

GEO: FOOD FOR THOUGHT

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ABSTRACT

Consider this: South Africa recently became the first country in the world to commercially release genetically engineered maize for human consumption. In contrast to the cautionary approach adopted by other African countries, South Africa has one of the fastest growth rates in genetically engineered crop cultivation worldwide, almost doubling the number of hectares of the country now planted with genetically engineered crops since 2001. Owing to the genetic engineering revolution in our food, it is no wonder that people are becoming more concerned about the food on their plates than ever before. It is essential that people consuming genetically engineered food become aware of who is benefiting and who is not benefiting from the biotechnological industry, by understanding the risks to health, the environment and the economy. If the food that consumers purchase is genetically engineered, consumers should have the right to know and make that choice to either purchase or avoid genetically engineered food. This topic is pertinent in South Africa, as the government has clearly decided that genetically engineered food is part of our future and, to date, the labelling of GE food is not mandatory.

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1. INTRODUCTION

Is there pig in my potato? This is not such a far-fetched question when considering that in the ten years since the United Nations Conference on the Environment and Development at Rio De Janeiro in 1992, genetic engineering of crops has escalated at a rate considered to surpass that of any other new technology ever embraced by the agricultural industry. Almost 53 million hectares of genetically engineered (hereinafter referred to as GE) crops are now grown worldwide, equal to an area twice the size of the United Kingdom.¹

In South Africa the situation is no less dramatic, with over 350,000 hectares of the country now planted with GE crops; a 50% increase from 2001 to 2002. Permits have been granted for field trials and experiments with cotton, maize, soybean, sugarcane, grapes and eucalyptus trees. The South African government has clearly decided that GE crops are part of our agricultural future.² To date South Africa continues to be the only African country that has approved transgenic crops³ for commercial purposes and is the leader in agricultural biotechnology research and development on the continent.⁴ For the purposes of this paper, only agricultural biotechnology will be dealt with, which comprises different techniques for the genetic improvement of crops.

Genetic Engineering of organisms was initiated in the country in the late 1970`s through the establishment of the South African Genetic Experimentation Committee (SAGENE) as the national advisory body on biotechnology research and development. The first field trials for GE crops were undertaken in 1990 and by 1997 the Genetically Modified Organisms Act 15 of 1997 (hereinafter referred to as the GMO Act) was implemented. The GMO Act together with regulations oversees biotechnology safety in this country. The GMO Act was enacted to promote responsible development, production and use of genetically modified

¹ M Butler and D Hallows *South African People and the Environment in Global Markets booklet 4 of 5: Genetic Engineering in Food and Farming* (2002) 1.

² Ibid.

³ Transgenic crop has genes from another source.

⁴ Internet homepage of the Africabio Association "South Africa Status and Future Prospects of Biotechnology". URL - www.africabio.com.

organisms. Both this GMO Act together with National Environmental Management Act 107 of 1998, (hereinafter referred to as NEMA) are responsible for providing the principles for environmental protection, responsibility and liability.⁵

Genetic engineering has been sold as a green technology that will protect nature and biodiversity. Those in favour of GE crops believe that genetic engineering of crops is about increasing the efficiency of food production and distribution, decreasing wastage and preserving the fragile environment. But genetic engineering of crops is not risk free and as governments become subservient to corporations instead of citizens, the environmental and health risks of genetic engineering are not the priority.⁶ If the process were transparent, consumers would have more faith in the GE agenda. A major concern amongst consumers is that some countries, which support the large corporations responsible for producing and marketing GE organisms, are preventing consumers from making their own decisions. They withhold knowledge from their citizens by stifling independent science and denying consumers the right to know what is in their food.⁷

Ultimately the choice should be left to the individual to educate himself or herself on the issue of GE crops and make an informed decision about whether to consume food that has been genetically engineered or not. However with the law as it stands in South Africa, food that has been genetically engineered does not have to be labelled. There are Draft Regulations to introduce labelling of foodstuffs that differ in composition, nutrition, intended use or safety from the conventional counterpart, but these have not yet been promulgated and thus consumers are unable to make an informed choice as to whether or not to purchase GE food. While consumers are ignorantly purchasing GE food, economists are determining if our local and national farming will be affected by this dramatic change in agriculture, and environmentalists are

Africabio is a non-political, non-profit biotechnical association for safe, ethical and responsible research of biotechnology and plays an active role in facilitating the development of biotechnology in South Africa.

⁵ Ibid.

⁶ M Butler and D Hallows op cit note 1 at 2.

⁷ V Shiva *Stolen Harvest: The Hijacking of the Global Food Supply* (1999) 95.

considering the ecological damage that GE crops may cause. Unfortunately these crops are already growing on millions of acres all around the world.⁸

The aims of this paper are to define genetic engineering and to explain the relevance to food crops. To discuss the myth and fact related to genetic engineering of food with particular emphasis of the affect on agriculture, food safety and the socio economic effects. In the field of food production the main profits are generated from the sale of patented transgenic crop seed and thus the issue of Intellectual Property Rights is explained. The situation in South Africa is discussed and a comparison is made with the European Community and United States on how the genetic engineering of food crops is regulated

⁸ M Teitel and K A Wilson *Genetically Engineered Food: Changing the Nature of Nature* (1999) 2.

2. WHAT IS GENETIC ENGINEERING

Genetic Engineering can be defined as the technique of isolating a gene and inserting it into the DNA of another organism. Biotechnology should not be limited to the genetic engineering of organisms only, as biotechnology refers to any applied form of biological science including conventional plant breeding. Genetic engineering has allowed scientists to splice fish genes into tomatoes, virus genes in squash and human genes into tobacco, normally the boundaries between species are set by nature, and until recently those biological barriers had never been crossed.

2.1. RELEVANCE OF DNA IN GE

Genes are a functional unit of a molecule called DNA (deoxyribose nucleic acid). Genetic engineering usually involves the insertion of a gene or genes from one species into another species. Genetic information is contained in DNA and organisms total DNA is called a *genome*.⁹

DNA is composed of a double helix, consisting of two DNA strands that are held together by weak bonds linking the bases (which if, we could see it, would look like a twisted ladder). Four bases occur: *adenine* (A), *thymine* (T), *cytosine* (C) and *guanine* (G). Particular base pairs form between two nucleic acid strands with A always pairing with T and C always pairing with G. Each sub unit of DNA is called a *nucleotide* and has one base.¹⁰

The sequences of bases along a DNA strand form the genetic code. Genes occupy a particular position on DNA molecule, with sequence of bases and have a particular function. Genes are transferred between species to produce transgenic organisms by engineering techniques.¹¹

⁹ S Nottingham *Eat Your Genes: How Genetically Modified Food is Entering our Diet* (1998) 11.

¹⁰ *Ibid.*

¹¹ *Ibid.*

2.2. PROTEIN SYNTHESIS

Genetic engineering alters an organism's characteristics. This is possible because the genes that are manipulated direct the synthesis of *proteins*. A gene is said to be *expressed* when the protein it encodes is synthesized. Protein consists of one or more long chains of amino acids. The most important proteins coded by DNA are called *enzymes*, which regulate the biochemical process within an organism. Therefore, by modifying the action of enzymes, genetic engineers can potentially modify any biochemical reaction in an organism to produce a desired change in a character.¹²

The two key processes are the transfer of the genetic code from DNA to an intermediate messenger molecule (*transcription*) and the construction of the proteins from the code on this messenger molecule (*translation*).

Transcription involves another nucleic acid called RNA, and it differs from DNA in having different sugar (ribose instead of deoxyribose) and the base *uracil* (U) instead of *thymine* (T). During the process of transcription messenger RNA is formed known as mRNA. mRNA¹³ is able to carry the genetic code for one gene transcribed from DNA, and assist in the formation of ribosomes where protein synthesis occurs. The process of translating the genetic code from mRNA into protein molecules occurs in the ribosomes. The coding sequence on the mRNA determines the order in which the 20 possible amino acids, the building blocks of proteins, are synthesized.¹⁴

2.3. HOW GENETIC ENGINEERING WORKS IN RELATION TO OUR FOOD CROPS

Genetic engineering is often referred to as genetic recombination because it literally recombines DNA inside a plant. Several different terms are used to refer to the results of genetic engineering, such as recombined, engineered, modified or manipulated. A crop that has been genetically engineered is called a

¹² S Nottingham op cit note 9 at 12.

¹³ mRNA is the messenger RNA that is a smaller more mobile molecule formed in the process of transcription, and carries the genetic code for one gene.

transgenic crop, meaning it contains genes from another source. In genetic engineering of food crops a gene or a piece of DNA from one source (e.g. a fish) is isolated and removed, it is then pasted into the DNA of another source (e.g. a tomato). The DNA is removed from one living organism by enzymes, and then moved into another living organism to be rejoined with its host DNA in a new combination.¹⁵

In simple terms genetic engineering or gene splicing of a food crop takes place as follows:

1. A plant that has a desired characteristic is identified.
2. The gene that produces the desired characteristic is identified, and cut out of the plants' DNA.
3. To get the gene into the cells of the plant that is going to be genetically engineered the gene needs to be attached to a *vector*, which functions as a carrier. A piece of bacterial DNA called *plasmid* is joined to the gene to act as a carrier.
4. A type of switch called a *promoter* is also included with the combined gene and plasmid. This assists the gene to work correctly once it is inserted into the plant.
5. Only a small number of cells in the plant being genetically engineered will actually take up the new gene, so the new gene includes a marker gene to identify it.
6. The new gene is then inserted into the plant and the plant tissue that has taken up the new gene is then grown into a full size GE crop.¹⁶

2.3.1. METHODS OF GENE TRANSFER TO CROPS

In order to understand the effect of GE on humans, agriculture and the environment, a better understanding of the above process is necessary and thus the most important parts of the process will be discussed in more detail below.

¹⁴ S Nottingham op cit note 9 at 13.

¹⁵ M Teitel and K A Wilson op cit note 8 at 8.

2.3.1.1. VIRAL VECTORS

Vectors function like the carriers. In genetic engineering viruses are commonly used as vectors because viruses typically attack the hosts cells and slip into the cells DNA. Genetic engineers attach a piece of DNA to a viral vector and then insert the vector into a new organism so that it can infect the cells of the target organism, thus delivering the new DNA fragment in to the DNA of the target.¹⁷ The nucleic acid from viruses is directly infectious to plants and transfer can be achieved simply by rubbing the solution onto a leaf. Following the inoculation viruses spread to every cell in the plant.¹⁸

There are fairly low rates of success with transformation, which are due to relatively haphazard insertion methods currently available. Many transformations are unstable and the interaction of the transferred gene with the plant gene is likely to vary depending on where in the genome it finds itself. The incorporation of marker genes is required for the transformation to take place. In order to keep track of the new DNA, scientists often mark the vector with antibiotic resistant genes so that normal cells can be distinguished from genetically engineered cells. The cells are doused with antibiotics, and those cells that have incorporated the foreign DNA and the resistant genes from the vector will grow, while those that have not been modified die. Moving a gene around may or may not produce the same result each time because the gene and protein environment can be extremely complex and infinitely variable.¹⁹

2.3.1.2. BACTERIAL VECTORS

The first transgenic plants produced were tobacco, petunia and cotton, which were modified using *Agrobacterium rhizogenes*, a bacterium that causes gall disease and hairy root disease. These bacteria naturally infect over one hundred plant species, causing aberrant plant growth by transferring some of their genes into the nuclear genome of the plant. The gene transfer method using *Agrobacterium* as a vector is

¹⁶ Food Standards Agency “GM Food Opening the Debate” Published by the Foods Standard Agency in February 2003.

¹⁷ M Teitel and K A Wilson op cit note 8 at 8.

¹⁸ S Nottingham op cit note 9 at 17.

¹⁹ Ibid.

very labour intensive and has a major limitation in that it does not naturally infect monocotyledonous plant species such as cereal crops (rice, wheat and maize), but is successful with dicotyledonous plants such as potato and tomato.²⁰

2.3.1.3. GENE GUNS

Transgenic animals and fish are produced by a direct insertion method: microinjection. A fertilised egg is taken from an animal and is injected with the foreign DNA using a small syringe. The injected DNA integrates itself randomly into the chromosomes. Fish offer a number of advantages for genetic manipulation. They have an external fertilisation and development, which means that the eggs need not be removed from the body before the foreign gene is inserted.

With plants there are two methods commonly used the “Bolistic” method and the “Accell” method.

The Bolistic method occurs when magnesium, tungsten or gold particles are coated with DNA and literally blasted into the plant cells using a gunpowder detonation in a particle gun. The particles carrying the DNA enter the plant at a high velocity and penetrate the cell walls.

The Accell method uses particle acceleration by electrical discharge to propel DNA coated gold particles into plant material.²¹

2.3.1.4. GENE SILENCING

Gene silencing manipulation involves the suppressing of genes using the antisense constructs to block protein synthesis. Gene Silencing works by either preventing mRNA being formed or disabling it before it can arrive at the ribosome, the site of protein synthesis.²²

²⁰ Ibid.

²¹ M Teitel and K A Wilson op cit note 8 at 11.

²² S Nottingham op cit note 9 at 21.

3. TYPES OF GENE CROPS

As discussed in the previous chapter, genetic engineering modifies organisms by recombinant DNA techniques, which allow a more precise, and time saving, alteration to plants traits, facilitating the development of characteristics that are not feasible through the traditional plant breeding methods. Genetic engineering allows scientists to target a single plant trait, thus decreasing the number of unintended characteristics that often accompany traditional breeding techniques. The three most common types of GE crops: insect resistant, virus resistant and herbicide resistant, will be discussed in detail in this chapter.

3.1. INSECT RESISTANT CROPS

Bacillus thuringiensis (Bt) is a soil bacterium that accumulates high levels of insecticidal proteins during sporulation.²³ Bacterial spores are formed in order to survive adverse environmental conditions. They can remain dormant for considerable periods of time in the soil, before the bacteria's life cycle is resumed. When insect larvae ingest the bacterial spores, the spores dissolve in the highly alkaline gut to release the toxins. The toxins bind to the gut of the insect paralyzing the gut and preventing nutrient intake as a result of which the insect will die.²⁴

The first DNA sequence of a gene coding Bt toxin was obtained in 1985. The Belgian based company "Plant Genetic Systems" first engineered genes expressing Bt toxins into the crop plant tobacco using *Agrobacterium*. The result was that crop plants were being genetically engineered with the Bt toxin gene to give them a built in insecticide. These GE insect resistant crops were initially experimented on the tobacco plant and the GE Bt toxin was produced in the plants when they were growing.²⁵ As a result insects are continually being exposed to the toxin and are therefore under constant pressure to develop resistance. Pests can develop resistance because constant exposure to the Bt toxin allows them to develop a tolerance

²³ When bacterial cells transform themselves into spores.

²⁴ In the final chapter of the highly acclaimed " Silent Spring" published in 1962, Rachel Carson saw Bt sprays as the way forward from environmentally damaging insecticides such as DDT.

²⁵ Internet homepage of the Greenpeace Organisation "Insect Resistant Crops". URL - www.greenpeace.org/international.

to it. The ones that survive to mate and pass on their genes are those most resistant to the poison. Unless the pesticide kills every insect, it functions over time as a mechanism to select for insects that are resistant to that insecticide. In the short term, the GE crops with the Bt toxin are more effective in combating pests than conventional insecticides because the Bt toxin cannot be washed off by rain or broken down by other environmental factors.²⁶

A common insect resistant crop is the Yield Gard corn. It provides a naturally occurring *Bacillus thuringiensis* protein that protects Yield Gard corn from several damaging insect pests including the European core borer.²⁷

3.2. VIRUS RESISTENT CROPS

Virus genes are being genetically engineered into plants to make them resistant to viral infections. Insects, which can be controlled with insecticides, spread some of those viruses, but those viruses that aren't have been difficult to control until scientists developed GE virus-resistant crops. GE virus resistant potato, papaya and squash have already been cleared for commercial production in the USA. Genetic engineers have managed to protect a crop from a virus by copying a virus gene that encodes a protein in the virus outer coat, into the plant DNA. The plant then makes the coat protein which is harmless but which stimulates the plants' natural defenses. The induced resistance principle employed in the development of most virus resistant transgenic crops is similar to that used to produce vaccines in animals. Gene coding for proteins found in viral coats are integrated into the plant genome. These coat proteins prime the plant to fight the real virus when it is encountered. GE virus resistant crops contain viral genes in all their cells when they are growing. Virus resistant traits have been introduced into many more crops such as beets, lettuce, melon, pepper, sunflower and watermelon.²⁸

²⁶ W D McBride and C J Fernandez "Adoption of Bioengineered Crops" ERS Agricultural Economic Report NO AER810.67, (May 2002).

²⁷ Internet homepage of the Monsanto Company "Yield Gard corn". URL - www.Monsanto.com/Monsanto/layout/our_pledge/pss_YieldGardcorn.asp.

A common insect and virus resistant crop is the New Leaf Y potatoes, which produce *Bacillus thuringiensis*, which protects New Leaf Y potatoes from damage by the Colorado potato beetle and contains a protein gene that provides protection from the common potato virus (PVY).²⁹

3.3. HERBICIDE RESISTANT CROPS

The most widely adopted GE crops in the USA are those with herbicide resistant traits. These crops are developed to survive the application of specific herbicides that previously would have destroyed the crop along with the targeted weeds, and provide farmers with a broader variety of herbicide options for effective weed control. Herbicide resistant soybeans first became available to farmers in the USA in 1996.³⁰

Monsanto's³¹ Roundup Ready Soybean is an example of such a herbicide resistant crop. The Roundup herbicide is Monsanto's most famous herbicide, which according to the corporation is a glyphosate-based herbicide that is able to destroy all weeds economically. However, according to Vandana Shiva, director of the Research Foundation for Science, Technology, and Natural Resource Policy and a renowned physicist, Roundup is a non-selective herbicide that does not distinguish between weeds and desirable vegetation, and thus will kill all plants, which is in no way economical. Roundup herbicide controls a range of weeds by inhibiting EPSP synthase, an enzyme essential to a plants growth and by establishing a block in the plants metabolic pathways. The gene inserted in Roundup crops increases the amount of EPSP synthase protein in the plants, providing a detour around the Roundup herbicide block. The weeds and all other plants that do not have this gene will not survive.³²

²⁸ Internet homepage for the Green Peace Organisation "Virus Resistant Crops" URL - www.greenpeace.org/international.

²⁹ Internet homepage for the Monsanto Company "New Leaf Potato". URL - www.Monsanto.com/Monsanto/layout/our_pledge/pss_/NewLeafpotato.asp.

³⁰ Internet homepage for the Economic Research Service of the USA Department of Agriculture "Adoption of Bioengineered Crops". URL - www.ers.usda.gov/publications/der810.

³¹ Monsanto is one of the largest corporations in the world, based in the USA, involved in the manufacturing and distributing of genetically engineered food and crops.

³² V Shiva op cit note 7 at 98.

4. MYTH AND FACT RELATED TO GENTETICALLY ENGINEERED FOOD

“ Let them come and see men and women and children who know how to live, whose joy of life has not been killed by those who claimed to teach other nations how to live ”³³

It has been argued by genetic engineers that the only way to prevent starvation and malnutrition of the world’s population is through genetically engineered crops. Harvests will be more plentiful, fewer chemicals will be used, and plants will begin to provide medicine to many diseases. However what has become apparent with the introduction of GE crops across the globe is that the promises of bumper harvests have failed to materialise. Pests have developed resistance to the poison produced by the new GE crops and cross-pollination has produced weeds resistant to strong herbicides. The result is that the balance of the global food economy has changed with disastrous results for the worlds poorest.³⁴ This chapter will expose some of the myths associated with GE crops and shed some light on the facts with particular focus on the effects of GE in agriculture, on human health and the extent of the socio-economic effects.

4.1. GENETIC ENGINEERING IN AGRICULTURE

It is important to be aware of the close connection humans have to agriculture in order to understand the impact of the genetic revolution in agriculture. Before agriculture human beings collected the wild growing food that was needed to survive. Then they began to plant the seeds of those plants that they favored, and eventually began to realise that by saving the seeds of the most successful crops they could ensure the success of the next generation of crops. Thus human kind, by selecting what they liked to eat, gradually shaped food to their liking and created a very close relationship between plants and humans. Human food plants are responsible for the creation of human communities, and food tastes are a powerful aspect of community coherence and identity. One of the great threats of GE food is the disruption and destruction of these essential connections between culture and food and people and plants.³⁵

³³ A Chinua *“No Longer at Ease”* (1960) 45.

³⁴ J Humphrys *The Great Food Gamble* (2001) 196.

³⁵ M Teitel and K A Wilson op cit note 8 at 86.

4.1.1. AGRICHEMICAL USE: ON THE INCREASE?

The argument by those in favour of GE crops is that crop plants can be refined by biotechnology to fight off many pests of their own. This can reduce insecticide use up to 50% leading to less insecticide in run off water. This means less damage to our waterways and less exposure of farm workers to insecticides when applied to fields and when crops are harvested.³⁶

The development of herbicide resistant and pest resistant crops accounts for more than 80% of the biotechnology research in agriculture. Evidence is already available that rather than controlling weeds, pests and diseases; genetic engineering increases the use of chemicals and can create super weeds, super pests and super viruses. Herbicide resistance accounts for almost three-quarters of the applications of genetic engineering. Through genetically engineering herbicide resistance into crops, corporations are increasing sales of both chemicals and seeds. As discussed Monsanto's Roundup Ready soybeans are an example of such a herbicide resistant crop used in conjunction with Roundup herbicide which, is a non-selective herbicide that does not distinguish between weeds and desirable vegetation. Since most crops have a diversity of insect pests, insecticides may still have to be applied to GE crops engineered to withstand one pest.³⁷

4.1.2. FOOD SECURITY: INCREASED YIELD AND RETURNS?

Corporations that promote GE crops state that agricultural biotechnology provides benefits to a world that needs increasing amounts of food to survive with less environmental damage. New farmland is limited, and the worlds' population is growing; agricultural biotechnology can help develop crops with higher yields that can grow in less optimal soils and climates. It can assist developing countries by providing crops that are hardier and that farmers can grow on their own farmlands with yields that can support their families.³⁸

³⁶ W Gruissem "Biotechnology Helping to Save the Environment" Department of Plant and Microbial Biology University of California (1999).

Biotech Knowledge Center. URL - www.biotechknowledge.monsanto.com

³⁷ V Shiva op cit note 7 at 98.

³⁸ W Gruissem op cit note 36.

According to California Center for Ethics and Toxics (CETOS) staff Britt Bailey and toxicologist Marc Lappe's report in their book "Against the Grain", herbicide resistant Soybeans yielded 36 to 38 bushels per acre, while hand tilled soybeans yielded 38.2 bushels per acre. According to the authors this raises the possibility that a gene inserted into these engineered plants may selectively disadvantage their growth when herbicides are not applied. Monsanto is also famous for the genetically engineered Bollgard cotton³⁹. When it failed to produce the high yields it promised, the Mississippi Seed Arbitration Council ruled that in 1997 Monsanto's Roundup Ready cotton failed to produce as advertised and recommended payments of \$2 million to three cotton farmers who suffered crop loss.⁴⁰

In the UN Research for Social Development (UNSD) 15 nation study of the impact of the high yielding seeds, Dr Palmer concluded that the term "high yielding varieties" is a misnomer because it implies that the new seeds are high yielding in themselves. The distinguishing feature of the seeds however is that they are highly responsive to certain key inputs such as fertilizer and irrigation. Palmer suggested the term "high yielding" should be replaced with the term "high responsive varieties". In absence of additional inputs of fertilizers and irrigation, the new seeds perform worse than indigenous varieties. With the additional inputs, the gain in output is insignificant when compared to the increase in inputs. A further concern is that in a country like India crops have been traditionally bred and cultivated to produce not just food for man but also fodder for animals and organic fertilizer for the soil.⁴¹

The multinational companies involved in producing GE crops claim that genetic engineering can help alleviate hunger and starvation in developing countries. Critics argue that such claims ignore the main cause of hunger and starvation on the planet, pointing out that the increase in the amount of food on the planet is not necessarily the solution to feeding the hungry among the world's population. World food production has been growing by 1% per annum over recent decades, but the number of people with

³⁹ Bollgard cotton developed by Monsanto in 1992 produces insect control protein that is derived from naturally occurring soil bacterium *Bacillus thuringiensis*, which provides protection against key insect pests such as the tobacco budworm and pink bollworm.

⁴⁰ V Shiva op cit note 7 at 100.

⁴¹ V Shiva *Violence of the Green Revolution* (1991) 72.

insufficient food is rising⁴². Hunger is the result not of insufficient food being grown but of people being excluded from access to that food. According to the Food and Agricultural Organisation (FAO) of the United Nations, it is estimated that around 40% of the world's population suffer from malnutrition. Malnutrition is essentially caused by poverty. A complex mix of social and political factors creates poverty. Population growth is of great importance but it is intrinsically interlinked with issues of poverty and food security.⁴³

Africa's ability to feed itself over the past few decades has been steadily diminishing as export crops have displaced food crops grown for local consumption. The production of export crops is not related to the domestic food needs of the developing countries, with the result that crisis-hit countries can have thriving export agriculture sectors. For example when famine occurred in the Sahel countries of Burkina Faso, Mali, Niger, Senegal and Chad in the mid 1980's these countries were producing record harvests of cotton to export to the industrialized nations.⁴⁴

Many developing countries possess the genetic resources to guarantee a sustainable food supply. In India for example, farmers grow over 50,000 varieties of rice. In a single village in the North East of India farmers grow over 70 varieties of rice. This strategy shows that while some varieties of the rice may be susceptible to the problems of pests or disease in one year, other varieties will survive. Despite the suggestions made by multinational companies, a balanced diet based on one food crop is no substitute for a balanced diet based on a diversity of crops. The introduction of such a GE crop monoculture with its high genetic uniformity and high chemical input requirements is more likely to undermine food security and biodiversity.⁴⁵

⁴² Report of FAU/UNFPA Expert group meeting on food production and population growth, Rome, 3-5th July 1996. URL - www.undp.org/popin/fao/expmtg.htm.

⁴³ S Nottingham op cit note 9 at 157.

⁴⁴ S Nottingham op cit note 9 at 157.

⁴⁵ S Nottingham op cit note 9 at 158.

4.1.3. GENE FLOW

Gene flow occurs when GE genes pass to neighboring crops. For some time the biotech industry has insisted that pollen cannot travel very far and so GE characteristics would be confined to the fields of farmers who choose to use the technology. The assertion goes contrary to the experience of worried organic farmers, who by 1999 were starting to fail tests for GE free organism labels in Europe⁴⁶. The modified species may have acquired new characteristics, which make it new to the environment. The newcomers to the environment may cause changes to the plant, animal or microorganism communities through the usual ecological interaction of competition, predation, pathogenicity or parasitism.⁴⁷

Many skeptics of this new agricultural revolution share concerns for genetic pollution. In the United Kingdom, Charles Prince of Wales has stated that the reason for the concern of the use of GE crops is that “We simply do not know the long term consequences for human health and the wider environment [of GE crops]. If something does go badly wrong we will be faced with the problem of clearing up a kind of pollution, which is self-perpetuating. I am not convinced that anyone has the first idea of how this could be done”.⁴⁸ This approach is born out of a life time of listening to experts tell us there is no risk, only to discover years later that many of them were wrong. They may have been acting in good faith at the time, but they simply did not know enough. In Europe, consumer resistance to the introduction of GE crops has initiated a looming trade war between Europe and the USA with major implications for food security, agriculture and trade.⁴⁹

A gene introduced into a given variety may find its way in to other varieties of the species and into other species either through sexual reproduction or through horizontal transfer⁵⁰ (as opposed to transferring genes vertically from parent to offspring). Horizontal transfer may happen naturally, but that combining of the

⁴⁶ M Teitel and K Wilson op cit note 8 at 94.

⁴⁷ T Berhan and V Shiva “ Biotechnology and the Issues Interconnected with and through it” A paper prepared for the World Council of Churches Eighth Assembly, Harare, Zimbabwe 7 December 1998.

⁴⁸ M Teitel and K A Wilson op cit note 8 at 115.

⁴⁹ M Butler and D Hallowes op cit note 1 at 2.

⁵⁰ Horizontal gene transfer is defined as the transfer of DNA from one species to another.

gene with a bacterial, viral or jumping gene vector enhances the possibility of horizontal transfer. A gene expected to be useful in a given variety could have adverse environmental effects in another.⁵¹

For example a gene that produces a chemical toxic to insects has been taken from the bacterium *Bacillus thuringensis* and introduced into cotton to make crops resistant to insect attacks. If this gene becomes transferred to another species, many unintended insects could be killed.

Plants, animals and microorganisms are now being genetically engineered to provide large quantities of specific chemicals. Even when the use of these chemicals is no longer needed it may not be possible to withdraw the transgenic organisms producing those chemicals and, as a result, a new form of chemical pollution may arise.⁵²

GE crops increase chemical use and add new risks of genetic pollution. As already mentioned, herbicide resistant crops are designed for intensive use of herbicides in agriculture, but they also create the risk of weeds being transformed into super weeds. Research in Denmark has shown that oil seed rape genetically engineered to be herbicide tolerant could transmit its introduced gene to a weedy natural relative through hybridization. The weedy natural relative rapes are quite common in Denmark and converting these weeds into super weeds that carry the gene for herbicide resistance would promote increased use in herbicide, and high crop losses.⁵³

4.2. ARE GENETICALLY ENGINEERED FOODS SAFE?

One of the most profound flaws in the justification of GE organisms is the statement that since the availability of GE organisms in the market place, there has not been a single documented incident of public harm. A vast number of people are eating GE food, mostly maize and Soya beans, and because no harmful effects of any kind have been documented, the conclusion drawn is that GE food is safe. This is incorrect

⁵¹ T Berhan and V Shiva op cit note 47.

⁵² Ibid.

⁵³ V Shiva op cit note 7 at 105.

and the reason is in the logic that makes it impossible to prove that GE food is not safe. If a large part of the population is eating GE food and there is an increase in the number of people suffering from allergies of one kind or another it is very difficult to prove that it is attributable to a particular GE food. It is virtually impossible to prove a link to a particular food because of the vast number of environmental influences, and the manufacturers may prepare the food in many different ways. More importantly, every introduced gene is inserted into a different gene location and every gene differs in function and interaction within the genome, and every species can be expected to react differently in the gene introduction process. It is clear that the safety of one GE organism is in no way predictive of the safety of another GE organism.⁵⁴

A persons' diet is crucial to their health, which is why good food is vitally important. According to John Humphrey's in his book "The Great Food Gamble"⁵⁵ good food must be safe i.e. as free as possible of bacteria that might harm a person and chemical residues that might build up in the body. Food must be nutritious, a balance diet should contain all those essential, primary nutrients, vitamins and minerals and trace elements to build a healthy body. Food should also contain the secondary nutrients such as flavenoids and metabolites present only in a healthy plant with a strong defense system of its own. Finally healthy food can only come from healthy plants and animals. Modern agriculture is failing us in most of those respects and many people have become suspicious of their food no matter how brilliantly it is marketed or packaged, and rightfully so.⁵⁶ Human health issues associated with GE food with particular focus on allergens, antibiotic resistance and virus resistance in the human body from consuming GE food, "medical foods" and the effect on the nutrient level in GE foods, will be discussed.

4.2.1. ALLERGENS

Genetic engineered crops need to be tested for safety, and according to the corporations that manufacture these crops, are tested more strictly than crops developed by traditional breeding. An example of a possible safety issue was the case when genetic engineers transferred a gene from a Brazil nut to a Soya bean to get

⁵⁴ Professor Patrick Brown "The Promise of Plant Biotechnology – The Threat of GE Organisms" College of Agricultural and Environmental Science University of California May 2002.

⁵⁵ One of Britain's most respected BBC broadcasters and farmers.

a better quality protein. Some people are allergic to nuts and this fact was revealed during the testing, thus the project was abandoned. The GE industry cites this example to prove how thorough the testing process is. Proper tests were carried out and as a result the food was found to be seriously flawed.⁵⁷

The above example tells of half a story, because there was a team of highly qualified people supported by a grant to meet their costs, who knew precisely what they were looking for. The Brazil nut allergen was well known and could be specifically tested for, in other cases the allergens may not be known.⁵⁸ Each gene contributes a single protein to the gene pool that compromises a living organism. There is a clear association between proteins and allergens. When a person has an allergic reaction, what the body is reacting to is a protein, most often foreign or introduced. This raises the serious issue that if allergies are associated with proteins, and if GE food is by definition characterised by introduced genes that produce proteins, then caution about allergies is justified.⁵⁹

The cells in GE crops can begin to manufacture proteins in much higher levels and in incorrect quantities or at the wrong times. They may contain entirely new foreign proteins, bacteria or viral constructs that humans have never eaten before, some of which may be toxic. Proteins are the cause of allergic reactions and virtually every gene transfer will result in some protein production. Proteins will be entering food crops, not just from known sources of food allergens like shellfish and dairy, but from all kinds of plants, bacteria and viruses, whose potential allergenicity is unknown.⁶⁰

4.2.2. ANTIBIOTIC RESISTANCE

A major concern is the cause of antibiotic resistance. According to the United States Federal Drug Administration (FDA) GE organisms do not lead to antibiotic resistance because there is little transfer of genes from plants to bacteria; bacteria pick up resistance genes from other bacteria easily and often. The

⁵⁶ J Humphrys op cit note 34 at 46.

⁵⁷ C M Rader "Genetic Engineering in Agriculture: A Report on Genetically Engineered Crops" July 2002. URL - www.members.tripod.com/c_rader0/gemod.htm.

⁵⁸ J Humphrys op cit note 34 at 221.

⁵⁹ M Teitel and K A Wilson op cit note 8 at 46.

potential risk of transfer from plants to bacteria is substantially less than the risk of normal transfer between bacteria.⁶¹ The rising trend amongst genetic engineers is to phase out the use of antibiotic resistant genes and use a marker gene from a bioluminescent jellyfish, which promotes synthesis of a fluorescent protein. When the protein is exposed to ultraviolet light it glows a fluorescent green, indicating that the desired gene has been transferred to the target organism.⁶² The use of the bioluminescent jellyfish marker gene has not yet become standard practice. If the antibiotic resistant gene were completely safe, it would not make sense to phase out its use, unless of course there was some truth in the proposed harmful effects.

Most of the genetically engineered crops use genes that are resistant to anti biotics to help identify whether the genes that have been introduced from other organisms have been introduced successfully into the engineered crop.⁶³ These marker genes can exacerbate the spread of antibiotic resistance among humans. Based on this concern, Britain rejected Ciba Geigys' transgenic maize.⁶⁴ Frequent exposure to antibiotics can cause bacteria to develop antibiotic resistance; they kill the beneficial bacteria in the body that keeps fungus under control. When fungus grows out of control, the immune system becomes damaged and immune deficiency diseases such as allergies and arthritis develop.⁶⁵

4.2.3. VIRUS RESISTANCE

Unique ecological risks have been associated with virus resistant transgenic crop plants. Viruses have been shown to pick up genes from transgenic crops. In laboratory experiments, viruses from which genes for particular characters had been removed, reacquired those genes from GE plants that had virus genes inserted into the genomes. The transfer of viral genetic material means that other plants or viruses could pick up the transgenes. Virus resistant crops will contain viral genes in their cells for the lifetime of the

⁶⁰ R Cummins and B Lilliston *Genetically Engineered Food* (2000) 37.

⁶¹ L Thompson "Are Bioengineered Foods Safe" *FDA Consumer Magazine* (1999) Biotech Knowledge Center. URL - www.biotechknowledge.monsanto.com.

⁶² C M Rader op cit note 57.

⁶³ See Chapter 2.

⁶⁴ GE maize developed by Ciba Geigy now part of the Swiss based multinational Novartis Company incorporated a gene expressing Bt toxin against the European corn borer.

⁶⁵ Dr. Mae-Wan Ho "Genetic Engineering Dream or Nightmare" (1999). URL - www.twinside.org.sg/title/mae-cn.htm.

plant and, given the ability of viruses to acquire, recombine and swap genetic material, the deployment of large areas of these transgenic crops may create the ideal conditions for new disease-causing viruses to evolve⁶⁶. Many GE plants are engineered for resistance to viral diseases by incorporating the gene for the virus's coat protein. These viral genes may cause new diseases. New broad range recombinant viruses could arise, causing major epidemics. Upon consumption, the GE DNA of these foods can break down and enter the blood stream.⁶⁷

4.2.4. MEDICAL FOODS

The genetic engineering of foods for medicinal purposes has been seen by some as an important development in the field of medicine, especially with regard to vaccines. These new foods are often referred to as “medical foods” or “functional foods”.

Vaccinations provides a sample of the foreign protein into the body, without the attendant dangers of an infection, and gets the immune system geared up and ready to fight ⁶⁸

Foot and mouth disease was one of the first diseases to have been successfully researched by genetic engineers.⁶⁹The vaccine was not developed in food crops; an example of a food crop vaccine in Bananas carrying the vaccine for hepatitis B⁷⁰. The use of crops as opposed to animals has several advantages, including fewer ethical concerns, the production of large quantities of plant material, and plants such as GE bananas may provide an easy source of medicinal drugs to third world countries.⁷¹

One of the main concerns with “ medical food” is that experimental plants engineered to produce pharmaceuticals are being grown in protected fields around the world. Biotech companies are

⁶⁶ T Berhan and V Shiva op cit note 47.

⁶⁷ V Shiva op cit note 7 at 102.

⁶⁸ J Chermas *Man made Life: An Overview of the Science, Technology, and Commerce of Genetic Engineering* (1982) 174.

⁶⁹ Ibid.

⁷⁰ The virus of hepatitis B attacks the liver, causing debilitating and often fatal failure of the organ.

⁷¹ S Nottingham op cit note 9 at 77.

experimenting on corn, soy, rice and bananas that are genetically engineered to produce drugs designed to act as vaccines, contraceptives, generate growth hormones and propagate allergic enzymes. Should any of these genes find their way into other crops then, according to Larry Bohlen,⁷² we “ could be eating other peoples prescriptions in our corn flakes”. The chance that these crops may not be totally isolated is a risk to human health.⁷³ Genetic engineers are of the opinion that they can solve the malnutrition problem in developing countries by engineering foods to contain high levels of vitamins and minerals. An example is Monsanto’s high tea carotene oil, which when consumed could be used to increase the level of Vitamin A in humans. Further examples would be peanuts with higher levels of protein, garlic that produces more allicin, believed to help reduce cholesterol, and rice with higher protein. An obvious problem with this level of engineering is that the human body is conditioned to absorb a balance of necessary vitamins and minerals, which may be compromised should this intake not be monitored. For instance many women need extra iron as part of a healthy diet, and they may be able to handle higher levels of iron because their bodies expel iron during menstruation. Men have a lower ability to rid their bodies of excess iron, thus vitamin manufacturers often leave out iron in a mans supplement. Too much iron can cause neurological damage, thus there is a risk of vitamin overdose once the vitamins and minerals are in the food it will be difficult to monitor the quantity of vitamins and minerals the body is getting.⁷⁴

4.2.5. NUTRITION: YOU ARE WHAT YOU EAT

The occurrence of disease in humans can be attributed to a number of risk factors including dietary variables such as fat intake and antioxidant levels in food. GE of an organism used for food may alter the final product, being different to the conventional food it will replace. The risk of this is that if the cumulative effect of individually insignificant changes in the composition of the overall diet of the person is not monitored, the result may be an imbalance of diet.⁷⁵

⁷² L Bohlen, director of health and environment programmes in the USA.

⁷³ *Environmental News Service*: Issue July 16 2002.

⁷⁴ M Teitel and K A Wilson op cit note 8 at 111.

The question that consumers are asking is whether GE food has a different nutrition level to normal food? In 1999 CETOS (California Center for Ethics and Toxins), carried out extensive research to see if this was the case. The research was focused on the Monsanto Roundup Ready soybean, and it immediately became apparent that the government of the USA had accepted the research conducted by Monsanto's own scientists, submitted to demonstrate the safety of Monsanto's Roundup Ready soybean. The CETOS staff, Britt Bailey and toxicologist Marc Lappe` were concerned with the objectivity of the scientists work, and had independent scientific tests carried out. The CETOS staff observed that the soybeans tested by the Monsanto scientists were not an accurate representation of the soybeans that appear in stores as food because they were not tested with the Roundup herbicide, as they would be in reality. Scientific tests were carried out to compare Roundup Ready soybeans treated with Roundup Ready herbicide, with conventional soybeans identical to the Roundup Ready soybeans except for the missing engineered gene. The study was reported in a peer reviewed scientific journal in 1999. The process of peer review is important because it means that independent scientists can evaluate the study and determine whether it is based on sound and acceptable scientific evidence. In their study, CETOS found that there was a 12 to 14% decline in types of plant-based estrogens called phytoestrogens, which are associated with the protection against heart disease, osteoporosis and breast cancer. A 12 to 14 % drop in phytoestrogens is a significant nutritional difference. Monsanto then conducted a further study showing different results, but CETOS stood by its study, stating that Monsanto used older methods in some of its research and thus it was difficult to draw comparisons in the study.

The conclusion that can be drawn from the CETOS study is that there is a good need for further studies to determine possible nutritional changes in GE crops. There should be clear, unequivocal, labeling of GE food so that a person can make his or her own choice. ⁷⁶

⁷⁵ Professor Liam Donaldson Sir Robert May "Health Implications of Genetically Modified Foods" Department of Health UK (May 1999). Biotech Knowledge Center. URL - www.biotechknowledge.monsanto.com/biotech/knowcenter.nsf.

4.3. SOCIO ECONOMIC EFFECTS: WHO REALLY BENEFITS?

The global, social and political implications of modern biotechnology are intimately linked with the present economic and political world structure and with its emerging trends. For the purpose of this paper this topic will be narrowed down to the socio-economic effects of GE crops.

The introduction of a GE crop, forest plant or domestic animal species into agriculture will cause disruptions in existing livelihood systems. The diversity of soils, climates and plants has contributed to a diversity of food cultures across the world. The maize based food systems of Central America, the rice based Asian systems, the teff based Ethiopian diet and the millet based foods of Africa, are not just part of agriculture; they are part of a cultural diversity. Food security is not just having access to adequate food. It is also having access to culturally appropriate food. For example, India is a country rich in a biological and cultural diversity of food systems. In the Himalayan Mountains people eat pseudo cereals such as buckwheat and chenopods, while in Eastern India people eat rice and fish. Each region has its culturally specific edible oil used as a cooking medium; in the north and east it is mustard and in the west it is groundnut.⁷⁷

Multinational companies are seeking to grow large areas of GE crops in the developing countries. For example, tomatoes and potatoes for the major food chains. These crops rarely fit in with the traditional local diets or plants of local farmers. Companies show little interest in foods grown primarily in the developing countries such as millet and yams. Multinational companies have concentrated on developing crops that will earn high profits and not crops that can best contribute to solving the worlds' food problem.

Cultivating GE crops is more expensive than conventional crops because of the higher costs of the seed, technology fees, and the need for an increase in chemical use. In organic agriculture, seeds are saved and cultivated the following season. When GE crops are cultivated all the inputs such as herbicide, fertilizer and irrigation have to be paid for. This can be illustrated by what happened in Punjab in the 1980's when

⁷⁶ M Teitel and K A Wilson op cit note 11 at 48.

the Green Revolution⁷⁸ took place.⁷⁹ According to Vandana Shiva⁸⁰, after two decades of the Green Revolution Punjab had been left with diseased and pest infested soils, waterlogged deserts, and indebted and discontented farmers. The Green Revolution created even more of a gap between the wealthy and the poor as only the best-endowed regions and farmers were utilised. The increase in resource intensity of inputs for Green Revolution agriculture implied the increase in capital intensity of farming and as a result, the poor peasants were unable to maintain their land holdings under such high economic input.⁸¹ According to critics of the Green Revolution, a parallel can be drawn between the Green Revolution and genetic engineering of crops which has been termed the Gene Revolution, in that just as the Green Revolution resulted in huge loss in genetic diversity, so too will the Gene Revolution. The loss would be not only through forcing reliance on monocultures, thus reducing agro biodiversity, but also through the pollution of the wild crop species with genes from their genetically engineered relatives.⁸²

Africa relies largely on the export of cocoa, which is an important tropical commodity in international trade. Small holders in the West of Africa grow most of the worlds' cocoa. The threat posed to these farmers is that American companies, such as Hershey foods, are developing new cocoa varieties by enzymatically transforming cheaper vegetable oils or growing yeasts with engineered fatty acids. In developing countries sugar exports are also at risk with the assistance of the biotech industry with the production of sugar substitutes. For example high fructose corn syrup made from maize was the first alternatives to sugar produced using enzyme technology. Far from feeding the hungry, the new agricultural technologies may be increasing the problem in developing countries.⁸³

⁷⁷ V Shiva op cit note 7 at 21.

⁷⁸ Green Revolution is the name given to the science-based transformation of third world agriculture.

⁷⁹ V Shiva op cit note 7 at 101.

⁸⁰ See Chapter 3.3.

⁸¹ V Shiva op cit note 41 at 221.

⁸² M Butler and D Hallows op cit note 1 at 11.

⁸³ S Nottingham op cit note 9 at 170.

5. INTELLECTUAL PROPERTY RIGHT: DO BIG CORPORATIONS OWN THE WORLD?

Biological diversity is undergoing a dangerous wave of privatisation under the label of intellectual property rights (IPR's), such as the patenting of plants and animals which, for the purposes of this paper, will be discussed in more detail in respect of the patenting of plants. Patents give multinational companies, which hold patents on a wide range of GE organisms, exclusive property rights. Patent rights are granted in exchange for disclosure of information. This information prevents other people from infringing on the patent. Today IPR's, of which patents are one type of right, underpin the profitability of the biotechnology industry, and provide the mechanism by which investments are recouped.

The term "intellectual property rights" is generally held to encompass five definable types of right:

1. Patents: A patent is a legal title granting the holder exclusive rights to make use of the invention for a limited area and time by stopping others from, amongst other things, making, using or selling it without authorisation.⁸⁴
2. Copyright: Traditionally used to protect the creations of literary or artistic works, but are not reserved exclusively for such creations.
3. Trademarks: The purpose of a trademark is to prevent competitors from using a mark similar to or identical with that of the holder for the purpose of deceiving or confusing the purchaser as to the products origins.
4. Trade Secrets: In the United States of America the "Federal Uniform Trade Secrets Act of 1980" defines trade secrets as "Information, including a formulation, pattern, compilation, program, device, method, technique or process that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means, by other means, who can obtain economic value from its disclosure or use and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

⁸⁴ TD Burnell *South African patent Law and Practice* (1972) 1.

5. Plant Breeders Rights: Historically the patent-like protection of life forms has been treated separately to patents involving inanimate objects. Plant Breeders Rights were awarded to plant breeders to safeguard new crop varieties.⁸⁵

5.1. THE ORIGINS OF THE PATENTING OF LIFE

In the USA prior to 1930, the “Product of Nature” doctrine effectively excluded the granting of patents in plants. This doctrine was applied and may be illustrated in the United States of America case of *Ex parte Latimer*⁸⁶, in which the fibers of an evergreen tree were held to be unpatentable. The patenting of plants and seeds was thought to be outside the scope of patent law. Plant Breeders Rights (PBR’s) were awarded to plant breeders to safeguard their new crop varieties. In the USA these rights were first granted in 1930 with the passing of the Plant Protection Act to cover asexually reproducing varieties. The Act was introduced primarily to remove the discrimination between industrial inventors and plant breeders who had not been offered any reward for their efforts in the development of new plant varieties⁸⁷. Since the Act only applied to plants which had been asexually propagated, thereby excluding major crops such as wheat, barley and rice to which such techniques could not be applied, the Plant Variety Protection Act of 1970 (PVPA) was introduced which extended PBR’s to include sexually reproducing varieties. These new PBR’s protected against the resale of seeds, but permitted the use of seeds by any plant breeder as a parent for future generations. It further allowed farmers to store and resow seeds. In 1961 the International Convention for the Protection of New Varieties of Plants of 2 December 1961 was signed by 18 countries and gave breeders intellectual property rights over new varieties⁸⁸.

5.2. INTERNATIONAL KEY ORGANISATIONS

⁸⁵ B V Hickman *The Importance of Biological Diversity and the Possible Application of Intellectual Property Rights as Mechanisms for its Conservation* (unpublished LLM dissertation for the University of Natal 1998).

⁸⁶ Comm. ‘n December 123 (1889).

⁸⁷ N J Seay “Protecting the Seeds of Innovation: Patenting Plants” 16 *AIPA Quarterly Journal* (1989) 418.

5.2.1. THE UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV)

Formed in 1991, this body is responsible for laying down rights for commercial breeders of plant varieties, and permitting the patenting of plant varieties. The UPOV provides that a plant breeder will be provided with protection “whatever may be the origin, artificial or natural, of the initial variation from which has resulted, but the variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge at the time when the protection is applied for...”⁸⁹ Common knowledge may be established with reference to several factors: previous cultivation or marketing thereof, inclusion in a reference collection, description or publication.⁹⁰

The UPOV does not define the term breeder, but South Africa is a member of the UPOV and the Plant breeders Act 15 of 1976, defines breeders as “...the person who directed the breeding of the new variety or who developed or discovered it”⁹¹

The term “breeder” implies that there is an intervention of some form of human agency such as manual cross-pollination and thus would exclude naturally occurring species. It is not clear whether or not this is in fact the case. Regardless of whether or not the UPOV can be said to include naturally occurring varieties or undiscovered species, it clearly excludes all those species, which have already been identified. These would fall under the “common knowledge” exclusion, and thus would be unable to provide an adequate level of protection for biodiversity on earth⁹².

5.2.2. THE WORLD INTELLECTUAL PROPERTY ORGANISATION (WIPO)

WIPO administers 23 international intellectual property treaties including the Paris Convention for the Protection of Industrial Property 1883 which founded international patent law.

⁸⁸ S Nottingham op cit note 9 at 105.

⁸⁹ Article 6 (1) (a) of the International Convention for the Protection of New Varieties of Plants.

⁹⁰ Ibid.

⁹¹ Section 1.

⁹² B V Hickman op cit note 85 at 51.

5.2.3. THE WORLD TRADE ORGANISATION (WTO)

This succeeded the General Agreements on Tariff and Trade (GATT) in 1995, as the legal and institutional foundation for a multilateral trading system, and was signed by 103 countries.

5.2.4. THE ORGANISATION FOR THE ECONOMIC CO OPERATION AND DEVELOPMENT (OECD)

OECD has interests in the economic and social issues of 30 democratic countries. The OECD explores the role of intellectual property rights through the study of the economic impact of intellectual property regimes in high tech industries and in the public research. It also assesses policies and institutional practices for intellectual property management and exploitation. The OECD held a workshop in Berlin in January 2002 on Genetic Inventions, IPR's and Licensing Practices which, amongst other things evaluated how licensing practices influenced the progress of research, product development and clinical use.⁹³

5.3. INTERNATIONAL PATENT LAW CONVENTIONS

5.3.1. THE EUROPEAN PATENT CONVENTION OF THE 5 OCTOBER 1973 (EPC)

The convention provides for the granting of European patents. The European Patent Office (EPO), which is based in Munich, is controlled through the executive body charged with the granting of European patents. Patents are granted through an application process to the EPO and then published. All Member States may apply to the EPO.⁹⁴

The EPC defines patentable inventions as

“inventions which are susceptible of industrial application, which are new and involve an inventive

⁹³ Internet Homepage for the OECD URL – www.oecd.org.

⁹⁴ Internet Homepage of the European Patent Office. URL – www.european-patent-office.org.

step”⁹⁵

EPC specifically excludes the granting of patents for plant and animal varieties or for “essentially biological processes” for the breeding of plants and animals, although this exclusion does not apply to microbiological processes or the products thereof.⁹⁶

The application of this exclusion may be illustrated in an EPO board of appeal decision⁹⁷. It was held that a claim defining genetically engineered plants, having a distinct, stable, herbicide-resistance genetic characteristic, was not allowable under Article 53(b) of the EPC. The reason was the claimed genetic engineering made the engineered plant a “plant variety” within the meaning of Article 53(b). Such exclusion was deemed permissible in terms of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which formed part of the Uruguay round of the General Agreements on Tariffs and Trade (GATT) in September 1986⁹⁸.

5.3.2. CONVENTION ON BIOLOGICAL DIVERSITY 5 JUNE 1992

The convention was born at the United Nations Conference on Environment and Development at Rio de Janeiro. It is the first global agreement on the conservation and sustainable use of biological diversity. It has three main goals; the conservation of biodiversity, the sustainable use of the components of biodiversity and sharing the benefits arising from commercial and other utilisation of genetic resources in a fair manner. It covers the expanding field of biotechnology and genetic engineering, addressing technology, benefit sharing and biosafety. It is a legally binding convention that has been signed by over 150 countries and ratified by 175 countries.⁹⁹

⁹⁵ Article 52(1).

⁹⁶ Article 53(b).

⁹⁷ T356/93 (OJ EPO 1999,545).

⁹⁸ B V Hickman op cit note 85 at 47.

5.4. INTERNATIONAL TRADE AGREEMENTS

5.4.1. GATT

GATT came into being in 1948 to discuss issues of free trade. The 7 rounds of GATT until 1986 had the main objective of tariffs' related to trade. Then in September of 1986, the eighth or Uruguay round began, which extended the issues to be discussed to include technological developments. In the Uruguay round, the patenting of life forms, using the concept of intellectual property rights was extended to a global level. The owner of a patent therefore became the recognised owner of a new life form worldwide with exclusive protection for a period of 20 years. These changes to GATT added even more protection barriers, erected by industrialised countries, against the third world. According to critics, the new GATT favoured the multinational companies.¹⁰⁰

5.4.2. TRIPS

TRIPS sets out a minimum standard of intellectual property rights, which may be adopted by nations to take account of their own circumstances. Article 27 of TRIPS is relevant to the genetic engineering of organisms, as it allows WTO members to prevent the patenting of otherwise patentable inventions, on the grounds of "ordre public"¹⁰¹, including to protect human, animal or plant life or health, or to avoid serious prejudice to the environment".¹⁰² Critics of TRIPS believe that, in effect, TRIPS has created a global regime of IPR's over life. Driven by the biotechnology and pharmaceutical industries, TRIPS facilitates corporate ownership of life and allows for monopoly control over knowledge.¹⁰³

⁹⁹ Internet Homepage for the Convention on Biological Diversity. URL – www.biodiv.org/doc/publications/guide.

¹⁰⁰ S Nottingham op cit note 9 at 115.

¹⁰¹ Derived from the French, it means public order but goes further than the meaning of public peace in that it refers to the fundamental principles underlying a nations society.

¹⁰² Preamble to Directive 98/44/EC.

¹⁰³ M Butler and D Hallows op cit note 1 at 14.

5.5.EC DIRECTIVES AND REGULATIONS

5.5.1. DIRECTIVE 98/44 EC.

In July 1997 a draft Directive on the Legal Protection of Biotechnological Inventions was approved by the EC. The Directive known as Directive 98/44 EC was formally adopted on the 6 July 1998 by the European Council and European Parliament, and came into effect on the 30 July 1998.

The Directive provides for the patenting of inventions

“ even if they concern a product consisting of or containing biological material”¹⁰⁴

Biological material is defined as:

“ any material containing genetic information and capable of reproducing itself or being reproduced in a biological system”¹⁰⁵

and including material

“ isolated from its natural environment or processed by means of a technical process...even if it already occurred in nature”¹⁰⁶

The effect of this directive allows for the patenting of biological material, which is identical to that found in nature without the need to show that it differed in degree or kind.¹⁰⁷ The Directive also provides that plant and animal varieties shall not be patentable, but inventions, which concern plants and animals, are patentable provided that the application of the invention is not technically confined to a single plant or animal variety¹⁰⁸. In other words the patent must be effective on numerous species or varieties of plant and animals in order to be patentable.

¹⁰⁴ Article 3 (1).

¹⁰⁵ Article 2 (1)(a).

¹⁰⁶ Article 3(2).

¹⁰⁷ B V Hickman op cit note 85 at 48.

¹⁰⁸ Article 4(1) and (2).

5.5.2. REGULATION 2100/94/EC

In Europe Regulation 2100/94/EC on Community Plant Variety Rights implements the 1991 UPOV Convention, which takes into account the recent developments in biotechnology, by introducing the concept of essential derivation. Essential derivation allows the holder of rights in an initial plant variety to, have the same rights in any variety which is essentially derived using biotechnological techniques, from that variety.

5.6. USA ADMINISTRATION ON PATENTS

The USA has possibly the most liberal patent regime in respect of living organisms. The Patent Act of 1988 basis its philosophy on the Constitution of the United States, which grants Congress the power to grant intellectual property rights in order to promote the “progress of science and useful arts”.¹⁰⁹ The philosophy behind this clause can be explained in the case of *Mazer Vs Stein*. Behind the empowering of Congress to grant patents is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through talents of authors and inventors in “science and useful arts”. Rewards are offered by means of a monopoly to prevent others from making, using or selling their invention.¹¹⁰

The USA Patent and Trademark Office (USPTO), is responsible for the examination of US patents, for disseminating information about patents and to give advice to the US government about trade related aspects of intellectual property rights.

The USA equivalent to Plant Breeder Rights is Plant Variety Protection, enforced through the Plant Variety Protection Act. The USA Department of Agricultural Marketing Services Plant Variety Protection Service Office administers this protection.

¹⁰⁹ Article 1 Section 8 cl.8.

¹¹⁰ 347 US 201, 219 (1954).

In January of 1994 the North American Free Trade Agreement (NAFTA) came into being which eliminated trade barriers between USA, Canada and Mexico.¹¹¹

5.7. UK ADMINISTRATION ON PATENTS

In the UK, the Patents Regulations 2000 amended the Patents Act 1977, which was introduced in response to the European Convention of 1973. The amendment was promulgated to make provision for Article 1 to 11 of the Directive 98/44 of the European Parliament and European Council of 6 July 1998, and for the implementation of Article 27(2) of TRIPS, relevant to the GE of organisms.

The UK Patent Office (UKPO) issues patents through an application process, and an application in terms of the European Patent, may be obtained through this office.

The UK Plant Varieties Act of 1997 was introduced in response to the 1991 UPOV Convention.

5.8. WHO BENEFITS?

In 1995 the USA Patent and Trademark Office (PTO) awarded a patent to the company Mycogen for the rights to any method of modifying Bt insecticidal protein genes to make them resemble plant genes. Monsanto, a much larger company, had developed similar technology. In order to prevent a costly dispute, Mycogen entered into negotiations with Monsanto with a view to a licensing agreement. Patents were usually awarded to individuals or small companies to give them intellectual property rights over their inventions. However it is now multinational companies that hold these patents.¹¹²

In the case of *Monsanto Canada Vs Schmeiser*¹¹³ Monsanto sued the Defendant Schmeiser, a Canola farmer, for patent infringement when GE Canola contaminated his fields patented by Monsanto. The judge

¹¹¹ S Nottingham op cit note 9 at 115.

¹¹² S Nottingham op cit note 9 at 108.

¹¹³ 2001 FCA 309.

ruled in favour of the Plaintiff and the Defendant appealed the decision in the case of *Percy Schmeiser and Schmeiser Enterprises Ltd Vs Monsanto Canada Inc and Monsanto Company*¹¹⁴.

One of the issues that the court had to decide was the issue of whether the patent had been infringed? The court held that “to determine whether a certain act amounts to infringement, the scope of the statutory monopoly must be determined by construing the claims of the patent...it is a fundamental principle that a patent claim must be given a purposive construction”.¹¹⁵

A purposive construction was defined in the case of *Whirlpool Corporation Vs Comco Corporation*¹¹⁶ as “...what the inventor considered to be essential elements of his invention”.

In this case it was held that there had been an infringement of the patent as the essence of each claim was the presence of the patented gene, which was not in dispute. Schmeiser was found guilty of having Monsanto’s genetics on his land and for not advising Monsanto to come and fetch it. The fact that Schmeiser did not benefit or intend to benefit from the genetics was irrelevant.

The implications of the decision is that all farmers who have their fields contaminated with GE seeds, are obligated to inform the company who has the patent, that they have infringed on their respective patents. This is done in the hope that when the patent right holder approaches them, it is not to institute legal action but rather to provide a solution. The farmer is not offered any protection from the contamination, and the problem becomes the farmers once the contamination occurs.¹¹⁷

This is a landmark decision for the multinational companies. The GE of crops depends for its existence on the patenting of life. Companies that invest large amounts of capital in the engineering of plants will only do so if they can protect those rights and obtain exclusive rights to the proceeds of those seeds. It would

¹¹⁴ 2002 FCA 309.

¹¹⁵ 2002 FCA 309 33.

¹¹⁶ 2002 2 S.C.R. 1067 45.

¹¹⁷ “The Crime of Percy Schmeiser” URL – www.percyschmeiser.com.crime.htm.

seem that the multinational companies are the ones that have the greatest financial benefit from promoting GE crop and crop products.

5.9. THE POSITION IN SOUTH AFRICA

In Africa this issue is especially pertinent because the continent has repeatedly reaffirmed their rejection of the patenting of life. Africa continues to lobby the WTO to allow member states the right to maintain systems of their own choice to ensure national food security, livelihoods, healthcare and the development of sustainable agriculture. South Africa is out of step with this view and patenting and biopiracy are especially relevant to this country as it has a unique biodiversity.

The Patents Act 57 of 1978, the Trademarks Act 194 of 1993, and the Copyright Act 98 of 1978 covers patents, trademarks and copyrights respectively. This legislation decides whether processes and genetically engineered plants and animals may be patented. The Biotechnology Strategy states that there is a lack of clarity on a number of issues, which may have implications for the harnessing of both intellectual property and indigenous knowledge in biotechnology. These include

1. No existing framework for the protection of indigenous knowledge.
2. No existing equivalent to plant breeder's rights for animals i.e. not possible to protect new varieties of animals from use by persons other than licensees or inventors.
3. Lack of sound information on what can be patented, as there is no precedent in the patent office to rely on.¹¹⁸

6. HOW THE EC REGULATES GENETICALLY ENGINEERED FOOD AND PLANTS

The European Union and other countries have banned the import of GE crops, and the animals which have been fed on them. Countries like the USA are strongly opposed to the moratorium and claim that it is having adverse effects on trade across the globe. On the 20 November 2002 the European Parliament adopted a resolution based on the European Commissions Communication on Life Sciences and

¹¹⁸ Strategy on Biological Diversity.

Biotechnology- Strategy for Europe, which strongly supported an end to the moratorium on GE food, in place since 1998. This was in order to promote innovation and to prevent a brain drain in that field of expertise. On the 2 July 2003 the European Parliament voted strict new standards for the approvals of GE crops and GE derived food. The new standards include regulations on GE Food, Feed and Traceability and Labelling, which were the result of negotiations between the European Commission, Council and Parliament. These regulations must be in place before the GE moratorium is lifted. In the meantime pending applications may move forward.¹¹⁹

6.1. DIRECTIVE 90/220/EEC AND DIRECTIVE 2001/18/EEC

The main legislation in place in the European Community (EC), under which experimental releases and placing on the market of GE organisms had been authorised was, up until 17th October 2002, Directive 90/220 EEC.¹²⁰

Directive 90/220 EEC came into effect in 1990 and numerous amendments were made until the new updated Directive 2001/18 EC repealed it on the 17th October 2002. Directive 90/220 EEC was relied on to obtain marketing authorisation of GE organisms within the EU, and authorised experimental releases of GE organisms within the EU.¹²¹

Directive 2001/18 EC puts in place a step-by-step approval process on a case-by-case assessment of the risks to human health and the environment before any GE organism or product consisting of GE organisms, such as maize or tomatoes, can be released into the environment or placed on the market.¹²²

Directive 2001/18EC updates Directive 90/220EC in the following respects:

1. More detailed environmental risk assessment.

¹¹⁹ European Parliament Plenary Session in Strasbourg, 20th November 2002 and 2 July 2003.

¹²⁰ S Nottingham op cit note 9 at 130.

¹²¹ Internet Homepage of the European Commission "Food Safety: Questions and Answers on Genetic Engineering". URL - <http://europa.eu-int/comm>.

¹²² Ibid.

2. Mandatory monitoring requirements of the long-term effects of coming into contact with GE organisms.
3. Mandatory information to the public.
4. A general rule on labelling and traceability at all stages of placing on the market.
5. First approvals for release of GE organisms to be limited to 10 years.
6. Obligation to consult the European Parliament on decisions to release GE organisms.
7. Council Members to adopt or reject a Commission proposal.¹²³

A company intending to market a GE organism must first submit an application to the competent national authority of the relevant Member State where the product is to be first placed on the market. The application must include a full environmental risk assessment. If the national authority gives a favourable opinion on the placing on the market of the GE organism concerned, the Member State informs the other Member States via the Commission. If there are no objections, the competent authority that carried out the original evaluation grants consent to place the product on the market throughout the EU. If objections are raised then the decision is taken at the European Community level. The Commission will first ask for the opinion of the Scientific Committee, which consists of independent, highly qualified scientists. If the opinion is favourable, then the Commission proposes a draft decision to the Regulatory Committee composed of the representatives of the Member States for their opinion. If the Regulatory Committee gives a favourable opinion, the Commission adopts the decision.¹²⁴

The European Directive represents the minimal consensus among Member States that the introduction of genetically engineered organisms should be regulated in order to obtain a harmonization of the internal market. The directive says that:

1. Living organisms may “reproduce, cross national frontiers and cause irreversible effects”.

¹²³ Part C of Directive 2001/18/EC.

¹²⁴ Homepage for the International service for the Acquisition of Agri-biotech Applications “Global Status Europe” URL – www.isaaa.org/kc/Global_Status/global/Europe/partA.htm.

2. It is required that prior to each GE organism release, “the applicant must submit an environmental assessment” e.g. such as regard the potential for ecological interactions. This requirement places the burden on the applicant.
3. “Member States may undertake all appropriate measures to avoid adverse effects on human health and the environment” from the release of GE organisms.¹²⁵

According to Dr. Rene Von Schomberg, who is contracted by the Scientific and Technological Options Assessment (STOA) of the European Parliament, the directive has numerous faults. He is of the opinion that such guidelines are not adequate as the directive does not define “evidence for safety” nor “environmental harm”, but rather provides flexible procedures in defining these terms in practice. Further the concept of “adverse effects on human health and the environment” is also left open for interpretation by Member States. The directive has an annexure with guidelines on what information could comprise of a “Risk Assessment” procedure, but the directive does not define the concept of risk .The directive states that for the market approval of a GE product, the application must be filed in the Member State where marketing is expected to begin. If the Member State recommends approval, the EU procedure allows for objections to be resolved by voting if necessary. Most importantly the final approval would then apply to all Member States. The effect of this is that the Biotech industry will rapidly find out the Member State with the most favourable position on GE products and have their products released there first, because it is left open to the Member States to interpret what constitutes a hazard and, as such, this leaves the field open to considerable arbitrariness. To date once a Member State has approved the marketing of a GE product, it is difficult for other Member States to prevent EU wide approval because of the strongly favourable attitude of the Commission. The Commission seems to have a very strong role to play and in some instances may even approve the marketing of a GE product when a majority of Member States disapproves. This was the case when the Commission decided to approve the Basta resistant corn to be marketed in Europe although 15 out of 16 Member States had voted against approval. The Commission can use its power to overrule the whole of the EU.¹²⁶

¹²⁵ Article 4.

¹²⁶ Dr R Von Schomberg “An Appraisal of the Working in Practice of Directive 90/220/EC on the Deliberate Release of Genetically Modified Organisms” Released by the STOA 2 January 1998.

6.2. REGULATION EC 258/97

Products derived from GE organisms, such as paste or tomato sauce from a GE tomato, are not covered by the horizontal Directive 2001/18/EEC, but by vertical legislation such as Regulation on Novel Foods and Novel Food Ingredients of the 17th January 1997, known as Regulation (EC) 258/97. Novel foods are food and food ingredients that have not been used for human consumption to a significant degree within the European Community before May 1997. Regulation (EC) 258/97 lays out detailed rules for the authorisation of novel foods and novel food ingredients. Foods commercialised in at least one Member State before the entry into force of Regulation (EC) 258/97 are on the EU market under “The Principle of Mutual Recognition”. In order to ensure the highest level of protection of human health, novel foods must undergo a safety assessment before being placed on the EU market.¹²⁷

Regulation 258/97 introduced a statutory pre-market clearance system for all novel foods which is binding on all Member States, and which is accompanied by Commission Guidelines on the data required to support an application and on how these applications should be assessed. They follow internationally accepted “Best Practice” which has evolved over the last 10 years in Europe. Under this Regulation, all Member States assess the safety of individual GE foods and, in the event of any difference in scientific opinion arising, it is resolved by reference to the Scientific Committees in the European Community.¹²⁸

The first step in an authorisation process is an assessment of an application to market the GE food or its products by a Member State with in which the food is to be marketed. In the case of a favourable opinion, the Member State informs the other Member States via the European Commission. If there are no objections, this Member State can authorize the product for marketing in the EU. If there are objections by other Member States a decision at the European Community level is required. The European Commission

¹²⁷ Internet Homepage for the European Commission “Food Safety: Novel Foods”. URL - <http://europa.eu.int>.

¹²⁸ Professor Liam Donaldson and Sir Robert May op cit note 75.

consults the Scientific Committee on matters relating to public health and the environment and adopts a decision.¹²⁹

There is an Advisory Committee on Novel Foods and Processes (ACNFP); an independent committee of experts called ACNFP advises ministers on all novel foods including those produced using GE organisms. This committee carries out safety assessments of individual novel foods as part of the pre market approval scheme controlled by EC Novel Food and Novel Food Regulations.¹³⁰

6.3. SAFETY ASSESSMENT

The safety of GE foods is assessed in a comparison with foods that they may replace. This concept of substantial equivalence, developed by the World Health Organisation and the Organisation for Economic Co Operation and Development, is used extensively in the process of assessment of safety of GE foods by expert assessment bodies worldwide. For example, a GE food might be compared with a non-GE variety provided it is essentially equivalent.

In this assessment method, the GE food is compared to its conventional counterparts. Consideration is given to the amounts of GE food humans are likely to consume, as well as a detailed description of what the food is, how it was produced, and a description of the GE process. An evaluation of any possible nutritional, toxicological¹³¹ and any adverse microbiological effects of the modified food, and any data on people eating the GE food under controlled conditions is carried out.¹³²

These comparisons can have three possible conclusions:

¹²⁹ Op cit note 121.

¹³⁰ Professor Liam Donaldson and Sir Robert May op cit note 75.

¹³¹ Toxicological refers to the level of undesirable substances in the food.

¹³² Professor Liam Donaldson and Sir Robert May op cit note 75.

1. GE food is substantially equivalent to the conventional counterpart in all agronomic¹³³, compositional information on nutrients and toxicological effects.
2. GE food is equivalent to the conventional counterpart except for a few differences with regard to the above respects.
3. GE food is not substantially equivalent to the conventional counterpart with regard to the above respects.¹³⁴

Critics of the “substantial equivalence” method are of the opinion that the assumption, that if the GE organism is similar to its natural counterpart i.e. substantially equivalent, then there is no reason to believe it is hazardous, is an incorrect assumption. The reason is that to decide if a GE food is substantially equivalent, according to this procedure, only a limited set of characteristics needs to be compared. If the procedure reveals no significant difference between the GE food and its natural counterpart, then no further safety testing is required. It is assumed that GE food is safe if it is substantially equivalent. However this assumption is incorrect. It could only be correct if genetic engineering is such a safe technology that it could never give rise to unexpected substances. The opposite is the case. Molecular biological theory, as well as experimental findings, indicates that unexpected substances may be created in GE food, such as substances that are toxic or allergenic as discussed in Chapter 4. This means that GE food may be hazardous even, if it is identical to its natural counterpart, because one unexpected toxic substance runs a risk to human health.¹³⁵

6.4. LABELLING OF GE FOOD IN THE EC.

The EU recognises the consumers right to information and labelling as a tool for making an informed choice. Since 1997, labelling to indicate the presence of GE organisms in food is mandatory.¹³⁶

¹³³ Agronomic refers to crop height, yielding and flowering of the crop.

¹³⁴ Professor Liam Donaldson and Sir Robert May op cit note 75.

¹³⁵ Homepage for the Physician and Scientists for Responsible Application of Science Technology “Inadequate Safety Assessment of GE Foods” URL – www.psrast.org/subeqow.htm.

The relevant legislation is as follows:

6.4.1. DIRECTIVE 2001/18/ EC

From 17th October onwards Directive 2001/18/ EC foresees that Member States shall take all the necessary measures to ensure that labelling of GE organisms and their products are in place at all stages of their marketing.

6.4.2. THE NOVEL FOOD REGULATION EC 258/97

The Novel Foods Regulation EC 258/97, article 8 provides for mandatory labelling of food ingredients which contain or consist of GE organisms without prejudice to other labelling requirements of European Community law.

6.4.3. REGULATION (EC) 1139/98

Regulation (EC) 1139/98 covers the labelling of GE maize varieties and GE soy varieties which do not fall under Regulation 258/97, concerning the compulsory indication of the labelling of certain foodstuffs produced from GE organisms as amended by Regulation (EC) 49/2000.

6.4.4. REGULATION (EC) 50/2000

In addition all GE additives and GE flavourings have to be labelled according to Regulation (EC) 50/2000 on the labelling of foodstuffs and food ingredients containing GE additives and flavourings.

6.4.5. REGULATION (EC) 49/2000

¹³⁶ Internet Homepage for the European Commission "Food Safety: Labeling". URL - <http://europa.int/comm>.

Regulation (EC) 49/2000 introduced a 1-% de minimus threshold for the presence of DNA resulting from GE organisms below which labelling is not required.

6.4.6.DIRECTIVE 98/95/EEC.

All GE feed varieties must be labelled in accordance with Directive 98/95/EEC.

7. HOW THE USA REGULATES GE FOOD AND CROPS

The United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), closely monitor the development and testing of GE crops and food products.

The USDA is responsible for monitoring plant pests, plants and veterinary biological products.

The EPA is responsible for monitoring microbial/plant pesticides, the new use of existing pesticide's and novel microorganisms.

The FDA is responsible for monitoring of food, food additives, veterinary drugs, human drugs and medical devices.¹³⁷

7.1. USDA

The USDA regulates the GE food through the Animal and Plant Health Inspection Service (APHIS), which administers the Federal Plant Pest Act¹³⁸ (FPPA). This legislation authorises the APHIS to regulate interstate i.e. between states movement, importations into the USA, and field testing of organisms and

¹³⁷ Internet homepage for the OECD "Regulatory Developments in Biotechnology in the USA".URL – www.oecd.org/oecd/pages/home/displaygeneral.

¹³⁸ 7 U.S.C.

products, altered or produced through GE, which are plant pests or where there is reason to believe they are plant pests.¹³⁹ A company, academic research institution or private scientist who wishes to move or field-test a GE plant must obtain the necessary permit before proceeding.¹⁴⁰

7.1.1. PERMIT PROCEDURE

There are three types of permits that an applicant who is developing a GE plant may be required to obtain:

1. Permit for Movement and Importation, which is required to move any GE organism, that is a potential plant pest into the USA or between states.
2. Permit for the Release into the Environment, which is required for field-testing which is also referred to as environmental release of GE crops.
3. Courtesy Permit, which is required to move or field-test a GE plant that is not regulated by the agency.¹⁴¹

7.1.2 ALTERNATIVES TO PERMITS

Should an individual not wish to rely on the permit process, he or she may rely on the Notification Process where the APHIS streamlined the permit process for importation, interstate movement and field testing of certain GE crops: maize, soybeans, cotton, potatoes, tomatoes and tobacco. These are crops with a history of safe release in field trials in the USA. Instead of applying for permit applicants can notify APHIS of the intended movement or field test.¹⁴²

Another alternative is the Petition Process, which allows anyone to request in writing that a regulated plant should no longer be regulated.¹⁴³

¹³⁹ Federal Register Volume 58.

¹⁴⁰ Webber G D “ Regulation of Genetically engineered Organisms and Products” (1996) Biotechnology Series B10-11, Office of Biotechnology State Iowa University Extension USA.

¹⁴¹ Ibid.

¹⁴² Ibid.

7.2 FDA

The FDA has a broad authority under the Federal Drug and Cosmetic Act 21 U.S.C. 301 et seq. (FFDCA), to regulate the introduction of new foods, whether conventionally produced or produced through genetic engineering. This Act gives FDA two kinds of authority to regulate the safety of foods:

1. Authorisation to remove unsafe food from the market place and take appropriate legal action against the wrongdoer.
3. Pre-market approval of food additives, unless they are recognised as safe.

In May 1992, the FDA determined that foods derived from new plant varieties produced by genetic engineering would essentially be regulated no differently from foods created by conventional means. In January 2001, the FDA released new rules on gene-altered foods.

The new rules require the manufacturer of foods derived from bioengineered plants and animal feeds to notify the FDA at least 120 days before the products are marketed. As part of the notification, the manufacturer must provide information showing that the GE foods or feeds are as safe as their natural counterparts. Manufacturers have completed voluntary consultations on many GE foods using the scientific guidelines published by the FDA in 1992. The proposal would make the current practice of voluntary consultations mandatory and require manufacturers to submit safety and nutritional information to the FDA.¹⁴⁴

Food safety evaluations may be required if one or more of the following applies to the product:

1. There are unexpected effects, which occur when the product produces unexpected genetic effects.
2. The presence of known toxicants in the food.

¹⁴³ Ibid.

¹⁴⁴ Formonek R “ Proposed Rules Issued for Bioengineered Foods” (2001) Internet homepage for the FDA. URL – www.fda.gov/fdac/features/2001/201_food.html.

3. The possibility of the nutrient level being altered in any way.
4. The introduction of new substances, which occur when a substance in the product differs to the substances currently found in food.
5. The possibility of allergenicity, which may arise should the product contain a substance that could give rise to an allergic reaction.
6. The product contains an antibiotic resistance selectable marker such as the antibiotic marker gene.
7. The Plant is developed to make specialty non- food substances e.g. plants developed to make pharmaceuticals.
8. Issues specific to animal feeds¹⁴⁵.

Labelling under the new rules is voluntary, and is probably unlikely, because the industry does not want it for fear that it may retard sales. Further, according to critics of the new rules, what seems to be missing is the need for testing to guarantee that the GE food will not cause allergies or create toxic reactions.

According to the FDA, however, testing is not necessary when it considers the GE crops and food to be the same as their conventional counterpart.

7.3. EPA

EPA regulates pesticide under two federal laws, The Federal Insecticide, Fungicide, Rodenticide Act 7 U.S.C. 135 et seq. (1972) (FIFRA), makes the EPA responsible for regulating the distribution, sale, use and testing of pesticides in order to protect humans and the environment. The Federal Food, Drug and Cosmetic Act (FFDCA) authorise the EPA to set tolerance levels or establish exemptions from the requirement of a tolerance for pesticide residues in or on food crops. A tolerance level is the amount of pesticide that may legally remain on a crop after harvesting.

The Food Quality Protection Act of 1996 Public Law 104 to 170 (1996) (FQPA) amended FIFRA and FFDCA sets tougher standards for new and old pesticides and to make uniform requirements regarding

¹⁴⁵ Federal Register Volume 57.

processed and unprocessed foods. This Act establishes a single safety standard under FFDCA by which a tolerance level is set and not a risk-based standard. It establishes a tolerance reassessment programme and sets out a schedule whereby the EPA must reevaluate all tolerances that were in place as of August 1996 over the next 10 years.

The Endangered Species Act of 1973 7 U.S.C. 136, 16 U.S.C. 440 et seq. (1973) (ESA) prohibits any action that can adversely affect an endangered or threatened species or its habitat. In compliance with this law EPA must ensure that the pesticide it registers will not harm these species.

The EPA provides guidance for producers of food plants that produce pesticides. If one or more of the following signals exist, the food producer must consult with the EPA for review under FFDCA:

1. The pesticide is not derived from a known food source. Bt is an example of this type of pesticide.
2. The pesticide is derived from a known food source and is introduced into a known food source, but the way humans are exposed to it in their diets changes, for instance the food may contain more of the pesticide than it did before.
3. The pesticide has a different structure, function or composition than its counterpart that already occurs in food. For example the structure of a protein pesticide that already occurs in food could be altered significantly.¹⁴⁶

State legislature has the authority to determine what products can and cannot be sold in a State. State regulation of GE plants varies from State to State. In general state departments of agriculture become involved in a process when a GE plant is moved in or out of the State or when it is to be field tested in the State. Regulating GE foodstuffs is a public process in terms of the Freedom of Information Act, which allows members of the general public to obtain copies of APHIS permit applications for moving or field-testing GE plants.

¹⁴⁶ Homepage for US Environmental Protection Agency: URL - www.epa.gov/pesticides/regulating/laws.htm.

The Federal Register Environmental Documents section contains the full text of selected Federal Register documents issued from the EPA or other Federal Agencies that concern environmentally related issues. The Code of Federal Regulations (CFR) is a codification of the rules published in the Federal Register by the Executive departments of the Federal Government. The CFR is divided into 50 titles, with environmental regulations contained in Title 40.¹⁴⁷

¹⁴⁷ Ibid.

8. THE POSITION IN SOUTH AFRICA

South Africa is far from an ideal crop producing country, as less than 15% of the land is arable. There are serious climatic constraints such as drought¹⁴⁸. This is probably the reason why South Africa's uptake of GE has been one of the fastest in the world. In 1999 250,000 hectares of the country was planted with GE crops. By 2000 this figure had increased by 50%. GE seed is the primary agricultural biotechnology import into the country. The major foreign biotechnology corporations are currently "Monsanto", "Pioneer Hi-bred International", "Syngenta" and "Aventis". The major governmental institutions in South Africa that conduct and promote public agricultural biotechnology research are the Agricultural Research Council (ARC) and Council for Scientific and Industrial Research (CSIR).

South Africa started to address issues related to GE in the 1970's through the establishment of SAGENE¹⁴⁹ as the national advisory body on biotechnology research and development, which was not adopted by the new Ministers at the end of the apartheid regime. SAGENE was primarily focused on food safety as a public good, and eventually the old biotechnology regulation was gradually replaced by a new regulatory system, of which the GMO Act was passed in 1997.

South Africa is the only one of the 14 Nation South African Development Community (SADC) to license the production of GE crops. South Africa has already planted its first GE crop suitable for human consumption, white maize, which is the staple food of many South Africans. The first two GE crops grown were not for human consumption. The first was pest resistant cotton and the second pest resistant maize for animal feed. South Africa has no GE labelling in place so the white maize that has been genetically engineered will not be labelled as such,¹⁵⁰ until the Draft Regulations on labelling published in the Government Gazette (R366) of 4 may 2001 are enforced.

¹⁴⁸ Homepage for the Department of Health URL – www.doh.gov.za

¹⁴⁹ South African Genetic Experimentation Committee.

¹⁵⁰ M Butler and D Hallowes op cit note 1 at 5

South Africa is the first country in the world in where small-scale farmers are planting GE crops. For example, since 1998 Bt cotton has been grown with reported levels of success in the Makhatini flats in Kwazulu Natal. It would seem that Monsanto has used this as a propaganda tool, but the reality is quite different and there is concern for the following reasons:

1. High Dependency: Uptake of GE cotton at the Makhatini flats has been made possible through the combined efforts of the Land Bank, Monsanto and the Department of Agriculture (DOA). Farmers have been granted easy access to the markets for their crops and credit to purchase inputs such as fertilizers, herbicide, pesticide and water.
2. Unequal Access: It is not the most marginalised producers that are benefiting from Bt cotton but rather the larger cotton producers who have easier access to land and credit to purchase expensive Bt cottonseeds.
3. Debt Trap: The farmers who access credit are locked in a debt cycle.
4. Short Lived Benefits: Reduced use of insecticide is not the case in Makhatini. Commercial farmers planting Bt cotton are already returning to normal spraying patterns because of outbreaks of secondary insects such as aphids and stinkbugs.
5. Planting and Ignorance: Many small-scale farmers plant Bt cotton with no understanding of the technology or their obligations under the licensing contract.¹⁵¹

A central criticism of the Makhatini Flats study is the fact that massive resources that were not previously available have been mobilized. Capital, insurance, chemicals, fertilizers and extension programmes from both the commercial and state sources, that were not previously present, have all become available in an endeavor to make this project a success.

8.1. HOW SA REGULATES GENETICALLY ENGINEERED FOOD

On a national level there are four main pieces of legislation:

1. Genetically Modified Act 15 of 1997 (GMO)
2. Environmental Conservation Act 73 of 1989 (ECA)

¹⁵¹ M Butlers and D Hallows op cit note 1 at 9.

3. Foodstuffs Cosmetics and Disinfectants Act 54 of 1974 (FCD)
4. National Environmental Management Act 107 of 1998 (NEMA)

8.1.1. GMO ACT

This is the main piece of legislation dealing with the trade and production of GE organisms. The Department of Agriculture (DOA) is the responsible government body to implement the Act. The Registrar located with the DOA administers the Act¹⁵². The Registrar receives all the applications for permits to conduct GE trials or to release commercial products derived from GE organisms. After processing the applications, the Registrar hands them over to the Scientific Advisory Committee¹⁵³ who conducts safety reviews and risk assessments. If the GE organism successfully passes the scientific review, the application is forwarded to the Executive Council¹⁵⁴; composed of representatives of the Ministries of Agriculture, Environmental Affairs and Tourism, Trade and Industry, and Health. It is an independent decision making body that will make decisions on all applications. The decisions are based on issues of trade, labour, and safety to humans, the environment and social economic effects.

The Act applies to living organism, not to processed goods such as flour and oil. The act defines genetically modified organisms as “an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both...”¹⁵⁵

The Act shall apply to:

- “a) genetic modification of organisms
- b) development, production, release, use and application of genetically modified organisms and
- c) use of gene therapy¹⁵⁶

¹⁵² Section 8.

¹⁵³ Section 10.

¹⁵⁴ Section 3.

¹⁵⁵ Section 1.

¹⁵⁶ Section 2.

8.1.2. PROBLEMS WITH THE GMO ACT

The GMO Act has been criticised for not focusing on the environmental concerns with regards to GE organisms; instead it has the primary focus of development, production, use and application of GE organisms.

No mandatory impact assessment is required. This requirement is left to the discretion of the Executive Council. Risk assessment procedure is not prescribed, the Act provides that the Minister may make regulations prescribing the procedure to be followed by an application for the purpose of drawing up risk assessment. It is unknown what is required in the risk assessment¹⁵⁷, as no risk assessment has been carried out to date because the government cannot afford to do so¹⁵⁸. The precautionary principle of NEMA is negated; the principle basically states that that if we are unsure about the safety of a technology we should not implement it. The GMO Act implies the opposite, stating that the lack of scientific knowledge about risk should not prevent implementation of the technology.

Section 17 of the Act states “Users shall ensure that the appropriate measures are taken to avoid an adverse impact on the environment, which may arise from the use of genetically modified organisms.” This indicates an awareness of the possibility of the risk involved when producing, using and distributing GE organisms.

The preamble of the Act it states, “to establish common measures for the evaluation and reduction of potential risks arising out of activities involving the use of genetically modified organisms”. Clearly the Act is encouraging activities involving GE organisms while acknowledging the possibility of the potential risks, this negates the principle of NEMA. The rest of Africa has operated on the precautionary approach where food should be proven to be safe rather than to be not proven to be unsafe.

¹⁵⁷ Section 20(1)(b).

¹⁵⁸ Biowatch Press Release “Parliamentary Promises to Improve GMO Act” URL – www.biowatch.org.za/pr16-04-03.htm.

Public participation is not adequately provided for. Civil Society participation has been excluded from the Advisory Committee, even though Section 10(1)(b) states that 2 people from the public Sector shall form part of the Advisory Committee, which is contrary to the principle of public participation set out in Section 2 of NEMA.¹⁵⁹ It would seem that the only opportunity for public participation is by way of notice and comment procedure linked to permit applications for environmental releases.^{160 161} However applications are being granted with no civil society representation on the Council and so it is not possible to tell what safety assessment is being used when making the decision to approve the application.

Section 17(1) and (2) of the Act deals with liability and attempts to absolve those responsible for the development of GE organisms by placing statutory liability for damage on the “users” of GE organisms. These provisions are in conflict with the “polluter pays” principle of government policy. Section 19 deals with the appeal process and it is evident that this procedure is only useful to members of the public if they know when an applicant has been notified of the approval. No provision is made for notifying the public of an approval. DEAT has no jurisdiction and is excluded from the process of permitting GE organisms to be released into the environment, although the environment is its responsibility.

8.1.3. ECA

On the 5th January 1998, Item 6 of the EIA Regulations, which relate to genetic engineering of organisms, came into force. The Environmental Impact assessments (EIA) are enforced through the ECA. The EIA Regulations have been criticised, as they require the EIA 's' to be conducted prior to the genetic engineering of the organism when the GE organism is being tested, rather than prior to the GE organism being released into the environment. The EIA provision on GE organisms only applies to genetic engineering that took place after the 5 January 1998.

¹⁵⁹ M Mayet “Analysis of South Africa GMO Act of 1997” URL – www.biowatch.org.za/gmoact.htm.

¹⁶⁰ Section 5(a).

¹⁶¹ Government Notices R1182, R1183 and R1174 of 5 September 1997 Government Gazette 18261.

8.1.4. FCD

Regulations governing the labelling of foodstuffs obtained through certain techniques of genetic engineering are enforced through the FCD Act. The Department of Health (DOH) administers the Act, which is enforced through the local government.¹⁶² At present the FCD does not require any GE food to be labelled as such. This decision may change with the Draft “Regulations Governing the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification”, published in the Government Gazette (R366) of 4 May 2001, where the Minister of Health aims to achieve 2 objectives:

1. To establish tracability that allows the withdrawal of foodstuffs from the market place that could be a risk to human health or the environment and
2. To assist in the control and verification of labelling claims.

The safety assessment of GE products falls within the ambit of this act as genetically engineered products do not fall within the definition of “Genetically Modified Organism” for the purposes of the GMO Act. The safety assessment is done as part of the safety assessment of foodstuffs. Although FCD requires foods to be safe before being released commercially, the DOH or any government department does no actual testing.

8.1.5. NEMA

There are numerous provisions in NEMA that are important and applicable to GE organisms, however for the purposes of this paper only the most relevant provisions to GE of organisms will be discussed.

This act is a framework for regulating activities, which may have an impact on the environment. Of particular relevance is the principle that the loss of biodiversity or disturbance of ecosystems is to be avoided, or where it cannot be avoided, be minimised and remedied.¹⁶³

¹⁶² Section 23.

NEMA stipulates that a “risk averse and cautious approach” must be applied in applying sustainable development.

Section 28 of the Act deals with the “duty of care” provision, which is important in the context of GE organisms as it creates the opportunity for new EIA’s to be carried out with existing commercial releases of GE organisms. The Act does not set out how the provisions should be enforced; the focus is on what should happen if a transgression occurs.

Section 33 of the Act deals with private prosecution and states that “ any person may (a) in the public interest (b) in the interest of the environment institute...a prosecution.” It will however be up to civil society to monitor compliance with the environmental laws pertaining to GE organisms.

8.2 NATIONAL BIOTECHNOLOGY STRATEGY

In May 2001, the Department of Arts, Science and Technology (DASAT) published a Biotechnology Strategy, which makes the assumption that modern biotechnology will deliver major benefits for agriculture, rural development and job creation. Its main aim is to motivate the allocation of government resources for developing “regional innovation centers” as plant farms for biotechnology, strengthening links between academia, industry and stimulating the creation of new IPR’s.¹⁶⁴

The main goals of the strategy are to ensure that the strategy meets national imperatives, to focus on comparative advantage, and to harness existing scientific and technological competencies. Further goals are to address issues of biological safety, and to review the strategy in the light of national priorities and international trends.¹⁶⁵

¹⁶³ Section 2(4)(a)(vii).

¹⁶⁴ M Butler and D Hallows op cit note 1 at 14.

¹⁶⁵ P Aerni *Public Attitudes Towards Agricultural biotechnology in South Africa* (A joint research project of the Center for International Development, Harvard University USA and the Southern Africa Labour and Development Research Unit, University of Cape Town) (2002) 12.

In the Executive Summary of the strategy it is suggested that these goals be achieved by stimulating growth in the field of biotechnology as it is believed that it will make an important contribution to national priorities of human health, food security and environmental sustainability. Throughout the rest of the report there is no mention of the kind of public policy needed to manage biotechnology as a public good that can help address these problems of national priority. Cuba is quoted as an example of how to invest in biotechnology to solve such problems but the report does not elaborate to what extent a similar approach would be appropriate for South Africa.

The strategy establishes the Biotechnology Advisory Committee (BAC), the responsibilities of which will be to implement strategy, coordinate biotechnology research and development and alignment with national priorities. It further creates regional innovation centres (RIC's) to act as platforms for the growth of biotechnology. RIC's will facilitate funding and better university-business linkages in biotechnology research.¹⁶⁶

8.2.1 PROBLEMS ASSOCIATED WITH THE BIOTECHNOLOGY STRATEGY

The strategy has been criticised heavily by the South African Freeze Against Genetic Engineering (SAFEAGE), who has called on a five-year freeze on GE in South Africa. SAFEAGE criticises the strategy particularly because of the proposed financial support of the biotechnology industry without any consideration for proven, more appropriate alternatives, in the absence of a national policy on biotechnology. At present South Africa's spending on social services is inadequate and there is a policy of privatization. It is difficult to understand the rationale behind financing the corporate sector that will then take the results patent them and make only their shareholders wealthy.¹⁶⁷

In the Foreword to the strategy is the statement: "We will need to ensure that the potential risks to human health and the environment arising from the commercial use of genetically modified organisms in food

¹⁶⁶ Ibid.

¹⁶⁷ SAFEAGE response/ comments to the National Biotechnology Strategy for South Africa June 2001 dated the 24th October 2001.

production are properly managed”. This statement ignores the fact that the British Medical Association has called for a moratorium on GE foods because of the risk of antibiotic resistance and allergies. There is a recognised risk to health in the United Kingdom, which has efficient monitoring capacity, and it seems unlikely that South Africa will be able to properly manage these risks.¹⁶⁸

It would seem that the strategy is based on the unquestioning and uncritical acceptance, on the basis of the information from the biotechnology industry, about the potential benefits to the environment, human health and food security. In the Foreword it states that the objective is to “protect and cherish our rich environment”. At present this is not synonymous with genetic engineering, which leads to monocultures and destruction of biodiversity. Numerous studies have shown that herbicide resistant crops are resulting in the development of super weeds through cross-pollination as discussed in Chapter 4 of this paper. The result is the increased use of environmentally harmful herbicides.

The strategy further refers to the assistance of the biotechnology industry in food security in South Africa. The strategy does not mention the effect on small emerging farmers; in particular of the increased seed costs and increasing costs of chemicals to combat super weeds and herbicide resistant insects, as discussed previously in this Chapter. Far more research needs to be done in this field in South Africa. The government cannot rely on overseas examples to illustrate the benefits as it does in the Biotechnology Strategy paper.

The proposed labelling legislation by the Department of Health is totally inadequate to protect consumers who are averse to consuming GE food. On the issue of labelling the strategy states “This also has implications for the general literacy levels of South African population.”¹⁶⁹ General literacy levels have not been improved to cope with present food labelling which includes an assortment of chemical agents. To imply that GE food labelling cannot be implemented because of low literacy levels is not an adequate reason.

¹⁶⁸ Ibid.

The strategy further refers to the South African Bill of Rights where it states that every South African has the right of access to health care, food, water and social security. Chapter 2 subsection 27(2) states that the state “ must take reasonable legislative and other measures...to achieve the progressive realisation of these rights”.¹⁷⁰This implies that, by relying on biotechnology, these aims will be achieved. What the strategy does not refer to in the Bill of Rights is Chapter 2 Subsection 12(2)(c), which states, “Everyone has the right to bodily and physiological integrity, which includes the right not to be subjected to medical or scientific experiments without their consent”. By exposing consumers to GE food without labelling it and without disclosing the full extent of the risks shows a blatant disregard for this fundamental right.

8.3. BIODIVERSITY BILL

The Biodiversity Bill provides for the establishment of a National Biodiversity Institute to replace the current National Botanic Institute, and sets out an enabling regulatory framework for the integrated management of South Africa biodiversity¹⁷¹.

The Biodiversity Bill has the following objectives:

1. To provide within the framework of NEMA, for the management and conservation of biological diversity within the Republic,¹⁷²
2. To give effect to the international agreements relating to biodiversity which are binding on the Republic.¹⁷³
3. To ensure that the state is the trustee of all biological resources,¹⁷⁴ and to provide for a National Biodiversity Institute to assist in achieving the above objectives.¹⁷⁵

¹⁶⁹ Biotechnology Strategy (Chapters 3.7, page 36).

¹⁷⁰ Biotechnology Strategy (Chapter 3.6 pages 34).

¹⁷¹ Government Gazette Volume 451 No 24311 Notice 49 of 2003.

¹⁷² Section 2(a)(I).

¹⁷³ Section 2(b).

¹⁷⁴ Section 3.

¹⁷⁵ Section 2(d).

As the lead agent, the Department of Environmental Affairs and Tourism (DEAT) has a responsibility to implement the Convention on Biological Diversity, to which South Africa is party, and the Biodiversity Act will be the appropriate legislative tool for achieving this.

8.3.1. PROBLEMS ASSOCIATED WITH THE BILL

According to Biowatch¹⁷⁶ the Bill may be criticised because, although negative impacts of GE organisms on biodiversity have been reported from many countries and in numerous scientific papers, guidelines to ensure that they are safely handled are not included in the Biodiversity Bill. Although a regulatory framework does exist under DOA in the form of the GMO Act, the main focus of the Act is to promote development and the production of GE organisms rather than to ensure that they are handled in an environmentally sound way. The appropriate authority to protect South Africa's biodiversity against the potential risks of genetic engineering is DEAT, and the appropriate Act within which to do it is the Biodiversity Bill.

Recognising the danger that alien invasive species pose to biodiversity, the Biodiversity Bill has a separate chapter dealing with them. The Bill loosely defines alien invasive as “species outside of its natural distribution range that a) threaten ecosystems, habitats or other species... c) may result in economic or environmental harm to human health”¹⁷⁷. For similar reasons GE organisms warrant provision in the Bill on how they should be safely managed, and yet there is no provision for the safe management of GE organisms.

The primary legislative regulation on the development, production, trade, use and application of GE organisms in South Africa is through the GMO Act, which is administered through the DOA. The responsibility of the DOA is agriculture, not biodiversity and environmental protection. The appropriate

¹⁷⁶ A non-governmental organisation, which monitors, publicises and researches issues of genetic engineering, biological diversity and sustainable livelihoods in South Africa. Apart from many other activities, Biowatch assists in training and awareness of the aforementioned among consumer groups, farmers and NGO's.

¹⁷⁷ Chapter 1 section 1.

body to administer GE organisms would be DEAT because the protection of the environment is its responsibility. If the Biodiversity Act is to provide for biodiversity to be managed and conserved to the full extent possible, and if DEAT, as the trustee of biodiversity in South Africa, is to fulfill its role then recognised threats to biodiversity must be dealt with within the Biodiversity Act. Failure to place GE organisms within the ambit of the Biodiversity Act will irrevocably undermine the conservation and management of biodiversity in South Africa.¹⁷⁸

8.4. THE WHITE PAPER ON THE CONSERVATION AND SUSTAINABLE USE OF SOUTH AFRICA'S BIOLOGICAL DIVERSITY NOTICE 1095 OF 1997

This paper was drawn up in order to incorporate the Convention on Biological Diversity (CBD). The White Paper identifies the CBD as a policy objective to regulate the transfer, handling, use and release of GE organisms in order to minimise the risk to biodiversity and human health. The paper identifies DEAT as the lead agent in its implementation and in fact designates DEAT as the “champion” of biodiversity.¹⁷⁹

The paper stipulates that government is of the belief that a proactive precautionary approach should be taken with regard to transfer, handling, use and release of GE organisms. This approach will balance risk against social, economic and environmental benefits. To achieve the objective, the paper states that Government will review existing and proposed legislation, and participate in international efforts to develop a Biosafety Protocol. It will further adopt a Code of Conduct for implementing, releasing or research of GE organisms and support research for future understanding, improve public education, and develop and support national training in risk assessment.¹⁸⁰

The role of DEAT with regard to administering the Convention on Biological Diversity is to promote global regional and national cooperation with regard to conservation of biodiversity, and to formulate and review policy, while strengthening communication networks with the provinces and national government

¹⁷⁸ “Input on Biodiversity Bill as Published on the 24th January 2003” Biowatch-URL-www.biowatch.org.za/biodiv_input.htm.

¹⁷⁹ Ibid.

departments. Promoting and facilitating the integration of biodiversity considerations into sectoral and cross-sectoral plans, programmes and policies, and organising the participation of national provincial government are further roles.¹⁸¹

Due to the cross- sectoral nature of biodiversity, several other national government departments will play a vital role in the implementation of the policy. The Department will include Agriculture; Land Affairs; Water and Forestry; Trade and Industry; Foreign Affairs; Health; Transport; Housing; Welfare and Population Development; Arts, Culture, Science and Technology and Finance.¹⁸²

8.5. INTERNATIONAL TREATIES AND CONVENTIONS

South Africa has ratified a number of international treaties and conventions that have implications for how the country exploits genetic engineering.

8.5.1. TRIPS

TRIPS, in particular Article 27(3)(b), has already been discussed and which has implications for ownership through intellectual property rights.

8.5.2. INTERNATIONAL UNDERTAKING ON GENETIC RESOURCES OF FOOD AND AGRICULTURE

The International Undertaking on Genetic Resources of Food and Agriculture facilitates easy access to organisms, including propagating material for food security purposes under the auspices of the Food and Agriculture Organisation.

¹⁸⁰ Chapter 3 sections 1.7.

¹⁸¹ White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity (Chapter 4, Section 4.2.1).

8.5.3. CONVENTION ON BIOLOGICAL DIVERSITY

This has already been discussed, and is relevant to GE of organisms because it has several provisions relating to the development and use of biotechnology and the safe application of products.¹⁸³ The CBD recognises that it is indigenous and local people who have granted and given us knowledge and technologies on biodiversity sustainability. It stipulates that the knowledge, technologies and biodiversity of indigenous and local people should be accessed and used with their prior informed consent and with their involvement. It also stipulates that IPR's should be supportive of, and should not run counter to, the CBD objectives, which are the conservation and sustainable use of biodiversity and the fair and equitable sharing of its benefits. Article 22 of the CBD states that "the provisions of this convention shall not affect the rights and obligations of any contracting party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to the biological diversity." When this provision is seen as the vantage point, patenting of life forms and biological process should not be allowed. But seen from the vantage point of TRIPS Article 27(3)(b) enables the effective control of the use of some technologies mostly owned by the more western countries. TRIPS insists that microbiological applications and plant varieties shall be protected by IPR's¹⁸⁴. South Africa is party to both agreements, and thus the question that should be asked is what should a country that is party to both agreements do? South Africa should decide which of the two is the more valid instrument for helping benefit from its biological resources and conserving them, and for maximising the benefits for the local indigenous communities. It should evaluate its decision based on its economic and social life. Further TRIPS looks merely at the trade side when it allows IPR protection, not as to whether it effects biological diversity, thus if IPR protection becomes harmful, obviously there should be no trade in it.

8.5.4. PROTOCOL TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

¹⁸² White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity (Chapter 4, Section 4.2.1).

¹⁸³ A National Biotechnology Strategy for South Africa (Chapter 3.5.1.).

The Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological and Toxin Weapons and on their Destruction Convention was signed in 1975 and has already been implemented in South Africa.

8.5.5. CARTAGENA PROTOCOL ON BIOSAFETY

South Africa is party to the Cartagena Protocol on Biosafety by accession on the 12 November 2003, although she did not sign. The protocol covers the protection, handling and use of living modified organisms and the conservation of sustainable use of biological diversity.¹⁸⁵

¹⁸⁴ T Berhan and V Shiva op cit note 47.

9. CASE STUDY ON THE PUBLIC ATTITUDES TOWARDS AGRICULTURAL BIOTECHNOLOGY IN SOUTH AFRICA

This survey was carried out in co-operation with the South African Labour and Development Research Unit and the University of Cape Town in November 2001. The study was funded by grants from the Swiss National Science Foundation and the Hochstrasser Stiftung. There were 48 respondents from the following categories:

1. Academia: 12 respondents from the field of agronomy, biotechnology, natural and social sciences.
2. NGO's: 13 respondents from various NGO's
3. Government: 8 respondents from government agencies related to health, agriculture and education. Also from Research Councils and Advisory Committee.
4. Business: 7 respondents from biotech food and retail industries.
5. Other: 8 respondents.

The first part of the questionnaire asked the question " Which of the following problems in agriculture do you consider to be the most important in your country and how do you assess the potential of genetic engineering for solving the problems?"

The main concerns were drought, soil erosion, reduced soil fertility, high use of pesticide, pest infestation and plant disease as well as inadequate agricultural policy. All the respondents seemed to agree that drought resistant maize could have a positive impact for both small and large-scale farmers. The same applied to Bt cotton.

Part 2 of the questionnaire consisted of positive and negative statements regarding genetic engineering in agriculture. The positively worded statement that "agricultural biotechnology is just a new tool that helps to solve problems that cannot be solved by conventional breeding" received the highest agreement amongst the respondents. This was followed by the negative worded statement that "Organic Farming Integrated Pest Management is a better solution for resource poor farmers to ensure their food security". The third

most popular statement chosen seemed to contradict the previous two statements and stated “genetically engineered food can contribute to food security”. The reason provided for this decision was that it was probably believed that large scale farmers would have access to GE crops, and thus they would increase food production, which would ultimately lower food costs. A further confirmation was the rejection of the statement that a “combination of organic farming and agricultural biotechnology might particularly benefit the poor”. It further became apparent that the respondents believed that the input costs would lead to more indebtedness. However, the respondents were all of the opinion that GE crops do not pose a serious health risk.

Part 3 of the survey was about trust and legislation. Most of the respondents had reservations about the current biosafety regulation and its implementation, as well as doubts regarding the sustainability of the Bt crops because of the possibility of the pests becoming Bt resistant.

The second section of part 3 dealt with the debate on mandatory labelling. According to the respondents the statement that received most agreement was that mandatory labelling was necessary in a democracy where consumers were supposed to have the right to choose the products they prefer. A concern that did arise in the questionnaire was that mandatory labelling would cause additional costs and consequently raise the prices of food products and make them less accessible to low purchasing income groups.

In conclusion it would seem that the survey showed that the respondents recognised biotechnology as having a significant potential to solve the problem of drought, and other important agronomic problems such as pest infection and plant disease. Moreover the transgenic crops already under cultivation in South Africa such as Bt cotton and drought tolerant corn were considered to have a positive impact for large and small-scale farmers alike. Further there was a strong support for mandatory labelling based on the right to choose.¹⁸⁶

¹⁸⁶ Aerni op cit note 165.

This survey may be compared to another similar survey conducted at the same time in South Africa by the Foundation for Education, Science and Technology in South Africa (FEST) in October 2001.

The purpose was to determine the public knowledge and understanding of GE foods, as well as to review public attitudes about usefulness of the technology, its acceptability to consumers, and whether or not they thought the technology should be encouraged.

The survey was carried out using 1000 South African's between the ages of 16 and 60 living in the major metropolitan areas of the country.

The results were as follows:

1. 27.4% of the respondents felt somewhat familiar with the term "genetically modified".
2. More than 60% said that they did not know whether GE food was being sold in the supermarkets.
3. Only 3.6% of the black respondents indicated that they were familiar with the above term.
4. Almost 40% of the respondents agreed that the use of modern biotechnology was a way to improve our nutritional value and taste of foodstuffs, while 41.7% were unsure.
5. Almost half of the respondents would be willing to buy GE food if it improved the taste, while 34% were unsure and 21.2% would not buy GE food.
6. More than 60% agreed that GE food should be clearly labelled. When only looking at the respondents with degrees, that figure increased to 86.1%.

This survey indicated that there needed to be more public awareness and education on GE food; in particular, amongst the less educated and poorer communities. The public was currently ill informed and uncertain about this topic. The survey also confirmed that consumer's trust would depend on the clear labelling of GE foods. ¹⁸⁷

10. CONCLUSION

The agriculture that produces food is crucial for all human life. The nutritional value, and safety, of our food is the basis of human health. In addition to these qualities, food holds a special place in the communal, personal and spiritual lives of many people. Furthermore, the agriculture that produces food has an effect on biodiversity, and there are indirect benefits for humans from an environment that is rich in biodiversity. For instance, it is better to walk through a countryside where you will see life, wild flowers and birds singing, rather than through a countryside where the hedges have disappeared, where vast fields of GE crops spread endlessly, and where the only sound to be heard, is the roar of a tractor pulling a boom sprayer. It is obvious which experience stimulates pleasure, and a sense of well being that is good for human health. Modern food production methods have a vast impact on human health before one even enters the debate of the physically harmful effects of GE organisms on human health, the environment and the economy.

The belief that hunger is due to a gap between food production and human population density is one that has long since been discredited. Multinational companies have concentrated on developing crops that will earn high profits, not crops that best contribute to solving the world's food problems. One can conclude that instead of alleviating world hunger, GE crops threaten rural livelihoods, food security and local control over biodiversity. The food shortages in developing countries are a complex interplay of drought, poverty, lack of transport and storage infrastructure and political instability. It is simplistic to contend that the biotech industry can alleviate these shortages by selling expensive seed to small-scale farmers, who subsequently become entangled in a debt cycle.

The safety of GE food, which may cause allergens, antibiotic resistance and virus resistance in human beings, is a major concern. The imbalance of nutrients and the risk of contamination are still very grave risks when food crops are genetically engineered

¹⁸⁷ M Joubert “Despite Ignorance and Uncertainties Many SA Support Biotechnology in Food” A Study at

Where GE seeds are patented, it is difficult for a farmer who has used his own seed for generations to understand that, as a result of policies determined by governments and multinational companies, there are IPRs' over living organisms.¹⁸⁸ The very existence of GE crops depends on multinational companies being able to patent life. Companies that invest large amounts of capital in the engineering of plants will only do so if they can protect those rights and obtain exclusive rights to the proceeds of those seeds. The controversial TRIPS agreement has created a global regime of IPR's over life.

It would seem that USA is moving rapidly in an attempt to distribute and trade in GE food. It is the leading country in the use and production of GE food. The FDA and the USDA regulate the development of animal and human health products including those developed through genetic engineering. The FDA has reviewed all GE food brought to market and has found no reason to believe that it could pose any threat to human health. Further the FDA has not required all GE food to be labelled as such solely because it is involved in genetic engineering. In Europe, consumer resistance to the introduction of GE crops has initiated a looming trade war between Europe and the USA with the European Union banning the import of GE crops and animal feed, with major implications for food security, agriculture and trade.

South Africa, it would seem, is embracing GE agriculture despite the rest of Africa applying the precautionary principle. The GMO Act, which is the central piece of biosafety legislation, is widely considered to be out of step with NEMA and the Constitution. Its provisions for the assessment and monitoring of environmental impact assessments and risks are wholly inadequate and contravene the basic principles of public participation and transparency in decision-making. Liability for any damage caused is placed on the user of the product and not the proponent of the technology. The responsibility of the DOA is agriculture, not biodiversity, and while it does have a general duty to uphold environmental protection via NEMA, it is not the appropriate organ of state for protecting biodiversity from GE organisms.

Understandably the GMO Act was implemented at a time when the country was rising out from the apartheid era and, due to its numerous inadequacies, it is under review at the moment. However, in a country ranking as the third most biologically diverse in the world, it is unacceptable that no EIA has been

the Science Communication Research at FEST October 2001.

but, rather, promotes the release and use of GE organisms as part of South Africa's future. To make matters worse, there is no mandatory labelling of GE food, which further adds to the mistrust of the biotech industry.

The general public's acceptance of GE food may depend on the perception of risk and benefits. Do the benefits of these risks outweigh the risks that they pose? Risk is the estimation of the chance that undesirable effects may occur. There is a perception by the public that GE is to some extent risky and this is because of the secrecy, for commercial reasons, the lack of segregation and labelling of foods, and poor public relations on the part of the food industry. Science bases the risk theory on whether something can be proved or disproved. To apply this principle in every day life is difficult, however. For instance it is difficult to prove that a small amount of pesticide on a specific food product will cause a harmful effect. As previously discussed, there are too many factors and influences involved.¹⁸⁹

Ultimately the choice should be left to the consumer to educate themselves on the issue of GE crops and make an informed decision of whether or not they wish to consume food that has been genetically engineered. However, with the law as it stands currently in South Africa, food that has been genetically engineered does not have to be labelled. To date, the Draft Regulations for labelling have not been promulgated. Even if the labelling of GE food does become mandatory, those consumers who would prefer not to have animal derivatives in their food would not be able to determine if the genetic engineering occurred used animal genes. Scientists argue that a gene loses its identity when it is copied and the copy is inserted in to the target species, therefore losing the animal characteristics. With this in mind the idea of "pig in my potato" may just become a reality.

Whether or not we could do without GE, it would seem that SA government has clearly decided that it is part of our future. For it to develop usefully, there is a need for national biosafety laws that have rigorous provisions on risk assessment and risk management, to ensure human health, biodiversity

¹⁸⁸ Krige Dulcie "There are Better Ways to Feed Africa than with GM Crops" Sunday Times March 2003.

and environmental integrity, as well as socio economic well being.

¹⁸⁹ J Humphrys op cit note 34 at 201.

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