.0
1984-96	3.91	1.55	0.14	10.2	8.1	8.5	6.4

Source: Lin (1998).

Table 13 - Major science and technology policy measures related to biotechnology in China since the early 1980s.

Policy measures	**Description**
Technological Transformation	Providing criteria of royalty and advanced payment to the scientists and the institutions for the technology transformation. The "Temporary regulation of technology transfer" was issued in 1985. The Technology Contract Law (draft) was issued in 1987, amended and completed in 1998. It was implemented by the State Economic Commission and includes both domestic and imported technologies.
Key Breakthrough S&T Program	Since 1982 the State Planning Commission (SPC, the later SDPC) has formulated the Program and updated every five years and approved. The projects are increasingly open to tenders from competing research institutions. One of major components of these projects is on biotechnology.
Patent system	Patent law promulgated 1985. Introduced as a complement to S&T awards in order to provide incentives for the discovery and dissemination of new technology. A total of 1599 applications on genetic engineering for invention patents were filed in past 14 years (1985 to 1999).
National Biotechnology Development Policy Outline	Prepared by more than 200 scientists and officials under the leadership of MOST, SDPC, and the State Economic Commission in 1985 and revised in 1986. Formally issued by State Council in 1988. The Outline defined the research priorities, development plan and measures to achieve the targets.
National Key Laboratories (NKLs) on Bioetchnolgy	Key laboratories equipped with advanced instruments have been established in agricultural biotechnology fields by the SDPC and the MOA since 1985, the laboratories should receive both domestic and foreign guest researchers and call for open projects. A total number of 30 NKLs in biotechnology have been established, and 15 NKLs are focused on plant, animal, and agriculturally related biotechnology. The MOST is responsible for

	NKLs establishment and assessment.
S&T Firms	Promotion of new research, development and production ventures. These may be established jointly by research or production and entrepreneurial units or may be independently operated by research or entrepreneurial units.
National Program for Key S&T Projects	Started in 1982 to promote the modernization of traditional industries and to enhance the nation's S&T capacity.
The Climbing Program	A National Program for Key Basic Research Projects.
Natural Science Foundation of China (NSFC)	Established in 1986 to support basic science research complementary with "863 plan" according to criteria of academic excellence. Life science and Agronomy are two support areas related to the agro-biotechnology.
High Technology Plan (863)	Established in 1986 to support a large number of applied research projects with 10 billion RMB for 15 years to promote high technology R&D in China. Biotechnology is one of 7 supporting areas with a total budget of 0.7 billion RMB.
Biosafety regulations	MOST issued the Biosafety Regulations on Genetic Engineering in July of 1993, which include the biosafety grading and safety assessment, application and approval procedure, safety control measures, legal regulations, et al.
Agricultural biosafety regulations	MOA issued the Safety Administration, Implementation, and Regulations on Agricultural biological Genetic Engineering in July 1996.
"973 Plan"	Initiated in March 1997 to support the basic S&T research. Life science is one of the key supporting areas.
Safety Committee	Bioetech Safety Committee was set up in MOA in 1997. The committee is in charge the implementation of agricultural biosafety regulations
Special Foundation for Transgenic Plants	A 5-year-program launched in 1999 by the Ministry of Science and Technology to promote the research and development of transgenic plants in China. The total budget of this program in the first 5 years is 500 million RMB.
Key Science Engineering Program	Started in the late 1990s under MOST and SDPC to promote basic research, including biotechnology program. The first project on biotech (crop genoplasm and quality improvement) was funded in 2000 with 120 million RMB.
Special Foundation for Hightech Industrialization	A program supported by the SDPC to promote the application and commercialization of technologies, started from 1998
Bridge Plan	In 1999, MOA initiated the Bridge Plan, focused on diffusion of new technology that is about ready for diffusion.
New varieties protection	Regulation on the Protection of New Varieties of Plants was issued in 1999
Seed law	A first Seed Law was issued in December 2000. The Law indicates that the selection/breeding, GM plant varieties, experiment/testing, certification/approval, and extension must follow the safety evaluation

	procedures according to the regulation issued by the State Council. The sale of GM plant variety seeds should be labelled clearly and remind the safety control measures when applying the seeds.

Source: Huang *et al.* (2001a).

Table 14 - Numbers and Composition of Plant Biotechnology Research Staff in Sampled Institutes, 1986-99.

Year	Professional staff			Support staff			Total staff
	Mgt	Research	Sub-total	Technical	Other	Sub-total	
			Staff number				
1986	82	203	285	80	276	356	641
1990	114	295	409	98	301	399	808
1995	164	371	535	111	322	433	968
1999	207	484	691	133	381	514	1205
1999a	264	705	969	233	455	688	1657
			Composition (%)				
1986	13	32	44	12	43	56	100
1990	14	37	51	12	37	49	100
1995	17	38	55	11	33	45	100
1999	17	40	57	11	32	43	100
1999a	16	43	58	14	27	42	100
			Staff number by institute and university in 1999a				
University	52	72	124	15	27	42	166
Research institute	212	633	845	218	428	646	1491

Note: All data are from 22 biotechnology research institutes except for those with 1999a that includes 29 institutes in 1999. These 29 institutes account for about 80% of research staff, about 85% of research expenditure, and more than 90% of research output in China's plant biotechnology.

Source: Huang *et al.* (2001b).

Table 15 - Plant Biotechnology Professional Research and Management Staff by Education in Sampled Institutes, 1986-99.

Year	Professional staff by education				Total
	Ph. D.	MS	BS	Others	
	Staff number				
1986	5	39	172	69	285
1990	31	90	197	91	409
1995	72	112	238	113	535
1999	141	159	269	122	691
1999a	203	279	343	144	969
	Composition (%)				
1986	2	14	60	24	100
1990	8	22	48	22	100
1995	13	21	44	21	100
1999	20	23	39	18	100
1999a	21	29	35	15	100
	Staff number by institute and university in 1999a				
University	58	35	27	4	124
Research institute	145	244	316	140	845

Note: All data are from 22 biotechnology research institutes except for those with 1999a that includes 29 institutes in 1999.

Source: Huang *et al.* (2001b).

Table 16 - Professional Research and Management Staff in Full-Time Equivalent and by Gender in Sampled Institutes, 1986-99.

Year	Staff number		Gender share (%)		Full-time Equivalent
	Female	Male	Female	Male	
1986	94	191	33	67	236
1990	139	270	34	66	344
1995	182	353	34	66	457
1999	228	463	33	67	608
1999a	349	620	36	64	874

Note: All data are from 22 biotechnology research institutes except for those in the last low that includes 29 institutes.

Source: Huang *et al.* (2001b).

Table 17 – Plant Biotechnology Research Budget by Source in the Sampled Institutes, 1986-99.

Year	By source								Total
	Core	Project	Equipment	Commerce	Consultant	Contract	Donors	Others	
Million RMB yuan in 1999 price									
1986	4.2	5.4	4.9	0.0	0.0	0.0	1.5	0.0	16.0
1990	4.1	13.3	8.1	0.0	0.0	0.0	2.1	0.0	27.7
1995	4.8	20.3	3.3	0.1	0.0	0.0	2.6	1.5	32.7
1999	14.4	60.0	8.1	0.3	1.0	0.1	6.9	2.0	92.8
1999a	19.4	86.9	10.9	0.3	1.3	1.1	7.6	3.3	130.8
Composition (%)									
1986	26	34	31	0	0	0	9	0	100
1990	15	48	29	0	0	0	8	0	100
1995	15	62	10	0.3	0	0	8	5	100
1999	16	65	9	0.3	0.1		7	2	100
1999a	15	66	8	0.3	0.8		6	3	100
Research budget by institute and university in 1999a									
University	2.4	29.4	2.6	0.2	0.0	0.0	0.8	1.3	36.7
Research institute	17.0	57.5	8.2	0.2	1.2	1.1	6.9	2.0	94.1

Note: All data are from 22 biotechnology research institutes except for those with 1999a that includes 29 institutes in 1999.

Source: Huang *et al.* (2001b).

Table 18 – Plant Biotechnology Research Expenditure by Category in the Sampled Institutes, 1986-99.

Year	Personnel	Operating	Capital	Total
		Million RMB yuan in 1999 price		
1986	4.7	3.0	5.5	13.2
1990	5.1	10.3	8.8	24.1
1995	7.8	15.6	6.0	29.5
1999	14.0	44.0	21.5	79.5
1999a	22.8	56.2	29.3	108.2
		Composition (%)		
1986	36	23	42	100
1990	21	43	37	100
1995	26	53	20	100
1999	18	55	27	100
1999a	21	52	27	100

Note: All data are from 22 biotechnology research institutes except for those in the last low that includes 29 institutes.

Source: Huang *et al.* (2001b).

Table 19 – Plant Biotechnology Research Expenditure per Staff in the Sampled Institutes, 1986-99.

Year	Thousand RMB yuan in current prices		Thousand RMB yuan in 1999 prices	
	Professional	Total staff	Professional	Total staff
1986	17.5	7.8	46.4	20.6
1990	34.0	17.2	59.0	29.8
1995	54.5	30.1	55.1	30.5
1999	115.0	66.0	115.0	66.0
1999a	116.6	65.3	116.6	65.3

Note: All data are from 22 biotechnology research institutes except for those in the last low that includes 29 institutes.

Source: Huang *et al.* (2001b).

Table 20 – Research Focus of Plant Biotechnology Programs in China.

Crops/traits	Prioritized areas
Crops	Cotton, rice, wheat, maize, soybean, potato, rapeseed, Cabbage, tomato
Traits	
Insect resistance	Cotton bollworm and aphids
	Rice stem borer
	Maize stem borer
	Soybean moth
	Potato beetle
Disease resistance	Rice bacteria blight and blast
	Wheat yellow dwarf and rust
	Soybean cyst nematode
	Potato bacteria wilt
	Rapeseed sclerosis
Stress tolerance	Drought, salinity, cold
Quality improvement	Cotton fiber quality
	Rice cooking quality
	Wheat quality
	Maize quality
Herbicide resistance	Rice, soybean
Functional genomics	Rice, rapeseed and arabidopsis

Source: Huang *et al.* (2001b).

Table 21 – Available GM Plant Events in China by 1999.

Crop	Introduced Trait	Field Trial	Environmental Release	Commer-cialized
1. Cotton	Insect resistance	Yes	Yes	Yes
	Bollworm (Bt)	Yes	Yes	Yes
	Bollworm (Bt+CpTI)	Yes	Yes	No
	Bollworm (CpTI)	Yes	No	No
	Bollworm (API)	Yes	Yes	No
	Disease resistance	Yes	Yes	No
	Verticillium & Fusarium (Chi)	Yes	Yes	No
	Verticillium & Fusarium (Glu)	Yes	Yes	No
	Verticillium & Fusarium (Glu+Chi)	Yes	Yes	No
2. Rice	Insect resistance	Yes	Yes	No
	Stem borer (Bt)	Yes	Yes	No
	Stem borer (CpTI)	Yes	Yes	No
	Rice planthopper	Yes	Yes	No
	Disease resistance	Yes	Yes	No
	Bacteria blight (Xa21)	Yes	Yes	No
	Fungal disease	Yes	Yes	No
	Rice dwarf virus	Yes	Yes	No
	Herbicide resistance	Yes	Yes	No
	Salt tolerance (BADH)	Yes	No	No
	Ac/Ds (rice mutant)	Yes	No	No
3. Wheat	BYDV resistance & quality improvement	Yes	No	No
4. Maize	Insect resistance (Bt) & quality improvement	Yes	Yes	No
5. Soybean	Herbicide resistance	Yes	Yes	No
6. Potato	Disease resistance	Yes	Yes	No
	Bacteria wilt	Yes	Yes	No
	PVY resistance	Yes	Yes	No
	Viroid resistance	Yes	Yes	No
	Disease resistance & quality improvement	Yes	Yes	No
7. Oil rape	Disease resistance	Yes	Yes	No
8. Tobacco	Insect resistance (Bt or CpTI)	Yes	Yes	Yes->No*
	TMV resistance	Yes	Yes	No
9. Peanut	Stripe virus reistance	Yes	No	No
10. Chinese cabbage	Turnip mosaic virus resistance	Yes	No	No
11. Tomato	CMV resistance	Yes	Yes	Yes
	TMV & CMV resistance	Yes	No	No
	Time-altered shelf life	Yes	Yes	Yes
	Cold tolerance (asp)	Yes	Yes	No
12. Melon	CMV resistance	Yes	No	No
13. Sweet pepper	CMV resistance	Yes	Yes	Yes
14. Chilli	CMV/TMV resistance	Yes	Yes	No
15. Papaya	PRSV resistance	Yes	Yes	No
16. Poplar tree	Insect resistance	Yes	Yes	No
17. Pertunia	Flower-color altered	Yes	Yes	Yes
18. Pogostemun	Bacteria wilt resistance	Yes	No	No

* Commercialized in 1992 but stopped in the middle 1990s due to trade issues

Source: Huang *et al.* (2001b).

Table 22 – Number of cases submitted and approved for field trials, environmental release, and commercialization in China from 1997 to 1999.

	1997	1998	1999	Total
Plant				
Field Trial				
--Submitted	7	21	14	42
--Approved	5	20	20(11+9)*	45
Environmental release				
--Submitted	35	16	53	104
--Approved	29	8	28	65
Commercialization				
--Submitted	6	9	30	45
--Approved	4	2	24	30
Microorganisms				
Field Trial	5	20	14	39
--Submitted	5	20	13	38
--Approved				
Environmental release				
--Submitted	2	2	10	14
--Approved	1	2	6	9
Commercialization				
--Submitted	0	0	4	4
--Approved	0	0	3	4
Animal				
Field Trial				
--Submitted	2	0	0	2
--Approved	2	0	0	2
Environmental release				
--Submitted	0	0	0	0
--Approved	0	0	0	0
Commercialization				
--Submitted	0	0	1	1
--Approved	0	0	0	0
Total				
--Submitted	57	68	126	251
--Approved	46	52	94	192

Source: Huang *et al.* (2001b).

- Among 20 cases approved for field trials in 1999, nine cases were those applied for environmental release, but approved for additional field trials only.

Table 23 – Number of cases of approved for field trials in China.

	1997	1998	1999 (July)	Total
Rice				
Resistant to insects	1	3	9	13
Resistant to diseases		1	3	4
Resistant to salt	0	2	0	2
Others	0	1	1	2
Wheat				
Resistant to herbicide and quality improvement	1	0	0	1
Maize				
Resistant to insects	1	1	0	2
Cotton				
Resistant to insects	0	1	4	5
Resistant to diseases	0	3	1	4
Others	0	0	1	1
Tomato				
Resistant to diseases	0	1	0	1
Cold-tolerance	0	2	0	2
Tobacco				
Resistant to insects	0	1	0	1
Resistant to diseases	0	1	0	1
Papaya				
Resistant to diseases	1	0	0	1
Peanut				
Resistant to diseases	0	1	0	1
Melon				
Resistant to diseases	0	1	0	1
Cabbage				
Resistant to diseases	0	1	0	1
Pogostemun				
Resistant to diseases	1	0	0	1
Total	5	19	20	44

Source: Huang *et al.* (2001b).

Table 24 – Number of cases of approved for environmental release in China, 1997-July 1999.

	1997	1998	1999 (July)	Total
Rice				
Resistant to insects	0	1	1	2
Resistant to diseases	4	1	1	6
Resistant to herbicide	1	1	0	2
Maize				
Resistant to insects	1	0	3	4
Soybean				
Resistant to herbicide	1	0	0	1
Cotton				
Resistant to insects	6	2	6	14
Potato				
Resistant to diseases	4	1	1	6
Quality Improvement	2	0	0	2
Tomato				
Resistant to diseases	1	0	0	1
Ripe-delayed (long shelf)	2	1		3
Cold-tolerance	0	0	1	1
Tobacco				
Resistant to insects	2	1	0	3
Resistant to diseases	2	0	0	2
Sweet pepper				
Resistant to diseases	2	0	0	2
Poplar tree				
Resistant to diseases	1	0	1	2
Total	29	8	14	51

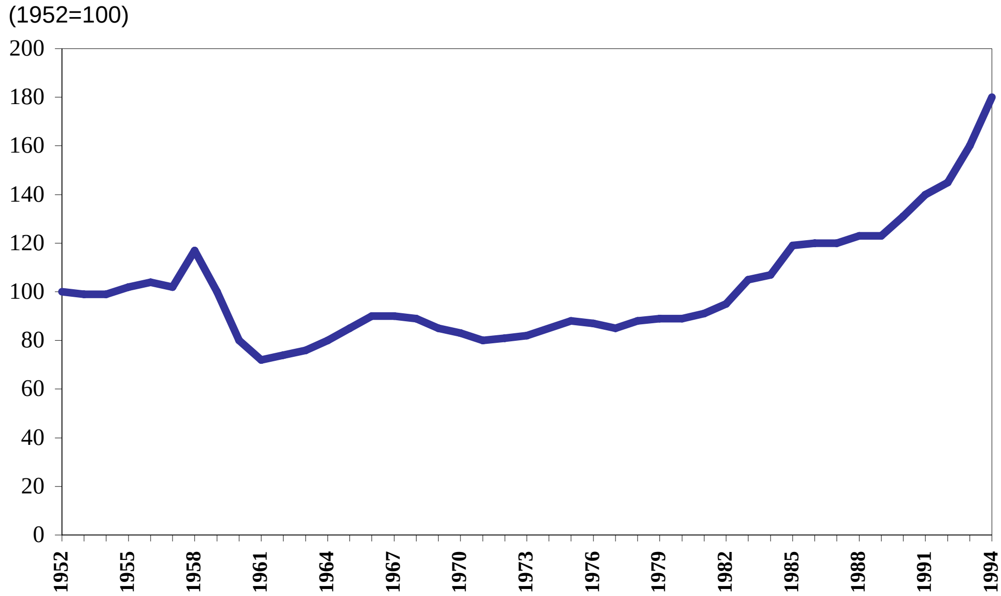
Source: Huang *et al.* (2001b).

Table 25 – Number of cases approved for commercialization in China, 1997-July 1999.

	1997	1998	1999 (July)	Total
Cotton				
Resistant to insects	2	0	14	16
Tomato				
Resistant to diseases	0	1	3	4
Ripe-delayed (long shelf)	1	0	0	1
Sweet pepper				
Resistant to diseases	0	1	3	4
Petunia				
Flower-color-altered	1	0	0	1
Total	4	2	20	26

Source: Huang *et al.* (2001b).

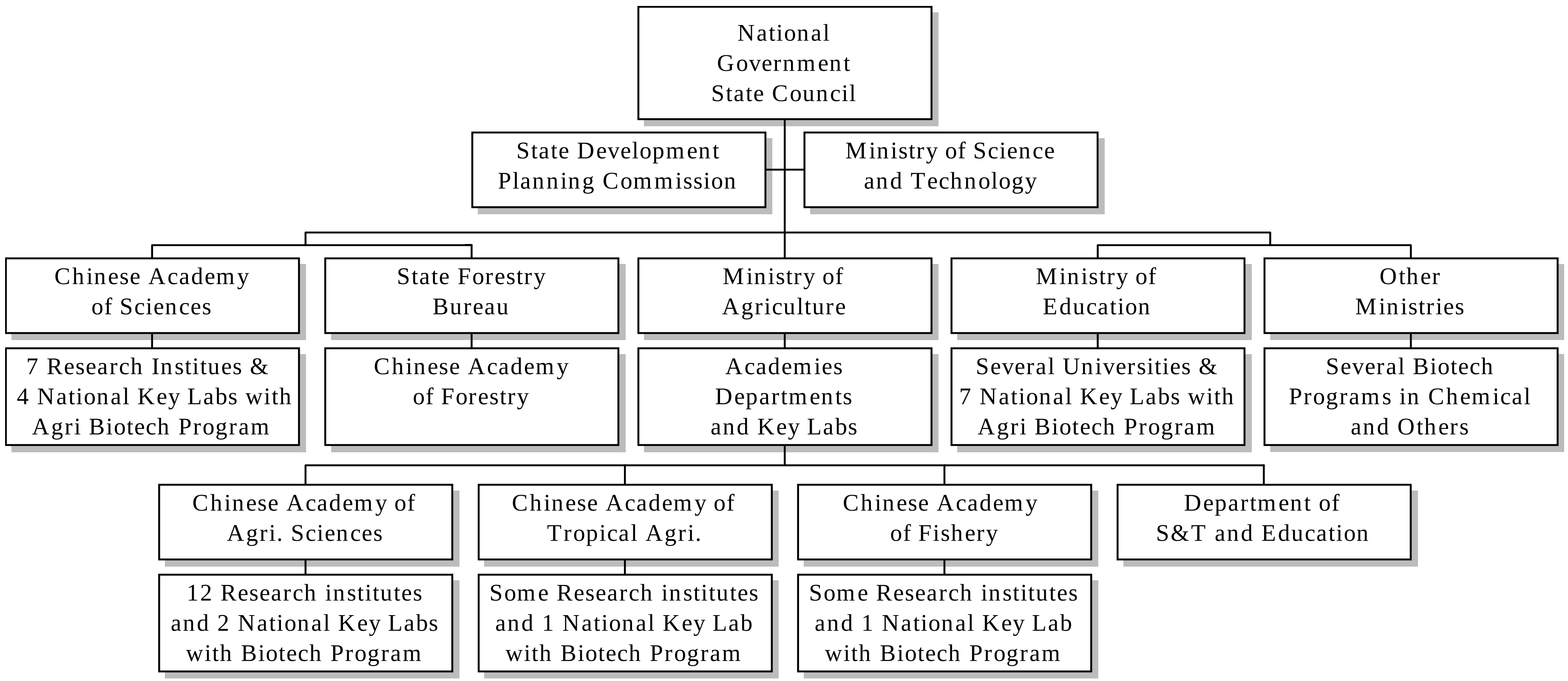
Figure 5 – Total factor productivity in agriculture in China.



Source: Lin (1998)

Figure 6 – Organization chart for agricultural biotechnology research

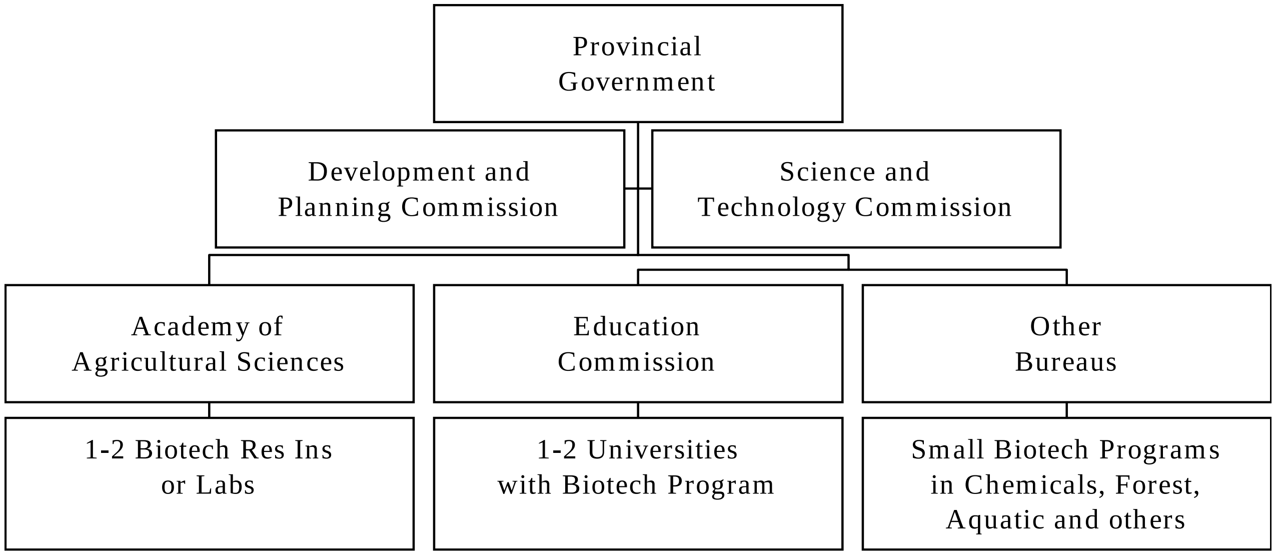
At National Level



Source: Huang *et al.* (2001a)

Figure 6 (continued) – Organization chart for agricultural biotechnology research

At Local Level



Source: Huang *et al.* (2001a)

Figure 7 - Administrative Chart of biotechnology programs. Source: Huang *et al.* (2001a).

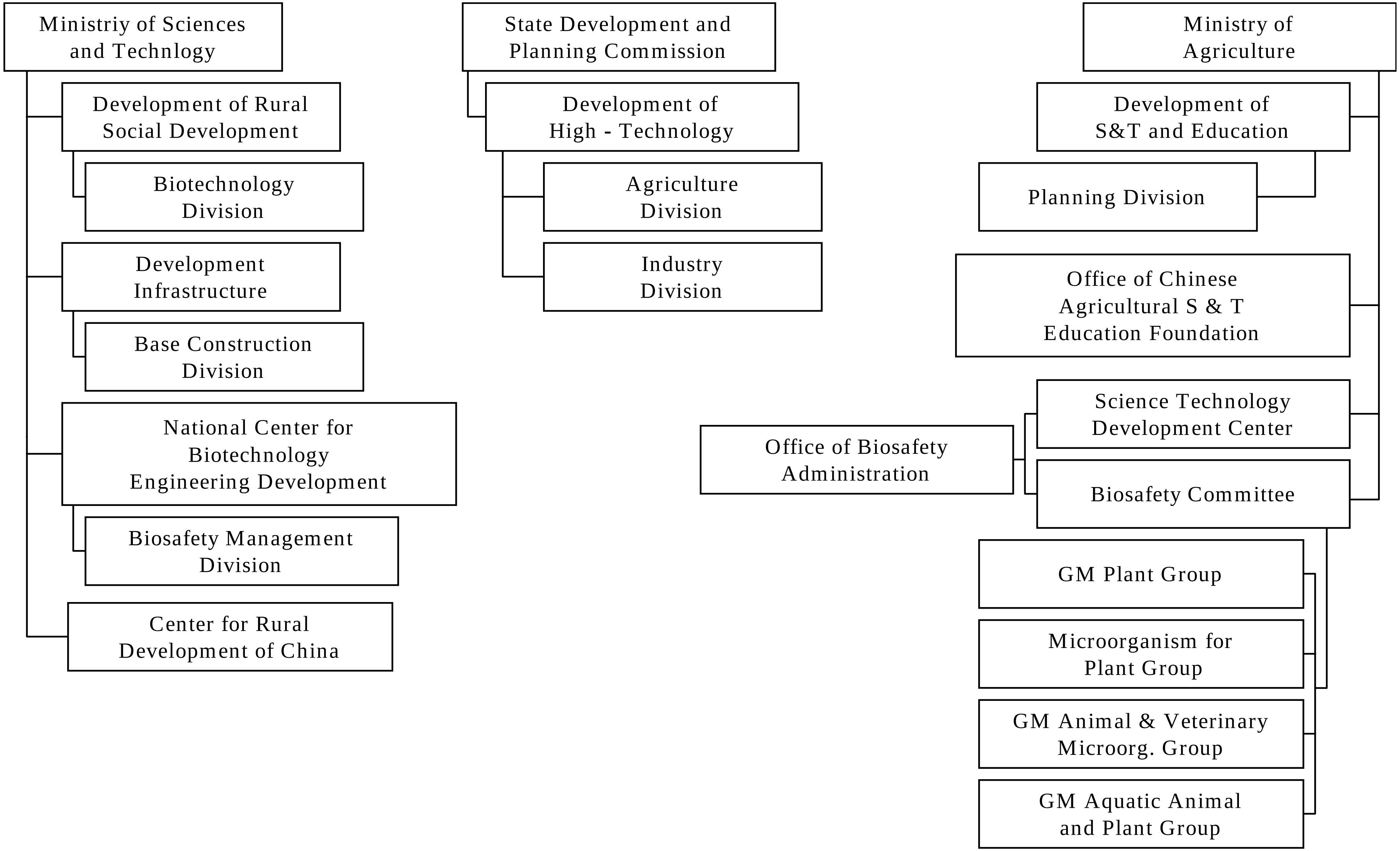
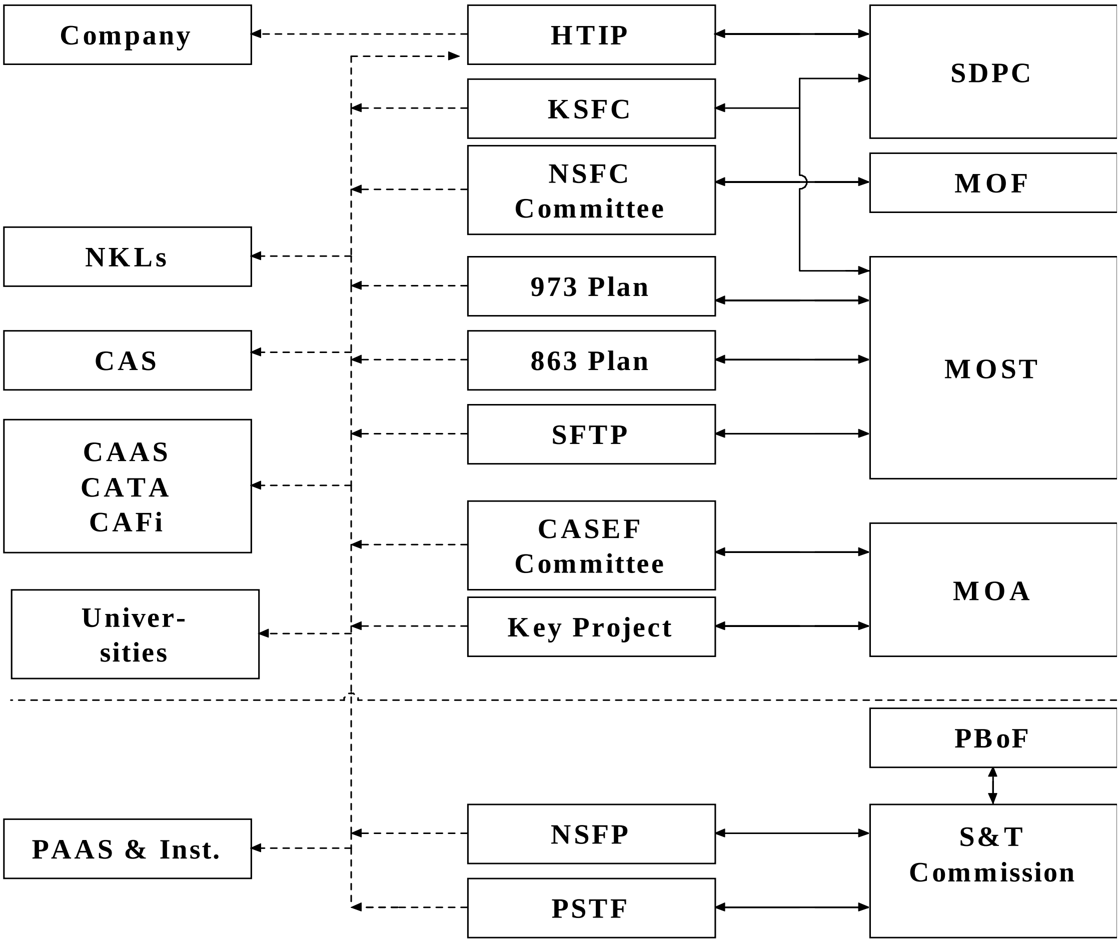


Figure 8 – Flow chart of agricultural biotechnology R&D funds.



Source: Huang *et al.* (2001a)

↔	Requests for R&D funding and return flow of funds
→	Flow of funds

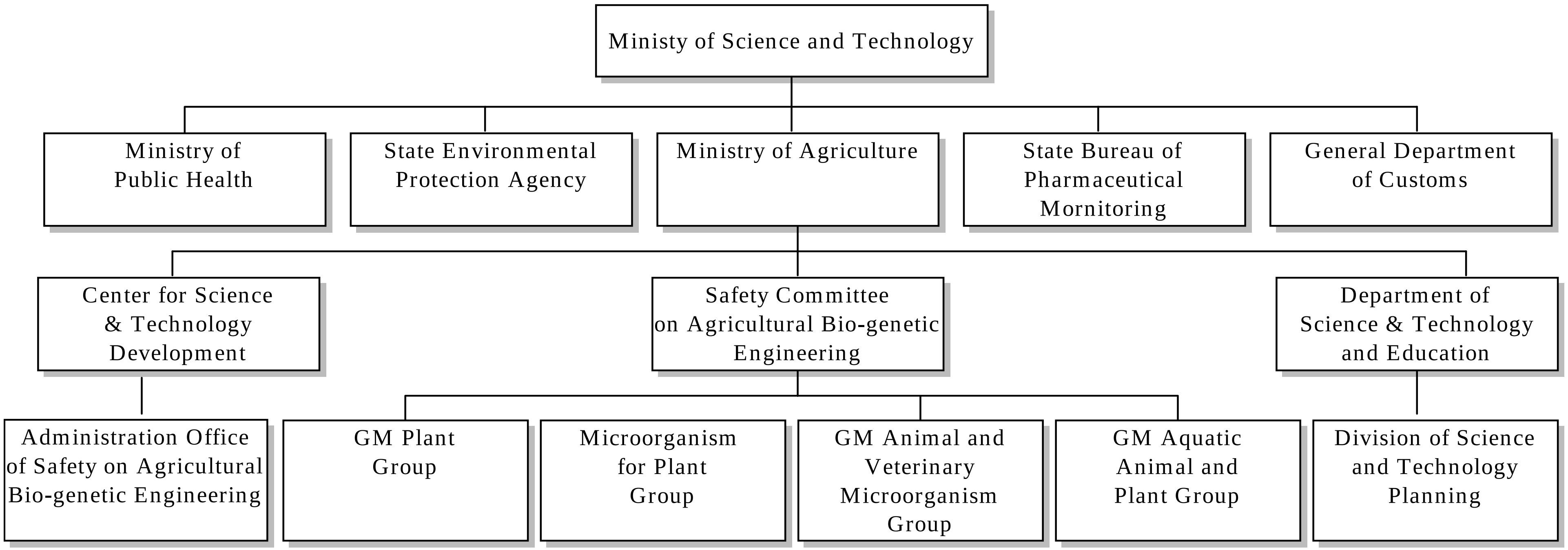
CASEF	China Agricultural Sciences and Education Foundation
HTIP	High-tech Industrialization Program
KSEP	Key Scientific Engineering Program
NSFC	Natural Science Foundation of China
NSFP	Natural Science Foundation of Province
PAAS	Provincial Academy of Agricultural Sciences
PBoF	Provincial Bureau of Financial
SFTP	Special Foundation of Transgenic Plants

Key Project: Stopped in 1998

Figure 9 – Map of Chinese Provinces.

Souce: www.chinapage.com/map/map.html

Figure 10 – Authority System of Biosafety Administration on Agricultural Biological Genetic Engineering



Source: Huang *et al.* (2001a)