Background report

Genetically modified crops revisited

GM crops in the agro-industrial commodity market

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Preface

This report is the product of an internal project of AIDEnvironment. The primary objective of the project was to gain a deeper insight in the issues surrounding genetic modification. During the project, we have indeed increased our knowledge in this respect. Nevertheless, it became clear that definitive answers are very hard to find in this field. The fierce debate on the benefits and risks of GM stands in the way of a progressive intellectual analysis of GM and its impacts on economic nature and environment and the well-being of human kind. This has inspired us to write a short analysis, titled Towards an effective GMO debate. In this analysis, we observe that the development and application of GM increases worldwide in spite of ongoing protests by NGOs. We argue that the NGO influence in the debate is diminishing, while their concerns remain legitimate and unanswered. We advise NGOs to invest in the issue of GM by increasing their knowledge and putting more time and effort in this mega-trend. We also challenge them to leave their polarized points of view and to involve the public and all southern NGOs in the debate, regardless of their view of GMO. We hope this background report will be an effective first step in increasing the NGO knowledge level for those people who have not been deeply involved in the debate so far. Those who have are free to distribute this background report to anyone who may be helped by it.

We would like to express our gratitude to Dr. Simone Mattar Altoë for contributing to our research process and spending many hours on a pro bono basis to help us understand the complex issues at hand. We also want to thank the participants of the NGO Expert meeting that we organized in October 2006 for sharpening our understanding of the public debate in the Netherlands and Europe. We hope the eventual analysis fulfils their expectations and can be of guidance in their important efforts towards a sustainable society.

Amsterdam,

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Chapter 1 Principles of Genetic Modification

1.1 Definitions and History

Genetic manipulation/modification is not synonymous for biotechnology and *vice versa.* Originally, biotechnology referred to traditional fermentation processes such as cheese and beer making. Then, 15 to 20 years ago, it started being used for <u>all</u> processes and technologies implying some "control" the biological systems/cells. Whether or not the yeasts or embryo cells (for example) had been modified. So nowadays, beer making is (conceptually) just as much biotechnology as cloning. Nevertheless, a lot of confusion seems to surround the subject and a proper (present day) definition is needed to set the conceptual boundaries.

Biotechnology has been defined in many ways, but probably the most useful of the definitions is the one from the OECD (Organization for Economic Cooperation and Development). It defines biotechnology as *"the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services"* [1]

Agricultural biotechnology has been used for a long time, as farmers and scientists have sought to improve important plants by selection and breeding. However, historically, biotechnology was an art rather than a science and the molecular mechanisms were not totally understood[2]

One of the most important studies in plant breeding is the one of Gregor Mendel, in 1865. Most of Mendel's experiments were carried out on garden peas (*Pisum sativum*). Mendel's experiments involved the separate examination of seven different characteristics of peas. The idea was of transferring characteristics from parents to offspring. The parents would have dominant (AA) or recessive (aa) characteristics and their offspring would carry AA, aa or hybrids (Aa) characteristics. Mendel's work was unique in showing the mathematical relationship between generations. Mendelism was concerned with the simple inheritance of major genes which control character differences. The characteristics which he studied were each controlled by one gene[3] .

Later on in the early 1950s, researchers working on DNA were using the term "gene" to mean the smallest unit of genetic information. The discovery of the structure of DNA in 1953 and the identification of DNA as genetic material allowed a better understanding of life-forms. It became clearer now that genes were discrete segments of DNA that encoded the information necessary for assembly of a specific protein. The work of James Watson and Francis Crick marked a milestone in the history of science and gave rise to modern molecular biology. In short, their discovery yielded insights into the genetic code and protein synthesis[4].

Figure 1.1 depicts very schematically how a chromosome is made of DNA and in turn the DNA of genes. A gene being either a single "rod" or a set of "rods". One "rod" is called base-pair.

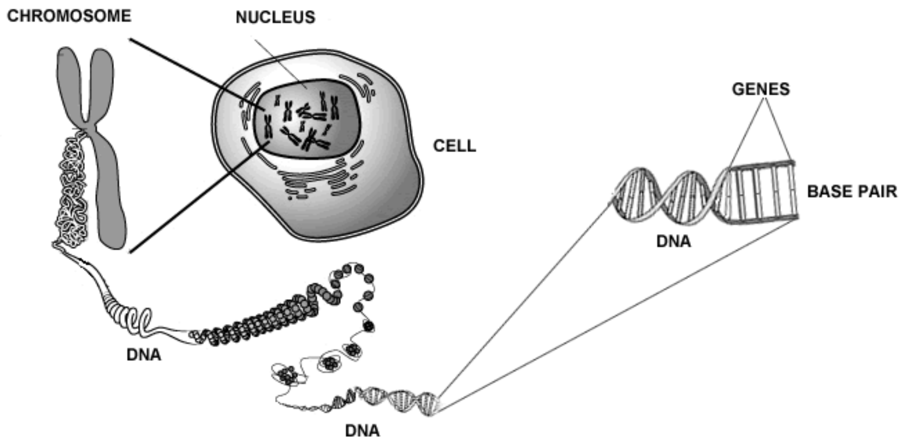


Figure 1.1 Chromosomes, DNA and genes.

From 1953 onwards biotechnological science changed substantially. Finding the genetic code of animal and plant genomes became the greatest challenge:

- In October 1972, the first recombinant DNA molecule was created - recombinant DNA (rDNA) technology is a field of molecular biology in which scientists "edit" DNA to form new synthetic molecules. It is a practice of cutting, pasting, and copying DNA - or, as de media would nicely put, "cloning"[5];
- In 1977, scientists from Harvard developed methods for sequencing DNA - the DNA is composed of four individual nucleotides: adenine (A), thymine (T), cytosine (C), and guanine (G). To decipher a particular piece of DNA, it is necessary to determine the exact sequence of these nucleotides. The sequence of the nucleotides determines the genetic information encoded in a DNA strand. This discovery made mapping and sequencing of genetic material possible[6];
- In September 1994, scientists from the University of Iowa published a complete genetic linkage map of the human genome;
- In 2002 the draft version of the complete map of the human genome was published, and the first part of the Human Genome Project came to an end. Scientists made great progress in elucidating the factors that control the differentiation of stem cells, identifying over 200 genes that are involved in the process[7].

Plant genome mapping has also evolved along the years. In Africa, Australia, Europe and North America dozens of plants are being mapped. Beans, corn, peaches, cotton, wheat and potato are just some examples[8]. The most recent and commercially interesting discover took place in the USA. In September 2006 scientists mapped the genome of a poplar tree. Sustainable or renewable energy - in the form of bio-ethanol, for example - can be produced by trees. [9]. The mapping of the poplar genome (or any other organism) is usually the first step towards before altering its characteristics for economical purposes.
Mapping the DNA of trees and other plants is a tool used to further develop biotechnology. Projects like the Rice Genome Research Program in Asia are changing the dynamics of local (national) agriculture in terms of culture and economics, However, it is just one small part of biotechnology used in agriculture. Plant biotechnology is approached in many different ways.

1.2 Types of Genetic Modification

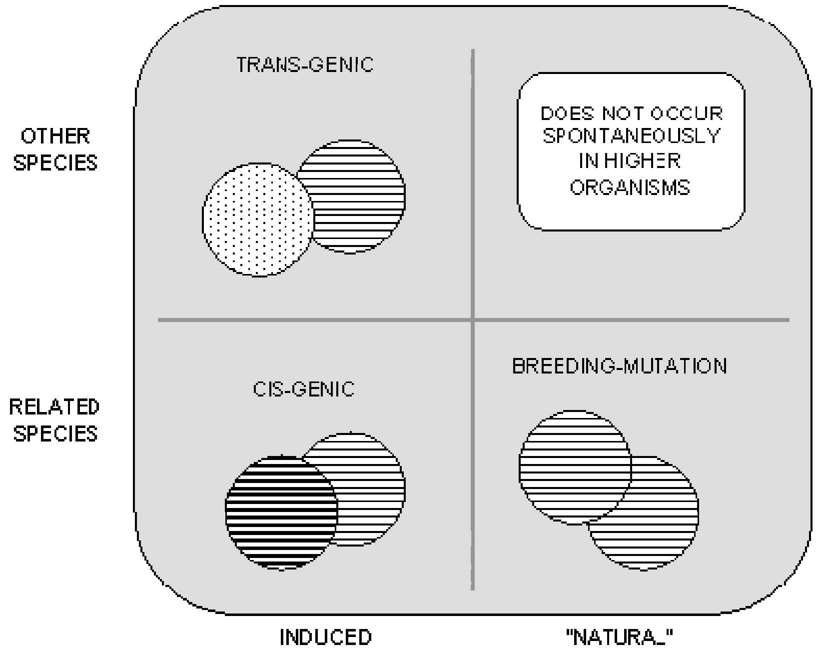


Figure 1.2 Schematic overview of the types of Genetic Modification

1.2.1 Traditional Plant Breeding

Traditional plant breeding aims to develop new varieties from an original plant, combining its qualities with an improved feature that is present in another plant of the same species. This feature may be the resistance to a particular pest or disease, or tolerance to climatic conditions. Basically, traditional plant breeding involves the transfer of pollen containing the gene for a desired trait from one crop variety to another. Eventually, the desired trait will appear in a new family of plants.

In the traditional plant breeding, the desired gene is transferred to the recipient variety without being isolated. When the desired gene is transferred other unwanted genes are also transferred. For this reason, takes years for farmers and scientists to get the desired final product.

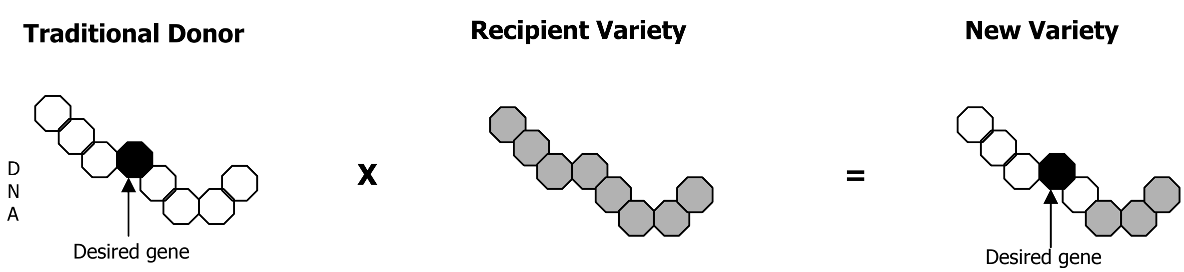


Figure 1.3 Traditional Breeding Model

In traditional breeding, crosses are made in a relatively uncontrolled manner. At the genetic level the results are unpredictable. DNA from the parents recombines randomly, and desirable traits such as pest resistance are bundled with undesirable traits, such as lower yield or poor quality. Traditional breeding programs are time-consuming and labour-intensive. A great deal of effort is required to separate undesirable from desirable traits, and this is not always economically practical[10].

1.2.2 Cisgenic Modification

A cisgenic plant is a crop plant that has been genetically modified (under controlled lab conditions) with one or more genes isolated from a crossable related species. The introduced gene has already been present in the species or in crossable relatives for centuries. Cisgenesis does not add an extra characteristic to the species. It does not introduce a change that could not also occur through traditional breeding or in nature. The same may be true for environmental risks, such as effects on non-target organisms or soil ecosystems, and for usage in food or feed[11], it does not add new elements to the equation.

However, cisgenic modification requires the use of alien DNA (for example CMV and / or antibiotic markers) to insert the cis-gen in the target cell[12]. Thus, although the desired gene is not alien, the 'helper' genes to insert it are, and therefore organisations like Greenpeace considers cisgenic modification as dangerous and unacceptable as transgenic modification.[13]

In the cisgenic plant breeding the desired gene from the traditional donor is first isolated and then transferred. The traditional donor and the recipient are from the same species, i.e. corn A / corn B. The desired gene is transferred without any other unwanted genes creating a new variety that could possibly be naturally obtained.

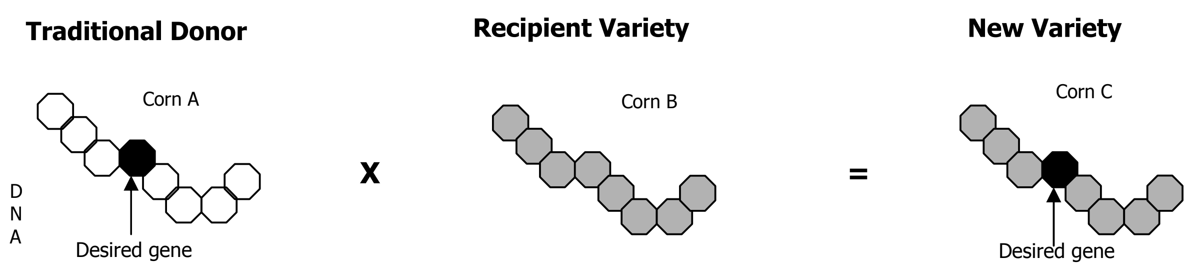


Figure 1.4 Cisgenic Breeding Model

Considering the equivalence of products resulting from cisgenesis and traditional breeding, it is possible that cisgenic plants could be handled at the regulatory level like traditionally bred plants (that is, those created via long-standing cross breeding, in vitro fertilization, or *mutagenesis* with chemicals or irradiation). An increasing number of functional genes from crops and their crossable wild relatives are being isolated and can readily be used to create cisgenic plants.

To date, the majority of established regulations on genetically modified organisms (GMOs) worldwide have not discriminated cisgenic from transgenic plants. This may be because until now cisgenic plants have been almost absent in applications for approval of deliberate release of transgenic plants into the environment.

1.2.3 Transgenic Modification

A transgenic plant contains a gene or genes, form an unrelated species, which have been artificially inserted. The inserted gene sequence (known as the transgene) may come from another plant, or from a completely different species (plant, animal or microbe): Transgenic Bt corn, for example, contains a gene from a bacteria. Plants containing transgenes are often called genetically modified or GM crops.

As stated in Figure 2.1, gene flow between higher species does not occur spontaneously. This does not however mean that it cannot occur in nature at all. Strictly speaking, there are various types of viruses which find its way to higher species DNA and are able to modify or combine with it, making it in effect transgenic. However, these viruses usually represent a disease, and usually lead to damage of the host organism. Hence are not considered in this report, as our main interest is for organisms that at least maintain their functional properties. Furthermore, commercial transgenic crops are usually “made-up” of such totally unrelated species that these certainly do not occur spontaneously.

(As an analogy, consider, justifying or discussing nuclear energy, by taking into account that radio-activity is also found naturally occurring. Nobody will argue against this, but the occurrence, its forms and dangers are obviously of a total different magnitude than man made radio-activity).

In the transgenic plant breeding the desired gene from the traditional donor is first isolated and then transferred. The traditional donor and the recipient are not from the same species, i.e. fish and tomato. The desired gene is transferred without any other unwanted genes creating a new variety that cannot be naturally obtained.

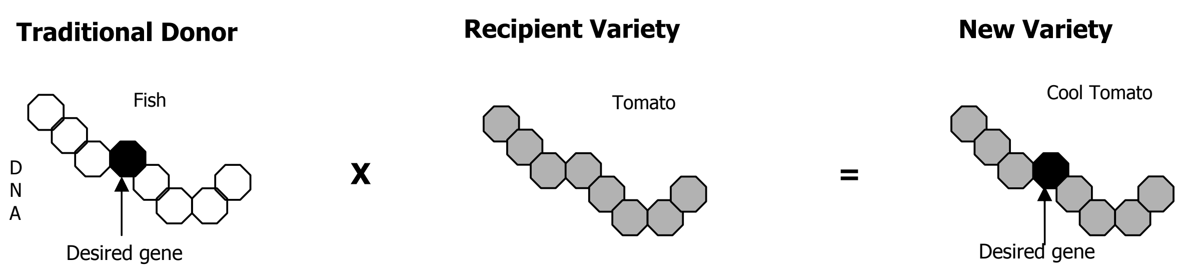


Figure 1.5 Transgenic Breeding Model

Chapter 2 Genetically Modified Crops

In the early 1980s transgenic plants were first created. The experiments were held by four groups working independently: 1) at Washington University, Missouri; 2) at Monsanto Company, Missouri; 3) at the Rijksuniversiteit, Belgium; 4) at the University of Wisconsin. On the same day in January 1983, the first three groups announced at a conference in Miami, that they had inserted bacterial genes into plants. The fourth group announced at a conference in Los Angeles, in April 1983 that they had inserted a plant gene from one species into another species.

The Washington University group produced cells of Nicotiana plumbaginifolia, a close relative of ordinary tobacco, that were resistant to the antibiotic kanamycin. The Belgium group produced tobacco plants that were resistant to kanamycin and to methotrexate, a drug used to treat cancer and rheumatoid arthritis. Monsanto produced petunia plants that were resistant to kanamycin. And the Wisconsin group inserted a bean gene into a sunflower plant[14].

These early transgenic plants were laboratory specimens, but subsequent research has developed transgenic plants with commercially interesting traits such as resistance to herbicides, insects, and viruses. GM crops are generally not food crops; soy and corn, good for over 80% of GM area are mostly used for feed. Only the oil fraction of soy and canola enters the human food chain. So far, only two applications of transgenic crops have found widespread commercial adoption. These are described below.

2.1 Herbicide Tolerant Crops

Weed control is one of farmers' biggest challenges in crop production. Poorly controlled weeds drastically reduce crop yield and quality. Many herbicides on the market control only certain types of weeds, and are approved for use only on certain crops at specific growth stages. Residues of some herbicides remain in the soil for a year or more, so that farmers must pay close attention to the herbicide history of a field when planning what to plant.

Herbicide tolerant crops resolve many of those problems because they include transgenes providing tolerance to the herbicides Roundup® (chemical name: glyphosate) or Liberty® (glufosinate). These herbicides are broad-spectrum, meaning that they kill nearly all kinds of plants except those that have the tolerance gene. Thus, a farmer can (in theory) apply a single herbicide to his fields of herbicide tolerant crops, and he can use Roundup® and Liberty® effectively at most crop growth stages as needed. Another important claimed benefit is that this class of herbicides breaks down quickly in the soil, eliminating residue carry-over problems and reducing environmental impact. However for several years, scientists have investigated the impact of glyphosate (Roundup®) on soil microbial communities. These investigations revealed increased colonization of the roots of Roundup Ready (RR) soya with the fungus *Fusarium* in midwestern fields during 1997 to 2000. At the same time, large scale cropping with herbicide-tolerant cultivars was found to increase soil-borne plant pathogens; Brazilian soils showed increased microbial activity for several seasons. There is some evidence that repeated glyphosate applications over several seasons increases soil-borne pathogens[15].

Box 1: Roundup Ready Soybean

Monsanto's Roundup Ready Soybean (RRS) is a genetically engineered variety of soybeans, which contains gene sequences from a cauliflower mosaic virus (CMV), a petunia, and a bacterium. The two bacterial genes provide for resistance against Roundup Herbicide, resulting in a crop of soybeans that can be sprayed with Roundup to protect it from weeds, while not injuring it

The system set up by Monsanto to have their RRS cultivated is quite interesting. Farmers that choose to use Roundup Ready seeds can only use Roundup, because any other broad spectrum herbicide will kill their crops. Every time a farmer decides to plant RRS, he has to buy a season worth of Roundup as well. Farmers then have to enter into a legally binding contract promising not to sell, or give away any seeds or save them for next years planting, and the company has the right to go to the farmers' house and inspect for any violations. Monsanto contends that the more the farmers rely on Roundup, the less they will need harsher herbicides and that the savings for farmers in herbicides will offset the premium price of seeds. However, it is possible that over time farmers will have to use greater amounts of Roundup to combat weed problems and there is also a danger of the emergence of new herbicide tolerant weeds through increased reliance on glyphosate, as has occurred in the United States.

2.2 Bt Insect-Resistant Crops

"Bt" is short for *Bacillus thuringiensis*, a soil bacterium whose spores contain a crystalline (Cry) protein. Insecticides containing Bt and its toxins (i.e. Dipel, Thuricide, Vectobac) have been sold for many years. These insecticides are considered safe for mammals and birds, and safer for non-target insects than conventional products. However, many question remain regarding the allergenic properties of the toxin and its breakdown during digestion in mammals. Nevertheless, as in the case of StarLink Bt-corn, it has been allowed for use in feed, but not food.[16]

The mode of action is such that in the insect gut, the protein breaks down to release a toxin, known as a delta-endotoxin. This toxin binds to and creates pores in the intestinal lining, resulting in ion imbalance, paralysis of the digestive system.
In the case of the sprays there is one crucial technical limitation: Since the corn borer moth lays its eggs on the outside of the plant, the larvae have to be stopped before the eggs hatch and the larvae eat their way into the plant; once inside they are not affected by insecticide or other control methods. This means farmers have to monitor their crops and hope the weather won't prevent spraying the day the larvae hatch.

Bt crops, solve this problem by having a modified version of the bacterial Cry gene incorporated into the plant's own DNA, so that the plant's cellular metabolism produces the toxin. When the insect chomps on a leaf or bores into a stem of a Bt-containing plant, it ingests the toxin and dies within a few days.
They are effective against different orders of insects, or affect the insect gut in slightly different ways. There are several versions of Bt-crops commercially available from several different companies.

Chapter 3 Market Analysis and Value

For the present report we will consider GM "food" as raw and processed products derived from GM crops and used for food and/or animal feed. In 2004, these products represent an average trade value of $42 billion/year.[17]

3.1 Production

3.1.1 Area Planted[18]

Unfortunately, there is no concise registration of areas and volumes of GM crops planted and produced. ISAAA, an industry-sponsored agency that promotes the use of GM technology in developing countries produces annual statistics based on expert judgement where official statistics are not available. ISAAA figures for countries such as Brazil and Paraguay are disputed by NGO's. According to ISAAA, 90 million hectares of biotech crop were planted in 2005, an increase of 11% compared to 2004. Specifically, since biotech crops were first commercialised in 1996, the number of countries using biotech crops increased from 6 to 21; 11 developing countries and 10 industrial countries. GM production is concentrated in a small number of countries; about 95% of GM area is found in the top-5 producer countries (table 3.1). The rate of increase being almost the same in industrial and developing countries.

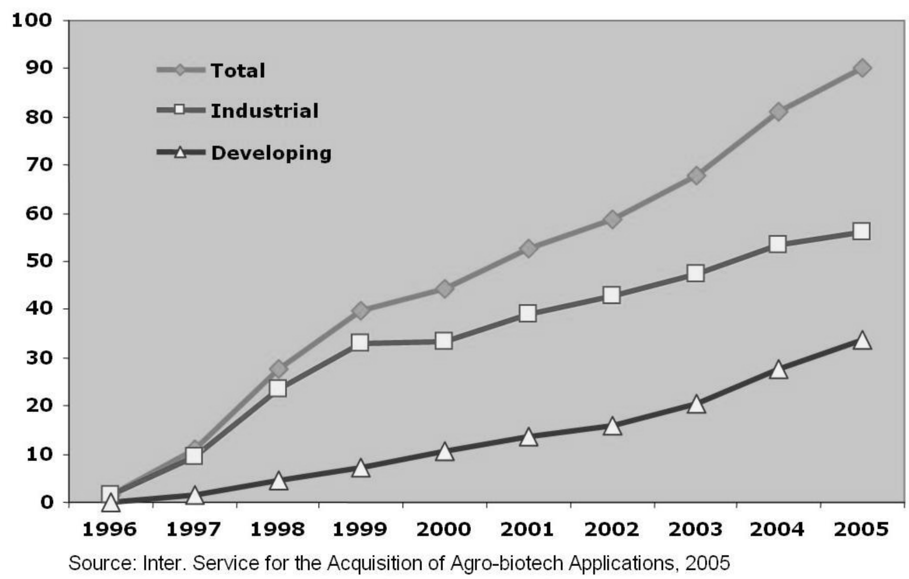


Figure 3.1 Total area (million hectares) biotech crops: Industrial and developing countries.

The largest increase in any country in 2005 was in Brazil, provisionally estimated at 4.4 million hectares (9.4 million hectares in 2005 compared with 5 million in 2004), followed by the US (2.2 million hectares), Argentina (0.9 million hectares) and India (0.8 million hectares). India had by far the largest year-on-year proportional increase, with almost a three-fold increase from 500,000 hectares in 2004 to 1.3 million hectares in 2005.

More than one-third (38%) of the global biotech crop area in 2005, equivalent to 33.9 million hectares, was grown in developing countries. The increasing collective impact of the five principal developing countries (China, India, Argentina, Brazil and South Africa) representing all three continents of the South, Asia, Latin America and Africa, is an important trend to watch.

Table 3.1 Area and main crops per top 21 countries; 2005

Rank	Country	Area (million hectares)	Biotech Crops
1	USA	49.8	Soybean, Maize, Cotton, Canola, Squash, Papaya
2	Argentina	17.1	Soybean, Maize, Cotton
3	Brazil	9.4	Soybean
4	Canada	5.8	Canola, Maize, Soybean
5	China	3.3	Cotton
6	Paraguay	1.8	Soybean
7	India	1.3	Cotton
8	South Africa	0.5	Maize, Soybean, Cotton
9	Uruguay	0.3	Soybean, Maize
10	Australia	0.3	Cotton
11	Mexico	0.1	Cotton, Soybean
12	Romania	0.1	Soybean
13	Philippines	0.1	Maize
14	Spain	0.1	Maize
15	Colombia	<0.1	Cotton
16	Iran	<0.1	Rice
17	Honduras	<0.1	Maize
18	Portugal	<0.1	Maize
19	Germany	<0.1	Maize
20	France	<0.1	Maize
21	Czech Republic	<0.1	Maize

Source: International Service for the Acquisition of Agri-Biotech Applications 2005

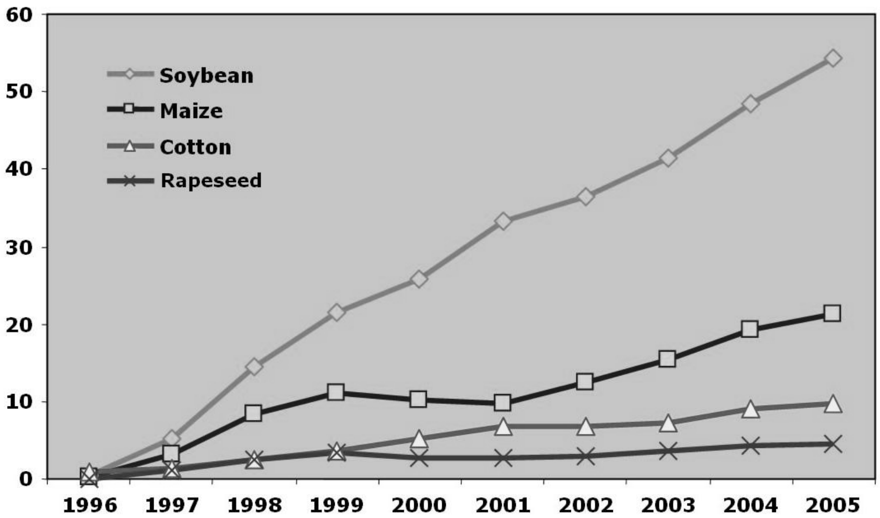
Note: All data are hectares are rounded off to the nearest 100,000 hectares and in some cases this leads to insignificant variances.

3.1.2 Main Crops

More that a quarter of the global GM plantings is dominated 4 crops: soybeans, corn, cotton and oilseed rape. Global trade of these crops and main derivatives are dominated by GM material: 90% of soybean trade, 80% of maize trade, 70% of oilseed rape trade and 45% of cotton seed trade.[19]
These figures include pure GM lots and mixed ("contaminated") lots, i.e. GM mixed with IP[*] non-GM. Because of this contamination, these mixed lots are treated as GM.

Biotech soybean continued to be the principal biotech crop in 2005, occupying 54.4 million hectares (60% of global biotech area), followed by maize (21.2 million hectares at 24%), cotton (9.8 million hectares at 11%) and rapeseed (canola) (4.6 million hectares at 5% of global biotech crop area).[1]

[*]IP: Identity Preserved: System of crop or raw material management which preserves the identity of the source or nature of the materials. Nowadays, mostly used for non-GM as this crop wants to prove it is "pure" and not contaminated with GM material.



Source: Inter. Service for the Acquisition of Agro-biotech Applications, 2005

Figure 3.2: Global area (million hectares) : per crop

3.2 Structure of the GM Value Chain

Similar to the value chain of the conventional non-GM crops, the value of the GM commodity chain has 3 main components: farm level – trading Level – derivatives processing and food companies level. The last segment could be subdivided into a few distinct groups (food, drinks, feed, pharma, etc.) but that goes beyond the scope of this report.

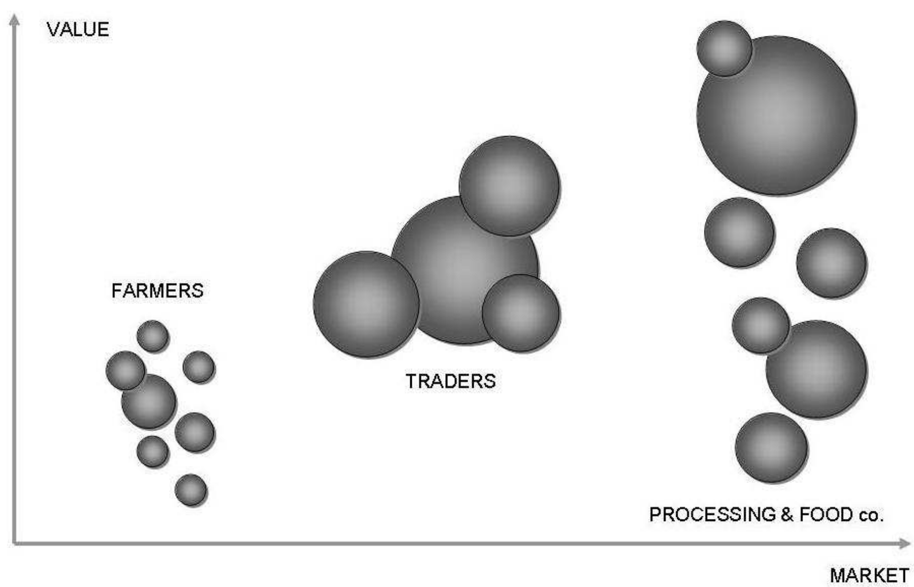


Figure 3.3 Simplified Value Chain structure: non-GM crops.

The overall structure of the GM value chain, negotiating power of all parties involved and the socio-economic impact on the long run, is expected to change from a conventional agricultural value chain, as depicted in figure 3.3; to a new and more concentrated one, as shown in figure 3.4, having direct forward and backward influence (grey triangles):

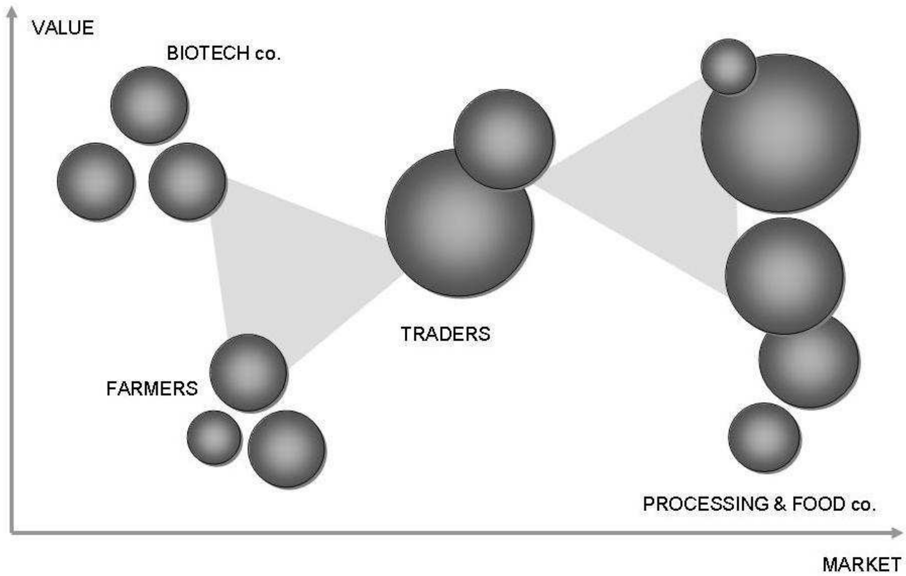


Figure 3.4 Simplified Value Chain structure: GM crops.

Due to the novelty and/or convenience characteristics built into the GM crops, unlike the non-GM these GM crops show signs of "creating" its own premium prices. This has had and will have profound impact on the structure and "balance of power" with the value chain in the future.

For example, consider a soy crop containing vitamins A(retinol and β-carotene) and D (ergocalciferol , cholecalciferol).
Soy oil based margarine, also contains these same vitamins as nutritional additives. Tailor-made soy oil, already containing a percentage of these vitamins would probably reduce production costs significantly since industrial vitamin preparations are usually very costly. Baring this example in mind:

Box 2: Expected Trends GM Value Chain

1. Biotech companies themselves have become part of the value chain; unlike the traditional seed companies. Even having influence on the price of the end products.
2. Biotech companies will effectively determine what is planted;
3. Traditional (small-scale) farming will be displaced from the chain as suppliers to the processing and food-industry (as seeds for tailor-made crops will be kept in close control);
4. The roles of biotech-farming-trading will be more and more integrated as can be seen in the case of Cargill;
5. On the other hand, trading-processing-manufacture will also see more concentration; as is also the case with Cargill; selling itself modified soy to produce protein extrusion for pet-food.

3.3 Value Contribution with Present Value Chain

On the one hand we can identify, the crop market itself, which can in turn be sub-divided in seeds and crop protection. The crop protection dimension, is often used as an example by the biotech companies themselves; arguing that their GM crops reduce the dosage level, and hence costs of pesticides.

> Box 3: Farm Value Contribution
>
> - In the long term, at the FARM level initial reductions in production costs are levelled out between GM or non-GM.
> - Ease of crop management and harvesting. Due to royalty costs mainly of importance for large scale mechanized farms.

In 2005, the global market value of biotech crops was estimated at $5.25 billion. The $5.25 billion biotech crop market comprised of $2.42 billion for biotech soybean (equivalent to 46% of global biotech crop market), $1.91 billion for biotech maize (36%), $0.72 billion for biotech cotton (14%), and $0.21 billion for biotech rapeseed (4%). The market value of the global biotech crop market is based on the sale price of biotech seed plus any technology fees (royalties) that apply. The global value of the biotech crop market is projected to be over $5.5 billion for 2006[14].

Another component is the value generated by the trading itself; of for example, the raw materials grain, oil or cotton. Theoretically, the generated revenues fall in the same segment as the conventional non-GM raw materials. However, to avoid complications (questions, certification issues, documents bureaucracy and unexpected shortages) many traders prefer not to enter non-gmo trade, effectively stimulating GM trade; without per se preferring it.

due to the perceived security of supply and homogeneity, that some of these products provide, GM crops specific prices (and revenues) can already be observed in the market. Alas, because these represent the competitive edge of one company over another, information and statistics are difficult to come by and requires more research.

For example, consider possible revenue generated by crops that can be harvested earlier or later than the conventional crops. Or for which processing plants are willing to pay a premium price, because the uniformity or homogenous quality of the raw materials, reduces production costs and cuts losses.

> Box 3: Trading Value Contribution
>
> - Trading has the most marked influence on the market prices. Specially *futures* trading can drive prices up or down based on market expectations and speculation.
> - Due to this same speculation even processing companies have little choice but to purchase raw material when offered or said to be available;
> - GM dimension: In theory it should make prices and supply more stable. However, the very nature of trading is to exploit uncertainties.

The last component refers to semi-commodity derivatives produced from the GM crops. This represents the most critical element in the value chain as it produces all raw materials that are hereafter processed in food, feed and other end products. As a general idea, Table 3.2 gives a short overview of a few derivatives and its food applications. Any of these products can contain GM raw-materials or not, depending on the source and application per country:

Table 3.2 Application and uses examples per crop.

CROP	DERIVATIVE	APPLICATION / USE
Corn	Corn grits Oil Starch Glucose, fructose, sorbitol, mannitol, xylytol	Beer brewing Veg cooking oil Thickening agent Sweeteners
Soy	Lecithin Texturized protein Oil Tocopherols	Emulsifier eg. mayonnaise Canned pet food Veg cooking oil Anti-oxidant (eg margarine)
Cotton seeds	Oil Linters / short chain fibers	Refined oil blends eg. Dressings Cellulose for food thickening

Box 4: Derivatives Value Contribution

- The wide product range and end industries served, makes it possible for traders and processing companies to exert considerable pressure on the supply levels;
- As explained in Box 3 , mainly TRADING determines the pricing of the raw materials, but as end users such as food companies require more quality and security of supply, they also drive up the prices;
- Costs of adding product functionalities at the DERIVATIVES segment, can be "pushed back" to the crop engineering side, in the long run skipping trading altogether. Eg. Adding *nutraceutical* properties to milk, in the genes of the cow or the feed crop.
- Processing, derivatives and specialty companies will continue to push for more GM supply as means to have more control over pricing and functionalities of their end products. In this way, effectively stepping out of the conventional trading markets. Farmers that do not follow these trends, or are financially unable to do so, will be left out of these high margin (specialty) corps.

Chapter 4 Regulations for Genetically Modified Organisms

This section provides a basic outline of the current regulation landscape. An overall detailed analysis of the legal frameworks and regulations goes beyond the scope of this report, because of the complexity of the legal systems of each country. Each specific country has its own approach, nevertheless, basically the whole regulations issue concerning GMOs can be subdivided into two different approaches:

- The EU regulations follow an approach based on the "precautionary principle" and consumers' "right to know," with stringent approval, labeling and traceability standards on any food produced from or derived from GM ingredients.

- The U.S. regulation approach is based on differences in the end product, and includes a voluntary safety consultation and voluntary labeling guidelines for GM food.

Most other developed countries, including Japan, Canada, or Australia have introduced intermediary regulations between these two "extremes".

In the developing world, some of the large agricultural producers (such as Brazil) have developed biosafety and marketing regulations on GM food, but at the same time many other developing countries have not adopted any specific regulation of GM food because they lack the capacity to do so, or perhaps they have adopted a position of wait and see.[20]

At the international level, two main institutions have worked in an effort to provide harmonized regulations on agricultural biotechnology: the Cartagena Protocol on Biosafety, which is part of the United Nations (UN) Convention on Biodiversity, and the Codex Alimentarius Commission, under the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO). In addition, discussions over the regulation of agricultural biotechnology has arisen at the World Trade Organization (WTO) as the United States, Argentina and Canada launched a trade dispute against the alleged EU moratorium on approval of new GM crops in 2003. U.S. observers believe that another trade dispute may follow on the strict traceability and labelling requirements replacing the moratorium in the EU since April 2004.
In general, regulations apply to food and feed crops and although there are some regulations on non-food or non-feed products from GM crops (e.g, cotton fibers derived from GM cotton, or ornamental GM plants), there are no internationally accepted or binding trade regulations for these non-food crops.

A decade, after the introduction of the first GM crop, there is large heterogeneity across nations in the regulations of GM food. At a macro level, countries can be divided into three groups according to the status or type of their regulations[21]:

- first, countries with a comprehensive and stringent regulatory framework applied to GM food, including mandatory safety approval and mandatory labelling; eg. The whole EU, Eastern Europe, Brazil, China and Switzerland;
- secondly, countries that have adopted a regulatory approach based on the notion of substantial equivalence with voluntary labelling instead of mandatory labelling for GM food; eg. USA, Canada and Argentina; and
- third a large number of countries either without regulations or pending towards adopting certain regulations on GM food approval and marketing; eg. most African countries, Indonesia, Mexico and Vietnam.

Currently, developed countries are in the first and second group, while most developing countries are in the third group, with a few notable exceptions.
The distinction between voluntary and mandatory labelling is important, because it drives a number of necessary regulatory requirements. Mandatory labelling requirement affects the whole agro-food channel from the retailers to the producers requiring them to acquire and transmit information about the presence or origin for each food product, whereas voluntary labelling is driven by private incentives and the presence of market niches for non-GM food[22].

Countries continue to hold rather diverging views about the risks and opportunities that agro-biotechnology may bring. Furthermore, the lack of conclusive scientific evidence on the actual or potential impact of agricultural biotechnology on human and animal health and on the environment, makes any significant international agreements even more difficult.

Those views are reflected in domestic regulations on the approval, marketing, labelling and documentation requirements for GMOs and GM products that vary substantially from one country to another. The legislation on GMOs and GM products enacted in some regions, and especially in the European Union, is alleged to hamper international trade in those products, and it is also claimed to be having indirect negative implications on the trans-boundary movement of conventional agricultural products[23].

Various government organisations and international social and commercial institutions (see references for suggestions) are focused on these matters and specially the differences that exist between countries and how these could or should be integrated or not.

These last considerations are crucial for the success of any future agreements and policies. Without basic policies, a simple matter such as keeping import and export statistics becomes almost impossible. And without these statistics the quantifying the scale, impacts and value of the GM business (see section 3.3) is not possible.

Chapter 5 Risks and Benefits of Genetically Modified Crops

This chapter provides an overview of the main claimed risks and benefits (and terminology) of GMOs, that have been identified, up to date. This does not mean however that any of these issues has hence been settled, or that the list is exhaustive.
Furthermore, we refer to the risks and benefits as claimed because for most of these subjects, no definite scientific proof is readily available. Studies have been carried out, but more often that not, it has happened that another institution (independent or not) carries out the same study with totally different results. Neither side accepting the results. A difference has been made between scientifically researched and not scientifically researched; but that nevertheless dominate public opinion.

Every day, new information becomes available and advantages/disadvantages are revised. This overview, therefore describes very dynamics issues and should hence be view critically. It is mainly intended as an attempt to point and list the subjects that are already well established in the present debate and do not need to be revived every time, making the debate stagnate.
An example to illustrate the situation: The claim that GM soy may be weaker and less resistant to drought seems indeed to be the case form observations; but no scientific method/study has yet proven this within the boundaries of a normal field experiment.
In such a case it appears more effective to discuss (for example) how to carry out and finance such an experiment, rather than discussing if it is true or not.

5.1 Scientifically Researched Risks and Benefits of GM Crops

	Risks	**Benefits**
Consumers	Allergic reactions Insertion of allergens Antibiotic resistance	Changes on nutritional value
Environment	Genetic instability Contamination of varieties Antibiotic resistance Effects on the ecosystem Leakage of GM protein to the soil	
Development Issues	Dependent farmers Lack of hard proof on the risks of GMOs Poor regulations Patent	.. In case of better traceability & labeling

The list describes three levels of interest and where applicable, its claimed risks and benefits or opportunities for improvement; only the

5.1.1 Consumers

Risks

Allergic reaction: A novel genetically engineered food may have the potential to cause new allergic reactions if it contains proteins that the conventional food doesn't have. If the protein in the GM food happens to have been an allergen in the original allergenic food, then it is possible that the GM food will also cause allergies. For example, people who are allergic to Brazil nuts may also be allergic to a GM soybean containing a Brazil nut protein (the product mentioned has been developed, but never commercialized).

Insertion of known allergens: To improve the nutritional quality of soybeans, researchers at Pioneer Hi-Bred International developed a line of genetically engineered soybeans that produces a methionine-rich protein from Brazil nuts.

Insertion of unknown allergens: Bt-toxin proteins belong to the group of "unknown" allergens. Because they are quickly degraded in the stomach, Bt-toxins have not been considered an allergy risk. However, tests submitted by Aventis to the EPA[†] suggested that the Cry9C version of Bt-toxin in StarLink, corn may be more heat-stable and digestion-resistant than other members of the Bt-toxin family-making it a higher risk for allergenicity. For this reason, initially the EPA did not allow the use of Starlink in human food.

Antibiotic resistance: The evolution of antibiotic resistant bacteria is a critical issue for human health. When bacteria become resistant to an antibiotic, the antibiotic will no longer kill the bacteria, and thus no longer able to prevent the human disease caused by the bacteria. Many scientists have become increasingly alarmed by the growing number of bacterial strains that are resistant to multiple antibiotics, making the treatment of some diseases very difficult.

Benefits

Intended changes on nutritional value: The Golden Rice Project was born out of an initiative by the Rockefeller Foundation, based on a widely recognized need for a sustainable bio-fortification program to solve the micronutrient deficiencies worldwide. Golden rice was developed as a fortified food to be used in areas where there is a shortage of dietary vitamin A. The varieties are not yet commercially available for human consumption.

5.1.2 Environment

Risks

Genetic instability: Biotechnology relies to a large extent on our ability to introduce foreign genes into cells. A major problem with present day technology is the non-predictability of the integration of such transgenes. DNA introduced into plant cells mostly integrates at random, i.e. at non-predetermined positions of the genome. The biological process ultimately responsible for random integration is known as illegitimate recombination. DNA integrated at random frequently contains multiple copies and often copies are scrambled.

Contamination of varieties (intra-species): In September 2001 Nature Magazine reported on the findings of Mexico's Ministry of the Environment that GM maize contamination had been found in farmers' varieties in two states. In November 2001, a peer-reviewed article, also in Nature, offered scientific evidence of the Mexican contamination.

Antibiotic Resistance: Researchers from the University of Illinois and Illinois State Geological Survey used a DNA-amplification technique to analyze samples from lagoons, wells and groundwater on and near two Illinois facilities. "We found tetracycline resistance genes in soil and groundwater bacteria. The genes are transferred to this type of bacteria, where they can survive and travel long distances in the environment. It has been suggested that there is horizontal transfer of antibiotic resistance genes, but we had only seen it in laboratory experiments, not in in-situ studies. Here, we see such a transfer is occurring in the environment." said a visiting professor of animal sciences at the University of Illinois.

[†] U.S. Environmental Protection Agency

Effects on the Ecosystem: In a laboratory assay scientists from Cornell University found that larvae of the monarch butterfly, *Danaus plexippus*, reared on milkweed leaves dusted with pollen from Bt corn, ate less, grew more slowly and suffered higher mortality than larvae reared on leaves dusted with untransformed corn pollen or on leaves without pollen.

Leakage of GM protein to the soil: In 2001, a study conducted in Quebec was cited as revealing heavy contamination of the sediment of the Saint Laurence River by the Bt corn toxin. The scientists observed that the sediments drawn/taken from the Saint Laurence contained concentrations of the Bt-toxin that were 5 times higher than in drainage waters and sediments near agricultural land.

5.1.3 Development Issues

<u>Risks</u>

Dependent farmers: The technology agreements that farmers are required to sign when they purchase seed containing Monsanto's patented technology is a legal threat to farmers in the US. These agreements force the farmer to buy new seed every season, rather than saving and replanting seed in the age-old farming tradition. With these agreements in place, Monsanto effectively gains a license to control the seed even after the farmer has bought, planted and harvested it. This unprecedented level of control has had a profoundly negative impact on the livelihoods of many US American farmers and world-wide.

Regulations: Regulations and guidelines based on how plants should be studied and how companies should work with new biotechnologies are still lacking. For example, currently, there are no binding FDA regulations to protect the environment or consumers from the possible risks of the genetically engineered foods.

Lack of hard proof on the risks of GMOs (Precautionary Principle): Europe has adopted the precautionary principle to underpin decisions about environmental and human health risks and this has been included in the regulations governing the safety of GMOs. Under the precautionary principle, where serious harm may arise, lack of evidence of harm should not preclude action to prevent harm.

Patent: A plant patent is granted by the US Government to an inventor who has invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state. The grant, which lasts for 20 years from the date of filing the application, protects the inventor's right to exclude others from asexually reproducing, selling, or using the plant so reproduced.
There are 108 biotech varieties in the database of Agbios. The information includes not only plants produced using recombinant DNA technologies (e.g., genetically engineered or transgenic plants), but also plants with novel traits that may have been produced using more traditional methods, such as accelerated mutagenesis or plant breeding.

5.2 Non-Scientifically Researched Risks and Benefits of GM crops

Again, the following table provides non-exhaustive overview of the claimed risks and benefits of GM crops

	Risks	Benefits
Consumers	Allergic reactions	Nutrition
Environment	Horizontal Gene Transfer (between species) Weaker crops	Less herbicides Increased yields Coexistence
Development Issues	Patents disputes Product/trade disputes Overproduction	Increased return

5.2.1 Consumer

Risks

Allergic reactions: The film "The Future of Food" by Deborah Koons Garcia shows an infamous Starlink incident in the USA, where a woman had an allergic reaction to taco shells containing Starlink corn. The fact was highlighted as instances of regulatory problems. The film makes a case for consumer choice through labelling.

Benefits

Nutrition: It is claimed that GMOs will help to decrease hunger and malnutrition. 'Golden Rice', for example, was developed as a fortified food to be used in areas where there is a shortage of dietary vitamin A. Note that golden rice has not been introduced in the food chain and the vitamin a level is contested to contribute significantly.

5.2.2 Environment

Risks

Horizontal Gene Transfer (between species): Potential gene flow between genetically engineered canola and related weed species, wild mustard and black mustard was examined by considering gene flow by seed and pollen movement along with cross compatibility, under glasshouse and field condition.

Weaker Crops: Rio Grande do Sul state, the biggest adopter of GM technology, has been the hardest hit by the drought in 2005. Brazil's agricultural department estimates that yields are down 72% in Rio Grande do Sul. Monsanto representative Ricardo Miranda concedes that yield losses are 80% in some areas. Soy exports from Rio Grande do Sul dropped around 90% in that year. Crop losses in adjacent mostly GM-free Paraná, which also suffered from the drought, were much lower.

Benefits

Increased soybean yields: According to the USDA in Argentina, soybean production rose almost 20 percent in 2005. Nearly ideal growing conditions benefited flowering and pod filling soybeans during January and February in the main growing areas. This study has been challenged by many organisation that consider these studies biased [24],[25].

Less Herbicide: Monsanto declares that the RR package decreases the amount of herbicide necessary for soybean production. It is perceived that during the first 05 years this assumption may be true, but it is arguable in a longer term.

Coexistence: The International Federation of Organic Agriculture Movements EU Group remains opposed to the introduction of genetically modified crops in Europe. The Federation does not believe that genetically modified crops offer any substantial benefits for society, the environment or the economic prosperity of EU agriculture.

5.2.3 Development Issue

Risks

Patents disputes: Due to patent claims by companies and payment of royalties farmers (large and small) become more dependent on the biotech seed companies.

Product, market and trade disputes: Combined with the previous patent issue, biotech companies may claim their right to seize product loads exported from countries that do not accept their conditions. A typical example of this product-international trade combination is the soy form Argentina being seized upon arrival in Europe. This whilst the farmers themselves, are acting within the law in their country.

On the other hand, as was the case when StarLink Bt corn was recalled farmers suffer an enormous loss in market and revenues[26]. In some cases losses were compensated, but it generally a loss for many formars in the USA and Mexico.

Overproduction: GM crops have been an economic disaster in the USA and Canada according to a report published by the Soil Association, Britain's leading organic organization. Engineered soybeans, corn and canola are estimated to have cost the US economy at least $12 billion from 1999 to 2002 in farm subsidies, lower crop prices, loss of major export orders and product recalls. Farmers are not achieving the higher profits promised by the biotechnology companies as markets for GM food collapse. Widespread GM contamination at all levels of the food and farming industry is the major cause of these difficulties.
In Argentina the same trends can be observed[27]

Benefits

Increased returns for farmers: In theory, the returns for farmers should increase due to lower labour costs and pesticide usage. However, different organisations have different views about this matter[28],[29],[30], and more extensive studies are needed if a proper conclusion is to be drawn.

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