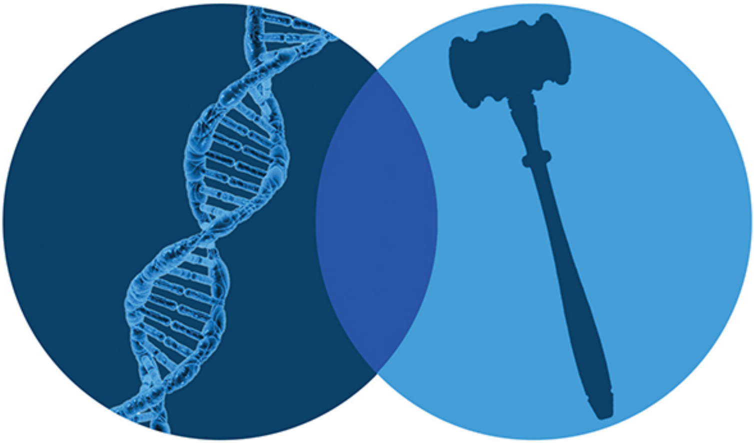

Genetically Modified Organisms and Regulations Concerning Biotechnological Products

Iraz Haspolat Kaya

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By

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Cambridge Scholars Publishing

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To Ada Kaya, my beloved daughter

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Assoc. Prof. Dr. Iraz HASPOLAT KAYA

PREFACE

The world today is exposed to insufficient food that does not adequately feed its inhabitants. More solutions have been formulated to fight this problem but no suggestion is better than plant biotechnology where, with modern genetically engineering, plants and seeds are modified to grow faster and in greater numbers.

Today, the market of GMOs is characterized by three different approaches; the first is the idea that GMOs are not healthy and are dangerous to human life, the position that is held by most fundamentalist ideologies; the second approach is the idea that GMOs do have positive sides and negative sides, features that anything can have. The last approach is non-discriminative insight where people in this category do not have to care which is GMO and which is not.

The market of GMOs at the global level is a game of perception and mentality that consumers have, concerning a certain product. Due to their productions in high numbers, GMOs tend to be at a lower price than non-GMOs on the global marketplace.

In this book, we will enlighten on the importance of GMOs and risks, consumer perception, GMO restriction as well as relevant regulations regarding them, and the place GMOs have on the global market where we will divide the global market into two parts – developing countries and developed ones. The developments in biotechnology continue to make headlines about organisms other than human beings: the first form of synthetic life is close – cloned animals will soon be on our dining menus – without considering the myriad of genetically modified animals and plants that inhabit our laboratories and our "natural" environment. These technologies are not without creating strong controversy, but it is their application to human beings that raises fundamental questions: a genetically modified human being or cloned, for example, do they deserve to be called a human?

The science behind biotechnology is packed with wonders that are waiting to be revealed and yet undoubtedly it is a challenge to the international community and a hard task for international law. It challenges lawmakers in almost at all structures of the law with so many worries; should manipulated genomes count as property rights that would make private high-tech companies rich? This question is not simple to answer since this kind of ownership would affect all basic needs for the health and welfare of billions of people around the world. On the export issues, international law has concerns on regulations regarding the information that could be given to the states of import about any biotech products which are about to be exported to their territories and what would be the grounds to prohibit such transactions.

This work consists of three main chapters: Chapter one will explain GM products and their benefits; Chapter two will provide the reader with details of the situation of GMOs around the world; Chapter three will focus on the regulations of biotechnological products and on the concerns that the international community has regarding the development of this field.

List of Abbreviations and Acronyms

ABNE	African Biosafety Network of Expertise
AIA	Advance informed agreement
BCH	Biosafety clearing-house
BT	*Bacillus Thuringiensis*
CFT	Confined field testing
DNA	Deoxyribonucleic acid
DR	Disease resistance
EU	European Union
FFP	Feed or for processing
FT	Field trials
GATT	General Agreement on Tariffs and Trade
GMO	Genetically modified organism
HT	Herbicide tolerance
IR	Insect resistance
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
LMO	Living modified organisms
MLT	Multi-location trials
N/A	Not applicable
RNA	Ribonucleic acid
SPS	Sanitary and phytosanitary
ST	Stacked traits
TBT	Technical barriers to trade
UN	United Nations
UNECA	United Nations Economic Commission for Africa
USDA	United States Department of Agriculture
WTO	World Trade Organization

Chapter One

Genetically Modified Organisms

Scientists, farmers, agribusinesses and public authorities have always striven to develop crops, animals and more resistant species, with increased nutritional qualities and a more attractive presentation to consumers. This approach is part of the usual improvement process that is practised in our societies. So why are genetically modified organisms regularly causing concerns today? To answer this question we need to first explain what GMOs are.

Genetically modified organisms (GMOs) represent all organisms whose arrangement of genomes respond to a laboratory plan to fit the wanted physiological features. Under modern biotechnology, recombinant DNA technology and reproductive cloning are considered to be the main techniques used to produce GMOs.

Figure 1-1 below shows the techniques of recombinant DNA as manipulated by geneticists in a biotech laboratory. Recombinant DNA technology means the act of joining two DNAs from different species in order to obtain a new kind of organism made with predicted compositions under laboratory conditions. This technique serves as the main tool used by geneticists to select a portion of a desired gene or any other division of DNA with the aim of studying the sequence of its nucleotide and change it in a highly specific way so that it can be ready to be reinserted into a living organism.[1]

It is a result of manipulation of genetic code of an organism by humans in order to make it more resistant, to improve its nutritional qualities, or to give it properties that prevent a disease. This research focuses mainly on plants (corn, rice, rapeseed, soybean, etc.); the disadvantage is that transgenic plants often cannot reproduce on their own; one-year seeds cannot be used for the next year, thus increasing seed producers' control over their distribution.

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[1] Julia Diaz and Judith Fridovich-Keil, "Genetically modified organism", *Encyclopaedia Britannica*, 7 June 2019.
https://www.britannica.com/science/genetically-modified-organism

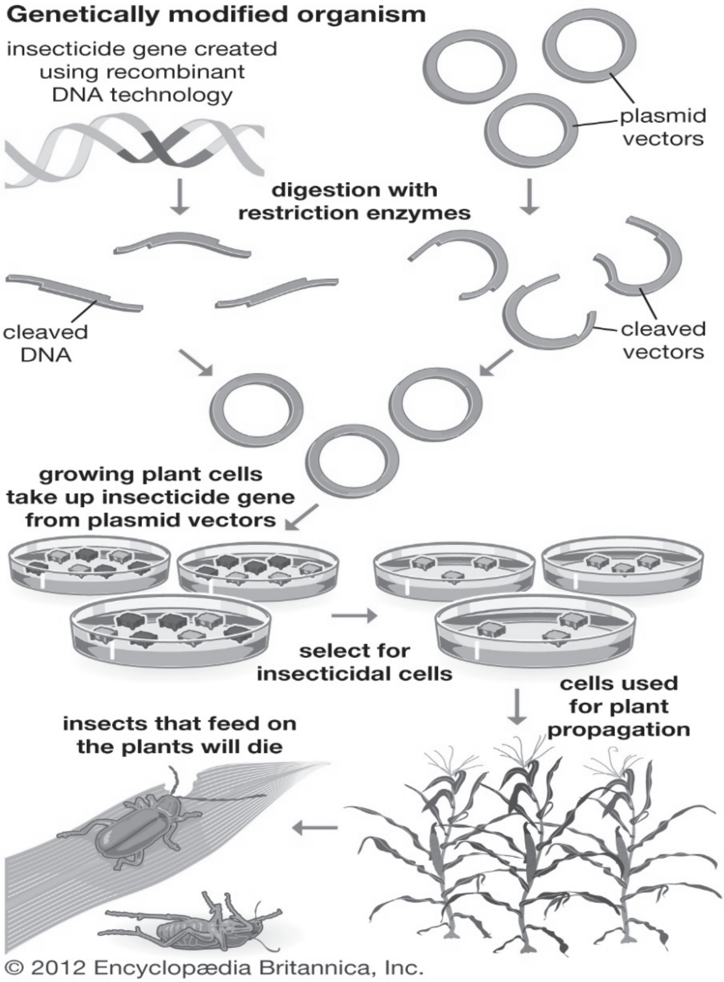

Figure 1-1: GMP Production[2]

Transgenesis is a technique that involves introducing into a body a gene (or a small number of genes) from another organism, whatever the origin of these genes (microorganism, plant of the same species or of another species,

[2] This is a representation of GMO production by the way of recombinant DNA technology. Anthony Griffiths, "Recombinant DNA", *Encyclopaedia Britannica,* 5 June 2019. https://www.britannica.com/science/recombinant-DNA-technology

animal or human) and by a method other than sexual reproduction. The organism obtained is described as a genetically modified organism (GMO). This chapter will focus on the application of transgenesis to plants, but animals, vertebrates or invertebrates and microorganisms may also be modified by these methods, as we will see in the last chapter.

The gene transfers between different species – or even between different kingdoms – which are carried out by transgenesis are made possible by the universality of the genetic code[3] and its transcription mechanisms in the cells of living organisms. Mechanisms of regulation and expression, still rather poorly known, modulate the expression of this genetic code between different species, depending on environmental conditions.

The gene, or the few genes, introduced into the recipient genome are included in a complex genetic construct called a transgene, which sets various functional elements side by side that aim to correctly express the foreign transgene:[4]

- one or more promoters, which are genes that allow the initiation of the reading of the information, either permanently and ubiquitously, or in a more limited manner (for example only in the leaves or in the seeds or at a given moment);
- regulatory sequences, which act by modulating the level of appearance of a particular gene;
- one or a few genes of interest, which contain the character that one seeks to give to the GMO (genes of interest which can themselves be modified, even synthesized);
- marker genes, which are used to select, after the transgenesis operation, the target cells having integrated the transgene;
- termination sequences, which mark the end of the informative segments of the transgenes.

In plants, the introduction of the transgene into the recipient genome is done either by mechanical methods (biolistic = bombardment of target cells

---

[3] Universal coding system of genetic information at the DNA level, ensuring the correspondence between the nucleotides constituting the sequence of the DNA and the amino acids constituting the sequence of the proteins synthesized from this DNA. Each amino acid is encoded by a set of three successive nucleotides, called the codon; this correspondence is valid for all living beings.

[4] Marie-Pierre Arlot, et al., "OGM et agriculture: options pour l'action publique", (in French) accessed 14 November 2018 https://www.ladocumentationfrancaise.fr/var/storage/rapports-publics/014000692.pdf.

by a large quantity of transgenes) or by bacterial vectors, which inoculate the transgene with the target cells of the recipient plant. In the current state of techniques, the implantation site and the number of similar transgenes in the genome of the recipient cells are not controlled and may be variable from one cell to another. It is therefore necessary to go through a phase of selection of the cells having integrated the transgene, then to regenerate whole plants from the transformed cells, to sort out the plants having the desired characteristics and to locate in these plants or the site(s) insertion of the transgene. The proportion of transformed cells that give plants with the expected characteristics remains rather low, of the order of a few per thousand to few per cent of the treated cells. However, for these plants, the transformation event is a transgene placed at a specific place in the genome, which is described by its border fragments.

Different technical variations as to the components and vectors of the transgene can be developed; those that seem to open new perspectives of evolution of transgenesis will be detailed in the second part of this book. At present, the very broad a priori possibilities of transgenesis are only partially exploited. In order to understand the topic concerning the importance of GMOs on the global market, we first need to understand their historical path and why they have been developed from time to time.

1.1 Historical Background of Genetically Modified Organisms

GM crops are a very recent step in a crop improvement practice that began more than 12,000 years ago and includes corn, wheat, tobacco, grapes and so on. These traditional and empirical techniques of plant breeding, which lasted until the dawn of the twentieth century in Europe, continue to be practised widely in the world for many species. Plant breeding involves a variety of techniques, starting from traditional plant crosses to in vitro crosses and reproduction. It also uses artificial induction techniques of plant genome mutation to look for interesting traits, practises different sterilization techniques to control crosses, and is already making extensive use of molecular genetic techniques with genetic markers.[5]

[5] A marker gene is a portion of known sequence DNA and/or localization that is used as a reference to locate other genes.

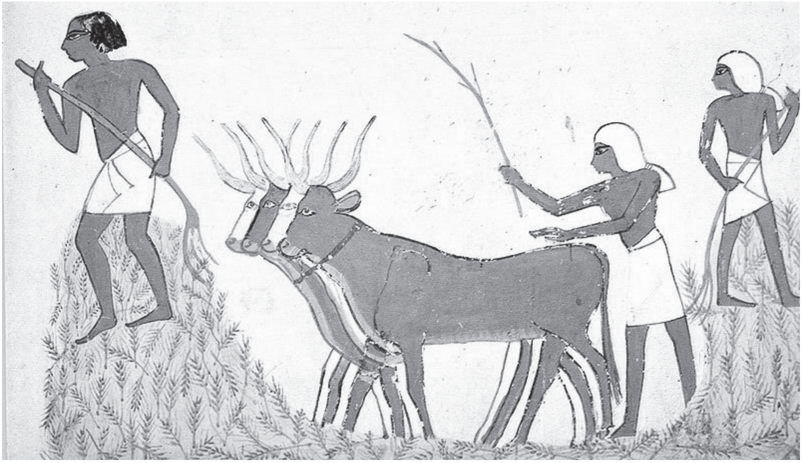

Figure 1-2: Illustration of agriculture in Ancient Egypt[6]

Humans have arguably been trying to think about how their crops will be good almost from the time they knew they could grow something from the soil. From the discovery of agriculture approximately 12,000 years ago, humans never ceased to search for durability in their crops by even intervening with food and their genes. By choosing some qualities over others, humans manipulated their harvest into something greater than what they had before; for example to be tastier, bigger and juicier. As a researcher in biotechnology at the University of Illinois, Bruce Chasey noted in his 2007 paper, "Plants such as strawberries, wheat, cabbage, corn, and almost all the rest of our crops descended from ancestors that were nothing like strawberries or wheat or corn from back in the day".[7] Interestingly, sweet potato is an example of one of food that only existed because humans bred it; humans bred sweet potatoes out of swollen regular potato roots 8,000 years ago.[8]

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[6] Figure 1-2 shows how Ancient Egyptians started to modify their seed expecting a better crop. https://images.medicaldaily.com/sites/medicaldaily.com/files/styles/full_breakpoints_theme_medicaldaily_desktop_1x/public/2015/07/21/ancient-egypt.jpg

[7] Lecia Bushak, "A brief history of genetically modified organisms: from prehistoric breeding to modern biotechnology", 22 July 2015, https://www.medicaldaily.com/brief-history-genetically-modified-organisms-prehistoric-breeding-modern-344076

[8] Bushak, "A brief history".

Below we are going to establish a short chronological development of GMOs from the nineteenth century, because this century was the start of modern genetic engineering.

In the 1800s one of the most popular biologists, Charles Darwin, published his book on the origin of species (*The Origin of Species Through Natural Selection*) in 1858 with which he provoked a revolution in the thoughts of biologists of his time. He proved that species are unstable – they change and evolve – and they have evolved from the simplest to the most complex plants, animals or humans. According to Darwin, the driving force of evolution is in natural selection in which only the strongest species will survive. However, it is Darwin's contemporary, the Czech Gregor Mendel, who described the laws of heredity by observing the results of crossing peas and transmitting characteristics such as size, shape or colour.[9] By crossing hybrids, he described the so-called classical selection method. Gregor Mendel then found other ways to improve cultivated plant species.

In the 1950s, James Watson and Francis Crick discovered the structure of DNA (deoxyribonucleic acid, the molecule that carries the genetic code) in 1953, which was an important turning point in the genetic field. This discovery laid the foundation for a new discipline called molecular biology. In 1958, Edward Tatum confirmed the concepts of the young discipline:[10]

- All biochemical processes in all organisms are under genetic control;
- These biochemical processes are reducible to sequences of individual reactions;
- Each isolated reaction is controlled by one gene.

The 1970s showed the potential of genetic modification. Genetic engineering had brought a first practical use, the manufacture of new drugs, for example insulin that is used even in our time. The topic of GMOs was widely discussed and this debate was not limited to the issue of risk alone. Beside the particular successes, this method brought many questions that were not answered, especially those related to potential consequences of genetic modification on the variety of life on earth or human safety. **Chemist John Franz** developed glyphosate as an herbicide in 1970, the product that is being used in major GMO-producing mega companies to this day.

From 1972 to 1973 two American biochemists, Herbert Boyer and Stanley Cohen, invented a method to separate DNA pieces from one main

[9] Orel Vítězslav, *Gregor Mendel, Founder of Genetics* (Blok Brno, 1965), 43–45.
[10] Hervé Kempf, *La guerre secrète des OGM*, (Paris: Le Seuil, 2003), 16.

DNA and inserted those specific fragments to the DNA of other different organisms, which took contemporary biotechnology to another chapter of its history. This invention happened at exactly the same time the first debate about the health-related risks of genetically modified products was taking place. Biotechnology became commercialized in 1976, when permission was given to companies to conduct experiments on genes for various applications including food, medicine and chemistry.

In 1982, the decision of the United State Supreme Court concerning patent rights over GMOs gave Exxon Oil Company permission to use an oil-eating microorganism in its business.[11] In 1983, biochemists who were working for Monsanto were the first to pioneer the genetic modification of plants and tested their first GMOs five years later. In 1988, scientists inserted genes into soybeans, which gave rise to the most common GMO: glyphosate-tolerant soybeans. Soon after, scientists manipulated other GMO seeds such as potato, cotton, rice, sugar beets, sugarcane and tomatoes in order to make them more resistant to diseases, herbicides, insects, antibiotics and pesticides.

In 2003 in the framework of the UN, the first international agreement on GMOs, the *Cartagena Protocol on Biosafety Relating to the Convention on Biological Diversity* was established with the aim to "establish appropriate procedures to improve biotechnology security in line with the overall objective of the Convention, which is to reduce all potential threats to biological diversity, also taking into account risks to human health".[12] This is a very useful document in regulating biotech products, as we will see later in this book.

1.2 Benefits of Genetically Modified Crops

The benefits of GMOs can be found in different levels but here we will focus on two types of benefits: economic benefits and environmental benefits. According to a British agency for agriculture and other related resource sectors, PG Economics, the global benefits of genetically modified crops since they were first planted has reached $150.3 billion.[13]

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[11] David Biello, "Silk solution: How Microbes will Clean up the Deepwater Horizon Oil Spill". *Scientific American,* 25 May 2010. https://www.scientificamerican.com/article/how-microbes-clean-up-oil-spills/

[12] The preamble of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, Montreal 2000.

[13] Graham Brookes and Peter Barfoot, *GM Crops: Global Socio-economic and Environmental Impacts 1996–2014*. Dorchester: PG Economics May 2018.

1.2.1 Economic Benefits

Genetically modified technology played a key role in raising farm-based income from a mixture of strengthened output and efficiency advantages. The above report argued that in 2014, the direct farm income benefits reached $17.7 billion, which suggests that worldwide production of crops of cotton, corn, soybeans and canola had increased by 7.2%.

The maize sector for 2014 produced the largest gains in farm income, over $5 billion; insect-resistant GM (GM IR) was the creator of this massive income. The maize sector alone is responsible for adding 6.1% of the value of the crop in the developing states. We summarize the farm income from 1996 until 2014 in the table below:

Table 1-1: Worldwide GM crops income between 1996 and 2014 (US$M)[14]

Features	**Income as of 2014**	**1996–2014**	**Percentage (2014)**	**% of benefit**
GM herbicide-tolerant soybeans	5,221.4	46,643.4	4.6	4.2
GM herbicide-tolerant and insect-resistant soybeans	853.5	1,174.7	0.75	0.69
GM herbicide-tolerant maize	1,600.1	9,050.4	1.8	1.0
GM herbicide-tolerant cotton	146.5	1,654.2	0.5	0.3
GM herbicide-tolerant canola	607.1	4,860.0	6.6	1.8
GM insect-resistant maize	5,296.0	41,407.3	6.1	3.2
GM insect-resistant cotton	3,940.8	44,834.3	12.5	8.9
Others	79.7	652.4	–	–
Totals	17,745.1	150,276.7	7.3	7.2

[14] Brookes and Barfoot, “GM crops, environmental impacts”.

After a look at the global scale, we can see what happened in selected countries from 1996 up to 2014. The US heads the list and is followed by Argentina among the countries that have profited more in our time frame; India occupies third place on the list even though its data on the most verified GMOs are unknown. The fact that the production of GM IR cotton has been multiplying over time make it one of the leaders in this list.[15]

[15] WHO, "20 questions on genetically modified foods". May 2014. http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html

	HT soybeans	HT maize	HT cotton	HT canola	IR maize	IR cotton	HT/IR soybeans	Total
US	*21,400.3*	*6,106.1*	*1,074.1*	*311.4*	*32,198.3*	*4,750.2*	*N/A*	*65,840.4*
Argentina	*16,435.6*	*1,243.0*	*145.0*	–	*678.3*	*803.0*	*33.5*	*19,338.4*
Brazil	*6,317.0*	*1,368.3*	*133.3*	–	*4,787.1*	*72.3*	*1,100*	*13,778.2*
Paraguay	*1,029.2*	*0.9*	–	–	*13.1*	–	*26.3*	*1,069.5*
Canada	*613.3*	*137.4*	-	*4,492.8*	*1,229.5*	–	–	*6,473.0*
South Africa	*18.1*	*48.3*	*4.2*	–	*1,711.9*	*30.9*	–	*1,813.4*
China	–	–	–	–	–	*17,537.6*	–	*17,537.6*
India	–	–	–	–	–	*18,268.4*	–	*18,268.4*
Australia	–	–	*91.5*	*55.8*	–	*801.7*	–	*949.0*
Mexico	*6.1*	–	*183.2*	–	–	*194.3*	–	*383.6*
Philippines	–	*141.6*	–	–	*418.3*	–	–	*559.9*
Romania	*44.6*	–	–	–	–	–	–	*44.6*
Uruguay	*143.2*	*1.2*	–	–	*24.8*	–	–	*183.3*
Spain	–	–	–	–	*231.7*	–	–	*231.7*
Other EU	–	–	–	–	*22.2*	–	–	*22.2*
Colombia	–	*3.8*	*23.0*	–	*82.5*	*19.0*	–	*128.3*
Bolivia	*636.0*	–	–	–	–	–	–	*636.0*
Myanmar	–	–	–	–	–	*185.0*	–	*185.0*
Pakistan	–	–	–	–	–	*1,954.0*	–	*1,954.0*
Burkina Faso	–	–	–	–	–	*177.6*	–	*177.6*
Honduras	–	–	–	–	–	–	–	*9.6*

Why did genetically modified crops bring a big economic benefit? The boost in dollars did not just come by itself; GMOs showed a difference in comparison with non-GMOs because the former are proven to be insect resistant (IR), herbicide resistant (HR) and disease resistant (DR).[16] Other benefits can be that genetic engineering can produce plants that are nutritionally enriched in vitamins more than in natural crops,[17] plus they do not need as long in the fields and are able to grow during any season, which all show why the economic benefit is remarkable.

1.2.2 Environmental Benefits

Any agricultural activity, including the cultivation of a given plant, produces an obvious effect on the environment. Cropping patterns determine the weed and insect species that invade the fields, agricultural machinery squeezes the soil, consumes fuel and releases CO_2, while excessively applied fertilizers stay in the soil. A plant producing a large amount of pollen and nectar is able to draw pollinators such as bees, while another plant will tend to proliferate and stifle local vegetation.

For example, abandoning oat farming to maize directly affects the environment. Additionally, properties of plants (such as insect resistance) can also affect the environment. It is possible to obtain new properties by applying plant breeding methods that use the most old-fashioned methods, such as crossbreeding or genetic manipulation, or even newer ways with even more targeted action in the DNA of plants.[18] However, the environmental impact of a plant, whether genetically modified or not, or a property of the plant obtained by means of GMO technology or not, depends in the first instance on the plant or the property per se and not the technology that was used to develop it.

With regard to GMO plants, four important properties feature in what is now available on the market. Some properties such as resistance to viruses, insects and drought aim to mitigate the influence of farming activities on the environment. Further properties, such as herbicide resistance, have the primary purpose to improve the efficiency of food production. In other words, these properties are not all likely to promote environmentally

[16] WHO, "20 questions".

[17] WHO, "Modern food biotechnology, human health and development: an evidenced-based study", 1 June 2005, http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf

[18] VIB, "Van plant tot gewas: Het verleden, heden en de toekomst van plantenveredeling" (in Dutch), 2016, http://www.vib.be/nl/educatie/Pages/Dossier-plantenveredeling-.aspx

friendly farming. However, and contrary to the alarming news relayed by the media, the figures of the environmental impact of GMO plants give a different view. Overall, GM crop cultivation has provided a significant environmental benefit over the last eighteen years.[19] Insect-resistant crops have shrunk the utilization of insecticides by up to 230 million kilograms. From the introduction of zero tillage, herbicide-tolerant plants reduced fuel consumption and CO_2 releases by 6.3 billion litres and 16.8 million tonnes, respectively. All GM plants combined, the environmental benefit can be as high as 37%.[20]

The current environmental situation that can be easily seen is the increasing population, a high rate of loss in biodiversity and global warming. As often predicted by different reports, the world population could reach 9 billion by 2050 which means that in only 32 years (from 2018) 1.3 billion people will join the 7.7 billion[21] we have today.

Even if we number about 7.7 billion, cases of hunger exceed 850 million today.[22] We have to expect in 32 years' time, more hunger and more deaths if nothing different is done. Among others, strategies aimed at generating more to eat and a fair distribution of it will allow us to maintain security of food on earth. However, with the high rate of population and the day-by-day decrease in arable land in the search for human habitat, the only solution lies in using technology by producing more food from smaller portions of land.

On the environmental level, GM crops do have benefits for the environment: research on the worldwide cost-effective and ecological impact of manipulated crops showed that from 1996 until 2015 within 20 years of using GM crops, thanks to the implicated technology pesticide spraying shrank by 6,191 million kilograms. The study also demonstrated that genetic engineering contributed to an 18.6% decrease in environmental impact associated with pesticide utilization. Furthermore, the study

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[19] Graham Brookes and Peter Barfoot. "Environmental impacts of genetically modified (GM) crop use 1996–2015: Impacts on pesticide use and carbon emissions." *GM Crops & Food*, 8, No. 2 (May 2017) https://www.researchgate.net/publication/316174866_Environmental_impacts_of_genetically_modified_GM_crop_use_1996-2015_Impacts_on_pesticide_use_and_carbon_emissions

[20] Brookes and Barfoot, "Environmental impacts".

[21] "Current world population", Worldometers, accessed 13 October 2018, http://www.worldometers.info/world-population/

[22] World Hunger Education Service, "2018 World Hunger and Poverty Facts and Statistics", accessed 7 February 2018, https://www.worldhunger.org/world-hunger-and-poverty-facts-and-statistics/#produce1

indicated that technology reduced greenhouse gas releases from agriculture, which correspond to eliminating 11.9 million vehicles from the roads.[23]

This technology also helped to reduce the application of pesticides by 37% as reported by a statistical analysis conducted on the impact of manipulated crops.[24] Adopters of herbicide-tolerant maize used 1.2% which equates to 0.013kg/ha less herbicide than non-adopters, whereas the former used 11.2% insect-resistant maize which equals 0.013kg/ha less insecticide than the latter, after a study conducted on US maize and soybean farmers during the period 1998 to 2011.[25]

The reduction of pesticide use attained 78,000 tons of formulated pesticides after an experience of using Bt cotton in 2001 in China.[26] In addition to this, a study based on the information gathered between 1999 and 2012 concluded that the use of cotton with the Bt trait was the cause of an important decrease in pesticide utilization.[27] Research also showed that Bt cotton might considerably minimize the possibility of pesticide dangers (such as poisonings) to farmers.[28] Cotton fields in Australia and the USA were one of the best examples to prove the positive impact of biotech cotton on the number and diversity of important insects.[29]

For soil and diversity conservation, GM technology proved to be a good choice. For example, zero tilling or a direct drilling system as a method to cultivate different crops over time with no harm to the soil by the way of

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[23] Brookes and Barfoot, "GM crops, environmental impacts": 1–201.

[24] Wilhelm Klümper and Matin Qaim, "A Meta-analysis of the Impacts of Genetically Modified Crops", *PLoS ONE* 9, No. 11 (November 2014): e111629. https://doi.org/10.1371/journal.pone.0111629.

[25] Edward Perry, Federico Ciliberto, David Hennessy and Gian Moschini, "Genetically Engineered Crops and Pesticide Use in U.S. Maize and Soybeans", *Science Advances* 2, no. 8 (August 2016): e1600850. http://advances.sciencemag.org/content/2/8/e1600850.full.

[26] Carl Pray, Jikun Huang, Ruifa Hu and Scott Rozelle, "Five Years of Bt Cotton in China – the Benefits Continue", *The Plant Journal* 31, no. 4 (August 2002): 423–430.

[27] Fang-bin Qiao, Ji-kun Huang, Shu-kun Wang, and Qiang Li, "The Impact of Bt Cotton Adoption on the Stability of Pesticide Use", *Journal of Integrative Agriculture,* 16, no. 10 (October 2017): 2346–2356, doi: 10.1016/S2095-3119(17)61699-X.

[28] Ferdaus Hossain, Carl Pray, Yanmei Lu, Jikun Huang, Cunhui Fan and Ruifa Hu, "Genetically Modified Cotton and Farmers' Health in China", *International Journal of Occupational and Environmental Health*, 10, no. 3 (July–Sept 2004): 296–303.

[29] Janet Carpenter, Allan Felsot, Timothy Goode, Michael Hammig, David Onstad and Sujatha Sankula. (2002). *Comparative Environmental Impacts of Biotechnology-Derived and Traditional Soybean, Corn and Cotton Crops* (Ames, Iowa: Council for Agricultural Science and Technology, 2002).

conservation activities in USA saved almost 1 billion tons of soil per year.[30] As for diversity protection, the use of corn with the Bt trait in the Philippines did not show any indication of any negative impact on insects and diversity as concluded by research on the use of Bt corn in this diversity paradise.[31]

One question someone might ask a geneticist or another biotechnologist: "Is GM technology risk-free to the environment?"

The potential risk of GM crops is actually assessed before their introduction into a field and after their planting; this includes the fact that they can outcross with wild relatives unintentionally and create a new kind of weed or just become wild themselves. Regarding this issue, after ten years of research, in 1990 the conclusion was that there was no conclusive way to decide on the danger of intrusiveness or perseverance in the wild for manipulated plants. However the study stated that results found "do not mean that genetic modifications could not increase weediness or invasiveness of crop plants, but they do indicate that productive crops are unlikely to survive for long outside cultivation."[32]

Concerning imminent dangers, another study conducted in May 1999 confirmed that pollen originating from *Bacillus Thuringiensis* (Bt) insect-resistant corn demonstrated an adverse effect on Monarch butterfly larvae. The study itself raised important issues for probable hazards to these butterflies or to other relevant organisms. As it was raising concerns, some scientists however focused on the interpretation this study's results have been given because the research was conducted in a laboratory and implies that it could show different results when exposed in outside laboratories. The author of the study strongly indicated, "Our study was conducted in the lab and, while it raises an important issue, it would be inappropriate to draw any conclusions about the risk to Monarch populations in the field solely on these initial results."[33] Another study published by the journal *Proceedings of the National Academy of Sciences* (PNAS) undertaken in 2001, two years

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[30] Richard Fawcett and Dan Towery, "Conservation Tillage and Plant Biotechnology: How New Technologies can Improve the Environment by Reducing the Need to Plow", West Lafayette, Indiana: Conservation Tillage Information Center, January 2002, http://ctic.purdue.edu/CTIC/BiotechPaper.pdf

[31] Jose Yorobe Jr and Cesar Quicoy, "Impact Assessment of Bt Corn in the Philippines", *The Philippine Agricultural Scientist* 89, no. 3 (September 2006): 258–267.

[32] Government of Canada, "Assessment criteria for determining environmental safety of plants with novel traits", Dir. 9408, 16 December 1994. Plant Products Division, Plant Industry Directorate, Agriculture and Agri-food Canada.

[33] Mark Sears, et al. "Impact of Bt Corn Pollen on Monarch Butterfly", *PNAS* 98, No. 21 (October 2001): 11937–11942.

after the previous one, concluded that *"the impact of Bt corn pollen on Monarch butterfly populations is negligible."*[34]

The number of variables determining the influence of farming on the environment is extremely important. In addition to the cultivation method, the intrinsic properties of a specific plant (yield potential, resistance to disease, etc.) play a key role in the environmental impact. These two parameters of culture mode and properties of the plant do not depend, however, on the technology used to improve the cultivated plant. All improved plants, whether using traditional plant breeding methods or GM technology, do expose important effects on the environment. The regulations, however, establish a large differentiation of both methods. While harvests obtained by old-fashioned plant breeding and mutation can be freely marketed in the European market, strict risk analyses are required to identify the possible impacts of GM crops on the environment. From this point of view, GM plants are compared to non-GM plants grown according to conventional farming practices.

Insect-resistant, drought-tolerant and virus-resistant plants do have direct or indirect impacts on the environment, as do all cultivated plants with specific properties. Interestingly, impacts can be either helpful or harmful, but combine the two in most situations. It is therefore important to carry out the risk analysis of each case individually and the ecological impact of the crop use based on a cost–benefit analysis. Finally, how do you assess what is the tolerable and intolerable environmental effect considering the benefits of a given crop?

The assessment of the environmental hazards and the stringent regulations exist to guarantee that GM crops whose negatives influence the environment do not do so more than non-GM crops on the market.

1.3 Genetically Modified Organisms: Human Health and Biodiversity

When it comes to consumption, GMOs can be highly controversial. Several government bodies have been regulating the consumption of GMOs in their respective countries. For instance, in the European Union, the European Food Safety Authority as an EU agency as well as each country in the Union have a strict establishment of full risk assessment requirements of GMOs in the community.

[34] Mark Sears et al. "Impact of Bt Corn Pollen".

Biodiversity refers to the variety of numbers and species of living things present in a certain environment. Man started to grow plants to yield enough food and be less dependent on fruit gathering and animal hunting.

Agriculture leads to the systematic clearing of natural areas and deforestation, but producing food by way of agriculture further enhances the natural balance. In fact, plants are the foundation of each diet programme, not only for humans but also for other animals. However, plants are attacked by phytophagous viruses, vertebrate bacteria, fungi and insects. Furthermore, the productive land on which the plants are grown is the preferred location for weeds or weeds that compete with crops. In short, for humans and other animals to have sufficient food, we have to keep the population of these other living things under control. Their removal from the field and, in many cases, their elimination affect biodiversity, both directly and indirectly. For example using chemical substances to eliminate these other living things in the fields would constitute a direct effect on an ecosystem. Bird biodiversity can also be indirectly endangered as insects and weeds are part of the diet of some of them.

The impact of phytosanitary products is obvious. However, other agricultural practices also have a serious impact on biodiversity. Thanks to the ploughing technique, the plough makes it possible to turn the soil several times a year, even though the plough and the heavy tractors compress the deeper layers of soil. These works have consequences for life in the ground.[35] In addition, the spreading of farm manure or chemical fertilizer increases the presence of nitrogen and phosphate in the ground, something that exposes massive impacts on the forms of life available in the soil and groundwater. In arid agricultural areas, irrigation reduces the chances of survival of weeds by drought. Nevertheless, this effect is not necessarily adverse because it also gives rise to new ecosystems that enrich biodiversity.

People have consumed GM foods across the globe over a period of more than sixteen years and there has never been a reported case of illness or a legal case concerning any harm caused by GMOs. For long time it has been argued that, the mere existence of an alien DNA in the diet cannot cause any serious damage to human health.[36]

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[35] USDA, Soil Quality Institute, “Agricultural Management Effects on Earthworm Populations”, *Soil Quality Agronomy Technical Note 11,* (June 2001): 1–8, https://directives.sc.egov.usda.gov/OpenNonWebContent.aspx?content=18543.wba

[36] FAO/WHO, “Evaluation of Allergenicity of Genetically Modified Foods: Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology” (Geneva: FAO/WHO, 2001).

Normally, in all foods with a high number of DNA and RNA eaten in a range between 0.1 and 1.0g per day[37] it is likely that the protein made by the transgene can be poisonous. In the case of the host systematically consuming the transgene made for a poison, this would be realized. However, this probable occurrence of the toxicity of protein found in a GM diet is the main reason the safety assessment is undertaken.[38] Another popular concern about GM foods is their allergenicity. In fact, products out of GM techniques or conventional breeding are both likely to be allergenic. The reasons for this allergenicity can be summarized in two factors: a known allergenic crop may be introduced into a non-allergenic one and the new creation consists of unknown allergens by either installing a novel gene into crops or modifying the immunogenicity of endogenous proteins. The issue concerning the possible allergenicity of these GM crops has been a concern of various regulatory bodies.[39] These official bodies are responsible for determining which products contain a compound of gene coming from an allergenic plant and establish a kind of hierarchical approach.

1.4 Use of Pesticides

The first pesticides were used around 2,000 years ago. Sumerians and Chinese used both plant and sulphur products to protect crops.[40] The twentieth century revolutionized the uses in this area. Intensive research in the chemical sector was the main cause of discoveries that resulted in a large number of weeds, fungi and insects being destroyed, and developments that led the agricultural sector to dramatic increases in yields.

The destruction of organisms in a field to protect crops produces effects on the environment, which is tolerated in many cases. In fact, the aim is to yield sufficient food for all animals including humans; however, insects and fungi are not the subject of this aim. In case this approach is implemented, however, it is important that the action of the phytosanitary products used be as specific as possible. In this context, we are talking about target and non-target organisms. Target organisms are, for example, certain insects

[37] Walter Doerfler and Rainer Schubbert, "Fremde DNA im Sciugersystem", (in German) Deutsches Ärzteblatt, 94 (1997): 51–2.

[38] Trish Malarky, "Human Health Concerns with GM Crops", *Mutation Research* 544, no. 2–3 (November 2003): 217–21.

[39] WHO/FAO. "Strategies for Assessing the Safety of Foods Produced by Biotechnology. Report of the Joint WHO/FAO Consultation", Geneva: FAO/WHO, 1991.

[40] Erich-Christian Oerke, "Crop Losses to Pests", *Journal of Agricultural Science* 144, no. 1 (February 2006): 31–43.

that hinder plants in their growth or attack crops. Insects that do not damage the plant and the beneficial insects that protect it as pest predators are among the few organisms that are not targeted. The application of such an approach has to sustain the lives of these insects; the use of chemicals against insects is expected to eliminate more targeted organisms and expose the least possible effect (ideally none) on non-target organisms. However, whatever the phytosanitary method used (chemical or biological), it is difficult to fight a flea without lamenting undesirable side effects. For example, pyrethrin, a biopesticide authorized in organic agriculture against insect infestations, also generates adverse effect on bees and other types of beneficial insects.[41]

With the introduction of GMO plants, two issues have been raised: fighting hunger to maintain food security, and scepticism about possible influences on the environment. To which level of certainty is the action of GM plants' resistance to insects measured? Can they also harm beneficial insects or organisms? Can herbicide-tolerant genes be found in weeds and make control less effective?

There are different ways to develop new plant varieties. For example, potatoes resistant to mildew can be obtained using conventional breeding techniques or by using GMO technology.[42] The potential impact of GMO and non-GMO plants, for example their increase and their impacts on beneficial insects as well as on the ecosystem, has a certain degree of similarity. However, the impact of GM products must be examined and verified, especially the impact of GM crops on the environment when planted on large areas of land. Available science on the GM as of today makes it possible to obtain previously non-existent properties among plants.

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[41] Reed Johnson, "Honey bee toxicology", *Annual Review of Entomology* 60, No. 1 (2015): 415–434.
[42] VIB, "Een schimmelresistente aardappel voor België" (in Dutch), 2015, http://www.vib.be/nl/educatie/Pages/Dossier-plantenveredeling-.aspx

CHAPTER TWO

THE SITUATION OF GENETICALLY MODIFIED CROPS AROUND THE WORLD

By the time the US Food and Drug Administration (FDA) had authorized them for consumption, market demand for GMOs had elevated despite all obstacles and criticism on their safety regarding human health. According to a press release[43] published in April 2019, the production of GM crops is expected to increase from 112 million tons in 2015 up to 130 million tons by the year 2021. To understand the market for GMOs globally we have to classify them by type such as vegetables, crops, animal products and fruits; by traits such as herbicide tolerance (HR), insect resistance (IR) and stacked traits (ST); or by regions such as North America, Latin America, Western and Eastern Europe, Asia-Pacific and RoW (rest of the world). In this book, because we are targeting the global market, our segmentation will mainly focus on the regions and where possible, individual countries.

Four[44] GM crops represent 99% of GM crops in the world: corn, canola, soybeans and cotton. As shown by the following diagram, soybean occupies 50% of all agriculture of GM crops globally. Some exceptions include GM sweetcorn in the US and Canada, some varieties of GM squash are grown in the US, GM papaya is grown in the US and China, and small quantities of GM eggplant are grown in Bangladesh. Nevertheless, all of these GM fruits and vegetables with GM sugar beet grown in Canada and the US, and

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[43] Market Watch, "Global Genetically Modified (GMO) Food Market Analysis & Opportunity Outlook 2021", press release April 2019, https://www.marketwatch.com/press-release/global-genetically-modified-gmo-food-market-analysis-opportunity-outlook-2021-top-key-players-syngenta-switzerland-monsanto-us-sakata-japan-bayer-crop-science-germany-2019-04-03.

[44] See for example the annual briefs on the global status of GM crops by ISAAA, 1996–2014 (these four crops are the only GM crops produced in significant quantities in the last 20 years), www.isaaa.org

GM alfalfa grown in the US, account for less than 1% of the GM crop area in the world.[45]

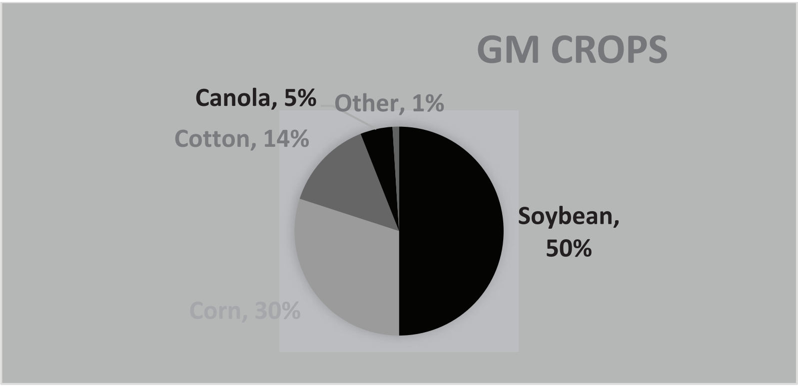

Figure 2-1: GM crops

Another interesting characteristic of GM crops is that 85% of GM crops around the world have herbicide tolerance.

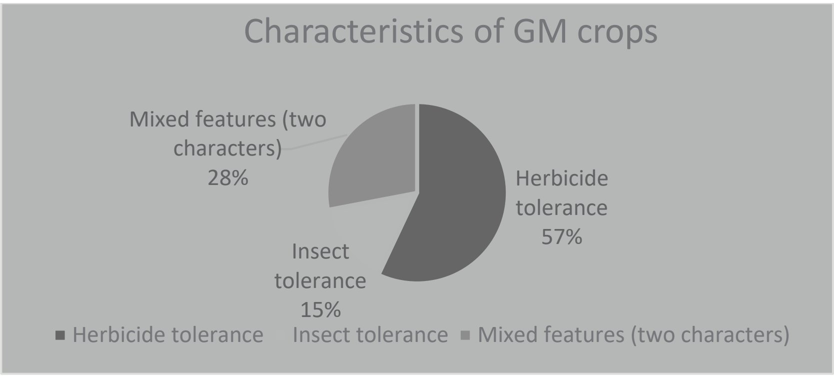

Figure 2-2: Characteristics of GM crops

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[45] Clive James, "Global Status of Commercialized Biotech/GM Crops: 2014", *ISAAA Brief no. 49* (Ithaca, NY: ISAAA, 2015). https://isaaa.org/resources/publications/briefs/49/default.asp

Also, 98% of genetically modified crops in the world are concentrated in ten countries; most countries do not grow GMOs. Only 3.7% of arable fields is dedicated to GM crops worldwide and less than 1% of farmers worldwide grow GM crops. Those countries shown in Figure 2-3 are the main exporters of almost everything we have as GM crops. The United States leads the list with 40% of land reserved for GM crops, followed by Brazil with 28%.

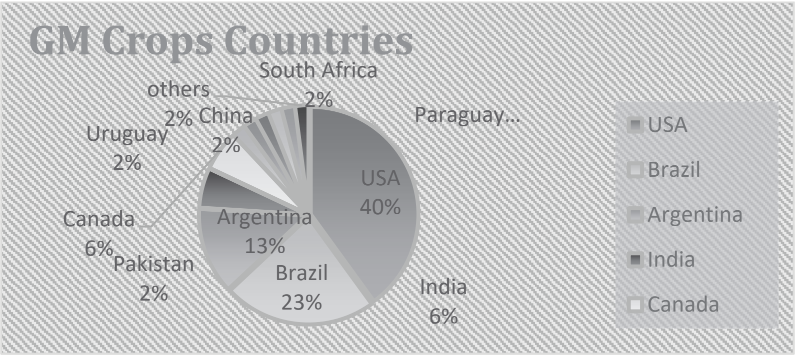

Figure 2-3: GM crops countries

In 2004, more than 78 million hectares contained GMOs in North and Latin America. This particular region represents 94% of the world's manipulated crop region; here, the top four largest producers are located (USA, Argentina, Canada and Brazil).[46] The most popular GMOs in this area contain varieties of maize, canola or cotton that are herbicide-tolerant, with a Bt gene for IR, or with both. The point of interest is that all kinds of these popular GMOs were introduced in the Americas before spreading to the rest of the world. Canada and the USA in the north were the first to lead others in the development, testing and regulatory authorization of genetically modified organisms. Further south, Mexico and Brazil developed a significant biotechnology research capacity to undertake testing. As can be seen in Tables 2-1 below, countries in North and Latin America allowed different crops to be commercialized in 2005.[47]

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[46] Clive James, "Preview: Global Status of Commercialized Biotech/GM Crops: 2004", *ISAAA Briefs No. 32* (Ithaca, NY: ISAAA, 2004).
[47] Greg Traxler, "The GMO experience in North and South America", *International Journal of Technology and Globalisation* 2, No. 1–2 (2006): 46–64.

For example, Table 2-1 shows how GMO events have been approved country by country as of September 2005.[48,49]

Table 2-1: Approval of GMO events country by country as of September 2005

State	Approved events	Authorized crops	Capacity (1,000 ha)	Approved for trade
USA	*68*	*14*	*47,600*	*Cotton, soy, maize, canola*
Canada	*48*	*13*	*5,400*	*Soy, maize, canola*
Argentina	*9*	*3*	*16,200*	*Cotton, soy, maize*
Mexico	*8*	*2*	*100*	*Cotton, soy*
Brazil	*2*	*2*	*5,000*	*Soy*
Colombia	*1*	*1*	*5*	*Cotton,*
Uruguay	*2*	*2*	*300*	*Soy, maize*
Honduras	*1*	*1*	*0.5*	*Maize*
Paraguay	*0*	*0*	*1,200*	*Soy*

The Americas (North, Central and Latin America) occupy a significant position in the race to produce GM crops worldwide. In this part, we will discuss the cultivation of these GM crops in the countries that produce the most, starting with the leader of the GM market in the world – the USA.

2.1 The Situation of GM Products in the USA

The United States as the pioneer of GM technology now has nine genetically modified crops that are available for commercial purposes. These are corn, soybeans, cotton, canola, alfalfa, sugar beet, papaya, squash and potato. Up to 2016, these crops were occupying the following hectarage in the USA:

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48 AGBIOS GM Crop Database 2005 http://www.agbios.com/main.php, accessed 26 October 2018.
49 Clive James, 2004.

Table 2-2: USA GM crops by hectare

Crop	*Capacity (Mha)*	*Harvest capacity (in millions of ha) and percentages*					*Overall percentage*
		IR	*HT*	*IR-HT*	*Other features*	*Overall*	
Soy bean	*33.87*	*n/a*	*31.84 (100%)*	*n/a*	*n/a*	*31.84*	*94*
Maize	*38.10*	*1.14 (3%)*	*4.95 (13%)*	*28.96 (76%)*	*n/a*	*35.05*	*92*
Cotton	*3.98*	*0.16 (4%)*	*0.36 (9%)*	*3.18 (80%)*	*n/a*	*3.70*	*93*
Canola	*0.69*	*n/a*	*0.62 (100%)*	*n/a*	*n/a*	*0.62*	*90*
Sugar beet	*0.47*	*n/a*	*0.47 (100%)*	*n/a*	*n/a*	*0.47*	*100*
Alfalfa	*8.46*	*n/a*	*1.21 (98%)*	*n/a*	*0.02*	*1.23*	*14*
Papaya	*<0.01*	*n/a*	*n/a*	*n/a*	*<0.01*	*<0.01*	*<0.01*
Squash	*<0.01*	*n/a*	*n/a*	*n/a*	*<0.01*	*<0.01*	*<0.01*
Potato	*<0.01*	*n/a*	*n/a*	*n/a*	*<0.01*	*<0.01*	*<0.01*
Total	*85.60*	*n/a*	*n/a*	*n/a*	*n/a*	*72.92*	*86*

In 2016 in the USA, 72.92 million hectares were farmed with manipulated plants occupying 39% of all production planted globally, which makes the US the leader in genetically engineered crop production.[50] In the last two decades, (1995–2015) statistics show that the financial benefit of biotech crops reached $ 72.9 billion, and reached $ 6.9 billion in 2015 alone.[51]

However, a new arctic apple that came from Canada recently can now be found in US grocery stores.

[50] Clive James, "Global Status of Commercialized Biotech/GM Crops: 2016", *ISAAA Brief No. 52* (Ithaca, NY: ISAAA, 2016), https://www.isaaa.org/resources/publications/briefs/52/download/isaaa-brief-52-2016.pdf

[51] James, "Status of Commercialized Biotech/GM Crops: 2016".

Figure 2-4: The GM or artic apple (See Maxmen, “Genetically modified apple”)

In Figure 2-4, the GM apple or the arctic apple on the right hand side does not bruise any time it is exposed to oxygen because it lacks a gene encoding an enzyme that causes plant cells to brown.[52] This helps to avoid food waste that often occurs in developed countries such as the USA, Canada or France.

Among farmers, some GM varieties are popular. For example in the USA, these GM varieties represented 95% of sugar beets, 88% of corn and 94% of soybeans. Some GM crops are produced and used for human food purposes like the case of Hawaiian papaya and a handful of squashes. Other products like corn and soy are used to make ingredients used in related products such as starches, sugars or oils. In the USA or other developed nations, GMOs that are not mainly agricultural crops are used to produce enzymes that are helpful in the production of fermented beverages, starch products or those found in cheeses.

Figure 2-5[53] can help to understand the adoption of GMOs in the period from 1996 until 2018.

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[52] Amy Maxmen, “Genetically modified apple reaches US stores, but will consumers bite?” *Nature* 551, No. 7679 (November 2017), https://www.nature.com/news/genetically-modified-apple-reaches-us-stores-but-will-consumers-bite-1.22969 accessed 10 November 2018.

[53] USDA, “The Adoption of Genetically Engineered Crops in the United States, 1996–2018”, https://www.ers.usda.gov/webdocs/charts/58020/biotechcrops.png?v=0 accessed 12 November 2018.

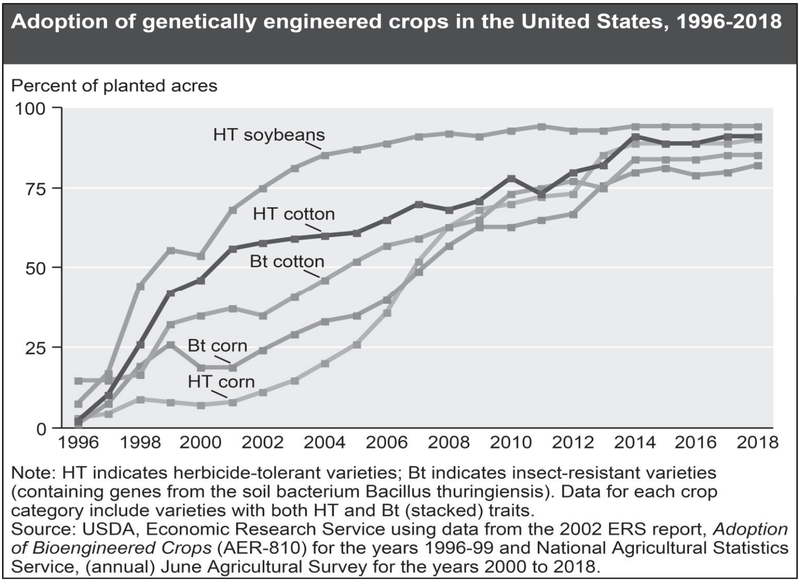

Figure 2-5: Adoption of genetically engineered crops in the United States, 1996–2018

Herbicide-tolerant (HT) crops are very useful for effective weed control because of their ability to tolerate potent herbicides such as dicamba, glufosinate and glyphosate. The study conducted by the USDA demonstrated that the acreage of local soybean plants using herbicide-tolerant seed rose from 17% in 1997 to 68% in 2001, before a reaching a state of stability and little change in 2014. As the chart shows, HT cotton rose from something like 10% in 1997 and reached 56% in 2001, before attaining a peak of 91% in 2014. Another important note in the chart is that the rate of HT corn reduced just as the genetically engineered (GE) seeds became available for commercialization. However, we can see that current numbers show about 90% of domestic corn has been produced with HT seeds.

Since 1996, insect-resistant strains for corn and cotton have been available. These crops possess a good number of genes made from soil bacterium Bt and generate insecticidal proteins. As the study shows, Bt corn rose from roughly 8% in 1997 to 19% in 2000, before reaching a high of 82% in 2018. As for Bt cotton, its adoption rate rose from 15% of domestic cotton acreage in 1997 to 37% in 2001. Nowadays, US cotton acreage with Bt reaches 85%.

Some varieties are called 'stacked' because they contain both HT and Bt features; the acceleration of their adoption appeared in the current decade. For example, in 2018 about 82% of land for cotton and 80% for corn were planted with a double quality, one for HT and another for Bt. Stacked seeds adoption can be observed in Figure 2-6.[54]

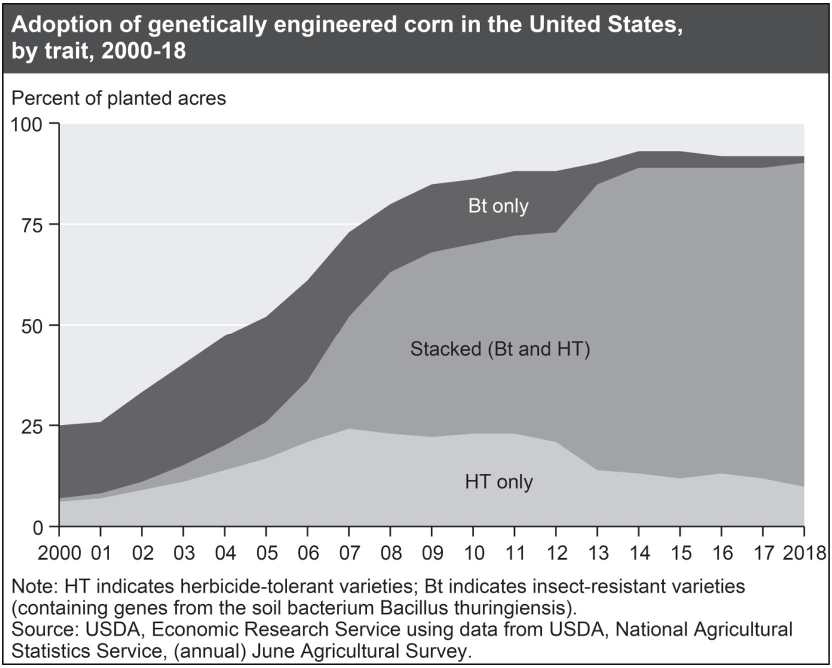

Figure 2-6: Adoption of genetically engineered corn in the United States, by trait, 2000–18

Figure 2-7[55] showing how stacked cotton has been adopted in the US can be summarized as follows:

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[54] USDA, The Adoption of Genetically Engineered Corn in the United States, by trait 2000–2018, accessed 12 November 2018
https://www.ers.usda.gov/webdocs/charts/55237/biotechcorn.png?v=0 accessed 12 November 2018.
[55] USDA, The Adoption of Genetically Engineered Cotton in the United States., by trait 2000–2018,
accessed 12 November 2018

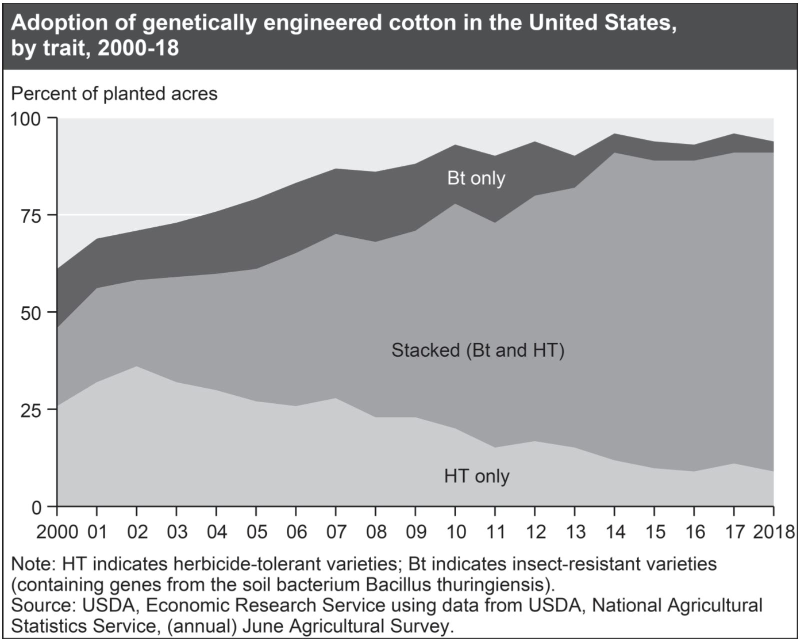

Figure 2-7: Adoption of genetically engineered cotton in the United States, by trait, 2000–18

The USDA reported that the USA is the biggest agriculture exporter, and the majority of exports in biotech varieties were corn and soy products. The report confirms that approximately 6.5 million tons and 85 million tons of soybeans have been exported to the European Union (EU) and China respectively; in addition, China also imported an estimated 3.17 million tons of corn from US grain markets in 2016–2017.[56]

To conclude, although many countries have developed ways to achieve food security by embracing biotechnology in food production, the USA still holds the leading position in this race. Three products: soybean, maize and cotton reached an adoption of 93%; other innovative products (such as potato and apple) and features (such as disease resistance) took another step

https://www.ers.usda.gov/webdocs/charts/56323/biotechcotton.png?v=0 accessed 12 November 2018.

[56] Council for Biotechnology Information, "GMO Globally" https://gmoanswers.com/gmos-globally accessed 10 November, 2018

and prepared for trade to customers with the purpose to cut down wastage of food and to boost taste as well as nutritional value.

2.2 The Situation of GM Crops in Brazil

Almost everyone who arrives in Brazil should expect a very good dining experience. However, after their stay they will also be able to say that they ate products containing GMOs. By production and consumption of GMOs, this South American country occupies second place in the world. According to the Brazilian Institute of Geography and Statistics (IBGE), considering the figures for 2013, 37.1 billion hectares was intended for the cultivation of GMO products.[57]

Administratively, the responsibility for biosafety management in Brazil lies in the hands of the National Technical Biosafety Commission (CTNBio). However, depending on the type of GMO, other institutions may have to decide (for example for transgenic plants resistant to insects, the authorizations of the Secretariat of Plant Protection, the Institute of the Environment and the National Agency for Health are required). The commercial cultivation of genetically modified plants was first authorized in Brazil in September 2003. About 3 million hectares of herbicide-resistant soybeans were planted during the first season.[58] The country adopted biosafety legislation in 1995; over the years, this law has been strengthened, particularly with regard to labelling. In July 2001, the Ministry of Agriculture decided to make the labelling of all products containing more than 4% genetically modified ingredients compulsory, and then in May 2003 this threshold was lowered to 1%. Fines for non-labelling of products containing GMOs can reach $ 6,000.[59]

This tightening trend was counterbalanced in May 2003 by the adoption of a law (No. 131) that allows for the commercial sale of illegally produced transgenic soybeans from Brazil (as illustrated below). The Brazilian Institute of Consumer Protection (IDEC) immediately announced that it would conduct detection tests on all products containing soybeans to verify compliance of the labelling. This soybean was supposed to be marketed until 31 January 2004, after which it would be destroyed by incineration and the fields cleaned.[60]

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[57] Brazilian Research Institute http://www.idec.org.br/consultas/dicas-e-direitos/saiba-o-que-sao-os-alimentos-transgenicos-e-quais-os-seus-riscos

[58] Clive James, "Global Status of Commercialized Transgenic Crops: 2002 Feature: Bt Maize", *ISAAA Briefs No. 29* (Ithaca, NY: ISAAA, 2003).

[59] James, Global Status of Commercialized Transgenic Crops

[60] James, Global Status of Commercialized Transgenic Crops

In the domain of intellectual property, Brazil is trying to put in place legislation to protect its natural resources through a national (*sui generis*) system, an alternative to Western patent law. In 1996, the federal authorities adopted a patent law and another one on the preservation of vegetal diversities, which prepared the country's compliance with UPOV-1978. Since these laws provide relatively good commercial protection for agricultural research products, they have led many industries active in plant biotechnology to set up subsidiaries in the country.[61]

2.2.1 The General Policy on Commercialization of GM Crops

In 1997, CTNBio authorized various multinationals to carry out field trials (with transgenic soy and cotton in particular). One year later, five varieties of transgenic soybeans were allowed to be grown and marketed. However, IDEC – later joined by Greenpeace and other organizations – soon filed an appeal against this decision, citing the fact that the CTNBio had not proceeded with the studies and the environmental impact was required by law. A federal judge then decreed a ban on the testing, marketing and cultivation of these varieties until their safety was demonstrated,[62] a decision against which Monsanto filed an appeal. This decision was reaffirmed in 2000 for a period of three years.

For his part, Brazilian President Luiz Inácio Lula da Silva had initially declared himself rather against GMOs, but in December 2002, his Minister of Agriculture, Roberto Rodrigues, affirmed his position in favour of the authorization of transgenic plant crops: "We must allow farmers who so wish, to cultivate transgenic plants under the condition of absolute control, labelling and scientific assurances that there are no effects on public health and the environment".[63] In addition, the United States is conducting major campaigns to promote GMOs in Brazil; executives from various Brazilian ministries have recently been invited to come and see for themselves the efficacy of transgenic crops in the fields of Arizona. The American

[61] It can be noted that in 2001, Monsanto built Camaçari's largest production plant outside the United States. It was intended to provide the products needed to manufacture its flagship product, Roundup Herbicide.

[62] Institute for Agriculture & Trade Policy, "Brazil Court Reaffirms Ban on Biotech Soybean Planting", *Dow Jones Newswires,* 16 August 1999, https://www.iatp.org/news/brazil-court-reaffirms-ban-on-biotech-soybean-planting

[63] ICTSD, "Brazilian AG Minister Speaks Out in Favor of GMOs", 20 December 2002, http://www.ictsd.org/bridges-news/biores/news/brazilian-ag-minister-speaks-out-in-favour-of-gmos accessed 18 December 2018.

resources recently committed in this country are also considerable through the ISAAA Biosafety Initiative.[64]

However, in March 2003, faced with the increase of illegal crops in the southern states of Brazil, the Lula government was forced to confer a provisional authorization for the harvest and sale of transgenic soybeans from the 2002/2003 harvest, which had been planted illegally. In September 2003, when more than 100,000 farmers were preparing to plant herbicide-resistant soybeans illegally, the government finally decided to allow their cultivation for the 2003/2004 season in the state of Rio Grande do Sul.

2.2.2 The Agriculture Sector in Brazil

The primary sector employs 25% of the labour force and contributes only 8% of the Gross National Product (GNP). The main agricultural products are coffee (first in the world), sugar cane (first), cocoa (second), soybean (second) cattle (second) and corn (third). Brazil is a glaring example of countries where there are significant imbalances between agricultural production and access to food. Multinational firms directly or indirectly own more land than all Brazilian farmers and use these areas for crops grown for export. In terms of agricultural exports, Brazil occupies the world's fourth place, although 40% of its population suffers from malnutrition.

In its border states with Argentina, many fields have already been grown with transgenic soybean (Monsanto's Roundup Ready) for several years. Seeds smuggled from Argentina were crossed with Brazilian seeds and sold to farmers. Brazilian seed producers estimate that about six million tons of soybeans produced in the 2002–2003 season in Rio Grande do Sul state were genetically modified. Following authorization to grow transgenic soybeans in September 2003, an estimated 3 million hectares have been planted.

The position of Brazil, which has seen the proliferation of illegal crops and which, in the attempt to normalize the situation, was then forced to authorize the cultivation, is now very uncomfortable. Indeed, Brazil was until now one of the largest suppliers of certified non-transgenic soybeans. Between 1996 and 2000, the volume of US soybean exports to Europe decreased from 9.2 million to 6.8 million tons, while in the same period exports of non-transgenic soy from Brazil to Europe rose from 3.1 million to 6.3 million tons. Brazil is also exporting its products to Japan and China, both of which are reluctant to import GMOs. This "GM-free" reputation has

[64] See more at Biosafety Clearing House: http://bch.biodiv.org/Pilot/ Record.aspx ?RecordID =100

also earned Brazil a surge in scandals such as "Starlink" corn.[65] In Europe, Spain had ordered 150,000 tons of non-GMO-guaranteed Brazilian corn, agreeing to pay US$ 6 more per ton than in the international market. The decision to authorize the cultivation of Monsanto's soybeans is therefore likely to call into question the comparative advantage conferred on Brazil by its certified non-transgenic crops.

Moreover, to cover its deficits – particularly for livestock feed – every year Brazil would need to import nearly a million tons of maize. In November 2002, the company National Starch Chemical Industrial chartered an American cargo ship containing 7,400 tons of genetically modified corn. Nevertheless, in January 2003, the Brazilian Minister of Agriculture said that this type of import (GMO) was illegal and that these shipments of maize from the United States had to be destroyed or returned to the United States.[66] In 2000, however, an import from Argentina that potentially contained GM maize was authorized in the context of an emergency for local poultry manufacturers who would be out of business if they did not access maize stocks urgently.[67]

Brazil has now decided to import its maize mainly from China, where maize production is still guaranteed non-GMO. In addition, Unilever and Nissin, as well as Sadia and Perdigäo (the two largest Brazilian Agri-food companies), have announced their intention to eliminate genetically modified ingredients from all their food products. This decision follows Greenpeace's discovery in 2002 of GM soybeans in five products sold by Perdigäo in Brazil. A recent public opinion survey conducted by the newspaper *Gazeta Mercantil* has revealed that 60% of Brazilian consumers do not want GMOs on their plate.[68]

The Brazilian government has for years been financing national agricultural research programmes under the auspices of EMBRAPA (Empresa Brasileira de Pesquisa Agropecuária – the Brazilian Agricultural Research Corporation). Research programmes at the genetic level include soybean, cotton, maize, potato, papaya, black bean, banana, cassava and

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[65] Christopher Noisette, "Starlink: chronique d'un scandale annoncé" (in French) *Inf'OGM, No. 18*, March 2001, http://www.infogm.org/IMG/pdf/doc-38.pdf

[66] Reuters "Brazil to Re-export or Burn US GM Corn Cargo" *IATP* 20 January 2003, https://www.iatp.org/news/brazil-to-re-export-or-burn-us-gm-corn-cargo

[67] Inf'OGM, Bulletin No. 37, December 2002: http://www.infogm.org/article.php3?id_article = 809&var_recherche =Br %E9sil

[68] Mirko Saam, Barbara Petriccione and Andràs November, "Les impacts des plantes transgéniques dans les pays en voie de développement et les pays en transition", *Revue européenne des sciences sociales* [En ligne], XLII-130 | 2004, mis en ligne le 16 novembre 2009, 23 novembre 2018, http://journals.openedition.org/ress/493 DOI 10.4000/ress.493

rice. In total, nearly US$ 5 million is invested annually in public research. Brazilian researchers have already patented an original system for transgenesis (applicable to several species) and have been able to test (in confined testing) their own herbicide-resistant soybeans as well as virus-resistant potatoes.[69]

2.3 The Situation of GM Crops in Argentina

Following decades of political instability and economic crisis, in the beginning of the 1990s Argentina was unable to repay its external debts, which reached more than $45 billion.[70] To meet the requirements of international financial organizations, the country liberalized its agricultural sector and encouraged foreign investment. In 1996, the arrival on the market of transgenic soya, resistant to glyphosate herbicides, gave rise to a real revolution in Argentinean agriculture.[71] Transgenic soy has experienced instant success and spread quickly across the country, now occupying 54% of all cultivated land. This metamorphosis of Argentine agriculture has resulted in significant social and ecological consequences. Farmland is concentrated in the hands of big landowners. The capacity of land reserved for agriculture has decreased by 30%[72] and the average agricultural exploitation area increased from 250 to 538 ha. Transgenic soy requires 30% less labour than traditional crops and farming unemployment reached a peak. Between 1991 and 2001, the rural population decreased by 13.5% in some regions; the small producers abandoned their land and moved to cities to try new life.[73] Other food crops have been abandoned to sow

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[69] Mirko Saam et al., "Les impacts des plantes transgéniques".
[70] Beniamino Moro and Victor Beker, *Modern Financial Crises: Argentina, United States and Europe* Financial and Monetary Policy Studies 42 (Cham, Switzerland: Springer, 2016), 31
https://www.springer.com/cda/content/document/cda_downloaddocument/9783319209906-c1.pdf?SGWID=0-0-45-1518077-p177543514
[71] Eduardo Trigo, "Twenty Years of Genetically Modified Crops in Argentine Agriculture", *ArgenBio*, November 2016,
http://argenbio.org/adc/uploads/20GM_2016/Web_English_20_years.pdf
[72] Rodolfo Bongiovanni and James Lowenberg-DeBoer, "Precision Agriculture in Argentina" *Journal of Technology Management and Innovation, July 2018*
https://www.researchgate.net/publication/228724914_Precision_Agriculture_in_Argentina.
[73] Jorge Morello, Silvia Matteucci and Andrea Rodríguez, "Sustainable Development and Urban Growth in the Argentine Pampas Region", *The Annals of the American Academy of Political and Social Science* 590, No. 1. (November 2003), 116–130.

soybeans for export. Due to this, food prices are rising and there is an increase in malnutrition problems.[74]

With the large-scale exploitation of transgenic soybeans in monoculture, soils are degrading. In the absence of an adequate fertilization plan, 3.5 million tons of nutrients are taken from Argentinian soil annually without being replaced. Land conversion for agriculture on fragile soils has accentuated erosion problems in some regions. Forests are given up to soybeans; the average annual rate of deforestation in Argentina, one of the highest in the world, has reached 1.35%. With the loss and the fragmentation of forest areas, habitats are degrading and biodiversity is being eroded. Between 1996 and 2005, annual carbon emissions from deforestation reached 20.875 Gg C/year.[75] Glyphosate herbicide consumption rose from 13.9 million litres in 1996 to 200 million litres in 2008.[76] Repeated use of the same herbicide resulted in tolerance in some weeds. The glyphosate has become ubiquitous in ecosystems, affecting aquatic organisms and terrestrial ecosystems, and creating health problems in human populations. Before this disturbing development, public sector and civil society actors were trying alternatives to the transgenic soybean model. The atmosphere is tense between soybean producers and the central government of Buenos Aires. However, several projects set up in collaboration with farmers demonstrate that profitable agriculture, in balance with ecosystems and socially equitable, is possible.

In terms of agricultural exports, Argentina held tenth place among the exporters of this sector worldwide. Argentina is an agricultural giant with a large share of useful agricultural land (147 Mha, of which only 37 Mha is grown outside orchards and vineyards). On the other hand, soil and climatic conditions are favourable in its main production areas (water availability, soil quality, etc.), and about 130 Mha are intended for pasture.[77]

Exports of grains, oilseeds and derivatives accounted for 45% of the country's agricultural and agri-food exports in 2015.[78] The main Argentinean crops are soybean, corn, wheat, barley and sunflower. Spread over 28.17 Mha, they occupy 92% of the land in annual crops. In 2014–2015, the

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[74] Lilian Joensen and Stella Semino, "Argentina's Torrid Love Affair with the Soybean", *Grain* 26 October 2004, https://www.grain.org/fr/article/entries/435-argentina-s-torrid-love-affair-with-the-soybean.

[75] Joensen and Semino, *Argentina's torrid love affair*

[76] Joensen and Semino, *"*Argentina's Torrid Love Affair*"*.

[77] Ministère De L'agriculture, De L'agroalimentaire Et De La Forêt (2014), Le politiques Agricole A travers le monde: quelques exemples, accessed 24 November 2018 http://agriculture.gouv.fr/sites/minagri/files/1606-ci-resinter-fi-argentine-v3.pdf.

[78] Ministère De L'agriculture, "Le politiques Agricole".

harvest of these five crops reached more than 97 Mt (out of a total grain production of 103.45) of which 60.8 Mt was for the sole production of soybeans spread over 19.3 Mha, 26.4 Mt of corn, 9.5 Mt of wheat, 4.3 Mt of barley and 2.5 Mt of sunflower; rice production was around 1Mt, mostly for the domestic market.[79]

Strange but a fact, 30 years ago soybeans were not a part of Argentine farming activities. However, as for today they stand as the cornerstone of the economy. By the capacity of soybean production, the country came behind only the United States and Brazil in 2015. Argentina exports more soybean oil and meal than any other country in the world and occupies second place in the exports of sorghum and sunflower derivatives (oil and cake). Argentina is also a big fruit producer. The crops are mainly in the provinces of Rio Negro, Neuquén and Mendoza. The country also came in at third place in the world in terms of lemon production in 2014–2015 with an average annual production of 1.15 Mt according to the USDA, and was the second largest exporter behind Turkey. The production of apples and pears is also significant and these two fruits account for 50% of fresh fruit exports. In 2012, Argentina was the world's third-largest pear producer behind China and the United States, and the leading exporter (about 890 Kt produced in 2014 according to the Argentine Ministry of Agro-Industry). In the same year, it was leading the world in terms of apple juice export, with apple production of 930 Kt.[80]

Argentina quickly adopted GMOs in 1996. In 2012, Argentine farmers used manipulated seeds to produce 98% of soybeans, 20% of cotton and 40% of maize. Argentina, which fears the "green protectionism" of developed countries, developed a discourse built on the interest of the system "GMO – direct seeding – glyphosate", a strategy to preserve soil and to increase harvest by restricting the requirement to utilize new surfaces. Nevertheless, it does not prevent resistance problems of weeds to glyphosate to develop in other countries since they are also using GM technology to improve their crops.[81]

These resistances have led to, according to the Buenos Aires Grain Exchange, a decline in the use of direct seeding in 2014, from 94% to 92% of the area cultivated in the six main crops of the country, which had not happened since the generalization of the use of this technique in 1998. The legislation allowing genetically manipulated seeds to be used carried on to

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[79] Joensen and Semino, "Argentina's Torrid Love Affair".

[80] See more at https://ipad.fas.usda.gov/highlights/2014/01/Argentina

[81] Moises Burachik, "Regulation of GM crops in Argentina", *GM Crops & Food* 3, No. 1 (January 2012): 48–51, DOI: 10.4161/gmcr.18905

expand with, inter alia, the approval of the PVY-resistant transgenic potato[82] in November 2015. Strong pressure was exerted to allow a variety of sugar cane resistant to glyphosate to be approved. Nevertheless, environmental risks and health-related damages have always been a subject of different organized and endless manifestations.

In Argentina, by 2017 three biotech crops were being planted on Argentine soil. As demonstrated in Figure 2-8,[83] the most populous crop, soybean, occupies 77% of all soil or 18.1 Mha, corn occupies second place with 22% which equates to 5.2 Mha and the list is closed by cotton on the percentage of 1% or 0.25 Mha.[84]

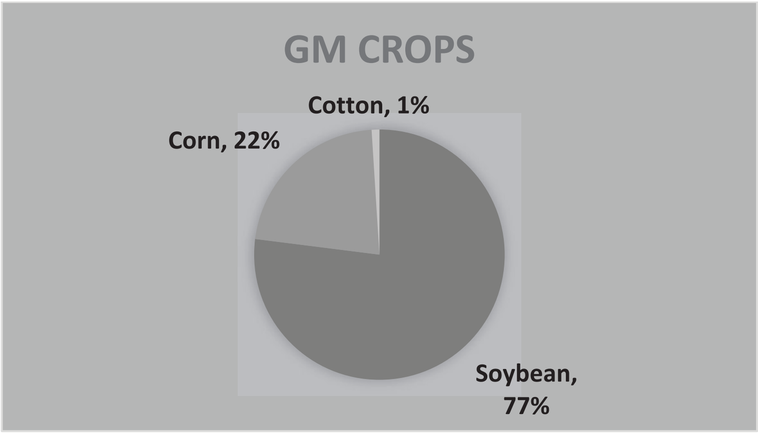

Figure 2-8: Share of three main GM crops

Argentina started its transgenic race in 1996. It has multiplied its cultivated area by three in fifteen years. A triumph from the financial point of view. GMO soy massively exported to Europe has allowed Argentina to fall back on its feet economically. Today, almost 100% of soybean produced

[82] Lukie Pieterse, "PVY-resistant GMO Potato Variety Approved by Argentine Authorities", *Potato News Today*, 21 August 2018: https://potatonewstoday.com/2018/08/21/pvy-resistant-gmo-potato-variety-approved-by-argentine-authorities/

[83] ISAAA, "Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years", *ISAAA Brief No. 53*, 2017: 21, https://www.argenbio.org/adc/uploads/ISAAA_2017/isaaa-brief-53-2017.pdf

[84] ISAAA, "Global Status of Commercialized Biotech/GM"

in Argentina is GMO, and resistant to glyphosate. In just 21 years of their introduction to markets, GM crops in Argentina have generated an income estimated at US$ 23.7 billion among which 2016 alone, a yearly income reached US$ 2.1 billion.[85] Economic benefit has been huge for over 130,000 Argentine farmers and their families.

2.4 The Case of India

India licensed Bt cotton in 2002; this cotton that produces its own insecticide, and has had huge success since its introduction in Indian fields. Today, 95% of the 116 million hectares of cotton are Bt cotton and make India the second largest producer and exporter of cotton worldwide.[86] From this time, no one has to worry about whether the cotton that makes clothes is genetically modified or not. While cotton is not eaten but cottonseed[87] it is used to produce oil called "vegetable" oil, sometimes up to 30% of this oil is this same GM product and no one cares – even those of green ideologies.[88]

Witnessing this undeniable success for small farmers, Indian Prime Minister Narendra Modi decided to lift the ban on the cultivation of transgenic plants for food. His point can be summarized as simply as this: in 30 years' time, there will be 1.5 billion Indians and it will be necessary that this entire small world has enough to eat. However, it will also be necessary to preserve its environment, and "Bt" plants are good candidates for satisfying people's food needs because they require much less insecticide treatment. As a result, small farmers will no longer need to borrow money to buy expensive insecticides. Indeed, the productivity of

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[85] ISAAA, "Global Status of Commercialized Biotech/GM"

[86] Sourav Mishra "India Becomes Second Largest Producer of Cotton", *Down to Earth* 4 July 2015, https://www.downtoearth.org.in/news/india-becomes-second-largest-producer-of-cotton-8830

[87] Choudhary, Bhagirath, and Kadambini Gaur, "Biotech Cotton in India, 2002 to 2014: Adoption, Impact, Progress & Future", *ISAAA Series of Biotech Crop Profiles*, Ithaca, NY: ISAAA, 2015 https://www.isaaa.org/resources/publications/biotech_crop_profiles/bt_cotton_in_india-a_country_profile/download/Bt_Cotton_in_India-2002-2014.pdf

[88] Indra Singh, "Is PM Modi Pushing for GM Mustard? Swadeshi Activists Resist GMO", *The Quint*, 19 May 2017, https://www.thequint.com/news/india/is-narendra-modi-pushing-gm-mustard-genetically-modified-swadeshi-bayer

Indian agriculture is catastrophic and the authorization of transgenic plants for food could, according to the prime minister, improve the situation.[89]

Nonetheless, the transgenic food crop-seed market remains in the control of four companies: Monsanto, DuPont Pioneer, Dow AgroSciences and Syngenta. All the other actors in plant transgenesis have virtually disappeared under the pressure promoted by Indian environmental movements without even producing any comprehensive argument to justify the ban they imposed on transgenic plants. Prime Minister Modi thus exerts a constant pressure on the BJP (Bharatiya Janata Party) to authorize the cultivation of the transgenic oleaginous crop on Indian soil, in particular mustard. Mustard (Brassica juncea), of the rapeseed (Brassica napus) family, is an oilseed plant from Nepal with a high oil yield. A very high-yielding "made in India" transgenic variety was being tested close to the prime minister's residence, which is extremely interesting as this was the first field trial since the 2010 moratorium banning the continuation of field trials of transgenic rice, chickpea, maize or eggplant. It is important to note about mustard that India imports 60% of the US$ 10 billion of food oil consumed, the third most important import after oil, and gold for jewellery.

The central government has allowed unrestricted field trials and consequently the cultivation of transgenic plants to the dismay of environmental organizations including Greenpeace, which is in the line of sight of the Indian Ministry of Finance. Farmers wishing to cultivate genetically modified plants must nevertheless obtain local authorization.[90] This detail naturally offends Greenpeace, an organization that is increasingly lacking in arguments, especially in India since Bt transgenic cotton has been the subject of licence agreements with several Indian companies. As a result, Monsanto is no longer the pet peeve to fight in this country for this organization. At the instigation of the prime minister, various Indian academics tried, unsuccessfully, to show that transgenic food crops were dangerous for the environment, animal and human health.[91]

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[89] Sandip Das, "PM Narendra Modi Government Rethinking Plan to get GM Food in India for the First Time Ever?" Financial Express, 15 May 2017 https://www.financialexpress.com/india-news/pm-narendra-modi-government-rethinking-plan-to-get-gm-food-in-india-for-the-first-time-ever/668520/

[90] Rao., Sunkeswari R., "An Update: Biotechnology Regulation in India" *ILSI Research Foundation* http://ilsirf.org/wp-content/uploads/sites/5/2016/06/rao.pdf

[91] Mark Lynas, "The Complicated Truth Behind GMO Cotton in India", *Cornell Alliance for Science* 2 August 2018 accessed 12 November 2018 https://allianceforscience.cornell.edu/blog/2018/08/complicated-truth-behind-gmo-cotton-india/.

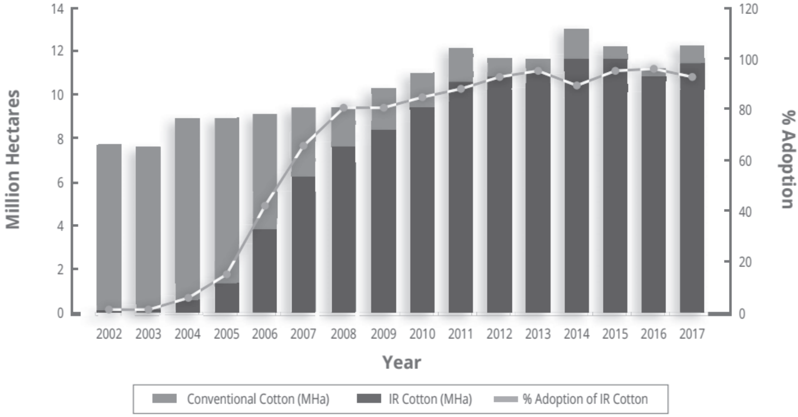


Figure 2-9: Adoption of cotton in India

Figure 2-9[92] demonstrates how cotton has been adopted by the Indian population by the time of its introduction in 2002 until 2017.

Table 2-3: Biotech mustard

Records	**2010–2011**	**Over checks**	**2011–2012**	**Over checks**	**2014–2015**	**Over checks**
Varuna (Barnase)	2,096	24	2,291	32	1,861	28
EH-2 (Barnase)	2,009	29	1,611	88	1,558	53
Varuna	2,093	24	2,272	33	1,887	26
EH-2	1,897	37	1,741	74	1,378	73
RL1359	2,037	28	2,016	50	1,776	34
DMH-11	2,600	–	3,025	–	2,386	–

[92] ISAAA, “Commercialized Biotech/GM Crops”, 30.

When it comes to biotech mustard (see Table 2-3),[93] Indian centres for growing mustard (2010–2011 as conducted in Kumber, Navgaon and Sriganganagar, 2011–2012 for Kumber and Navgaon, 2014–2015 conducted in Ludhiana, Bhatinda and the Indian Agricultural Research Institute), showed a great yield advantage of mustard hybrids in kg/ha.[94]

In 2005, the Indian government approved new demands. According to various reports, more than twelve multinationals and national agriculture companies were already in or interested in investing their money in GM crop technologies in India.[95]

2.5 The Case of Canada

Canada approved the use of GMOs in agriculture in the 1990s. The main GM crops grown today, including canola, corn and soybeans, had been approved in that decade. It was also in 1990 that an enzyme used to curdle milk, chymosin, made from a GM bacterium was approved.[96] In Canada, there is no difference between GMOs and conventional agricultural products in terms of regulations. The Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada are the main authorities for the approval of GMOs. Some GMOs are not approved and are therefore not marketed. This is the case for a GM soy line producing a Brazilian nut protein considered allergenic.[97]

Although some GMOs may be approved for marketing in Canada, not all are commercialized. In Canada, to know the distinction between approved GMOs and marketed GMOs is important. Currently, there are thirteen species of GM plants approved for commercialization in Canada. Field crops of canola, grain corn and GM soy that are marketed in Canada and Quebec are primarily for animal feed purposes. Commercial practices mean there is currently no GM fruit (apple, strawberry, blueberry, etc.) or vegetables (lettuce, carrot, cucumber, etc.) on grocery store shelves. In March 2016, a potato that produces less acrylamide during cooking was

[93] ISAAA, "Commercialized Biotech/GM Crops", 33.
[94] ISAAA, "Commercialized Biotech/GM Crops", 33.
[95] Ramanna, Anitha, "India's Policy on Genetically Modified Crops". *Asia Research Centre Working Paper 15,* 2006, https://www.lse.ac.uk/asiaResearchCentre/_files/ARCWP15-Ramanna.pdf
[96] Los Angeles Times, "FDA Approves 1st Genetically Engineered Product for Food", March 24, 1990, http://articles.latimes.com/1990-03-24/news/mn-681_1_genetically-engineered-product-for-food
[97] Nordlee, J. S., et al. "Identification of a Brazil-Nut Allergen in Transgenic Soybeans", *New England Journal of Medicine* 334, no. 11 (March 1996): 688–692.

approved for commercialization in Canada, but only started to be grown there in 2017.[98] Whether to sell a product or not often depends on its markets and demands in agricultural production. For example, in 1995, a delayed ripening tomato became the first transgenic plant on the market. However, it was quickly withdrawn from the Canadian market because of the indifference of consumers who, lamenting its bad taste, were no longer interested in buying the product.[99]

The thirteen species of GM plants approved for commercialization in Canada fall into six broad categories of traits.[100]

Table 2-4: Traits of GM plants in Canada

Features (Traits)	GMO
Insect resistance	*Bt corn-corn, sweet corn Bt* *Bt potato resistant to Colorado potato beetle ** *Bt tomato resistant to Lepidoptera ** *Cotton*
Herbicide tolerance	*Grain corn; sweet corn* *Soy* *Linen** *Canola* *Cotton** *Sugar beet* *Alfalfa* *Rice**
Resistance to viruses	*Squash** *Papaya** *Potato**

[98] Government of Canada, "Simplot Innate® Potato Events Gen1-E12, Gen1-F10, Gen1-J3, and Gen1-J55" 3 May 2016 https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/simplot-innate-potato-events-gen1-e12-f10-j3-j55.html

[99] Eric Rankin, "The 'Flavr Savr' Tomato, the World's First Genetically Modified Produce", accessed 15 October 2018 https://www.cbc.ca/archives/entry/the-flavr-savr-tomato-the-worlds-first-genetically-modified-produce.

[100] Government of Canada, "Approved Products", accessed 19 October 2018 https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html.

Delayed ripening	*Tomato**
Change of oil composition	*Soy ** *Canola**
Change of nutritional composition	*Corn**
Pollen control	*Corn* *Canola*
Bio/biofuels	*Corn*
Resistance to enzymatic browning	*Apple* *Potato*
Drought tolerance	*Corn**

The GMOs with an asterisk (*) are currently not grown in Canada for market or climate constraints or because varieties are not registered for seed sale.

The federal government considers GMOs approved as equivalent to standard and safe products. As a result, there is currently no mandatory GMO detection and traceability programme in Canada.[101]

Several products have been approved for commercial purposes however; in Canada, four products (corn, soybean, canola and sugar beets) are cultivated**.** Ontario and Quebec are considered as the two largest corn and soybean producers in the country. However, these products are also grown in other provinces of Canada in small percentages.

[101] Government of Quebec*,* La source d'information gouvernementale sur les organismes génétiquement modifiés, "Les OGM approuvés", http://www.ogm.gouv.qc.ca/utilisation_actuelle/cultures_ogm.html

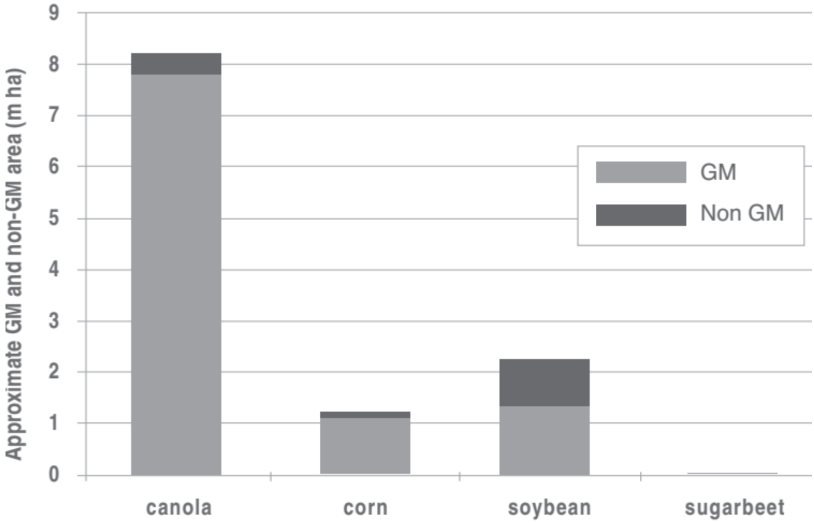
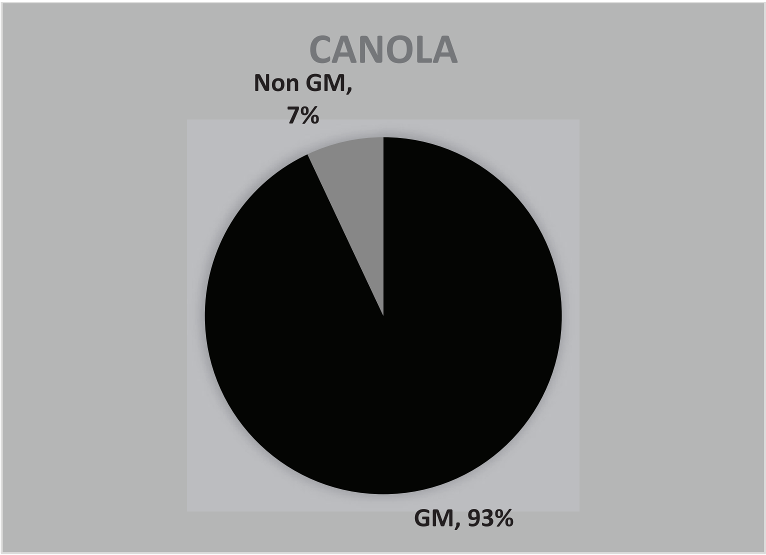
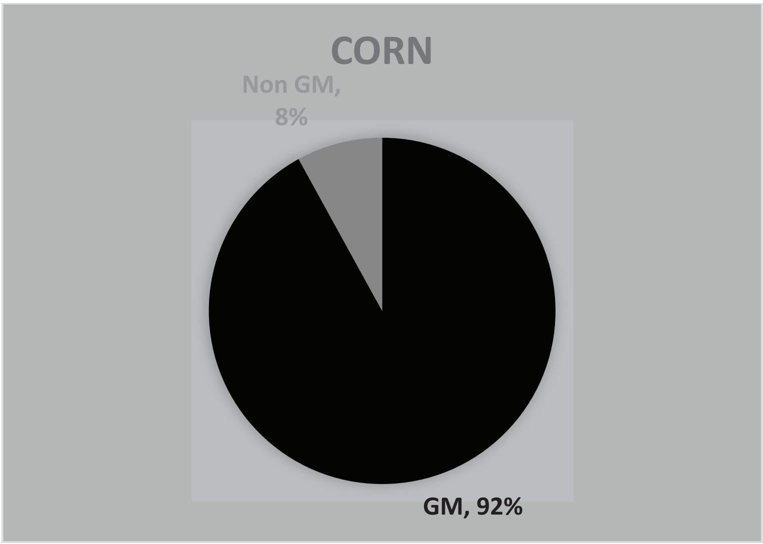


Figure 2-10: Approximate GM and non-GM areas of crops

Canola products occupy almost 95% of all GM crops in Canada.[102] If you consider GM and non-GM ingredients in the first three major crops in Canada (canola, corn and soybean), you will find that non-GM ingredients have been mostly overtaken by the GM ones. Let us consider for example the distribution of GM and non-GM species in Canada's principal field crops in 2016.

[102] Clive James, Global Status of Commercialized Biotech/GM Crops: 2014. *ISAAA Brief No. 49*. Ithaca, NY: ISAAA). The Canola Council of Canada did not respond to CBAN requests for information.


CANOLA
Non GM, 7%
GM, 93%


CORN
Non GM, 8%
GM, 92%

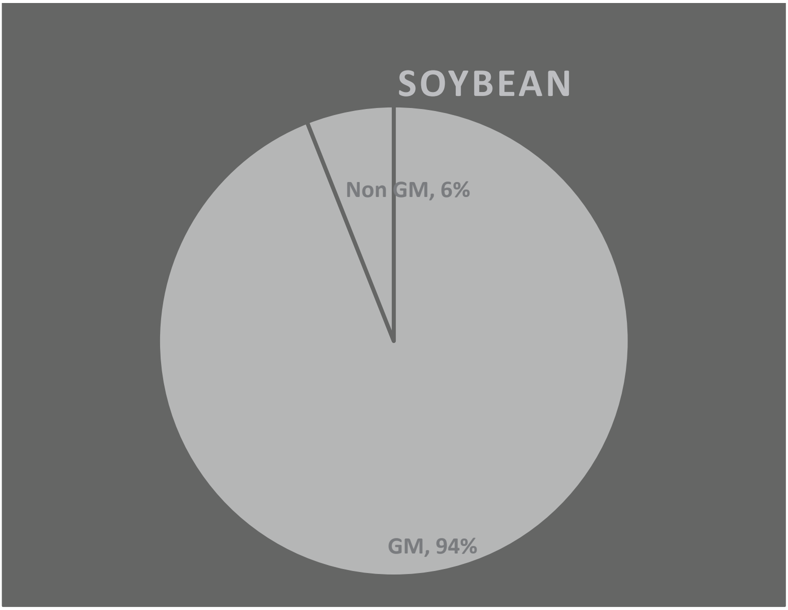


Figure 2-11: Distribution of GM and non-GM crops in Canada, 2016

In 2016, the main GM crops occupied 11.55 million hectares, or 93% of the total area used for the production of these crops.[103] Canada stands in fourth place among the largest producers of GM crops in the world with corn, canola (rapeseed), soybean and sugar beet (a GMO potato is also approved in Canada but has never been put on the market).[104]

2.6 The Case of China

For China as the most populated country in the world, it would be a surprise to not find its name among the largest producers of GMO crops because it has so many reasons to be included. Currently China comes at the sixth place in this agricultural race.[105] The Chinese government only

[103] James, "Status of Commercialized Biotech/GM Crops: 2016".
[104] Ariel Fenster, "OGM: France vs Canada", *Science Presse*, 27 May 2015, accessed 24 November 2018 https://www.sciencepresse.qc.ca/blogue/ariel-fenster/2015/05/27/ogm-france-vs-canada.
[105] Mark Petry and Wu Bugang, "China Peoples Republic Agricultural Biotechnology Annual GAIN Report 8/3/2009"

allowed four crop species a certificate for commercialization: insect-resistant cotton, virus-resistant papaya, virus-resistant peppers and delayed-maturing tomatoes.[106] According to the 2010 report of the ISAAA, China accounts for 3.5 million hectares of GM crops.[107] On November 27, 2009, the China Biosecurity Committee issued a positive opinion on the cultivation of transgenic rice.

Today, more than 50% of developing countries' investments in plant biotechnology are made in China. Compared to investments of developed countries that amount to 2 or 3 billion US dollars, Chinese investments remain modest. However, while in most other countries research programmes are conducted privately, in China, the government bears most of their funding. It is estimated that in 1999, China's expenditure on plant biotechnology amounted to US$ 112 million. In 2001, the budget for biotechnology research tripled from the US$ 120 million allocated to the 2000 budget. In addition, the government announced in 2001 that before 2005, this particular budget would have increased by 40%.[108]

Although larger areas of cotton are in USA and India, cotton is more intensively produced in China than any other place in the world. In 2001–2002, China cultivated 4.8 million hectares of cotton. With a high efficiency of 1,103 kg of fibre per hectare, it harvests 5.3 million tons, which corresponds to 25% of world cotton production. China also uses more cotton than any other country (5.4 million tons that corresponds to 27% of consumption in the world). Cotton is the most widely cultivated plant in China, but is subject to significant damage from a pest, the cotton weevil (Helicoverpa armigera).[109] The rest of the GM crops in China can be simply named GM non-cotton crops as we can see in this historical perspective in Figure 2-12[110] from 1997 to 2015.

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https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=AGRICULTURAL%20BIOTECHNOLOGY%20ANNUAL_Beijing_China%20-%20Peoples%20Republic%20of_8-3-2009.pdf

[106] Petry and Bugang, "Agricultural Biotechnology Annual GAIN Report"

[107] Clive James, "Global Status of Commercialized Biotech/GM Crops: 2010", *ISAAA Brief* no. 42, (Ithaca, NY: ISAAA, 2010).

[108] Tao Zhang and Shundong Zhou. "L'utilisation des OGM en Chine: enjeux et débats" in *Perspectives Chinoises*, no. 76 (2003): 52–60. https://doi.org/10.3406/perch.2003.2948https://www.persee.fr/doc/perch_1021-9013_2003_num_76_1_2948

[109] ISAAA, Coton Bt en Chine, accessed 10 November 2018 http://www.isaaa.org/kc/Publications/pdfs/reminder/Btcottonchina_french.pdf

[110] China AG, "The Splice Must Grow: The Bright and Shady Sides of GM Agriculture in China", accessed 10 November 2018 https://www.chinaag.org/markets/gm-agriculture-in-china/

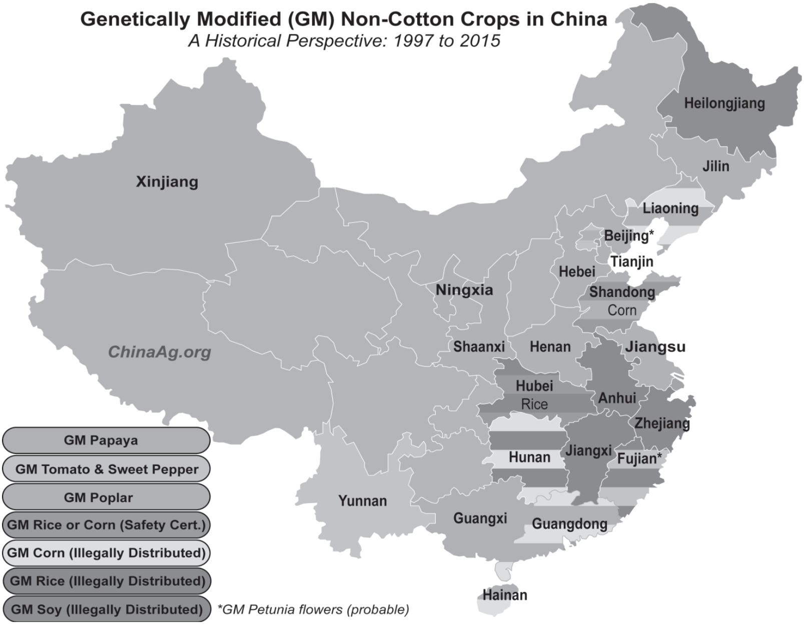

Figure 2-12: GM non-cotton crops in China

China invested heavily in the public sector research and development in crop biotechnology, estimated at US$ 112 million in 1999. This equates to more than half of all research and development expenditure on plant biotechnology in developing countries. China pledged to further increase its research and development budget for crop biotechnology by 40% in 2005 to US$ 450 million.[111] Bt cotton is the first GM crop from the Chinese public sector to be marketed in China and has already yielded a good dividend. The Chinese experience of Bt cotton has important implications for other developing countries that grow cotton such as India, which can also achieve similar benefits from Bt cotton and another fifteen plants for food and feed, and the fibre production that China is developing. This proves that GM crops can bring agronomic, economic, environmental, and social and health benefits, and reduce poverty in developing countries.

[111] ISAAA, Coton Bt en Chine,
http://www.isaaa.org/kc/Publications/pdfs/reminder/Btcottonchina_french.pdf

In China, everyone seems to believe in genetic manipulation. While Western countries are becoming increasingly sensitive to potential problems with genetically modified crops, Chinese authorities are making genetic research their scientific priority and see it as a stable source of food production and the instrument of their future national prestige. For Chinese entrepreneurs to increase local production, China remains a gigantic market where foreign firms come to sell their genetically modified seeds. Today, about 90% of the cotton grown in the central eastern province of Hebei is genetically modified and comes mainly from the Bollgard seed variety marketed by Monsanto.[112]

Table 2-5: Farm income from cotton Bt with IR traits in China 1997–2014

Time frame	Saved cost	Gross margins	National level income in farming ($ millions)
1997	194	333	11.33
1998	194	310	80.97
1999	200	278	181.67
2000	−14	123	150.18
2001	378	471	1,026.26
2002	194	327	687.27
2003	194	328	917.00
2004	194	299	1,105.26
2005	145	256	845.58
2006	146	226	792.28
2007	152	248	942.7
2008	167	224	933.7
2009	170	408	1,457.8
2010	176	503	1,736.5
2011	184	559	2,198.8
2012	27.5	401	1,583.7
2013	29.1	376	1,579.3
2014	28.2	319	1,306.8

[112] Karby Leggett and Ian Johnson, "Développement. Chine: au paradis des OGM" (in French) *Courrier International* 30 November 2004 https://www.courrierinternational.com/article/2000/04/20/chine-au-paradis-des-ogm

Table 2-5[113] depicts a study of farm income from cotton Bt with IR traits in China over the period 1997 to 2014. The national level income reached US$ 1.31 billion, whereas cumulative farm income since 1997 amounted to US$ 17.54 billion. The cost is estimated in US$ million per hectare.

China has been a pioneer in the development of GMOs. It has even produced, since 1988, tobacco plants resistant to viruses.[114] Nevertheless, today it only allows two transgenic crops for commercial purposes: cotton and papaya. Countless times, the ministry in charge of agriculture has publicly announced that there are no others. However, a first major scandal erupted in July 2014 in Wuhan, capital of a province in the centre of the country, Hubei. Thanks to *Xinwen diaocha* (News Probe), China Central Television's (CCTV) famous investigative programme, the debate on GMO crops had been taken up on a national scale. Journalists have shown that three of the five bags of rice they had bought from a city supermarket contained Bt 63 rice, whose genetic code was modified to produce a Cry1Ac toxin capable of eradicating moths that damage the plants. It was introduced by the team led by Zhang Qifa of the Chinese Academy of Sciences, professor at Huazhong Agricultural University Wuhan and head of the transgenic rice research programme.[115]

Five years later, a report from the Beijing-based China News Weekly magazine resumed the investigation and showed that planting was being carried out on a large scale in Hubei. Despite the lack of authorization, "the cultivation of genetically modified rice for commercialization is a tangible reality", noted the weekly. A new Greenpeace report from 2010 revealed that it was marketed (along with related products) in three other provinces in the southeast of the country (Guangdong, Fujian and Hunan). Two years later, Jiang Gaoming, Chief Researcher at the Institute of Botany of the Chinese Academy of Sciences, on his blog estimated that in another province, Zhejiang, eight and a half million people had already eaten transgenic rice, without suspecting it in the least.[116]

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[113] Graham Brookes and Peter Barfoot, "GM Crops: Global Socio-Economic and Environmental Impacts 1996–2014", Dorchester, UK: PG Economics Ltd, May 2016, 62–63,
https://www.pgeconomics.co.uk/pdf/2016globalimpactstudymay2016.pdf

[114] Zhang Tao and Zhou Shundong, "The Economic and Social Impact of the Use of Genetically Modified Organisms in China", China Perspectives, Hong Kong, March–April 2003.

[115] Zhang Zhulin, "Double jeu chinois sur les OGM", *le Monde Diplomatique* February 2018, accessed 19 November 2018
https://www.monde-diplomatique.fr/2018/02/ZHULIN/58362.

[116] Zhang Zhulin, "Double jeu chinois sur les OGM"

Officially, five steps must be taken to cultivate GMOs: laboratory research; intermediate tests lasting one to two years in a semi-enclosed site, the area not exceeding 0.2 hectare; environmental testing after cultivation in the wild on an area limited to 2 hectares for one to two years; pre-market test, one to two years; authorization by a biosafety patent. Beijing has granted only seven biosecurity patents: for tomato, petunia, chilli, rice, maize, papaya and cotton. Only the latter two can be grown and marketed.

Chinese officials often point to the country's dilemma; China owns roughly 7% of the agricultural land and has to feed almost 20% of currently living humans. In 2006, the government initiated a plan (2006–2020) that placed the search for transgenic varieties at the same priority as the development of oil and gas fields, or the big plane project in the aerospace programme. Two years later, the central government has planned to invest 20 billion yuan (US$ 2.876 billion) in research on GMOs by 2020.[117]

2.7 The Case of Paraguay

A landlocked country between Argentina and Brazil, Paraguay has become the third-largest river power, behind the United States and China. It ships through Rio Parana an increasing production of soybeans, for which it is the fourth leading exporter in the world. In the 1990s, as commodity prices soared, Paraguay began to sow massive amounts of soybeans. Paraguay's soybean production went from 700,000 tons in 1992–1993 to 4.5 million tons ten years later. A country of 7 million inhabitants more than Germany, Paraguay has established itself as the world's sixth largest producer of soybeans and the world's largest producer of soybeans per capita with an average of 727 kg per year. From 1996 to 2006, soybean crops grew from something less than a million hectares to reach two million hectares, an increase of 10% per year. The soybean industry contributes significantly to the 4% annual economic growth.[118] The most surprising of these statistics is that the cultivation of transgenic soybeans was not legally authorized in 2007 in Paraguay when it accounted for half of the cultivated area.

Paraguay approved four GM products with twenty-two events as reported by ISAAA[119]; cotton (Gossypium hirsutum L.) which is traded in

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[117] Zhang Zhulin, "Double jeu chinois sur les OGM"

[118] AFP, Le boom du soja fait du Paraguay la troisième puissance fluviale mondiale, *Le Point* 2 June 2018, accessed 12 October 2018 https://www.lepoint.fr/economie/le-boom-du-soja-fait-du-paraguay-la-troisieme-puissance-fluviale-mondiale-02-06-2018-2223525_28.php

[119] ISAAA, "GM Crop Events Approved in Paraguay",

four events, corn (Zea mays L.) traded under fifteen events and soybean (Glycine max L.) in three events.

The regulatory framework of Paraguay, in terms of activities with products of modern biotechnology or GMO, began in 1997 when the Executive Branch issued Decree No. 18.481/97, which was amended by Decree No 12.706 of 13 August, 2008. It is specific to the agricultural and forestry sector, and is of an essentially administrative nature, emanating from the Executive Power, and it regulates the biosecurity of the proposed use. In this last decree, the Ministry in charge of Agriculture and Livestock (MAG) is the competent national organ, which grants the authorizations and regulates the use of GMOs in field trials, confined releases and commercial applications, for which it has the Agricultural and Forestry Biosafety Commission (COMBIO), a collegiate body that acts as a biosecurity adviser. Biosecurity management is carried out through pre-existing legal systems, contained in regulations on plant health and animal health, seed health, food safety and compliance with environmental requirements such as impact assessment.[120]

With the latest commercial releases, Paraguay now has twenty-three genetically modified materials, of which sixteen are in corn, three in soybeans and four in cotton. In Paraguay, the organization of indigenous women (CONAMURI), part of Vía Campesina, carried out a campaign of great impact related to the death of the son of one of its militants, the child Silvino Talavera, caused by the fumigation of the soybean fields near their farm. The case generated an important precedent because it was the first time that a case of death due to glyphosate was won in a criminal trial, although the jail sentence for those responsible was never executed.[121]

2.8 The Case of Uruguay

In October 1996, Uruguay was among the first countries to approve the release to the environment of a transgenic crop. It was Monsanto's Roundup

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http://www.isaaa.org/gmapprovaldatabase/approvedeventsin/default.asp?CountryID=PY

[120] Tracy L. Barnett, "Paraguay Takes Hard Line on GMOs", *Huffington Post* 6 December 2017 https://www.huffingtonpost.com/tracy-l-barnett/paraguay-takes-hard-line-_b_701182.html

[121] Elisabeth Bravo, "Transgénicos en Sudamérica" (Transgenics in South America), edited by Instituto para el Desarrollo Rural de Sudamérica – IPDRS (Equator, September 2011),
https://www.sudamericarural.org/images/exploraciones/archivos/exploraciones_9_transgenicos_en_sudamerica3d85d721.pdf

Ready (RR) soybeans that represented the novelty of being tolerant to a herbicide developed by the same company, glyphosate. Twenty years later, five types of transgenic soybean crops and ten of corn in Uruguay have been released. In the 2016/17, the GM harvest covered 1.1 million hectares. Soybean has become the main agricultural crop in the country and the use of glyphosate-tolerant transgenic seeds has been a principal part of the development of a technological set that has given impetus to the soybean agribusiness.[122]

Much has been argued in favour of and against GM crops. The transnational biotechnology that developed them has self-assigned the role of providing the world with solutions through innovative technologies that promote “sustainable agriculture” and “food security”. In fact, after twenty years, they continue. There are two types of traits contributed by transgenic crops: tolerance to herbicides and toxicity to larvae of lepidoptera (certain moths and butterflies). The increase in crop productivity is linked to transgenic technology and in terms of the environmental sustainability of the agriculture, the Uruguayan experience and that of the Southern Cone as a region clearly show that the development of transgenic crops instead of solutions brought multiple problems.[123]

In Uruguay, GM corn and soybean crops are planted (see Table 2-6). All of them have one or both of the following characteristics: tolerance to herbicides and toxicity for larvae of some lepidoptera (insects such as butterflies). For soybean, there are five approved events[124] for cultivation, while for corn there are ten. The companies that own these events are Monsanto, Syngenta and Pioneer-Dow; the soybean events of Bayer and BASF are of little relevance in terms of their commercial use at the crop level.

[122] Trigo, “20 Years of Transgenic Crops”

[123] Trigo, “20 Years of Transgenic Crops”

[124] The term “event” derives from the term “transformation event”. During the procedure of cellular transformation, the transgene is transferred to several receptor cells. They incorporate the cells into different places of the genome; they can even incorporate several complete copies or partial transgenes. Consequently each transformed cell presents a particular pattern of transgene integration that configures a transformation event. In the case of vegetables, the term “event” refers to the plants derived from one of these cells.

Table 2-6: Transgenic events approved for commercial use in Uruguay[125]

	Event	Company feature *	Commercial name**	Year
Soybean				
	GTS 40-3-2	*Monsanto*	*TGli RR (Roundup Ready); GR; RG; RSF2012*	1996
	A2704-12	*Bayer TGlu*	–	2012
	A5547-127	*Bayer TGlu*	–	2012
	MON89788xMON87701	*Monsanto*	*TGli /RL IPRO (Intacta RR2 Pro); RSF IPRO*	2012
	BPS-CV127-9	*BASF TImi*	–	2014
Corn				
	MON810	*Monsanto*	*RL MG; Y*	2003
	Bt11	*Syngenta*	*RL/TGlu TD; BT*	2004
	GA21	*Syngenta*	*TGli G; TG*	2011
	GA21xBt11	*Syngenta*	*RL/TGlu,Gli GLStack; TD/TG*	2011

[125] ISAAA, "GM Crop Events"

	TC 1507	*Pioneer/Dow*	*RL/TGlu HX (Herculex); H*	2011
	NK603	*Monsanto*	*TGli RR; RR2; R*	2011
	MON810xNK603	*Monsanto*	*RL/TGli MGRR2; YR*	2011
	TC 1507xNK603	*Pioneer/Dow*	*RL/TGlu,Gli HXRR2; HR*	2012
	GA21xMIR162xBt11	*Syngenta*	*RL/TGlu,Gli VIPTERA3*	2012
	MON89034xTC1507x NK603	*Monsanto/Dow*	*RL/TGlu,Gli PW*	2012

* Traits: RL, resistance to lepidoptera; TGli, tolerance to glyphosate; TGlu, tolerance to glufosinate-ammonium; TImi, tolerance to herbicides of the imidazolinone group.

** The commercial denomination varies according to the seed company. Data collected from the National Registry of Cultivars (INASE).

The soya RR and the Intacta RR2Pro (both from the Monsanto company) are the transgenic soya crops that are preponderant in this country. They were approved for cultivation in 1996 and 2012 respectively. Both are tolerant to the glyphosate herbicide. Since 2003/04, soybean has been the main agricultural crop in the country. In the 2016/17 harvest, close to 1.1 million hectares were planted and 3.2 million tons of soybeans were produced (MGAP-DIEA, 2017). According to estimates of the private sector for this harvest, 98% of the soybean area corresponded to transgenic soybean (ISAAA, 2016). With all the area sown with transgenic seeds, according to ISAAA, 86% corresponded to RR soybeans and 14% to soy Intacta RR2Pro.[126]

The first GM transgenic events permitted for farming in Uruguay were the Bt maize[127] MON810 and Bt11 from the companies Monsanto and Syngenta respectively. Both produce a toxic Bt protein for larvae of some lepidoptera that are a corn pest. Then eight other simple and stacked events that produce Bt toxins and/or have tolerance to glyphosate and/or glufosinate-ammonium were approved. For all these transgenic events, three belong to the Syngenta Company, two to Monsanto, two to Pioneer-Dow, and one to an arrangement between Monsanto and Pioneer-Dow. In the 2016/17 harvest, 66,000 hectares of maize were planted in Uruguay (MGAP-DIEA, 2017). There are no official data regarding what percentage of corn is transgenic, but according to the private sector in that harvest, 86% of the area was sown with transgenic seeds.[128] Also according to ISAAA, 95% of the area of transgenic maize corresponded to events stacked with more than one transgene able to deal with herbicides (glyphosate) and produce Bt toxins. The remaining 5% corresponded to crops with tolerance to herbicides. To understand the extent soybean to which are grown let us refer to the example of the surface of transgenic crops in thousands of hectares, harvest 2016/2017:

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[126] Cárcamo María Isabel. "La situación de los transgénicos en Uruguay", en María Isabel Manzur et al. *América Latina. La transgénesis de un continente: Visión Crítica de una invasión descontrolada*. RALLT, RAPAL, SOCLA, Fundación Böll. Santiago de Chile, 2009, 34–37.

[127] Pablo Galeano, Martínez Claudio, Ruibal Fabiana, Franco Laura y Galván Guillermo. 2011. "Crossfertilization Between Genetically Modified and Non-Genetically Modified Maize Crops in Uruguay", *Environmental Biosafety Research* 9, no. 3 (July 2011): 147–154.

[128] Clive James, "Executive Summary", *ISAAA Brief 52-2016*
http://www.isaaa.org/resources/publications/briefs/52/executivesummary/default.asp

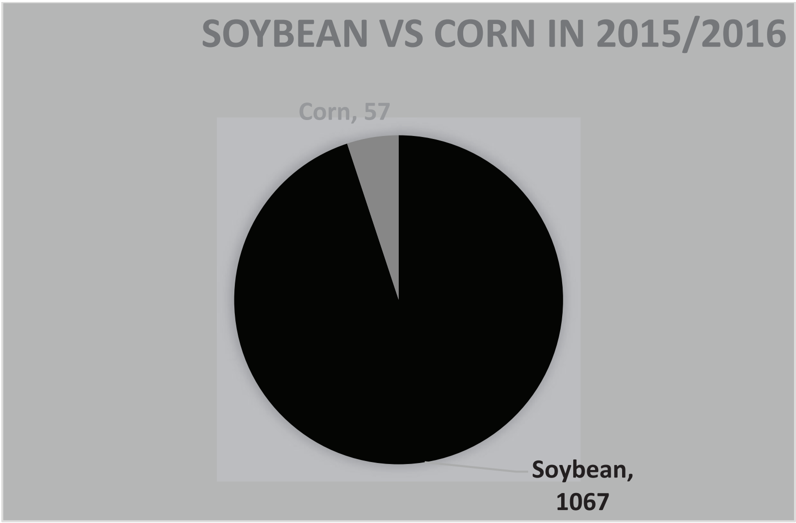

Figure 2-13: Hectarage of soybean vs corn

According to these data, during the 2016/2017 harvest over a million hectare of Uruguayan arable fields contained manipulated seeds, corresponding to 95% of this area (1,067,000 hectares) to soybean and 5% (57,000 hectares) to corn.[129]

The future of transgenic crops in South America is marked by antagonistic situations. On the one hand is the declaration of a suspension up to ten years for the release of transgenics in Peru, which was an achievement of the social organizations of that country, and on the other hand, it is always important to know what would be the decision of new governments. Laws and proposals of a similar nature to those of Peru and Bolivia are being introduced in almost all countries of Latin America, to which is added the fact that both Chile and Peru are now part of the UPOV Convention, which gives rights to industrial seed breeders.[130]

In Colombia, the approval of transgenic soybean with resistance to glyphosate was recently granted. The east of the country has vast plains where soybeans with herbicide resistance could spread, in the same way as it happened in the Southern Cone. The approval of transgenic soy in

[129] Petry and Bugang, "Agricultural Biotechnology Annual GAIN Report".
[130] Bravo, "Transgénicos en Sudamérica".

Colombia is closely associated with a growing process of foreignization of land in the plains area.[131]

In Ecuador,[132] canola is being introduced under the format of “inclusive rural businesses”, where an “anchor company” establishes contracts with small producers who are given seeds and technologies, which they then pay for with their production. There is no assurance that these projects will give good agronomic results, nor that the canola used will be transgenic.

2.9 The GMOs in Europe

Compared to the American continent, where GM cultivation areas are counted in millions of hectares, the European figures seem derisory. In 2016, four EU countries grew MON810 maize: Spain leads (129,081 ha), followed by Portugal (7,070 ha), Slovakia (112 ha) and the Czech Republic (75 ha). The cultivated areas and the number of countries concerned with the cultivation of GMOs have been decreasing since 2012. Many Member States have indeed chosen to abandon the farming of GMOs (Germany, Bulgaria, France which had cultivated 22,000 ha in 2007, and Sweden, Romania and Poland).[133]

Several transgenic plants have also been removed from the market: a potato (Amflora), three varieties of GM oilseed rapeseed and six varieties of GM corn including T25 and Novartis Bt176 (now Syngenta). To explain these withdrawals, companies most often argue the lack of commercial prospects in a continent that is globally hostile to biotechnology. However, there is also the opposition of the citizens, the national bans and the publication of scientific studies proving the inefficiency or the risks of the GM crops. For instance, considering the status of Bt176 maize, the withdrawal of the application for authorization in 2005 was preceded by studies demonstrating that its yield was not superior to that of a conventional variety when it is more expensive and it was a carrier of antibiotic resistance.[134]

Today, MON810, the star corn of the giant Monsanto, is the only GMO grown in Europe for human and animal food since 1998. With 136,000

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[131] Adriana Rojas, Silvio Lopez-Pazos, and Alejandro Chaparro-Giraldo, “Screening of Colombian Soybean Genotypes for Agrobacterium Mediated Genetic Transformation Conferring Tolerance to Glyphosate” http://www.scielo.org.co/pdf/agc/v36n1/0120-9965-agc-36-01-24.pdf

[132] Bravo, “Transgénicos en Sudamérica”.

[133] Charlotte Krinke, “Les OGM Autorisés Dans l’Union Européenne”, (June 2017), https://www.infogm.org/6210-ogm-autorises-europe-culture-importation

[134] Krinke, “Les ogm autorisés”

hectares planted, however, it represents less than 1% of maize produced by European farmers – a figure that continues to decrease. Almost all of these corns are produced by Spain (129,300 hectares), ahead of Portugal (7,100 hectares), then a very small amount is produced by Slovakia and the Czech Republic (112 and 75 hectares) respectively.[135]

Since then, all attempts to introduce other genetically modified seeds for cultivation have failed because of states' opposition. Europe had only given the green light in 2010 to the transgenic potato Amflora, but its German producer, BASF, stopped its development in 2012.

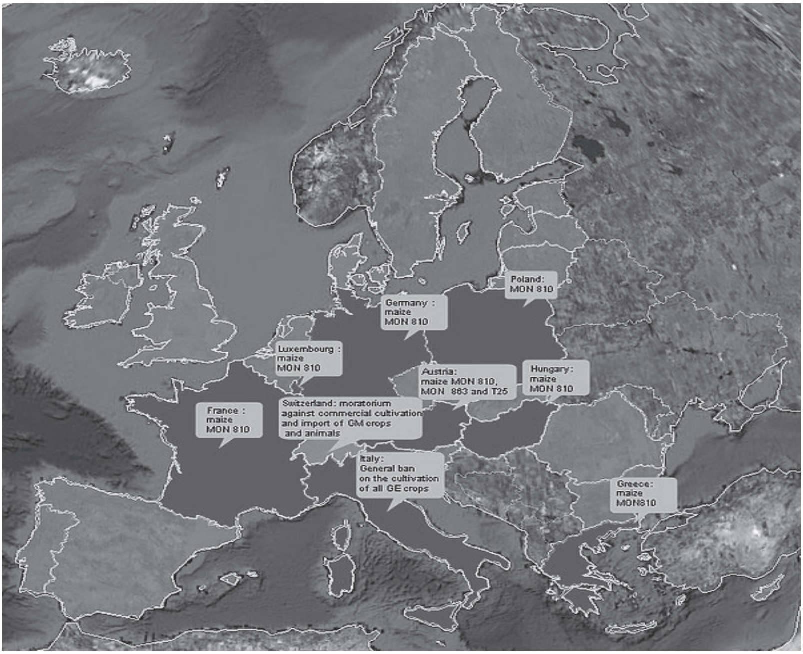

Figure 2-14: The map illustrates countries that banned the cultivation of GM corn (MON810).[136]

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[135] Audrey Garric, "L'Europe se divise sur la culture de trois OGM", *Le Monde*, 27 January 2017 https://www.lemonde.fr/planete/article/2017/01/27/l-europe-se-divise-sur-la-culture-de-trois-ogm_5070310_3244.html

[136] GMO-free Regions, "GMOs Cultivation Bans in Europe" https://www.gmo-free-regions.org/gmo-free-regions/bans.html

Despite public hostility, GMOs are still present in Europe through imports. A total number of fifty-one transgenic organisms have been approved for commerce as noted by Inf'OGM[137]: maize, cotton, beetroot, potato and especially soybean for which nobody communicates the total amount of imports. The EU stands as one of the top exporters in the world of genetically modified grains to feed its livestock. Each year, Europe imports almost 40 million tons of soybeans and France 4.5 million tons, of which more than half are genetically modified.

Figure 2-15 demonstrates what the EU has spent on agricultural imports especially foods and where they have come from (amount counted in billions of euros).[138]

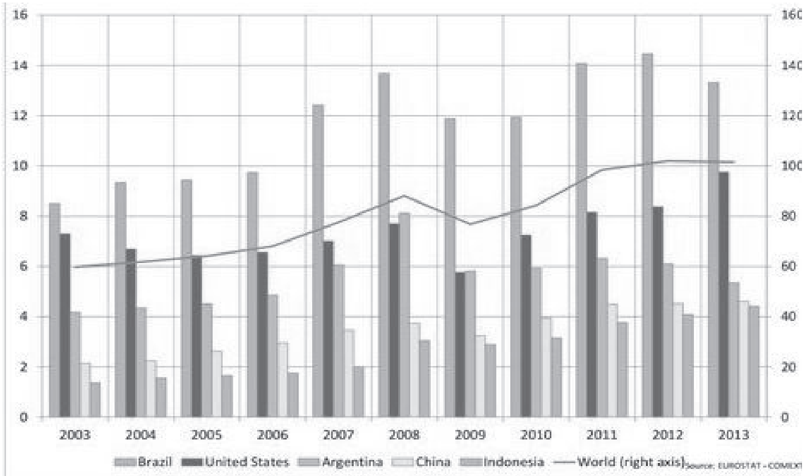

Figure 2-15: Agricultural imports to the EU

The import of GMOs into the EU highlights its high dependence on feed for its livestock since the majority of imported GMOs are used for this purpose. According to an estimate from the European Commission

[137] Krinke, "Les OGM autorisés"

[138] EuropaBio, "Why does the EU import GMOs?", accessed 25 October 2019 https://www.europabio.org/agricultural-biotech/faq/gmos-and-the-european-union/why-does-eu-import-gmos (infographic source at https://www.europabio.org/sites/default/files/infographic_eu_benefits_from_gm_trade.pdf).

published in 2016,[139] over the period 2013–2015 the EU imported more than 30 million tons of GM soy equivalent per year (about 85% of the total soy equivalent imported into the EU), between a half and three million tons of GM maize and around half a million tons of GM oilseed rape (about 5 to 10% of total rapeseed imports). As for France, it had to import GM oilseed rape in 2017 because of poor harvests. It generally imports about four million tons of transgenic plants per year, including Roundup Ready soybeans from the American continent.[140]

2.9.1 Socio-Economic Challenges of GMOs: The Growing Place of Biotechnologies in Research

2.9.1.1 The catch-up race of Europe

Through GMOs, genomics is engaged a global race to knowledge. While life sciences research has the hallmarks of excellence in Europe and Japan, the United States or Canada, American supremacy clearly appears in the field of applications. This includes those developed by companies and major industrial groups that are specializing in biotech in the pharmaceutical or agrochemicals and seeds sectors.

Several explanatory factors of a cultural nature are put forward to explain "Europe's backwardness": the tradition of sharing knowledge within the scientific community only and therefore the immediate publication of the results, and a greater reluctance to take action. Also patents, the weak link of the world of research with that of the economy and the slowness of European governments (except the United Kingdom) to become aware of the economic stakes involved.[141]

In the United States, biotechnology benefits from the interweaving of three worlds: university research, business and capital resource, and strong incentives from the public authorities. For transgenic plants, a "plant genome"[142] programme, launched in 1997 for a five-year period and endowed

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[139] European Commission, "Genetically Modified Commodities in the EU", Commission staff working document, March 2016.

[140] European Commission, "Genetically Modified Commodities".

[141] Sylvie Bonny, "Why are most Europeans opposed to GMOs? Factors explaining rejection in France and Europe", *Electronic Journal of Biotechnology* 6, no. 1 (April 2003) https://tspace.library.utoronto.ca/bitstream/1807/1199/1/ej03008.pdf.

[142] Académie Des Sciences, "Les plantes génétiquement modifiées", *Rapport sur la science et la technologie*, December 2002, no. 13 [cited 20 December 2002], 168. Paris: Tec & Doc (Lavoisier), English summary http://www.academiesciences.fr.

with $ 143 million in public funding, mobilized a public and private research network involved in plant genetics, making America a world leader in the agriculture sector.

The European Commission appeared in this field as an awakener of the conscience of European governments on the alleged delay. Since 1982, a first specific programme called the Biomolecular Engineering Programme (BEP) has been concerned with biotechnology and this action has continued under the framework programmes for research and development. Research and development funding, however, remains limited in Europe, even though the fifth research programme has planned to pay particular attention to biotechnology (representing about 4% of the then EU15 expenditure).

2.9.1.2 The development of the alliance between public and private research

Some European countries are seeking to learn from the American model, to develop the alliance between public and private research and to provide a regulatory framework more favourable to this evolution (the French law of 12 July 1999 on innovation and research is an illustration of this, even though it raised objections during its examination). This has included the establishment of biotechnology and business incubators in France, the United Kingdom and Germany. The establishment of genome networks, national platforms for the decoding of plant genomes, is an additional step. Some European states are planning to implement them and hope that such a project will lead to a European level network.

France created a network of this kind, the *Genoplante* programme, on February 23, 1999. This grouping of scientific interest, which must take the form of a group of economic interest, includes public bodies: the National Research Institute, the Agricultural Research Centre for International Development (CIRAD), the CNRS, the seed companies Biogemma and Bioplante and the agrochemical branch of Rhône-Poulenc. Its aim is to accumulate new knowledge about plant genomes and their functioning in order to integrate them into programmes for the improvement of cultivated species, and to take out patents. This project was expected to receive 1.4 billion francs (the currency used in France before adopting the euro) over five years, 70% of which was financed by public funds. That is to say it was difficult for France to adopt a consistent position with regard to GMOs, between the race for patents and the willingness to apply the precautionary principle by taking the necessary step back.

This encouragement has the alliance between public research and private; however, is questionable in many ways. In addition to the risk of a progressive dismantling of public research, whose objectives would be reduced to what can be marketable, there is the question of the democratic control of the choices made. Moreover, the emphasis on genetics should not be allowed to undermine the multidisciplinarity of science and the search for alternative solutions. Finally, the detection of GMOs and their impact are two aspects of applied research of major importance that should not be neglected. GMO detection techniques are functional, but they are not standardized at the French level as they are at the European one.

2.9.1.3 The problem of the patentability of living things and the appropriation of resources

Genetically modified organisms represent a new branch of innovation. Obtaining a patent, which gives its owner a temporary monopoly on these inventions, is an integral part of the business strategy and the programmes associating private and public research. It is part of the general problem of the patentability of life and raises the question of the right to use biotech assets and farmers' rights. Patents, and in particular the discovery of genes, can lead to the lock-in of the right to access and to use biotech assets, which is not acceptable.

The progressive extension of the patentability of living

The patent applied in principle to the inert material and, for a long time, the inventions of man from the living appeared to be incompatible with these requirements, in particular with the condition of the reproducibility of the invention from the description.[143] Nevertheless, the inventions related to biotechnology, and in particular GMOs, have gone into the mould of the patent with some modifications, including attractive-looking dyes that could conceal something dangerous.

Since 1963, the Strasbourg Convention[144] has expressly recognized the patentability of microbiological progressions and their outcomes while

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[143]The issuance of a patent is subject to several conditions: novelty – the invention must not be included in the state of the art; inventive activity – the invention must not flow from the state of the art; industrial application – the invention must be industrial in character and must be able to be manufactured by an industrialist or a farmer; the reproducibility – every businessman is able to execute this invention.

[144] Council of Europe, "Convention on the Unification of Certain Points of Substantive Law on Patents for Invention" *European Treaty Series No. 47,* Strasbourg, 27/11/1963

excluding from its scope of application genetic developments for obtaining new plants and animals. The Washington Patent Cooperation Treaty of 19 June 1970 and the Munich European Patent Convention of 5 October 1973 echoed these formulas.

The scope of the Strasbourg Convention does not consider vegetable varieties because they fall under a lower industrial property right than the patent itself. The International Union for the Protection of New Varieties of Plants (UPOV Convention) of 2 December 1961, updated in 1991, introduced a special system of protection for the benefit of the breeder of a variety of plants, with some exceptions, particularly for research and for farm seed, to preserve what is commonly called “the farmer’s privilege”. A competing breeder may freely access the genetic resources contained in the protected variety without permission to apply. Furthermore, in Article 15, as amended in 1991, the Convention opens the option for Member States to waive the rights of holders of plant variety certificates by recognizing the right of farmers to use part of the seeds for re-seeding, from a first crop obtained from the protected variety, but within rational restrictions and subject to the preservation for interests of legitimate breeders. Community Regulation No 21000/94/EC of 27 July 1994 introduced Community plant variety rights under this convention. The exception for farm-saved seed is subject to payment by “big farmers”[145]; an additional pressure to get farmers to give up this ancestral and free practice. France has ratified the UPOV Convention, but has not incorporated the amendments in its law, which were made in 1991 and, in particular, the exception for farm-saved seed. A bill was tabled in the Senate[146] in 1996 to introduce this exception by making it subject to payment of compensation. This text was the subject of a strong protest and a compromise text had to be worked out.

The Supreme Court in the case of *Diamond v. Chakrabarty* made a decisive step, in the extension of the patentability of the living, in the United States in 1980, when it admitted the patentability of a *genetically modified microorganism* (a bacterium capable of degrading hydrocarbons).[147] In

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https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168006b65d

[145]An exemption is provided for small farmers, whose precise definition is given in the regulation.

[146] Bill 145 concerning plant varieties and amending the Code of Intellectual Property and the Rural Code of 11 December 1996 (original text Projet de loi relatif aux obtentions végétales et modifiant le code de la propriété intellectuelle et le code rural https://www.senat.fr/leg/pjl96-145.html).

[147] “Diamond v. Chakrabarty”, *Oyez*, accessed 13 December 2018 https://www.oyez.org/cases/1979/79-136

1985, the court recognized the patentability of a transgenic plant: a corn allowing an overproduction of an amino acid. In 1987, the principle of the patentability of an animal, a genetically modified oyster, was accepted. The first patent for an animal was filed in 1989. It was a genetically modified mouse, called "oncogenous", that is, capable of developing cancer.[148]

The appropriation of resources

In addition to ethical considerations, the patentability of transgenic plants and animals, like living organisms in general, raises the issue of acquiring rights on "genetic assets" and the rights of farmers, particularly in the context of north–south relations.[149]

Access to "genetic resources" and farmers' rights

The US patent has a very wide scope and does not provide any exception to what can be patented except for human beings. Its scope is very wide because of the flexible application of the "utility" criterion, which can be translated by industrial application. It is also very protective. It prohibits any use of the process or product by a third party, including the formation of a different variety from the protected one, the preservation of part of the crop for farm-saved seed, and the marketing of the next crop as seed. The United States has admittedly granted protection to some types of plants in the form of the "plant variety protection certificate"[150], but manufacturers have the choice between this title and the patent and prefer to use the latter. The American system leads to a form of lock. It is a powerful tool to enable a company to gain a competitive advantage and block the progress of competitors. Unfortunately, it is accessible only to a small number of companies and helps to give them a dominant position because it is so expensive.

The European Directive on Biotechnological Inventions has recognized that plant or animal inventions may be patented, in case the application for patent rights is not restricted to diversities (flora and fauna) which are protected by the plant variety certificate. A complex articulation is foreseen with the right of the plant varieties in the form of compulsory licences of

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[148] Cynthia Ho, "Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men", *Washington University Journal of Law & Policy* 2, no. 1 (January 2000): 247–285.
[149] Ho, "Splicing Morality and Patent Law".
[150] USDA: "Plant Variety Protection", accessed 10 November 2018 https://www.ams.usda.gov/services/plant-variety-protection

exploitation for a fee. In addition, an exemption for farm-saved seed is envisaged under the same conditions as those recognized by the Community plant variety system. The farmer's privilege is recognized for livestock for agricultural purposes, but the terms are referred to national law.

This directive, based on the principle of the patentability of living things, is the subject of actual debate. It was mentioned at the meeting of the G8 Research Ministers (Canada, France, Germany, Italy, Japan, United Kingdom, United States and Russia) devoted to bioethics on 24 and 25 June in Bordeaux.[151] It had to be transposed into national law before July 30, 2000, but its future is not certain. In any case, for plants and animals, the need to maintain exceptions to patentability for ethical reasons such as animal suffering, or ecological issues, and to provide for derogations for research and farmers, are questions to which Community law must respond.

Access to "genetic resources" of developing countries

The patent section of TRIPS agreements requires the preservation of plant diversities by patents or a *sui generis* system. As of 1 January 2000, this agreement was to oblige seventy developing states to adapt their national legislations. Its review started in 1999. The United States is pushing for the alignment of the laws of these states on their patent laws. In these countries, exemptions for research and farmers' privilege are crucial. The EU must campaign for their application.[152]

In addition, developing countries have a large variety fund and are intensively bio prospected. The Convention on Biological Diversity of Resources, established in Rio de Janeiro in 1992, provided for the reasonable and impartial distribution of profits coming from the exploitation of genetic assets, as well as rights to acquire and transmit genetic technologies. If the patentability of genetic innovations is allowed, in return, it is necessary to recognize the part of the populations that provided and indicated the characteristics, or allowed the survival of the genetic material used. Directive 98/44[153] refers to this convention and invites Member States to consider it. It remains to define the concrete modalities of this articulation. In short, almost everything remains to be done in this area, to

[151] Also the ministers of research from Brazil, China, India and Morocco participated in this meeting.
[152] World Trade Organization "TRIPS Agreement"
https://www.wto.org/english/docs_e/legal_e/27-trips.pdf
[153] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:
31998L0044&from=EN

really enable the countries of the South to preserve and enhance their natural and genetic heritage.

Resistance movements against the patentability of genetic resources and transgenic plants are frequent in developing countries. In India, the ecologist Vandana Shiva[154] is at the forefront of the fight against patents filed for seeds and traditional Indian plants by foreign companies. According to her, "patents would destroy 75 per cent of the livelihood Indians derive from the land and free access to biodiversity". Farmers across the country are setting up seed banks to express their rejection of the intellectual property rights system. The introduction of GMOs has also provoked major protests. A powerful organization of peasants from the state of Karnataka, among others, set fire to transgenic crops in November 1998. Four Indian peasants travelled across Europe in June 1999 to denounce, among other things, the risks that may occur to their agriculture after the development of patents and the introduction of GMOs.[155] In Brazil, some southern states such as Mato Grosso and Rio Grande plan to ban transgenic plants on their territory.

2.9.2. Impact Difficult to Assess for European Agriculture

According to a 2017 report, farmers have planted GMO seeds on a surface of around 189.8 million hectares worldwide, including 75 million hectares in the United States. In Europe, although some states such as Spain are using GMOs on a large scale, their use remains very limited.[156]

The advantages and limitations of GMOs for agriculture are still difficult to evaluate. To evaluate this, one must distinguish between available GMOs and those promised for the future, the short and medium term, the specificities of agriculture in each Member State and almost every plot.

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[154] Vandana Shiva has become known thanks to the following books: *Ecoféminisme*, 1996, and *Ethique et agro-industrie*, 1999, Editions: *L' Harmattan*.

[155] The rapporteur organized a symposium on "Sustainable Agriculture in the North and the South" on 28 May 1999 at the National Assembly.

[156]Agribiotech lobby group ISAAA reports that global GMO acreage has grown to 189.8 million hectares in 2017, 3% or 4.7 million hectares more than in 2016. https://european-biotechnology.com/up-to-date/latest-news/news/gmo-acreage-growing-globally.html

2.9.2.1 Uncertain benefits

Potential benefits

Globally, first-generation GMOs (insect and total herbicide-resistant plants) are expected to improve techniques with a reduction of inputs, a decrease in the frequency of treatments, and more favourable technical itineraries. Environment and increased profitability will improve through lower production costs and improved yields. GMOs of the second generation suggest a decrease in losses (better conservation of plants after harvest, drought and frost resistance) and the production of plants better adapted to the expectations of consumers and industrialists.

Potential limits: general limits

In general, one can question the need to increase the yields of European agriculture, which has difficulty managing its surpluses. In addition, it should be noted that, given the mistrust of consumers regarding GMOs, the maintenance of GMO-free agriculture could be an asset.

New agronomic constraints: herbicide-resistant plants

A genetically manipulated seed to which a gene for herbicide tolerance has been conferred to, may lead to the emergence of wild relatives with this trait, to be eliminated by conventional treatments that the farmer did not want to use, or require regular weeding of plots around before flowering (mechanically or chemically). It is possible for herbicide-tolerant volunteers to persist in the soil and behave like weeds by competing with other plants. Farmers are used to this phenomenon, especially for rapeseed. However, if tolerant regrowth is to occur in a field of plants that are tolerant to the same herbicide as the regrowth, farmers will have to resort to the traditional treatments they have tried to avoid or curb the emergence of regrowth by ploughing stubble cultivation, false seeding. This situation has to be considered especially in Europe where crop rotations are practised. Some point out that when the number of herbicides to which the plants can be tolerant increases, the farmer will not know which herbicide to use to control the regrowth and it will be impossible to recognize the resistance of a regrowth in a given plot. The appearance of spontaneous resistance in cross-pollinated cross-breeders also worries the researchers.

The possibility of treating several crops on the same plot with the same herbicide successively could lead to plants being resistant to herbicides that had never caused spontaneous resistance in the past. To limit this risk, it would be necessary to provide a resistance herbicide per transgenic plant and set up rotations.

Insect-resistant plants

With regard to insecticidal transgenic plants, to prevent the phenomenon of insect resistance some companies advocate the establishment of safe havens, that is to say the creation of non-transgenic crop areas around transgenic crops. This fragmentation of the plots reduces the economic interest of using the transgenic plant, especially for farmers with small plots.

Contamination of the plots

Farmers who are using transgenic plants are likely to be forced to avoid contamination of non-GMO plots from their neighbours, which may involve the creation of increased safety zones or weeding restrictions. In the end, the use of transgenic plants should lead to an adjustment of cultural practices, which is not as simple as it seems.

2.9.2.2. Threats to organic farming

The arrival of GMOs may make it more difficult to practise organic farming. This sector wished to be free from GMOs. The various decision-making bodies ruling on organic farming have enshrined this desire, whether it is the community level,[157] the international level with the *Codex Alimentarius* or the national level (Directorate General for Competition, Consumer Affairs and Product Safety (*Direction générale de la concurrence, de la consommation et de la répression des fraudes*). However, GMOs pose several types of problems for organic farmers. They fear the contamination of their plots by GM crops and therefore the loss of their harvest. Then, they fear the appearance of insects resistant to Bt

[157] Regulation No. 1804/1999 / EC of 19 July 1999 on the organic production of agricultural products and its presentation on agricultural products and foodstuffs https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01999R1804-19990824&from=EN. "Genetically modified organisms (GMOs) and products derived from these organisms are not compatible with the organic production method; to preserve consumer confidence in the organic production method, genetically modified organisms, parts of these organisms or products derived from these organisms must not be used in products labelled as originating from the organic production method".

because it is one of the few ways to fight against insects that is allowed them. Finally, organic farming does not work in total autarky. Due to the limited quantity of organic products available, limited use of conventional products is permitted on several levels: seeds, ingredients in processed organic products and organic animal feed rations. These "external" products must not contain either GMOs or GMO derivatives. The lack of clear identification of products likely to contain GMOs and derivatives poses a problem for producers for whom the challenge is to develop supply chains for seeds, animal feed and non-GMO ingredients.

2.9.2.3 Reluctant European consumers

The arrival of transgenic plants and their incorporation in food has highlighted a new player: the citizen consumer, who had been forgotten in the research and crop phases and who was belatedly informed that they were consuming GMOs. Europeans seem reluctant to introduce GMOs into their diet and new expectations for their consideration are emerging. The European singularity is perhaps only superficial; in the USA, the full acceptance of genetically manipulated crops is also being called into question.[158]

The reasons for the growing hostility in Europe: A critical judgement

Deciphering the state of European public opinion is a delicate exercise. The European Commission regularly finances opinion surveys on this topic. The results of the Eurobarometer, conducted during the winter of 1999–2000 and published on 15 March, show that a significant proportion of Europeans are reluctant to introduce GMOs into the world. Nutrition: 59% consider it risky, only 37% consider that it is morally acceptable while 31% would be ready to encourage it. More than half of Europeans show intentions to buy expensively as long as they get non-transgenic diets. Applications of biotechnology that are considered interesting are the production of drugs and the development of genetic tests to detect hereditary diseases. Compared to the previous Eurobarometer of 1996, the survey highlights a clear decline in confidence in biotechnology to improve lifestyle.

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[158] Suzanne De Cheveigné, Daniel Boy, and Jean Christophe Galloux, *Les biotechnologies en débat: pour une démocratie scientifique.* Paris, Balland, 2002.

Multiple explanatory factors

Several types of factors are likely to explain the attitude of Europeans: a greater sensitivity to the question of food safety, but also a critical judgement concerning the social utility of the proposed innovations, and cultural and psychological considerations.

A lack of confidence in the evaluation and control bodies

The various health crises that have affected the EU and in particular bovine spongiform encephalopathy (mad cow disease) have placed food safety and quality at the heart of the public debate and severely undermined the confidence of Europeans in the evaluation of control bodies. It is often noted that the first freighters containing GM soybeans imported from the USA arrived in European ports in the midst of the mad cow crisis. In France, they were greeted by a title in the newspaper *Liberation* which caused a sensation: “The crazy soy landed in Europe”.[159]

The way in which the various applications for authorization of GMOs were handled at the level of individual country, as well as the EU, certainly did not contribute to strengthening the confidence of Europeans in their evaluation of control bodies and, beyond that, towards the scientific community. In the situation of GMOs, the important concern to arise is that of impartiality of experts, as the links between research and industry are close. The division of the scientific community on the existence of risks and the persistence of many uncertainties explain why Europeans are not completely reassured.

A disputed utility

The first applications of GMOs do not offer a direct benefit for consumers; it is indeed the applications with agronomic advantages that dominate. They do not meet any expectations. The scientist appreciates the risk for others, by studying the probability of its realization and the amount of damage that might result; the consumer naturally has a different perception of risk. It takes into account many factors and compares the risk of the product to the benefit it intends to derive from its use. In the food sector, the benefit of GMOs is not clearly perceptible to him. He is therefore not ready to run any risk, no matter how small. The fact that exposure to

[159] Daniel Boy, “L'évolution des opinions sur les biotechnologies dans l'Union européenne”, *Revue Internationale de politique comparée* 10, no. 2 (2003): 207–218.

risk is not dependent on the consumer, but imposed on him, also leads to making it less acceptable.[160]

A conflict of values?

Beyond the issue of health risk, the lack of enthusiasm by Europeans for transgenic foods also reflects other fears and refusals. It responds to cultural and psychological considerations.

The role of food in European culture

In European culture, food plays a special role. The food sociologists have highlighted the principle of incorporation that explains the prohibitions and eating habits in all civilizations: by ingesting a food, we identify with it by incorporating its symbolic values. As a result, dietary habits arise not only from the flavour of the food and its nutritional value, but also from the representation of these different foods. While the symbolic and affective approach to nutrition exists in all cultures, it is more pronounced in European countries. The food responds to several functions in Europe and embodies a link with nature; GMOs are the symbol of an artificialization of food, negatively connoted.

Increased sensitivity to ecology and rejection of some form of globalization

The opposition to GMOs certainly answers a philosophical or ethical questioning on the instrumentalization and the appropriation of the living and the status of the vegetable and the animal. It is the mark of a greater sensitivity to ecology. The action of so-called environmentalist organizations has influenced public opinion by attempting to deconstruct the triumphalism of the dominant discourse.[161] The refusal of the introduction of GMOs in food can be seen as a demonstration against the industrialization of agriculture, against the control of large multinational companies and the current conditions of globalization. This is a questioning of the standardization of a form of economic development, cultivation methods and eating habits.

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[160] Boy, “L'évolution des opinions”.

[161] Mark Lynas, “With G.M.O. Policies, Europe Turns Against Science”, *New York Times* 25 October 2015, https://www.nytimes.com/2015/10/25/opinion/sunday/with-gmo-policies-europe-turns-against-science.html

Numerous movements have been set up for the "defence of biodiversity", "against GMOs" in recent years in Europe. There is no formal meeting on biotechnology that is not hotly protested. These are well-known environmental movements, such as the Friends of the Earth or Greenpeace, as well as peasant or urban movements such as those in the social centres in Italy, who sometimes vehemently attack GMO crops (mowing, setting alight) or multinationals like Novartis or Monsanto, present on their soil. Initiatives consist of refusing the presence of GMOs in school canteens; these often come from parents of students, nurses or associations. In France, this movement is growing.[162]

The new expectations of "citizen consumers": security, freedom of choice, right of inspection and participation

The first consumer demand is of course safety. Not seeing the interest of GMOs in food, consumers do not want to run any additional risk, which seems rational. The second is freedom of choice. As consumers are reluctant to use GMOs, they wish to get information concerning the presence of GMOs in the products they are buying. Finally, consumers want to have a say in what is happening in the food sector and do not intend to impose the use of technologies without being able to express their expectations and fears; it is this idea that covers the notion of "consumer-citizen".

Labelling and traceability

The implementation of clear labelling of GMOs and a traceability mechanism, allowing the monitoring of products from their origin to their final destination, are two essential elements in meeting the expectations of consumers.[163] They are based on common foundations: consumer safety, product origin transparency, fair-trading and reliable information. Traceability also makes it possible to monitor the plausible effects of the introduction of manipulated seeds into the environment and to monitor unintended impacts on the safety of all animals because of GMO consumption, or even to implement recall measures on GMOs based on emerging scientific data.

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[162] Justice and Environment, "Friends of the Earth Europe, Greenpeace, Justice and Environment, and European Environmental Bureau Position Paper Regarding the Review of the Environmental Impact Assessment (EIA) Directive", http://www.justiceandenvironment.org/_files/file/EIA_Position_paper_final.pdf
[163] Petition available at http://www2.itif.org/2018-non-gmo-citizen-petition.pdf

The practicalities of labelling raise many difficulties. The first question is what products should be labelled. For some products derived from transgenic plants, no trace of transgenesis can be found. For others, detection tests may not be reliable (see Chapter 3). Consumers who refuse the techniques of transgenesis may want all products from transgenesis to be labelled, which favours labelling according to the technical manufacturing process. On the other hand, the perfect separation of the "GMO-free" and GMO-free production chains is presented as technically difficult, leading to the admission of a questionable threshold for accidental contamination. The question of the feasibility of a guaranteed GMO-free sector that is fully responsive to consumer expectations arises. Finally, the problem is who will bear the cost of implementing labelling and how will it be passed on throughout the agri-food chain?

The United States, an acceptance questioned?

The distrust of Europeans with regard to GMOs is sometimes presented as singular and in perfect opposition to the attitude of the Americans. However, the latter seem to evolve. While most processed food products in the United States contain GMOs, US consumers are very poorly informed of this fact. According to a study led in October 1999 by the *International Food Information Council,* only 38% of consumers are able to recognize that products derived from biotechnology are marketed. Their attitude towards GMOs still seems very positive: 77% of them declare themselves ready to buy products from plants resistant to insects and 62% of plants with delayed maturation or whose taste has been improved.[164]

However, various factors show that a change of perception is possible and that some concerns are shared on both continents. The opposition front widens and goes beyond the traditionally active associations in the sector. The Consumers Union, the largest consumer association in the US, has come out in favour of mandatory labelling of GMOs. In June 1999, a 500,000-signature petition was filed with the White House, Congress and the relevant federal agencies. The Food and Drug Administration (FDA) held three public meetings from November to December 1999 in Chicago, Washington and California on foods derived from GMOs and in particular, on assessment methods and labelling. A bill on labelling should be discussed in Congress.

[164] "Public perception of transgenic plants", Tom Hoban, quoted in "GMOs in Agriculture and Food: Face to Face United States/Europe", Pierre-Benoît Joly, *Cahiers français* no. 94, January–February 2000.

On the judicial front, a lawsuit was brought to the FDA by powerful religious organizations claiming the right to know "the origin of the genes" proposed for consumption. Another trial will open under the antitrust laws to counter the buyout of seed companies by companies in the phyto-pharmaceutical sector.

The reluctance of European, Japanese and American consumers is beginning to be perceived by American economic actors. In addition, US producers are complaining of difficulties selling their products. Some agri-food companies such as the baby food producer Gerber, which is still part of Novartis the world's second largest plant biotechnology group, are asking their suppliers for non-transgenic products. Other affiliates in these groups produce organic foods to cover the full spectrum of consumer preferences. For the 2000 planting season, transgenic plant surfaces have declined and some farmers are arranging to separate products in some areas.

2.9.3. Authorization of GM Products in the EU

The European Commission announced in a statement that it has authorized 19 GMOs. This is the first time it has made a decision of this magnitude. In total, seventy-five genetically modified organisms are now admitted to the Union.[165] However, that does not mean these GMOs will be planted on European soil. In fact, the only one authorized for cultivation in Europe is MON810 maize from the American company Monsanto. It is simply a green light for the marketing in Europe of products already legalized in the United States. As recalled from the site Inf'OGM, these manufacturers had begun to file a complaint in 2008 to denounce the slow process of authorization of their products, before a pro-industrial lobby took over in October 2014. The Commission has therefore given them compensation.[166]

There are seven plants that have already been authorized in the past and whose authorization is renewed, such as the controversial NK603. Ten new plants are also involved, including a variety of maize, rapeseed, five soybean and three cotton. The last two green lights are for transgenic flowers. The Monsanto firm markets the vast majority of these GMOs, but

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[165] European Commission, "Commission authorizes 17 GMOs for food/feed uses and 2 GM carnations", Press release, Brussels, 24 April 2015, http://europa.eu/rapid/press-release_IP-15-4843_en.htm

[166] Eric Meunier, "GMO Authorization in the EU: The Commission Once Again Attacked for 'undue delays'" *Inf'OGM* 15 December 2014 https://www.infogm.org/5762-gmo-authorisation-in-the-eu-the-commission-once-again-attacked-for-undue-delays

there are also the names of laboratories Bayer and BASF or the Dupont Company mentioned. In theory, they can be used for many uses. One of them in particular, Monsanto's MON87769 soybean, is thus included in the composition of "a variety of food products, including ready-made foods, cereals and breakfast seeds, pasta and sauces, meats, processed fruit juices, snacks, sweets ... but also aquaculture". Others can be used for cooking oil or biodiesels, disinfectants or soaps. The three forms of cotton are used in the manufacture of clothing.[167]

Some experts tried to analyse this decision of the EU; In fact, the importance of this decision is linked to criteria other than food. "Europe is engaged in negotiations with the United States on a free trade treaty [the Transatlantic Free Trade Agreement or TTIP], and GMOs are a point of contention. European sends a positive signal to the United States", decrypts Eric Meunier.[168] On the commercial side, the Commission's decision also has a consequence for American groups wishing to export to Europe. Today, merchandise containing more than 0.1% of unauthorized GMOs may be returned to the shipper. "By allowing these products, the Commission allows importers to no longer be exposed to this risk, while these organisms are increasingly used by countries of culture such as the United States or Brazil", describes Marc Richard-Molard, permanent delegate of Initiatives Biotechnologies Végétales (IBV).

This decision also masks a proposal made by the European Commission on 22 April 2015 that would authorize countries under the EU to place an embargo the import and consumption of GM crops on their territories. If this proposal is still far from being adopted, it sends a very special message. For Marcel Kuntz, also author of a GMO book, the political question: "the very fact that it is the Commission which proposes to grant states the possibility of banning, while pushing for European integration, is a historic message, the first event of European deconstruction."[169]

2.10 The Situation of GMOs in Africa

With regard to the policy on genetically modified plants, Africa is a field of struggles for influence and debate. The issues are economic, political and

[167] Meunier, "GMO authorization in the EU"
[168] Eric Meunier and Zoé Jacquinot, "Europe – OGM: *quand transparence veut dire confidentialité"* https://www.infogm.org/6788-europe-ogm-quand-transparence-veut-dire-confidentialite?lang=fr
[169] European Commission, "More Freedom for Member States to Decide on the GMOs use for Food & Feed", Press release Brussels, 22 April 2015, http://europa.eu/rapid/press-release_IP-15-4777_en.htm

ecological. Agriculture accounts for more than 25% of the GDP of most African states and employs more than 70% of their workforce.[170] Agricultural productivity is however undermined by a number of causes such as abiotic and biotic disturbances. The target of concern is to revolutionize industries that can overcome these adverse factors while being accessible to smallholder farmers with minimal external support. These technologies may include, among other things, the use of genetically engineered merchandise.

In Africa, biotechnology contributes to agriculture through the use of tools such as tissue culture. Tissue culture is currently being used in several African nations for the fast reproduction of seeds. Nevertheless, a low number of countries that adopted GM crop production or under agricultural research can be easily spotted in Figure 2-16.[171]

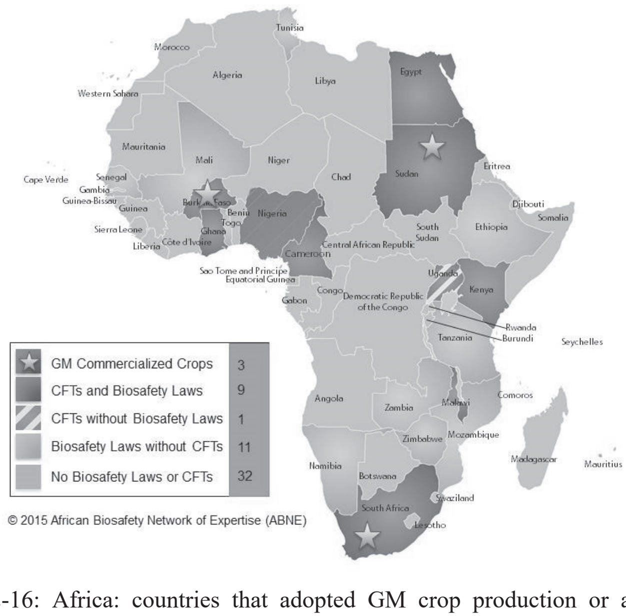

Figure 2-16: Africa: countries that adopted GM crop production or are under agricultural research

[170] UNECA, "Economic Report on Africa, 2009" accessed 14 November 2018 https://www.uneca.org/sites/default/files/PublicationFiles/era2009_eng_full.pdf.
[171]ABNE, "Status of Crops Biotechnology in Africa, 2015" accessed 14 November 2018 http://nepad-abne.net/biotechnology/status-of-crop-biotechnology-in-africa/

The situation of GMOs in Africa can be summarized into four stages of their applications: the first stage involves those GMOs that are allowed to be marketed. Only three countries are in the commercialization stage: South Africa (2.2 million ha of maize, cotton and soybean), Egypt (less than 100,000 ha of maize) and Burkina Faso. The second stage is for those products that are under CFT: this stage involves eleven countries (see Figure 2-16). The third stage consists of GM products under constrained research where at least sixteen countries are involved in this stage (see Figure 2-16). The last stage goes to those GM crops reserved only for agricultural research; this part consists of at least twenty-eight countries.

In Africa as mentioned above only three crops are grow for market purposes: cotton, corn and soybean. Several other plants with different features are reserved for research.[172] The following Table 2-7 [173] demonstrates countries that have allowed commercial activities towards GMOs, and corresponding traits.

Table 2-7: Countries with GMOs and their traits

Country	**GM Crop**	**features**	**Stage**
Burkina Faso	*Cow pea*	*IR*	*CFT*
	Cotton	*IR + HT*	*CFT*
	Sorghum	*Nutrient enhancement*	*Regulatory approval*
South Africa	*Corn*	*Drought tolerance*	*CFT*
		Herbicide tolerance	*FT*
		Insect resistance	*FT*
		Insect resistance and herbicide tolerance	*FT*
		Viral resistance	*CFT*

[172] Clive James, "Global Status of Commercialized Biotech/GM Crops: 2008", *ISAAA Brief No. 39* http://www.isaaa.org/resources/publications/briefs/39/
[173] Margaret Karembu, Faith Nguthi and Ismail Abdel-Hamid "Biotech Crops in Africa: The Final Frontier", *ISAAA AfriCenter* 2009 http://www.isaaa.org/resources/publications/biotech_crops_in_africa/download/Biotech_Crops_in_Africa-The_Final_Frontier.pdf

	Sorghum	*Nutrient enhancement*	*CFT*
	Cassava	*Starch enhancement*	*CFT*
	Cotton	*HT*	*FT*
		HT and IR	*FT*
	Potato	*IR*	*FT*
	Sugar cane	*Alternative sugar*	*FT*
Egypt	*Maize*	*IR*	*FT*
	Cotton	*Salt Resistance*	*CFT*
	Wheat	*Drought tolerance*	*FT*
		Fungus resistance	*CFT*
		Salt tolerance	*LAB*
	Potato	*Virus resistance*	*FT*
	Banana	*Virus resistance*	*Lab*
	Cucumber	*Virus resistance*	*FT*
	Melon	*Virus resistance*	*FT*
	Squash	*Virus resistance*	*Lab*
	Tomato	*Virus resistance*	*Lab*

Other African states such as Uganda, Nigeria, Ghana, Eswatini (Swaziland) and Kenya have considered GM crops at a certain level of tolerance and they have initiated important works regarding their developments, and laboratory researches.[174]

2.11 General Remark on GMOs Globally

Since the invention of agriculture, humans have manipulated plants and animals to improve their characteristics. Traditionally, this work is long since it is necessary to cultivate the species, to choose the individuals that present the desired characteristics, then to carry out this work for many years before obtaining a cultivar. The development of transgenesis, allowing the modification of the genetic material, allows not only choosing desired characteristics of the same species, but also of other species.

The main genetically modified (GM) crops in the world are soybeans, corn, cotton and canola. The two most common genetic modifications at present are herbicide tolerance and insect resistance. For herbicide

[174] Karembu et al., "Biotech Crops in Africa".

tolerance, agricultural yields would be greatly affected if weeds were not eliminated. Traditionally, it is by mechanical weeding that farmers remove weeds. For the farmer, weed control is greatly simplified by the use of herbicides. However, weeds are not the only ones to be destroyed by pesticides, where plants are also grown.

Researchers have therefore developed genetically modified plants capable of inactivating the action of certain herbicides. In other words, they are plants tolerant to a herbicide. These transgenic crops have been commercially used as "Roundup Ready" or "Liberty Link".[175] These GM crops, sold exclusively by the companies that produce the herbicides, can continue to grow normally, while the weeds gradually disappear after the application of the herbicide.

For insect resistance: insects are another problem the farmer faces. To remedy this problem, the scientists were inspired by a "biological" insecticide, or Bacillus Thuringiensis (Bt). Bt is a soil bacterium that causes the death of certain insects by producing a toxin that paralyzes their digestive system. The use of Bt is not recent. This insecticide is used in organic agriculture and in the fight against the spruce budworm. Bt as a biological insecticide is advantageous because it is not toxic to animals or humans. It also breaks down very quickly in the environment. Bt GMOs produce destructive protein in their leaves; insects that eat the leaves of these plants ingest the toxin and die a few days later, and this protein is not toxic to animals or humans. Multigenerational studies in cows, sheep, chickens, cattle, pigs and quails found no significant difference between animals fed with Bt corn and those fed non-GM grain corn.[176]

From 1965 to 2004, the demography of the world doubled and on average, each individual person consumed 10% more food than previously.[177] However, the agrarian area increased by only 2%, thanks to a better harvest per hectare resulting from the industrialization of agriculture. This revolution, which took place between 1960 and 1980, was marked by the

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[175] "A Guide to Using Roundup Ready® Herbicide with Plantshield® by Monsanto" http://www.monsantoglobal.com/global/au/products/Documents/A%20guide%20to%20using%20Roundup%20Ready%20Herbicide%20with%20PLANTSHIELD%20by%20Monsanto.pdf

[176] Chelsea Snell, Aude Bernheim, Jean-Baptiste Bergé, et al. "Assessment of the Health Impact of GM Plant Diets in Long-term and Multigenerational Animal Feeding Trials: A Literature Review". *Food and Chemical Toxicology* 50 (2012):1134–1148.

[177] James Stevenson, Nelson Villoria, Derek Byerlee, Timothy Kelley, and Mywish Maredia, "Green Revolution Research Saved an Estimated 18 to 27 Million Hectares from Being Brought into Agricultural Production", *Proceedings of the National Academy of Sciences of the United States of America* 110 (2013): 8363–8368.

advent of fertilizers, phytosanitary products and irrigation techniques, and coincided with the development of plant varieties that optimally responded to fertilizers.[178] Two economists; Evenson and Rosegrant, speculated that in 2000, the agrarian area would have increased by 3% to 5% if the agricultural plants had not been genetically improved by vegetal upbringing starting from 1965.[179] This represents a saving of nine to twelve million hectares of arable land in developed countries and fifteen to twenty million hectares in developing countries. The total savings of twenty-four to thirty-two million hectares made possible by the evolution of technology between 1965 and 2000 more or less correspond to recent data.[180] Based on a model involving more parameters, they calculated that an additional agricultural area of 18 to 27 million hectares would have been needed in 2004 if agricultural crops had retained their 1965 yield. They estimated that 12 to 18 million of this area has been preserved in developing countries and that deforestation of 2 million hectares would have been avoided.

These calculations show that increased yields per hectare have reduced the extent of the agrarian area. However, local socio-economic aspects can ruin this idyllic picture, because if better productivity is necessary to avoid the extension of the agrarian surface and the deforestation, that is not enough. An increase in productivity per hectare improves the efficiency of agricultural activities financially, which can in itself stimulate the expansion of agricultural areas. Advanced production for every hectare can also lower the price, thus increasing demand and hence production. Paradoxically, new technologies can consequently contribute to expanding arable land. This is the reason why British and Brazilian scientists have recently called on policymakers to take action, such as imposing economic sanctions (taxes, subsidies), preserving natural areas in farmland and issuing certificates.[181] Although high-yielding plants are an absolute necessity now, the fact remains that better surveillance, together with advanced agricultural strategy of local establishments, remains indispensable for combating the expansion of arable land.

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[178] Robert Evenson and Douglas Gollin, "Assessing the Impact of the Green Revolution, 1960 to 2000", *Science* 300, no. 5620 (2003): 758–762.

[179] Robert Evenson and Mark Rosegrant, "The Impact of International Agricultural Research" in *Crops variety improvement and its effect on productivity*, eds. Robert Evenson and Douglas Gollin (Wallingford, UK: CABI Publishing, 2003), 473–497. http://www.fao.org/docs/eims/upload/282053/9780851995496.pdf,

[180] Stevenson et al., "Green Revolution Research"

[181] Ben Phalan et al. "How Can Higher-yield Farming Help to Spare Nature?" *Science* 351, no. 6272 (January 2016): 450–451 https://science.sciencemag.org/content/351/6272/450/tab-e-letters.

CHAPTER THREE

THE COMPLEXITY OF BIOTECHNOLOGY AND THE REGULATORY FRAMEWORKS IN PLACE

As its name suggests, biotechnology is a fusion of biology and technology. It is a set of procedures and processes that utilize biological agents to produce goods or services. They cover many areas such as agriculture, agri-food, environment, energy, health and genetic engineering. For example, they are used to make genetically modified organisms and vaccines, to better understand disease and gene therapy. While the development of biotechnology must come primarily from those who are directly interested in the future of this sector, international politics is nonetheless essential. The countries in their legislative powers are obliged to establish legal mechanisms under which these activities are conducted, and especially to give impetus so that the catching up of the delay taken by the international community operates at the quickest possible level.

International regulation of biotechnology came to regulate problems like the complexity of the decision to export genetically modified bacteria, biological arms control, health and disease control, biological safety and security, protection of the environment, protection of intellectual property, control of drugs, and social and ethical impacts that can be obviously linked to the new technology found in biology today. We will be focusing on these issues in this chapter in order to establish the approach of international law.

3.1 Concerns about the Science of Biotechnology

Biotechnology uses genetic engineering to act directly on the genome of the cell. When looking at a cell under the lens of a very powerful microscope, there are long filamentous structures that are called chromosomes. Thanks to scientific discoveries, the researchers succeeded in the transfer of genes between cells of different organisms.[182] From these

[182] Ben Phalan et al. "How Can Higher-yield Farming Help to Spare Nature?" *Science* 351, no. 6272 (January 2016): 450–451

applications, various researchers have found four societal concerns[183] in relation to the development of this field: harm to the environment, bioterrorism, laboratory/production safety (biosafety concerns), and finally ethical concerns.

3.1.1 Environmental concerns

There is a range of environmental risks related to genetic technology. Joining two different genes of different species, geneticists are able to create a new organism, which may contain the features of the creator genes but still maintaining a new identity. In case this creation is engrained, the probability to affect wild vegetation is too high.[184] Science had not yet found the reason this pollution is even possible, yet the risk on a long-term scale can undermine the development of plants, essential insects and animals as well as have a negative impact on the surrounding biodiversity.[185] Alterations and modifications due to the science of biotechnology have affected the originality of species.

3.1.2 Bioterrorism

We call an attack biological when it involves a voluntary deliberation of a pathogen (an agent capable of infecting) or biotoxin (a poison from a living organism) against plants and animals, including humans. When this attack is directed to people, it may have various motives such as causing illness, threat or fear, killing, disordering communities and economic losses. On the other side, bioterrorism on plants or agriculture in general would mainly result in economic disturbance, turn food supply policy into a joke and loss of various diversities in plants. Biological agents can be categorized into two types[186]: agents that are proliferated from person to person like

https://science.sciencemag.org/content/351/6272/450/tab-e-letters.

[183] Phillips, Theresa, "Societal Concerns of Biotechnology", *The Balance* accessed 26 January 2018 https://www.thebalance.com/societal-concerns-with-biotech-3973289.

[184] Office of the Auditor General of Canada, "Environmental Risks" accessed 27 January http://www.oag-bvg.gc.ca/internet/English/parl_cesd_200710_02_e_23838.html.

[185] David Ervin, "Agricultural Biotechnology is a Double-edged Environmental Sword", Henry A. Wallace Institute. Remarks to the National Association of Agricultural Journalists, Washington, DC (1999, 19 April).

[186] National Academies and the U.S. Department of Homeland Security, "Biological Attack: Human Pathogens, Biotoxin, and Agricultural Threats, *News & Terrorism*, accessed 27 January, 2018 https://www.dhs.gov/xlibrary/assets/prep_biological_fact_sheet.pdf.

smallpox and Ebola or among other animals such as those causing diseases of foot and mouth, and agents with adverse effects that are not transmitted from contagious individuals to others such as anthrax and botulinum toxin.

Some biological agents may also be used as a means of war to kill or to weaken enemies through diseases, especially by disseminating poisons.[187]

3.1.3 Biosafety concerns

Being able to sustain life-saving materials in a microorganism may be classified as one of the best achievements of genetic technology. Other accomplishments involve the invention of golden rice and iron-rich rice, and various fertilizers as well as the production of different kinds of pesticides. Without any doubt, the good applicability of bioethics has made human life very easy and progressive, and the use of these biotechnological tools is of paramount importance in human activities. The safety concerns increased awareness among academics, farmers and consumers of GMOs, lawyers, environmental activists and regulatory bodies. Consequently, many states have elaborated policies and established organizations to take care of the safety of the public and the environment where this may be linked to GMOs. However, in the GMO market not enough effort has yet been made, especially for their release into the environment.[188]

3.1.4 Ethical concerns

As we have mentioned in the Introduction, ethical issues are also one of the biggest concerns in our society today as we are witnessing the rapid progress of genetic engineering like never before. After the success of cloning two monkeys named Zhong Zhong and Hua Hua on 10 January 2018 at the Chinese Academy of Sciences in Shanghai[189], many researchers in the field of biotechnology are asking questions about the future of various species including humans: the use of advanced technologies could accelerate their evolution, make the borders between species more permeable, or allow the creation of new ones. In such a context, the accelerated evolution of the human, and even its transformation into a new

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[187] US Department of Homeland Security, "What is Bioterrorism?" *Ready,* accessed 27 January 2018, https://www.ready.gov/Bioterrorism.

[188] Suresh Kumar "Biosafety Issues of Genetically Modified Organisms", *Biosafety* 3, no. 2 (July 2014): e150. doi:10.4172/2167-0331.1000e150

[189] Voice of America, "Move Over, Dolly: Monkeys Cloned; A Step Closer to People?", 24 January 2018 accessed 26 January 2018 https://www.voanews.com/a/monkeys-cloned-dolly-humans/4222494.html .

species, for example, might not seem so far-fetched. This possibility is seen by some as a denaturing of the human being to avoid,[190] while others see it as an opportunity to manage the future of humanity rationally to improve our lot.[191] It therefore seems appropriate to ask how the moral community of humanity, as an evolving subject of international law, considers the future of the human species.

3.2 The International Law's Approach vis-à-vis Biotechnology

Debates regarding whether genetic engineering's opportunities are far better than opposing due to probable risks are among the most viral topics on the global scale either in Internet discussions or in public debates. This has pushed the international community to try to define a conventional understanding on what biotechnology really means and the rules concerning this field.

The international community has tried to define biotechnology in legal boundaries. In the 1992 United Nations Convention on Biological Diversity, biotechnology is defined as "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use."[192]

The Cartagena Protocol on Biosafety also defines modern biotechnology as "the application of:[193]

(a) In vitro nucleic and techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
(b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection."

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[190] Francis Fukuyama, *Our Posthuman Future. Consequences of the Biotechnology Revolution*, (New York, Farrar, Strauss & Giroux, 2002); Leon Kass, "The Wisdom of Repugance", in *The Ethics of Human Cloning*, ed. Leon Kass and James Wilson, (Washington DC: AEI Press, 1998).
[191] John Harris, *Enhancing Evolution*, (Princeton, Princeton University Press, 2007).
[192] Article 2 of the 1992 United Nations Convention on Biological Diversity.
[193] Article 3 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted 29 January 2000

Even so, the international consensus on the legal meaning of biotechnology is still lacking.

The Convention on Biological Diversity holds a central position. In this respect, other international agreements and protocols to the Convention on Biological Diversity have been made, as we will discuss in the following points. As seen in Figure 3-1, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty, which targets the guarantee of the safe management and carriage of living modified organisms (LMOs) originating from genetic engineering that may contain a negative impact on natural diversities with a great concern on the safety of human health.[194] This convention added the Cartagena Protocol on Biosafety and the Advanced Informed Agreement (AIA), which was established by the conference of state parties to the convention in Cartagena, Colombia, in 2000. The protocol covers reference to protective methods by reaffirming the language in Principle 15 of the Rio Declaration on Environment and Development.[195] Following this protocol a Biosafety Clearing-House (BCH) was created to enable the sharing of information regarding manipulated living organisms and to support Member States in the implementation of the protocol.[196] When it comes to trade concerning GMOs, the Biosafety Protocol serves as the pioneer of all international legally binding conventions.

As Figure 3-1 shows, the protocol works through two different procedures. The first procedure involves LMOs projected for direct distribution into the environment under the AIA procedure, and another for LMOs for direct consumption as food, feed or for processing (LMOs-FFP).[197] According to the AIA regulations, any state that plans to export an LMO must solicit an approval from the country planning to import it, before its primary delivery. Before the decisions regarding the imports of LMOs are taken, countries must first assess their potential risks in a systematic way and using a transparent method. Given the outcome of the examination of risk assessment, any country may decide on whether to import an LMO or not. According to the procedure for the LMOs and FFP, any country which

[194] The Cartagena Protocol accessed 29 January 2018 https://bch.cbd.int/protocol/background/.

[195] The Rio Declaration on Environment and Development (1992), Principle 15 http://www.unesco.org/education/pdf/RIO_E.PDF.

[196] Der-Chin Horng, "International Law on Biotechnology", Institute of European and American Studies, Academia Sinica, Taiwan, ROC, accessed 28 January, 2018 http://www.eolss.net/sample-chapters/c14/e1-36-13.pdf.

[197] The Cartagena Protocol on Biosafety, accessed 30 January 2018 https://bch.cbd.int/protocol/cpb_otherpubl.shtml.

has considered sending a particular LMO to be sold is obliged to publicize such decision under the centralized information system, the BCH.[198]

If the country is not sure about whether any characteristic of an LMO can negatively affect the environment, it may in this case refuse to import it under the preventive approach. Furthermore, during the discussion about the possibility to import an LMO, a state may also consider socio-economic issues that may arise from the impacts of LMOs. All countries under this convention are obliged to consider the public while deciding on any attempt to import LMOs.[199]

3.2.1 The Cartagena Protocol on Biosafety to the Convention on Biological Diversity

In case a country agrees to import an LMO to release into the environment, the state must present a report regarding a concluded risk assessment to the BCH. The BCH helps with free access to main information regarding LMOs, such as a list of approved ones under an established registration and other scientific documents on these issues. After deciding on whether to allow an LMO to be imported, the protocol obliges that during this transaction the LMO in question be safely carried, managed and packed. Deliveries consisting of LMOs have to travel with documents that label them as LMOs. After this import, the importing country is required to respond appropriately for handling any kind of risks demonstrated under the assessment, or plausible ones. In case a new scientific research provides a different result on any LMO, all the assessments must be repeated and all decisions must be reviewed. According to the protocol, there is a well-defined mechanism for claiming restoration of damage caused by imported LMOs.[200]

This protocol was not adopted solely by developed nations; to some degree, countries with low incomes also supported the protocol only because they were afraid that their territories could be used for experimentation with the cultivation of GMO products. Under the protocol the nonexistence of science-backed proof on negative impacts a GM product may bring does not prevent the country from restricting its imports of such an organism, so reduces anticipated risks.[201]

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[198] Petry and Bugang, "Agricultural Biotechnology Annual GAIN Report".
[199] Petry and Bugang, "Agricultural Biotechnology Annual GAIN Report".
[200] Petry and Bugang, "Agricultural Biotechnology Annual GAIN Report".
[201] United Nations Environment Programme (UNEP), 2000. "Cartagena Protocol on Biosafety to the Convention on Biological Diversity", Montreal, 29 January 2000,

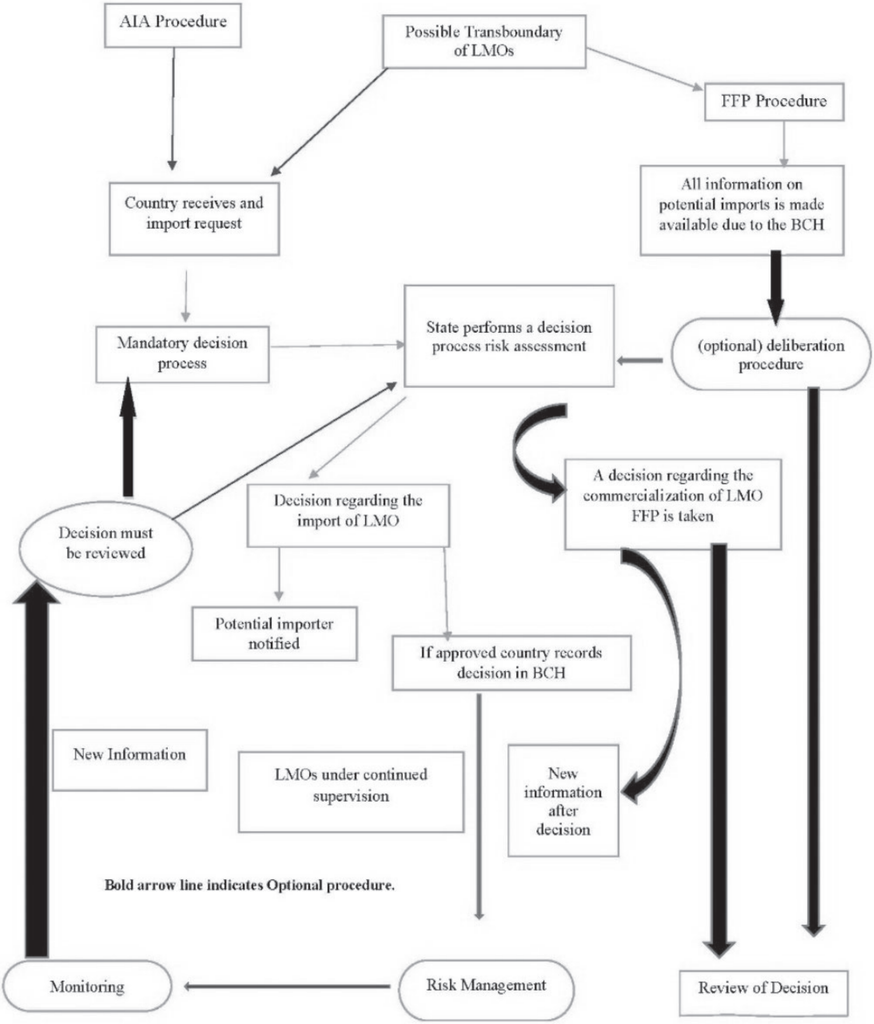

Figure 3-1: The Cartagena Protocol procedures

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https://treaties.un.org/doc/Publication/MTDSG/Volume%20II/Chapter%20XXVII/XXVII-8-a.en.pdf

3.2.2 Instruments relating to social and ethical impacts

Concerning ethical impacts, the international community adopted various documents to deal with all projects regarding the human genome but among them, as we will discuss in the following points to this, subsections four are most relevant.

3.2.2.1 Universal Declaration on the Human Genome and Human Rights[202]

The instrument in question was adopted before completing the human genome-sequencing project; it seeks above all to ensure that human rights and dignity in the framework of research in human genetics are respected. Humanity as a moral community, to the "great human family", seems to be based on the possession of a human genome[203], a biological attribute whose variability among human beings is also recognized, as well as mutability in time[204]. This variation should not be a source of discrimination against human beings[205].

This human genome at the level of the species is qualified as the heritage of humanity, although in a figurative sense only[206], thus making the link between the human species and the community of humans, which must protect its heritage. Transmitted from generation to generation, this genome indeed has one of the essential attributes of a heritage. This instrument prohibits the prevalence of projects concerning the human genome in the biological, genetic and medical research focusing on a particular group of people[207]. It also prohibits human cloning[208] and urges states to promote human rights in every research concerning the human genome[209].

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[202] (GC Res. 29 C/16, UNESCO (OR), 29e session, 1997; GA Res. 152, UN GAOR, 53e session, UN Doc. A/RES/53/152, 1999.)

[203] Article 1 of the Universal Declaration on the Human Genome and Human Rights states that: "the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity".

[204]See Preamble and Article 2 of the Universal Declaration on the Human Genome and Human Rights

[205]See Preamble and Article 3 of the Universal Declaration on the Human Genome and Human Rights.

[206]Article 9

[207]Article 10

[208]Article 11

[209]Article 25

The Universal Declaration on the Human Genome does not create any responsible authority to control the use of the human genome, but aims at the application by the states of the principles that it establishes. It deals with this issue at a certain level of abstraction, as a genome of the species in general. This is probably an aspect of the symbolic sense for the limits that should be included when dealing with the genome of a species.

3.2.2.2 UNESCO Universal Declaration on Bioethics and Human Rights

The United Nations Educational, Scientific, and Cultural Organization (UNESCO) established a declaration on 19 October 2005, concerning the rules to be universally applicable in all research of bioethics.[210] This declaration has served as the best example in the application of science and technology where ethics has been given particular attention.[211] Ethical concerns in life science and medicine have been the main purpose of this declaration.[212]

The provisions of Article 2 of this declaration may be challenged by the state in case of the *interest of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others.*[213] The absence of concrete legal support and explanations of informed consent in this declaration may favour therapeutic experimentations on children who are incapable of giving their consent[214].

Many ethicists, predominantly from southern-hemisphere nations, consider the declaration to be an essential document that will renovate the quality of research internationally and encourage high ethical standards in many countries where no standards exist at the present day. However, many criticizers think that the declaration is constructed with unclear provisions

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[210] UNESCO, "Universal Declaration on Bioethics and Human Rights", General Conference of UNESCO, 33rd Session (19 October 2005), accessed 27 January 2018
http://portal.unesco.org/shs/en/filedownload.php/46133eIf469Ie4c6e57566763d47 4a4dBioet hicsDeclarationEN.pdf.

[211] Koïchiro Matsuura, Dir.-Gen., UNESCO, Address at the Twelfth Session of the IBC, Tokyo, Japan, UN Doc. DG/2005/201 (15 December 15 2005), accessed 27 January, 2018 http://unesdoc.unesco.org/images/ 0014/001428/142832e.pdf.

[212] UNESCO "Universal Declaration on Bioethics", Article 1.

[213] UNESCO "Universal Declaration on Bioethics", Article 27.

[214] Anna Gercas, "The Universal Declaration on Bioethics and Human Rights: Promoting International Discussion on the Morality of Nontherapeutic Research on Children", *Michigan Journal of International Law* 27, no. 2 (2006), accessed 26 January 2018 http://repository.law.umich.edu/mjil/vol27/iss2/5.

that will only hinder scientific developments. Furthermore, critics maintain that by handing out strategies for bioethical questions, UNESCO has stepped beyond its field of expertise and its mandate.[215]

3.2.2.3 International Declaration on Human Genetic Data

The first Article of the declaration provides that the goal of this document is to mainly maintain the respect nobleness of human life and to protect all rights and fundamental freedom of humans as provided for in international human rights documents, to regulate the use of genomes when involving human genetic data, referred to in the declaration as "biological samples", by remaining in the limits of equity and justice while providing room for the freedom of thought and expression which may include the freedom of scientific research; to establish strong pillars which states can use as a base while making their legislations.[216]

Exploring genetic data has helped medical researchers to study individuals case by case, a step that enabled doctors to establish a comprehensive medical diagnosis. In addition to this, knowing genetic data has helped criminal justice to detect criminals using forensic science.[217]

3.2.2.4 The United Nations Declaration on Human Cloning

Surprised by cloning of a sheep named Dolly in 1996 by Scottish scientists, different states raised strong concerns regarding the plausible cloning of humans. This was no long a fictional movie, but a very possible reality and they established a ban on any laboratory experience regarding human cloning. This fear[218] made these countries establish legal frameworks to regulate actions, which included rules regarding the conduct of genetic engineering, experimentation and modification once they are being

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[215] Wolinski, Howard, "Bioethics for the World", *EMBO Rep*. 7, No. 4 (April 2006): 354–358. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1456905/ accessed on 28 January 2018

[216] UNESCO, International Declaration on Human Genetic DataParis, 29 September to 17 October 2003 available online at https://unesdoc.unesco.org/images/0013/001331/133171e.pdf#page=45

[217] UNESCO, "International Declaration on Human Genetic Data", http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/ accessed 6 February 2018.

[218] Michael J. Malinowski, "The Impact of Current Policy and Regulation on Future Stem Cell Human Health Applications", 39 New England review 647, 653 (2005).

effectuated.[219] However, these nations realized that it is not sufficient to abide on a national scale[220] while this is a concern of human race that is why this idea of creating an international instrument under the United Nations came into being.[221]

The concept of human cloning can be heard either as reproductive or therapeutic. Reproductive cloning "is a procedure used to create a person that has the same genetic make-up or DNA as another existing human."[222] This means that embryos can be created and implanted which will certainly result in new offspring.[223]

Therapeutic cloning involves creating embryos, which can be used in the treatments of various human embryonic disorders[224]. Therapeutic cloning uses nuclear transfer where individual soma can be transferred "into an oocyte from which the nucleus has been removed or rendered inactive."[225]

The declaration bans any kind of cloning that violates human dignity.[226] The document itself has no binding force; however, it urges countries to enact national laws that respect its provisions.[227]

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[219] Esther Seng, "Human Cloning: Reflections on the Application of Principles of International Environmental and Health Law and Their Implications for the Development of an International Convention on Human Cloning", *Oregon Review of International Law* 114, 114 (2003)
https://heinonline.org/HOL/LandingPage?handle=hein.journals/porril15&div=1&src=home

[220] Esther Seng, "Human Cloning", 115

[221] United Nations, "Declaration on Human Cloning", G.A. Res. 59/150, U.N. Doc. A/R/59/80 (23 March 2005) accessed 6 February 2018
https://digitallibrary.un.org/record/541409/files/A_C.6_59_L.27_Add.1-EN.pdf.

[222] Melissa Burchell, "Note, America's Struggle to Develop a Consistent Legal Approach to Controversial Human Embryonic Stem Cell Research and Therapeutic Cloning: Are the Politics Getting in the Way of Hope?", *Syracuse Journal of International Law and Commerce* 32, no. 1 (2004): 133

[223] Melissa Burchell, "America's Struggle to Develop", 146.

[224] Melissa Burchell, "America's Struggle to Develop", 146.

[225] Mikyung Kim, "An Overview of the Regulation and Patentability of Human Cloning and Embryonic Stem Cell Research in the United States and Anti-Cloning Legislation in South Korea", *Santa Clara High Technology Legal Journal* 21, no. 4 (2005): 645, 650.

[226] United Nations, "Declaration on Human Cloning".

[227] Hayley Cohen, "How Champion-Pony Clones Have Transformed the Game of Polo", *VF News, Vanity Fair*, 21 July 2015
https://www.vanityfair.com/news/2015/07/polo-horse-cloning-adolfo-cambiaso.

The provisions of this declaration could be interpreted to restrict human cloning including the therapeutic type of cloning[228] which the scientific community supports because it helps them to establish a good study of human genome. In addition, the countries that voted against it do still apply; it raised the possible conflict between the scientific community and human rights activists.[229]

3.2.3. The WTO Agreement on Technical Barriers to Trade (TBT Agreement, 1994)

The Technical Barriers to Trade (TBT) Agreement aims to ensure a standardization of trade on an international level by removing technical barriers and conformity in technical regulation that actually causes obstacles to the development of trade in general. Through this agreement, the World Trade Organization (WTO) members have the rights and freedoms to apply the provisions of the agreements into any policy that encourages and maintains a better condition for humans and their environments.

The TBT Agreement and SPS regulate matters related to labelling and its effects on international trade, however, the difference between the two agreements is that in case the labelling concerns the safety of food, only SPS can be applied. On the other side, the TBT Agreement will be applied as a guiding document if the labelling concerns the manufacturing processes that would influence the final product. In this case, deciding whether any genetically manipulation has a possible effect on the last manufactured organism, will be examined individually. The TBT Agreement does not apply to many genetically manipulated products; that is where in this case other WTO regulations will apply without exception. Article III of the GATT on unprejudiced examination, for instance, states that state parties to the agreement may not treat identical goods differently because of their country of origin.[230] Here, the likelihood and GMO trait sufficiency in a

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[228] United Nations, General Assembly, "General Assembly Adopts United Nations Declaration on Human Cloning by Vote of 84-34-37", UN Doc. GA/10333, Press Release, (6 February 2018),
http://www.un.org/News/Press/docs/2005/ga10333.doc.htm.
[229] Channah Jarrell, "No Worldwide Consensus: The United Nations Declaration On Human Cloning", accessed 6 February 2018
http://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1163&context=gjicl
[230] Christian Tietje, "Voluntary Eco-labelling Programmes and Questions of State Responsibility in the WTO/GATT Legal System", *Journal of World Trade* 29, no. 5 (1995): 123–157.

product will be the common denominator to interpret Article 3 of this document.

Local legal instruments will regulate the distribution of any imported product. Those who sell a genetically modified product may be compelled to follow these.

Among the sixty-four countries that require the registration "with GMO" on the products concerned are the (current) 28 Member States of the European Union. The label must be affixed if the threshold of GMO or derivatives in each ingredient of the product exceeds 0.9%. Other countries have similar requirements, such as Turkey, Saudi Arabia, Australia, Russia and Kazakhstan.[231]

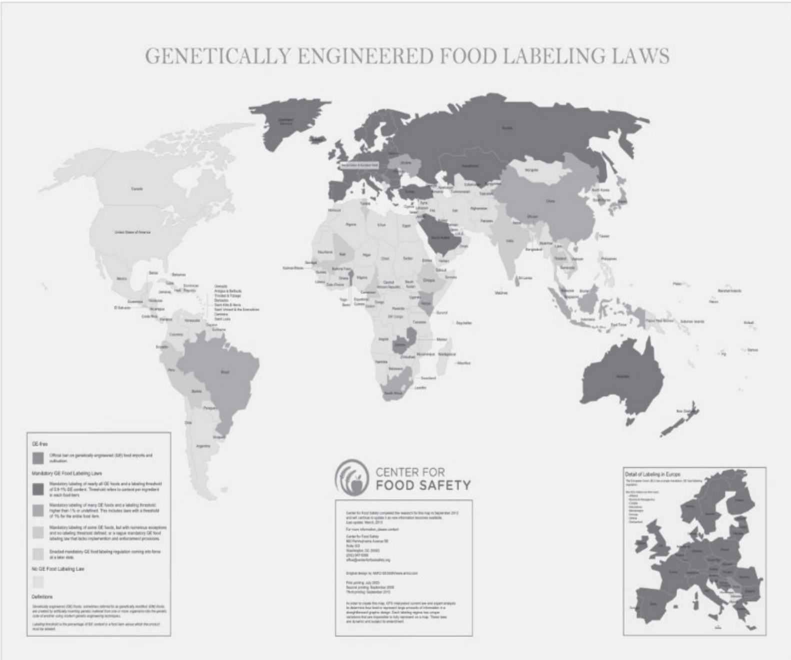

Figure 3-2: Genetically engineered food labelling laws. Source: http://media2.policymic.com/37c4 1

[231] Camille Jourdan, 14 May 2014, "64 pays étiquettent leurs produits OGM. Pas les États-Unis" http://www.slate.fr/life/87053/64-pays-etiquettent-ogm-etats-unis accessed 15 November 2018.

Promoted by consumers (at the end of 2013, 93% of Americans were in favour of GMO labelling, said a *New York Times* poll)[232] and contradicted by agri-food industries, GMO labelling fuelled the debate in the US, even though GMOs are contained in 80% of foods. Nevertheless, agri-food and agrochemical industries of the world's leading powers do not share this view. AFP recalls that "agri-food companies have spent nearly US$ 70 million in California and Oregon, defeating new guidelines that make labelling mandatory."[233]

By July 25, 2018 the verdict of the European Union Court of Justice on the legal status of genetically modified organisms (GMOs) by mutagenesis techniques obliged every single imported GM product to be labelled as a GM-containing product. However, the US as a leading country in exporting these crops did not welcome such a decision. Concerning critics, the US reaction was not long coming. Two days later, the US Secretary of Agriculture Sonny Perdue, a strong advocate of plant biotechnology[234], issued an offensive press release stating that the United States considered the verdict of the court as a setback "for policies that should inspire scientific research without crafting needless fences or unreasonably defaming new technologies". In addition, it described the European legislation on GMOs as "regressive and outdated".[235]

In the United States, a federal law obliges all food manufacturers to utilize labels on their products starting in 2020.[236] However, as the new guidelines propose, not all GM products will be covered; some foods whose basic ingredients are not GMOs like meat or beef stew will not be labelled as GMOs.[237]

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[232] Allison Kopicki, "Strong Support for Labeling Modified Foods", *New York Times* July 27, 2013, accessed 23 November 2018, https://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html?_r=1&

[233] Camille Jourdan, "64 pays étiquettent leurs produits OGM. Pas les États-Unis".

[234] Charlotte Krinke, "Info sur GMO "États-Unis: un pro-OGM nommé secrétaire d'État à l'Agriculture", *Info'gm* 20 January 2017 accessed 23 November 2018 https://www.infogm.org/6125-trump-ministre-agriculture-pro-ogm.

[235] USDA, U.S. Secretary of Agriculture Sonny Perdue on ECJ ruling on genome editing. Washington, 27 July 2018, https://www.usda.gov/media/press-releases/2018/07/27/secretary-perdue-statement-ecj-ruling-genome-editing accessed on 23 November 2018

[236]Amy Harmon, "G.M.O. Foods Will Soon Require Labels. What Will the Labels Say?" *New York Times*, 12 May 2018, accessed 23 November 2018. https://www.nytimes.com/2018/05/12/us/gmo-food-labels-usda.html accessed 23 November 2018.

[237]Amy Harmon, "G.M.O. Foods Will Soon Require Labels".

Internationally, the US government is involved in ongoing reflection work, whether in the OECD or the Convention on Biological Diversity (CBD). In November 2017, *Inf'OGM* reported on the US position in the CBD discussions on a possible future definition of synthetic biology, thus relating to modern biotechnology. The US government argued that existing legislation to regulate GMOs was sufficient and that it was not useful to adopt new specific regulations—an approach that would obviously restrict specific risk assessment, labelling or other monitoring procedures as required in the European Union or elsewhere.[238]

3.3 The European Regulatory Frameworks on Biotechnology

Although the early stages of the biotech industry are generally traced back to the US, Europe has been an important competitor and partner in the progress of ever better technologies to develop lives. With scientific and public concerns about the side effects of biotechnology, Europe has put in place different forums to deal with risk management as well as regulating biotechnological inventions.

3.3.1. The European legislation on GMOs

Since 1997, the European Union has been controlling genetically modified foods within the framework of the EU Regulation on Novel Foods and Novel Food Ingredients. This regulation deals with those kind of foods or ingredients of food, which have not been considered important in the history of the European Union, which are included in the following classifications[239]:

- *Category of foods that generally contain GMOs;*
- *Those elements produced from GMOs and those with a new or voluntarily manipulated molecule;*

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[238] See "Infos on GMOs" by Eric Meunier, 23 August 2018, *Nouveaux OGM: quel cadre au niveau international?*", accessed 23 November 2018, https://www.infogm.org/6618-nouveaux-ogm-quel-cadre-niveau-international

[239] Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council, Official Journal of the European Communities, L 253/1-36 (1997) https://eur-lex.europa.eu/eli/reg/1997/258/oj

- *Those alienated from or containing of fungi, algae or other microorganisms;*
- *Those alienated from or consisting of plants and animals except those produced traditionally with a good history of safety, or*
- *Those that significantly prove change in food production with no negative impact on its consumption.*

On the authority of regulation (EC) No. 1829/2003, the following are required for a GMO for food use[240]:

- *must not have adverse effects on human health, animal health or the environment;*
- *must not mislead the consumer;*
- *must not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.*

In the European Union GMOs must comply with the provisions of the Cartagena Protocol through BCH.[241]

To avoid any potential risks that may affect human health because of the use of GMOs, Member States are requested to report any reasonable concern of threat that can be propagated transnationally immediately to the Commission, other states, relevant international organizations and the BCH for undertaking a necessary remedy.[242]

3.3.1.1. Legal protection of biotechnological inventions in the European Union

The science of biotechnology embodies one of the main fields of discovery and innovation that emerged at the beginning of the twenty-first century. The subjects it covers are considerable, both ethically and economically, as well as for public health. In this important field, European

[240] Article 4(1) of the Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1829&from=en

[241] Article 4(1) of the Regulation (EC) No 1829/2003 of the European Parliament.

[242] Preamble 19 of the Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on Transboundary Movements of Genetically Modified Organisms (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1946&from=EN.

countries have lagged behind the United States and Japan because of a lack of a harmonized legal approach. Directive 98/44/EC responds to this situation by defining common principles and rules between the Member States of the European Union with regard to the conditions and limits within which patent protection can be obtained for inventions on biological matter. The European Parliament and the Council adopted it after lengthy and complex negotiations and after the failure of a first proposal for a directive on this subject in March 1995. Under this directive, the following biological inventions are not patentable[243]:

- *plant and animal varieties;*
- *essentially biological processes for the production of plants or animals;*
- *processes for cloning human beings;*
- *processes for modifying the germ line genetic identity of human beings;*
- *uses of human embryos for industrial or commercial purposes;*
- *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

For inventors, applicants and companies, this directive puts an end to a situation of legal uncertainty resulting from significant differences on these issues between national and international legislation and practices. Thus, under existing legislation, applicants could not always determine with certainty whether or not their inventions were patentable. On the other hand, the absence of specific provisions could make them hesitate about the scope that may be recognized in the granted title. However, inventors have no intellectual rights over animals and plants obtained under the biotechnological experiments.[244,245] In addition, human cloning is unacceptable and the EU Commission deals with ethics in this science.[246]

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[243] Article 4(1) and 6 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
[244] Directive 98/44/EC
[245] European Patent Office, Information from the EPO, accessed 7 February 2018 https://www.epo.org/law-practice/legal-texts/official-journal/2016/12/a104.html
[246] Article 7, Directive 98/44/EC of the European Parliament.

3.3.1.2 The protection of workers from risks related to exposure to biological agents at work

Whether they are bacteria, viruses, fungi or parasites, biological agents are microscopic organisms naturally present in the environment and in every living being. Some of them are very useful (used for example as drugs associated or not with other treatments) but others can cause diseases—we are talking about pathogens. It is primarily in the European context that biological risks have been considered in their entirety. Article 3(2) of the European Union Directive ensures that workers who made contact with biological agents of any type are well evaluated and reported for prevention of further risks that might harm them.

According to the SUMER 2003 survey, more than 15% of workers declare themselves to be exposed to biological risks as part of their professional activity. This figure is 27% in the personal services sector, 33% in agriculture, and 66% in the health/social work sector. It is very difficult to have reliable data on occupational diseases resulting from these exposures, as the numbers are underestimated because of a low reporting rate, either because the link to the profession is not established or because t the illness is cured without sequel (the interested parties do not consider it useful to establish a file of application for recognition of an occupational disease).[247]

In case workers have been exposed to dangerous biological agents, an assessment must be done and kept up to 10 years after the last day of exposure and up to 40 years for specific cases.[248] The biosafety has been a concern since the first invention in the domain of biotechnology but in Europe, the first association to enlighten on this issue was the European Biosafety Association (EBSA) in 1996.) EBSA is a European transnational association established in 1996 in more than twenty-four European countries whose members gather in a forum to talk about all issues concerning health risks that could result from working in biotech laboratories.[249] In addition to this, EBSA has different corporate partner members and organizations, which are mainly actors in their countries in the field of biosafety.[250]

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[247] *Risques au Travail*, accessed 10 December 2018, https://www.cdg62.fr/index.php/prevention/hygiene-et-securite-au-travail/les-risques-au-travail/11-prevention/296-le-risque-biologique#pageTop.
[248] Article 11(2), Directive 98/44/EC of the European Parliament.
[249] About EBSA, accessed 7 February 2018 https://ebsaweb.eu/about-ebsa.
[250] Partners, accessed 7 February 2018 https://ebsaweb.eu/ebsa-partner-organisations.

3.3.2 Comparative insight on EU and US regulatory processes

Concerning the health and safety of foods, neither the EU nor the USA are safe; they both experience the same struggles for credibility in food supply. On the one hand, the US regulatory system has maintained a liberal approach from 1980s until now, which is different to its former strict regulatory form. On the other hand, the EU has always been attracted to a mindful and conservative approach.[251]

[251] David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics* (New York: Council on Foreign Relations, 2001).

Table 3-1: Comparison between EU and US regulatory processes

Area of Comparison[252]	United States	European Union
Competent authority	Many agencies (FDA, USDA, EPA and many others). A primary authority may be established in case of jurisdictional conflict.	DG XI for environment, DG III for pharmaceutical manufacturing. However, all cases must first meet the approval from environmental risk assessment.
Ability to adapt to new scientific information	Flexible to revise with new scientific evidence.	Complex regulations, hard to revise.
Effective interagency coordination	Available since 1984.	Not open. Only ad hoc level of consultation is allowed.
Regulation debating process	Open to all concerned individuals or agencies.	Not open. Clients and DGs can discuss on an ad hoc level.
Input from scientific community	Extensive.	Very restricted. At least for some purposes (Science, Research and Development).

[252] Lee Ann Patterson, "Regulating Competitiveness: the Development and Elaboration of Biotechnology Regulatory Policy in the European Union". Ph.D. Diss., Graduate School of Public and International Affairs, University of Pittsburgh, 1998.

The authorization of GMOs in the European Union, the United States and Canada follows three main stages: the authorization of experimental cultures in a confined space, the authorization for open release and the authorization for the marketing of a new food. The evaluation modalities, the types of organizations responsible and the rules of approval vary from one country to another, but it can be said that there are two different conceptions of GMOs. In the United States, a genetically modified organism is considered a new variety of the organism from which it is derived. Its approval therefore tends to follow the rules in force for other types of food and disregards its mode of production. The European Union, for its part, considers the production of GMOs as a distinct food chain, requiring evaluation mechanisms of its own. The Canadian system applies the same principles as the United States, especially because this country undertook in 1998 to harmonize its practices with those of its neighbours to the south. The Canadian Food Inspection Agency (CFIA)[253] obtains from the producer information on the history of the transgenic plant and the changes made to it before allowing field trials. Before allowing large-scale cultivation, the CFIA asks the producer to provide information on threats regarding biodiversity. The CFIA makes its decision without making public either the experimental protocol or the results provided by the company seeking approval.

Around the world, thirty countries have imposed the labelling of GMOs. In Europe, any food that contains more than 1% must be labelled. In North America, where transgenesis is not considered to require special precautions, labelling is optional. Some American states, however, are considering imposing it. To be reliable, the information on the label must be based on a rigorous traceability system, which tracks the food from the farm to the table.

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[253] Quebec Government, "GMOs and Human Nutrition: Impacts and Challenges for Quebec", 2002, http://www.bape.gouv.qc.ca/sections/mandats/prod-porcine/documents/PROD41.pdf

Conclusion

The development of biotechnology has taken a great step in human history. However, the fear of a possible threat of biotechnological products to human, soil and diversity of animal safety have also made headlines. Given the existence of international community efforts, many steps have been taken concerning the use of biotechnology that can benefit human beings and their surroundings. Balancing the advantages of biotechnology against its disadvantages especially in food engineering, The United Nations Food and Agriculture Organization estimates that about 795 million people of the 7.3 billion people in the world, or one in nine, were suffering from chronic starvation in 2014–2016. Almost all the hungry people, 780 million, live in developing countries, representing 12.9 per cent, or one in eight, of the population of developing counties.[254] Producing GMOs is inevitable to fight hunger, and this stresses the importance of GMOs regardless of any side effect they can possibly provide. Regarding cloning, the regulations in place must be improved to match the speed of scientific inventions and ban even the action of cloning other primates because the level of probabilities to negatively impact human beings is too high.

The effects of adopting GMOs, even when measuring the potential economic gains in a static framework, are relatively complex. They are heterogeneous according to the regions of production. This is true in the simplistic framework, for example GMO adoption is assumed to result in a 5% productivity shock on corn and soybeans. In this case, the global gains are about US$10 billion a year that means a ban on imports of GMOs by many countries would be very costly in terms of welfare for the world population (assuming that the aversion to GMOs is not very important).[255] Policymakers must compare this cost to the possible voice they would gain by adopting such a radical vision of the precautionary principle as discussed earlier.

We are not intending to conclude a topic that merits an exhaustive study and an appropriate reflection, but it is necessary to raise some questions in

[254] World Hunger Education Service, "World Hunger and Poverty Facts and Statistics accessed 7 February 2018 https://www.worldhunger.org/2015-world-hunger-and-poverty-facts-and-statistics/.
[255] World Hunger Education Service "World Hunger and Poverty"

this regard. Beyond the current accession of farmers to systems of technological value contracts, an honest examination of the implications of it in terms of sovereignty; in case the economic scenario changes and puts in question the adhesion of producers to the aforementioned concerns of these new technologies, what will be the reaction of the state? It will be possible to ask ourselves retrospectively about the effects of the expropriated practices, access and control of genetic assets, distribution and appropriation of profits derived from its commercial use.

Ideally, firms should study staple crops in developing countries without filing patents on new species created without the new generation of seeds being sterile. After improving the staple food, agri-food companies should be able to offer poor countries the fruits of their research by explaining to them, for example: "Here is a new potato resistant to the devastating virus. If you buy our genetically modified seeds, we assure you, although nothing can be 100% sure, such annual yield, without risk of crop failure". However, research is very expensive so agri-food companies do not make their results available to producers. They file patents, make the seeds sterile and sell them at a much higher price than traditional seeds to pay back the years of work required to create these new products. It is sad to say, but it is the lure of gain that drives them to undertake such scientific achievements and their economic power is such that they can only annihilate small farmers with the prices they like by condemning them to borrow to get their seeds. The result is ultimately the opposite of that expected: the peasant, although perhaps independent to ensure his survival, is completely tied to the firm that provides seeds and is bogged down in the spiral of debt. We are well aware of the enormous gap between the possibilities of producers in rich and poor countries. Imagine a crop where modified seeds would not meet the promised expectations; the farmer in the developed country will have to give up the expected benefits as someone who has made a bad investment. The farmer in the developing country, who almost always has to go into debt to buy modified seeds, cannot afford not to have the promised yields that are in fact never 100% guaranteed. He has no way of turning against his supplier. The fight is lost in advance. Since he is in debt to buy the modified seeds and they have not returned as much as promised, he is forced to re-borrow money to repay his debts.

GMOs can therefore be a small part of the answer to the crisis of hunger in the world, but they are by no means the solution to this great problem as claimed by biotechnology companies producing genetically modified organisms. We must consider their usefulness on an individual basis without ignoring the alternative techniques that farmers have had for centuries to solve the problems of agriculture, and which are the subject of scientific research. For example, in 1995 the International Centre for Insect Physiology and Ecology Research received the World Food Prize for its work in developing the prey-predator system that regulates abundant and regular maize harvests without pesticides or fertilizers.

If GMOs are exploited in developing countries, it is essential to set up a structure regulating the extent of these crops, as is the case in industrialized countries, but which is often lacking in developing countries, which further extends the power of multinational firms. Ideally, the solution for this technology to be used wisely would be that agribusiness firms put their interests at the bottom of the agenda for the benefit of Third World farmers with urgent needs. This is far from being the case today and may never be feasible. Yet, I wonder if the capital invested in development and aid to developing countries could not be used to buy patents from firms, so that farmers can have modified seeds without the risk of being caught in a spiral of debt. If we consider GMOs as part of a solution, we must balance their benefits with the risks they generate. Is it more important to increase production efficiency by taking a risk on the future of the environment and our health, or do we sit down and wait for falling manna?

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