The adoption of genetically modified organisms and legal implications

A comparative analysis

A report for

by Cecília de Medeiros Fialho

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Executive Summary

The laws controlling the approval of genetically modified events in a particular country are very important, and must demonstrate their legitimacy while remaining safe for the use of animals, human beings and harmless to non-target plants. There are two major variables that determine the evolution of agricultural transgenes (and any other science) in a society: the scientific research and development, and legal support for it to act effectively. The present report explores the regulatory events of the approval of genetically modified materials in the countries of Brazil, China, the United States and the European Union.

Under a comparative method, the sequential steps are the update and validation of primary and secondary data and data processing, confronting the objects of study in consideration of four macro themes, which are: historical, institutional, regulatory and technical. The countries were then ranked, with Brazil's legislation being the most sophisticated and functional, followed by the United States, China and the European Union.

Brazil, although not having originated the case law that regulates biotechnology, was the one that approved the largest number of events in the shortest time. The United States, despite the traditionalism in the adoption of biotechnology, now faces a period of clear need to have laws reviewed: these laws often seem unintelligible to both applicant companies and the population in general, and are costly and time-consuming to apply.

China is structurally well organized on the evaluation of genetically modified organisms (GMOs), but faces the challenge of educating its large population to their use, which is a challenging and complex task compared to other countries. In addition, the lack of national genetically modified products points to a reserved stance from the government in allowing trade access to foreign biotech companies. This conservative position may also reflect a desire to make Chinese technology more internationally competitive.

The European evaluation system is flawed, considering that every decision on the approval of genetically modified events in the European Union rests with the European Commission. Member States, in most cases, are not purely scientifically motivated, but give more weighting to political and ideological reasons when refuting the technology. Consequently, they are often unable to declare their reasons officially, thanks to a system that only legitimizes science as the only possible evaluation criteria.

Looking forward, it was concluded that Brazil is heading towards the improvement of genome editing techniques, and the progressive use of biotechnology in health.

The United States seek to simplify, within their biosecurity criteria, their regulatory framework, and to lead research in improving management techniques and use of scientific data in the field.

China aims to prepare and establish a new position in the global agribusiness trade, even to being considered as a potential exporting agent, and for increased agricultural competitiveness, by making use of biotechnology in the launch of national genetically modified products.

The European Union is going through a decision-making change in defining the role of the European Commission, currently and improperly responsible for the approval of transgenic events. If it is approved that Member States start to take full responsibility in biotechnology-nature decisions, it could lead to a possible trade liberalization; the end of a single market would transform permanently the way the bloc interacts with international markets.

It is also expected that biotechnology will find more popular acceptance when it is applied to areas other than agriculture, which could ultimately promote the understanding of how the technology can be used in food production.

Table of Contents

List of Figures

Preface

The central motivation for the present study arose from investigations into the unusual position of biotechnology in Latin America. In research recently published by the technical team of Céleres® Consultancy (Céleres®, 2016), it was concluded that although countries are closely located and connected via free trade agreements, legislation on commercial approval of GMOs may differ widely between them. Even in very cohesive markets, both heterogeneity and territorial specifications in the treatment of genetically modified material are present; what does this say about the differences between larger players on opposite sides of the globe?

Contrary to what Friedrich List (a German economist and advocate of protectionist practices) thought, that the education about protectionism would be the best alternative to the development of the domestic industry, the world food market is conducted in a constant exchange of information, benchmarking, know-how and technology transfer. In the light of this study, biotechnology is a case study of how innovative processes can revolutionize an entire value chain. In this particular case, biotechnology can contribute to raising yields, capitalizing the small farmer and allowing cultivation of crops in areas initially adverse to planting.

As an extremely important discussion in the definition of food security and development of science as a whole, these factors will impact the world's population sooner than is expected, so the present time is appropriate to understand the reception and interaction of different nations to the biotechnology proposition.

In this report, the biotechnology paradigm is investigated under the perspective of the regulatory framework of four countries governing the global trading of agricultural commodities. It was sought to understand how different governments address the issue of food safety as affected by genetic manipulation, such as the influence of popular opinion in decision-making, and how the legislative and executive powers visualize the future of agriculture guided by transgenes.

The idea is that the construction of a comparative model that allows analyzing the performance of different countries, using the same units, will result in a method which could, optimistically, be extended to any of the nearly 200 countries around the globe.

Acknowledgements

The completion of this report would not have been possible without the wise guidance of Jim Geltch, Sally Thomson and all my friends and colleagues from the Nuffield organization. Thank you for welcoming me in this great and extraordinary family, and for showing me the ropes.

I also thank the TIAA-CREF investors for believing in my work and allowing me to travel the world in search of knowledge. This institution was the first partner of Nuffield International to assign a scholarship to Brazil, and their visionary approach and efforts to disseminate information must be emphasized.

My sincere thanks to Paula Carneiro and Anderson Galvão, for all the opportunities, leadership and valuable lessons, and for introducing me to Nuffield and encouraging me to join this global network of entrepreneurs.

Céleres' friends, thank you for the example and partnership. I am a professional in constant learning in my daily work with you.

To my family and friends, thank you for being present, for the words of encouragement and always relevant notes; I owe you for the last two years of incredible journey and construction. To Suely, in particular, I would not have done it without you.

To all who welcomed me around the world and were open to discuss the issue of agricultural biotechnology, for instructing me and sharing your rich experience in the subject, thank you. All interviews collected were fundamental in the design of this report and I hope I have lived up to your words. I thank in particular Barbara Glenn, Marie-Cécile Damave, Katy Lee, Patrick Trainor, Wyatt Muse, Scott Kuschminder, John Dillard, Scott Irwin, Todd Kuethe, Denise Dewar, Tim Sheehan, Damien Plan, Arnaud Petit, James Ede, Nilsy Desaint, Jon Biermacher, Steven Rhines, Billy Cook, Yuan Weimin, Peijun Tao, Ma Zhi-ying, Li Jin-cai, Zhang Yong-sheng, Chen Jing-tang, Xiao Kai, Ge Shu-jun, Zhang Cai-ying, Wang Xing-fen, Yang Min-sheng, friends of the Agricultural University of Hebei, the Academic Institute of Agriculture and Hebei Forestry Sciences, the Department of Agriculture of Hebei Province, the Group Xin Di and others who contributed directly and indirectly to this achievement.

All the credit belongs to you.

No man is an island.
John Donne, 1624

Abbreviations

Anvisa – National Health Surveillance Agency

AQSIQ – General Administration of Quality Supervision, Inspection and Quarantine

Asean – Association of Southeast Asian Nations

CIB – Council of Biotechnology Information

CIBio – Internal Biosafety Commission

CQB – Quality Certificate of Biosafety

CRISPR – Clustered Regularly Interspaced Short Palindromic Repeat

CTNBio – National Biosafety Technical Commission

DMFC – Fuel cell of direct methanol liability

EFSA – European Food Safety Authority

Embrapa – Brazilian Agricultural Research Corporation

EPA – US Environmental Protection Agency

FAO – Food and Agriculture Organization of the United Nations

FDA – Food and Drug Administration

FP7 – 7th Framework Programme for Research and Technological Development

GMA – Grocery Manufacturers Association

HBP – Human Brain Project

ICT – Information and Communication Technology

IR/HT – Stack

ISAAA – International Service for the Acquisition of Agri-Biotech Applications

LPMA – Planned Release on the Environment

MAPA – Ministry of Agriculture, Livestock and Supply

MMA – Ministry of Environment

NASDA – National Association of State Departments of Agriculture

OGM – Genetically modified organisms

WHO – World Health Organization

PIB – Gross Domestic Product

RI – Insect resistant

RRA – Roundup-ready

SSP – Subcommittees Permanent Sector

TH – Herbicide tolerant

USDA – United States Department of Agriculture

Objectives

This study aims to qualify, using a standard comparative model, the countries of Brazil, China, the United States and the European Union, with regard to the regulatory framework approving the commercial release of GMOs in their territory in the last 10 to 20 years.

It also seeks to explain the trends involving agricultural biotechnology, subject to implementation in the selected countries in the short and long-term, starting from interviews with officials, scientists and farmers in each location.

Introduction

Since agriculture was established ten thousand years ago, the Earth has been in constant transition. Judging from the average life expectancy of 20 countries that make up approximately 95% of the world's Gross Domestic Product (GDP), it is estimated that an average of four to five generations of human beings currently coexist. This population has witnessed some of the most striking facets of mankind's history. For example, two World Wars, the Cold War, the Green Revolution, oil crises and many commodities super-cycles. The present period, in year 2016, brings to light a backdrop of consolidation in emerging countries, industrial practices with negative and irreversible impacts to the environment, forecasts of the depletion of fossil fuels and an impressive population target of about 10 billion people in 2050 (CENSUS, 2016).

The discussion of the responsibility of agriculture and related industries in solving major structural problems is important to any policy maker. Meanwhile, there is one technology available, which can improve, or even remedy, issues related to sustainable production, food security and conservation of the terrestrial biome; this is biotechnology (James et al., 2015). It is essential to include it in any long-term plans to study a new order for global markets.

Legally, much has been made as to how each country covers the introduction of biotechnology in agriculture and other sectors. This is because the government, after the scientific community, is the most important player in ensuring that the proposed innovations are implemented, and which give effect to the transformation propositions. For this change to occur, it is imperative to understand the laws involving biotechnology controlling the major players of global agribusiness and how they interact with each other. That is the purpose of this study.

Besides this introduction, four chapters will be presented that deal with, respectively, the regulatory framework classification of the selected countries, their biotechnological context, the institutional and legal basis for the approval of GM introductions and future guidelines on biotechnology in each country.

The method chosen, developed by the technical team of Céleres®, consists of a comparative proposition that views the countries studied (Brazil, China, the United States and the European Union) from a similar perspective of regulatory frameworks in the use of agricultural GMOs. It was sought to understand whether, in the light of this analysis, legislation of such major players in global agribusiness covers similar levels of understanding of the applicability and impact of genetic engineering in agriculture. The core observation, albeit based on limited data, indicates important information about a timeframe in GM history, contributing to the understanding of how biotechnology is assimilated into each legislation, and how it is influencing the industry as a whole.

The investigation was limited to the examination of certain topics, considered to be the most relevant for achieving the classification, in descending order, the sophistication level of each country's laws concerning agricultural biotechnology. The selected items by country are as follows:

i) The historical context of agricultural biotechnology.

ii) Their institutional framework.
iii) The legal basis governing their response.
iv) The approval process and criteria.

The search and selection of rules that make up the regulatory framework of each country covered in the scope of this study were performed using both a scientific literature review and consultation with agencies or bodies involved in agricultural biotechnology. The first step consisted of scheduling interviews and meetings in the presence of professionals involved in the agricultural biotechnology sector in each country. This action made it possible to obtain and validate in-depth data, allowing great flexibility and adaptation via personal contact.

During meetings, issues related to legislation and its implementation have been validated. Thus, the main objective at this stage was to determine if the law, inherent in the subject, and its application were indeed aligned, or perhaps the legal application actually differed from what was declared. In each case, the understanding and identification of the factor that led to the divergence between practical application and existing legislation was explained.

In order to organize and conduct reasonable and clear meetings/interviews, a preliminary hot topic list was prepared on the subject, that would be discussed with each professional. In the data processing phase, characterization, interpretation and analysis of the information obtained were performed, including the discussion and systemic analysis of possible comparisons of the selected topics, by country.

After the research of rules, the institutional environment and the nation's approval process, via primary data, it was possible to qualify the condition of each country in comparison with others. The most relevant to biotechnology were then compared, and classified for each country.

Four macro themes were selected, considered to be the most relevant to the diagnosis, namely: historical, institutional, regulatory and technical regulations. For each theme, five qualification criteria were defined, namely the level of acceptance by:

i) Local consumers.
ii) Local farmers.
iii) The scientific community (academic).
iv) The Legislative Power.
v) The Executive Power.

At the institutional level, the five major factors were the:

i) Definition of the structure of institutions involved on the process of evaluation/inspection of GMO activities.
ii) Definition of the composition of institutions involved on the process of evaluation/inspection of GMO activities.
iii) Definition of the function of the institutions involved on the process of evaluation/inspection of GMO activities.
iv) Number of accumulated approvals for cultivation in the country.
v) Average time for GMO approval in the country.

At the legislative level, the five major factors were the:

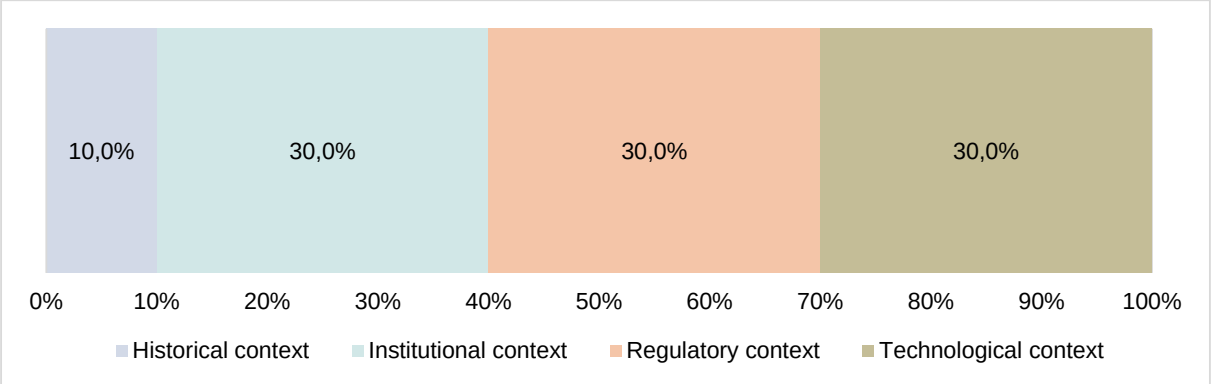
i) Structure of the regulatory system related to biotechnology in the country.
ii) Legislation related to crop protection and biotechnology in the country.
iii) Legislation related to the publicity/communication of biotechnology in the country.
iv) Legislation that stablishes the criteria of risks related to GMO activities.
v) Legislation that stablishes the risk management for cases of adverse risks (contention/mitigation/control).

At the technical level, the five most important factors were the:

i) Technical criteria related to processes of analysis of GMO activities.
ii) Understanding of processes of analysis and approval of new transgenic events.
iii) Evaluation of environmental risks and food safety.
iv) Qualification of the technical group responsible for GMO processes and activities.
v) Deliberative system for the approval of GMOs (voting – based on the technical analysis or linked to the government).

For the proposed scope, it was understood that the selected major themes could not be equally weighed. On an arbitrary basis, the historical major theme's relevance was reduced to 10% of the overall weight, while other macro themes were each given 30% of the total. Each theme was included in the survey and ranked after consideration of the perception of various social and political cores on agricultural biotechnology, which is important for the constitution of the law, but does not define it, as other themes do. The weight distribution is shown in Figure 1.

Figure 1 – Weights assigned to selected contexts in the analysis and countries classification



Source: Céleres®

Each qualification criteria valuation respected the following classification, with the respective grade:

• Rating: Excellent – attributed rate: 5.

• Rating: Good – attributed rate: 4.

• Rating: Neutral – attributed rate: 3.

• Rating: Some restrictions – attributed rate: 2.

• Rating: High risk – attributed rate: 1.

The parameters for allocating the grades related to each criterion were prepared by the Céleres® technical team, and can be applied to other States, as long as primary and secondary data required in the diagnosis are properly collected.

Given this methodological foundation, the classification of countries is described in Chapter 1 of this study.

Chapter 1

Regulatory framework classification of selected countries

The agricultural biotechnology theme is extensive and complex, is subject to various insights and covers different research areas. This study sought to address the lack of comparison, under the same analytical perspective, of the quality and sophistication of the regulatory frameworks in the adoption of GMOs in countries from all over the world. In an attempt to level the discussion on biotechnology worldwide, the Cartagena Protocol on Biosafety and the Codex Alimentarius were established.

The Cartagena Protocol on Biological Biosafety, which came into force in September 2003, is an international agreement. It aims to ensure handling, transportation and use of GMOs resulting from modern biotechnology that may cause adverse effects on the world's biological diversity, and also take into account potential risks to human health. The Protocol adopted by the Convention's members is an important step in creating an international legal framework that considers the environmental protection requirements, factors affecting animal and human health, and promotes international trade.

The Protocol creates an internationally common way to discuss procedures to guide the introduction of GMOs in each nation, and to establish agreements to ensure that countries have the necessary information needed to make considered decisions before agreeing to import GMOs.

The Codex Alimentarius is a code of conduct comprising internationally recognized standards relating to foods, food production and food security. It was established in 1963 by the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO). Its main objective is to make consumers around the world feel confident to rely on safety and quality of food products, and ensure that importers trust that the food they purchase abroad meets the required specifications. The major discussions that reflect the popular concern regarding the issue are biotechnology, pesticides, food additives, contaminants and others.

It is observed that nations are moving toward a convergence of understanding around biotechnology, although it presents, currently, more like an idealization than based on factual achievements. And even if agreements were at an advanced stage of negotiation, working out legal aspects in different countries, and correlating them, is a complex and difficult task that nations still seem not to be prepared to take. Therefore, it is up to the agents involved in this market, using individual methods of evaluating how the issue has been addressed in different countries, and what can be done so they collaborate with each other in building a consensus on the acceptance of biotechnology.

The comparative method adopted in this study brings different perspectives, from an historical analysis to the approval criteria itself, for a country to be globally positioned with respect to agricultural transgenes. Having the four macro themes described in the Introduction, the grades

distribution for the four objects of study proposed and consequent classification are shown in Table 1, followed by their rating scale, in Figure 2.

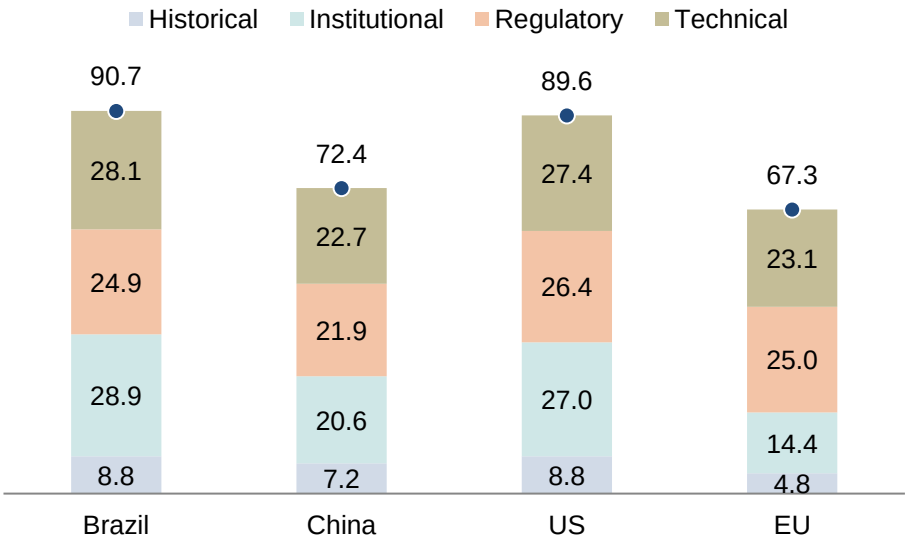
Table 1 – Grading and classification of countries

ID	Description of Qualifying Criteria	Great	Good	Neutral	With restrictions	High risk	Primary Data			
		5	4	3	2	1	Brazil	China	US	EU
HIS_01	Acceptance of local consumers	High support from local consumers	Support from local consumers	Neutral position of local consumers	Median restriction of local consumers	High restriction of local consumers	4,0	4,0	4,0	1,0
HIS_02	Acceptance of local farmers	High support from local farmers	Support from local farmers	Neutral position of local farmers	Median restriction of local farmers	High restriction of local farmers	4,5	4,0	4,5	1,0
HIS_03	Acceptance of the scientific community (academic)	High support from the local scientific community	Support from the local scientific community	Neutral position of local scientific community	Median restriction of the local scientific community	High restriction of the local scientific community	4,5	4,0	4,5	4,0
HIS_04	Acceptance of the Legislative Power	High support from the Legislative Power	Support from the Legislative Power	Neutral position of Legislative Power	Median restriction of Legislative Power	High restriction of the Legislative Power	4,5	3,0	4,5	4,0
HIS_05	Acceptance of the Executive Power	High support from the Executive Power	Support from the Executive Power	Neutral position of Executive Power	Median restriction of Executive Power	High restriction of Executive Power	4,5	2,5	4,5	2,0
INS_01	Definition of the structure of institutions involved on the process of evaluation/inspection of GMO activities	Appropriate organizational structure to the requirements for implementing the local biosafety law		Organizational structure in implementation phase		No organizational structure for the effective implementation of local laws	4,0	4,0	4,0	4,0
INS_02	Definition of the composition of institutions involved on the process of evaluation/inspection of GMO activities	Bodies composed of qualified personnel, with political and scientifical support		Technical staff with quantitative/qualitative limitations and political support		Technical staff with ideological, technological and political bias	5,0	3,0	5,0	3,0
INS_03	Definition of the function of the institutions involved on the process of evaluation/inspection of GMO activities	Expertise roles clearly defined and established in regulatory frameworks		Roles and responsabilities in the process of being established in the regulatory framework		Uncertainty and conflit of roles and responsabilities between different regulatory bodies	5,0	4,5	4,5	1,0
INS_04	Number of accumulated approvals for cultivation in the country	> 10 approvals for planting in 2 or more crops	From 5 to 10 approvals for planting in 2 or more crops	< 5 approvals for planting in 2 or more crops	< 5 approvals for planting in 1 crop	No approval for planting	5,0	2,0	5,0	2,0
INS_05	Average time for GMO approval in the country	< 2 years per process	2 to 3 years per process	3 to 4 years per process	4 to 5 years per process	> 5 years	5,0	4,0	4,0	2,0
REG_01	Structure of the regulatory system related to biotechnology in the country	Robust system of well-defined and efficiently used standards	Structured standards system and being implemented	Standard system to be structured	Scattered standards, not set and regardless of what happens in practice	Lack of rules that regulate biotechnology	4,5	4,0	4,5	3,0
REG_02	Legislation related to crop protection and biotechnology in the country	Existance of intellectual property protection mark, with rights granted to holders (breeding)	Existance of intellectual	Existance of legislation (sparse) related to the protection of plant varieties and biotechnology	Regulatory framework that ensures intellectual property rights in the process of discussion and implementation	Lack of intellectual property protection standards for genetics and biotechnology	4,0	4,0	5,0	4,0
REG_03	Legislation related to the publicity/communication of biotechnology in the country	Legislation **guaranteeing** effective and precise communication processes on biotechnology		Clear and well-defined legislation establishing the need for advertising/communication on biotechnology		Lack of legislation about standards of advertising/communication on biotechnology	4,5	3,0	4,5	3,0

REG_04	Legislation that stablishes the criteria of risks related to GMO activities	Legislation **guaranteeing** analysis processes of effective and precise risk criteria		Existance of clear and well-defined rules establishing the criteria for risks related to activities involving GMOs		Lack of legislation on the definition of the risk criteria related to the activities involving GMOs	**4,0**	**3,0**	**4,0**	**4,5**
REG_05	Legislation that stablishes the risk management for cases of adverse risks (contention/mitigation/control)	Legislation **guaranteeing** the process analysis and management of adverse effects, effectively and pricesely		Existance of a clear and well-defined legislation establishing the management criteria of adverse effects		Lack of legislation on the definition of management criteria of adverse effects	**4,0**	**4,0**	**4,0**	**4,0**
TEC_01	Technical criteria related to processes of analysis of GMO activities	Criteria based on technical concepts and publicly accepted		Technical criteria combined with political and socio-economic aspects		Technical criteria defined in political concepts	**4,5**	**4,0**	**4,5**	**4,0**
TEC_02	Qualification of the technical group responsible for GMO processes and activities	Highly technical decision-making body, with political support		Decision-making body divided between technical and political (or divergence between techniques of different agencies)		Decision-making body eminently political, without technical support	**5,0**	**3,0**	**5,0**	**3,0**
TEC_03	Evaluation of environmental risks and food safety	Existance of procedures for evaluating the environmental risks and food safety, observing the criteria of the Cartagena Protocol, with the case to case example, and the Precautionary Principle		Existance of procedures for evaluating the environmental risks and food safety		Lack of standards and criteria for the analysis of environmental risks and food safety	**5,0**	**4,0**	**5,0**	**4,5**
TEC_04	Understanding of processes of analysis and approval of new transgenic events	Clear approving orders, aligned with the agencies involved	Clear approving processes with low aligment between the agencies involved	Approving processes with low aligment between the agencies involved		Confusing or incomplete approving orders, without alignment between the agencies	**4,5**	**4,0**	**4,0**	**3,0**
TEC_05	Deliberative system for the approval of GMOs (voting – based on the technical analysis or linked to the government)	100% technical approval, with executive validation	Technical approval aligned with the executive approval	100% technical approval without the executive validation	Executive approval with technical support	100% executive approval, without technical validation	**4,5**	**4,0**	**4,5**	**3,0**

Source: Céleres®.

Figure 2 – Countries' grades and average per group (base: 100)



Although not the most traditional country in the adoption of agricultural biotechnology, Brazil was the best ranked in the comparative basis, mainly from the standpoint of structure and efficiency of the regulatory framework, and of GMO approval processes. The Brazilian current historical period points to a significant number of cumulative approvals for planting and less time spent in the average realization of such applications.

In relation to the technical criteria context, the robustness and regulation underlying new events approval processes must be highlighted, which allowed the risk analysis related to environment and human and animal health to be executed by highly skilled professionals. The competence in the post-commercial release phase certainly demonstrates the maturity of this regulatory system for agricultural biotechnology.

In second place, technically tied with Brazil, the United States fails because of excessively complex analytical procedures, less clarity in the conduction of processes and less flexibility in decision-making, which resulted in a lower ranking than Brazil, being mainly reflected in the assessment of technical requirements.

Third, China surprised in complexity and organization of its regulatory framework, but was penalized in the institutional analysis, especially with regard to the diversity of GM material approved in the country, and presented the lowest grade on the regulatory aspect, reflecting a system that has not yet found its optimum operating point, nor a balance between working in collaboration and allowing international exchange of knowledge and biotechnology content. The main Chinese concern is to ensure the protection of the intellectual property of its creations.

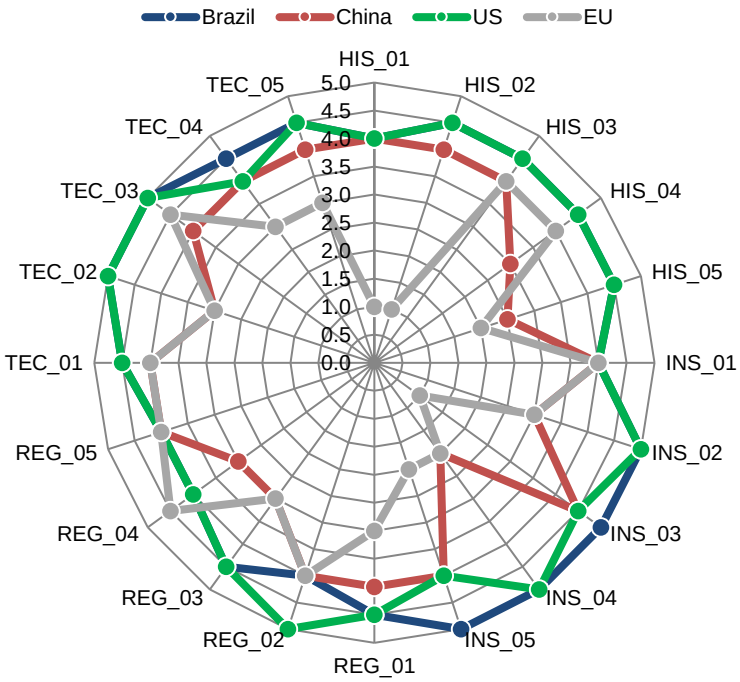
Fourthly, the European Union is going through, as is the United States, an historical time of change in the law that will potentially transform the lives of Europeans and determine how each Member State deals with research and biotechnology consumption.

Historically, the technology acceptance in the EU bloc has been widely contested for decades, with a larger number of Member States opposed to it than the ones in favor, either because

farmers do not see the benefits biotechnology, or because consumers feel insecure about its safety. In addition, both the institutional basis and the technical basis lost significant score in the general classification due to the impasse in the European Commission, which currently takes the role of decision-maker on the adoption of GMOs, being unable to determine how each Member State should act within its borders.

Figure 3 illustrates, in addition, the distributional score for each country, and the criteria (historical, institutional, regulatory and technical) that were mostly covered and the ones mostly neglected in each country investigated.

Figure 3 – Distributive score of the criteria analyzed for each country under investigation



Key to Figure 3

Historical:

HIS_01: acceptance of local consumers;
HIS_02: acceptance of local farmers;
HIS_03: acceptance of the scientific community (academic);
HIS_04: acceptance of the Legislative Power;
HIS_05: acceptance of the Executive Power;

Institutional:

INS_01: definition of the structure of institutions involved on the process of evaluation/inspection of GMO activities;
INS_02: definition of the composition of institutions involved on the process of evaluation/inspection of GMO activities;
INS_03: definition of the function of the institutions involved on the process of evaluation/inspection of GMO activities;
INS_04: number of accumulated approvals for cultivation in the country;

INS_05: average time for GMO approval in the country;

Regulatory:
REG_01: structure of the regulatory system related to biotechnology in the country;
REG_02: legislation related to crop protection and biotechnology in the country;
REG_03: legislation related to the publicity/communication of biotechnology in the country;
REG_04: legislation that stablishes the criteria of risks related to GMO activities;
REG_05: legislation that stablishes the risk management for cases of adverse risks (contention/mitigation/control);

Technical:
TEC_01: technical criteria related to processes of analysis of GMO activities;
TEC_02: qualification of the technical group responsible for GMO processes and activities;
TEC_03: evaluation of environmental risks and food safety;
TEC_04: understanding of processes of analysis and approval of new transgenic events;
TEC_05: deliberative system for the approval of GMOs (voting – based on the technical analysis or linked to the government).

As shown by the radar chart (Figure 3), and despite the lower weight given in the analysis (10%), the historical criteria were the lowest ranked, on average, in the diagnosis of the selected countries, followed by the institutional criteria; an expected result, as both categories are strongly correlated.

The present findings show that there is a chance for specific and critical paradigm breaks. It is interesting to observe how an historical approach can offer so much data, and yet so little information about the history of agricultural biotechnology in the world. Five years ago the scenario and grades awarded to each country were possibly considerably different, and the same is expected to happen in the next five years, or within a short period of time. It is deduced, therefore, that the ranking of the legal progress in each country, with its respective regulatory framework, should be constantly changing, given the sector's dynamism.

The historical and legal foundations for this analysis started with in situ studies and verification of each of the countries contemplated, which will be discussed in the following chapters.

Chapter 2

Context of biotechnology in selected countries

In 2015, biotechnology celebrated 20 years of commercialization in the world, with GM plants being grown on more than two billion hectares during this period. Transgenic seeds are present in approximately 30 countries, and it is estimated that the farming revenue originated from it has raised US$ 150 billion, a surprising result, considering that 90% of agents hold small productive units, and live in developing countries (James et al., 2015).

Currently, 179.7 million hectares of GM crops are planted worldwide (James et al., 2015), with the record volume achieved in 2014, totaling 181.5 million hectares. This fall from 2014 levels, though relatively small, results from a general decline in commodity prices, with storages filled in several countries, mainly consisting of soybean and corn. The main economies driving GM crop growth in the last four years were those belonging to the developing group, led by Latin American countries. Together, Africa, Asia and Latin America planted about 100 million hectares of the total in 2014, a trend that might be repeated in the next decade.

Qaim et al. (2014) recently concluded that the average adoption of GM technology has reduced pesticide use by 37% worldwide, increased yield by 22% and increased farming income by 68%.

In May 2016, the American National Academies of Sciences, Engineering and Medicine published the summary of over a thousand academic reports on GMOs. They presented more than 80 public hearings and workshops and analyzed 700 reviews of public authorship. They concluded that GMOs are safe for human consumption. According to these experts, there are no significant differences that point to GM foods posing a higher risk of harm when compared to conventional varieties. In addition, the study claims that conditions such as obesity, diabetes, kidney disease and others are not correlated to the use of GMOs, and do not, therefore, cause adverse implications for animal and human health. It was also concluded that environmental problems and genetically modified crops are not linked (IWC, 2016).

By being in the spotlight of public scrutiny since it was developed, agricultural biotechnology is thoroughly tested on all fronts, without, until now, concrete scientific evidence of lethal contamination or sequels unleashed by its use. A range of information and knowledge about the safety and benefits of biotechnology in the world is available. It increases yield, contributing to the maintenance of food security, promotes economic development for farmers without scale distinction, does not impact negatively on biodiversity, mitigates the challenges associated with climate change and increases stability in crop yields. In reality, however, what is observed is an extremely heterogeneous market where countries take very specific positions on the reception and development of the technology.

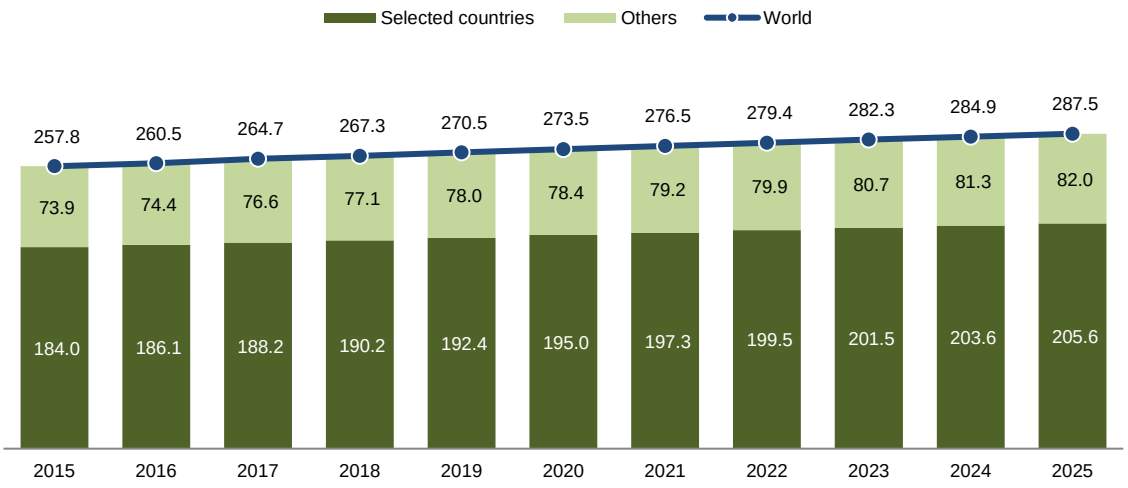
This is known as regulatory framework, the conduction of laws in different economies that have allowed access to biotechnology and other innovations in the field. In addition, it is sought to understand how the legal requirements on GMOs affect a country’s interaction in global trading

and what is the popular perception of it, resulting from the government's engagement efforts for science to reach all.

The model layout for analysis, under the same historical and quantitative perspective, brings four countries of fundamental importance to the agricultural global trading, divided between developed and emerging, and whether openly receptive or closed to biotechnology, which are Brazil, China, the United States and the European Union (assumed here to be a single national unit).

Regarding relevance, these four nations currently represent about 70% of all the animal protein produced in the world, considering broiler chicken, beef and pork. According to Céleres® projections (Figure 4), in ten years over 20 million tons of meat will be produced, and the four selected countries might sustain their competitiveness and current market shares.

Figure 4 – International projection of animal protein production (million tons).

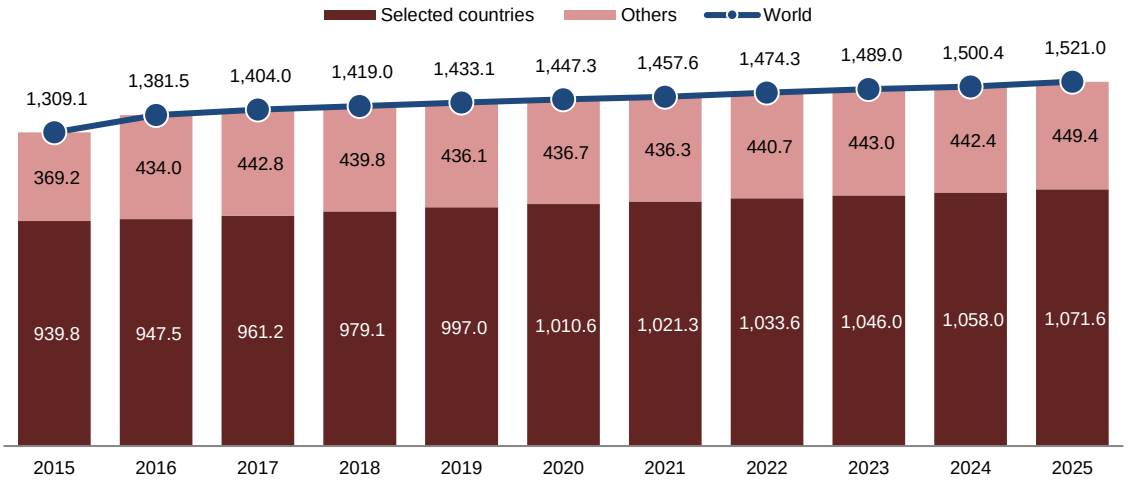


Source: Céleres®, 2016. Broiler, beef and pork production.

Pork takes the lead in production and global consumption, with broiler in second. China accounts for 52% of total world consumption of pork, followed by the European Union with 20%. The United States hold 20% of world beef consumption, positioned as leader, followed by Brazil with 16%. The US are also the major consumers of broilers (17%), followed by China with 12%.

On global grain production, the four nation’s behavior is similar to what is observed for animal protein (Figure 5).

Figure 5 – International projection of grain production (million tons).



Source: Céleres®, 2016. Cotton lint, corn and soybean production

72% of all grain produced in the world, including cotton, corn and soybean, comes from Brazil, China, the United States and the European Union. A slight retraction in share is expected in ten years (to 70%), which signals a possible breakthrough in the Indian cotton production. India is emerging as a strong player which, although not considered in this study, is going through an important moment of dissemination of GMOs among cotton farmers, allowing them to increase competitiveness and to support margins.

Also in grain trading, China stands out from other consumers, accounting for about 30% of all soybean and cotton consumed worldwide, and 22% of corn. The United States consume 31% of the total quota for corn and 20% of soybean, followed by Brazil, which is responsible for 15% of total soybean consumption (James et al., 2015).

Much of this prominent position from the selected countries in the global commodities ranking is due to the advent of biotechnology, which is solving problem-disease outbreaks, ensuring high and sustainable yields, and promoting cultivation in adverse climates and fragile soil. Therefore, it is necessary to understand the relationship of such economies with the technology investigated.

2.1 Brazil

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) (James et al., 2015), the total area of genetically modified seeds in Brazil is approximately 44.2 million hectares. The country remains a main driver of transgenic area expansion in the world, equivalent to 25% of the global agricultural growth, and about 40% of the area planted with GMOs.

The three categories of existing technologies include insect resistant (IR), herbicide tolerant (HT) and stacked (IR/HT), are expressed in the three major domestic crops: soybean, corn and cotton.

The economic benefits of the transgenic agricultural market in Brazil totaled US$ 24.8 billion, according to Céleres®, from the crop season 1996/97 to 2012/13. This successful trajectory on Brazilian soil confirms the country's potential in the development of biotech crops, important to meet the rapid growth of domestic demand and exports.

2.2 China

Despite the restrictions of GMOs on Chinese soil, the country currently cultivates about four million hectares of transgenic cotton and seven thousand hectares of transgenic papaya, limited to the Guangdong province. It is estimated that the number of Chinese farmers who benefit directly and indirectly from transgenic cotton amounts to 17 million (James et al., 2015).

The country spends considerable investment in research for the release of GMO varieties of rice and corn. In the Chinese conception, rice is the most important food for human life, and the most important for animal feed is corn.

The Chinese government has recently directed significant investment to research laboratories and national businesses, in order to develop transgenic seeds internally. Studies have shown that corn, when produced domestically and in a sustainable and competitive manner, contributes to the weakening of the Chinese dependence on cereal imports, which are 90% GM crops.

It is estimated that economic gains on the farm stage for cotton production added US$ 17.5 billion between 1997 and 2014, led by increased yield (+10% year on year) and reduction in pesticide applications (-60% for the period) (James et al., 2015).

2.3 United States

The United States are the largest producer of GM crops in the world, with a global share of about 40%. To date, the country approved about 190 transgenic applications for 20 different crops, the most popular being corn, cotton and soybean.

The country leads development in stack events, with 83% of its corn area and 84% of its cotton area sown to this technology. It has prioritized, in an attempt to solve a recurring problem in American farming, the development of crops tolerant to drought, which has caused severe losses to the agricultural sphere and domestic livestock.

According to ISAAA (James et al., 2015), studies such as Brookes and Barfoot (2016) argue that the economic benefits of biotechnology to US farmers totaled US$ 66.1 billion in the first 19 years of commercialization, which is 44% of the global amount, placing the country first in income from agricultural biotechnology to the local farmer.

2.4 European Union

Currently, five Member States plant transgenic corn in the European Union, totaling 117 thousand hectares. These are, in descending order, Spain, Portugal, Czech Republic, Slovakia and Romania. From this total, Spain plants 108 thousand hectares, with the remainder divided among others (James et al., 2015).

The EU bloc already uses almost its entire arable land, with little possibility of further rural expansion. From the existing crops, the transgenic component oscillates in size from year to year, thanks to a strong disincentive to cultivate GM crops. This arises either through bureaucratization or even adverse popular opinion, which is in majority. It is estimated that the economic benefits to European farmers between 2006 and 2014 totaled US$ 254 million, of which approximately US$ 30 million are exclusively related to the 2014 harvest.

Much of the market that mobilizes the income of agricultural biotechnology in Europe focuses, however, on import shipments, since the bloc consumes a considerable amount of feed beyond their production capacity, to sustain the strong local animal protein industry.

Chapter 3

Institutional and legal basis for the approval of transgenic introductions

As explained in the previous chapter, the analysis model investigated four countries relevant to the global trading of agribusiness, included two variables: the level of economic development and the legal attitude, both socioeconomic and political, to agricultural biotechnology. Table 2 shows the summary quadrant for the four selected countries according to the suggested variables.

Table 2 – Quadrant summary of the position of selected countries.

	Pro-biotechnology	**Against biotechnology**
Developed	United States	European Union*
Emerging	Brazil	China

***Referring to the European Union as a nation unit.**

3.1.1 Institutional framework and legal basis for the approval of GM events in Brazil

The Brazilian law regulating the adoption of GMOs is based on the precautionary principle; it requires scientific certainty of the absence of risk, respecting resources available for trial. This model mirrors the American deregulated process, which also endorses the safety of a genetically modified product when it is unable to prove, with all available resources, that it is harmful to the ecosystem.

In Brazil, GMOs were first legislated in 1995, under Law No. 8.974/1995, subsequently replaced by the establishment of the Biosafety Act in 2005, currently in force. This, under Decree No. 5,591/2005, introduces preliminary and general provisions governing The National Biosafety Technical Commission (CTNBio), its powers, composition, management structure, meetings and deliberations, processing procedures, technical decision, public hearings, general risk rating of GMOs, the issue of quality certificates in biosafety, the establishment of the National Biosafety Council, registration and inspection agencies and entities, creation of the Information Biosafety System and, finally, the Internal Biosafety Commissions (Céleres®, 2016).

In terms of labeling, it was established that food for human or animal consumption containing genetically modified material should, by regulation, display such information on package labels. For the commercial approval of new events, the risk assessment of any product presented by GMOs is conducted by CTNBio, which subsequently may give its assent for commercialization.

A preliminary theme investigation is made, in which CTNBio extends the administration to the Subcommittees Permanent Sector (SSP) for environmental, animal, human and plant health.

Such SSP promote monthly meetings to discuss the processes in their relevant areas, before forwarding requests to the plenary session. At this stage – and throughout the approval process – the following criteria are required:

i) **Precautionary principle**: the principle of origin from the Cartagena Protocol, is defined as: "*the absence of scientific certainty due to insufficient information and relevant scientific knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the import part, taking also into account risks to human health, shall not prevent that part, in order to avoid or minimize such potential adverse effects, making a decision, as appropriate, on the import of living modified organism*" (MMA, 2016).

ii) **Substantial equivalence**: compare new foods, including GM and conventional analog with a history of safe use. The morphological and agronomic characteristics and chemical composition are observed, allowing the identification of the differences between genetically modified crops from the conventional ones, which are usually due to the parenting of the genetically modified organism.

iii) **Case by case assessment**: the process of environmental risk assessment analysis of previously established GMOs is, at the same time, flexible enough to consider the specifics of each case, noting that different transgenes in each organism may present different risks (Céleres®, 2016).

Thus, the procedural steps under CTNBio responsibility for marketing approval of a new event consist of:

1) **Quality Certificate of Biosafety (CQB)**: applies to inaugural research in laboratory, containment regime or field safety. As part of the production process for commercial approval of GMOs, or the assessment of biosafety of GMOs, the entity or public institution or private must first establish an Internal Biosafety Commission (CIBio), indicating the main technicians responsible for the specific project. Later, it must require the CQB from CTNBio.

2) **Containment system**: the activities and projects with GMO are initiated in conditions that do not allow their escape or release into the environment, called the containment process. CTNBio actions at this stage are to establish criteria for GMO risk classification, to establish the biosecurity measures that must be applied, according to the risk class and to define the GMO as an organism of low risk to the community;

3) **Planned Release into the Environment (LPMA)**: the CQB owner institution can perform field experiments with genetically modified plants, releasing them into the environment under monitoring. After the planned release period ends, the CIBio of the applicant shall submit to CTNBio a detailed report within six months, covering the surveillance measures and experiments post-end results.

4) **Commercial release**: the institution or entity applying for commercial release of the GMO in question, and its derivatives, should follow rules set forth in the Rules of the CTNBio

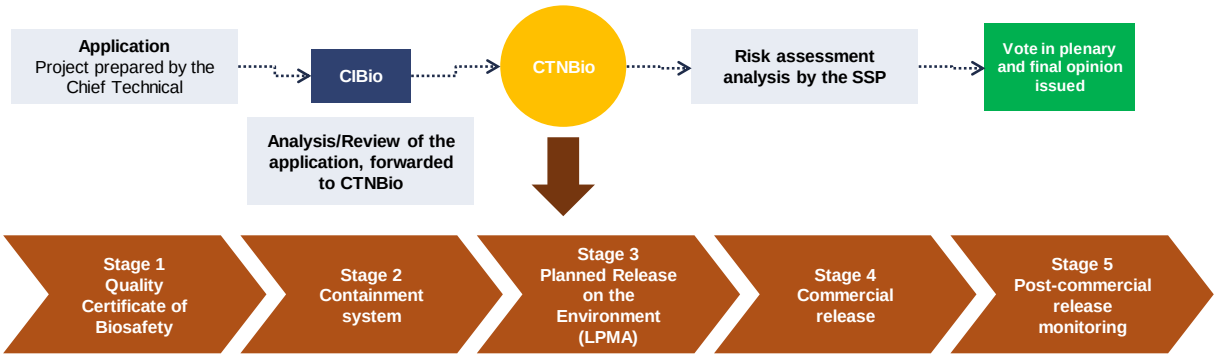
Resolution, and include the written permission of CTNBio, in accordance with all the conditions imposed in the authorization for the product's commercial release.

5) **Post-commercial release monitoring**: has the objective to monitor and obtain information on approved GMOs that may indicate adverse effects on the environment or human and animal health, in accordance with the intended application (Céleres®, 2016).

In planning such steps, the statement is addressed for risk assessments by the SSP, later entering the vote in plenary session for the final opinion.

The process is shown in Figure 6.

Figure 6 – GMO approval process in Brazil



Source: Céleres®.

3.1.2 Idiosyncrasies of the Brazilian approval process

Being a relatively new regulatory framework, the Brazilian set of laws adopted in the last ten years include more than 80 GMOs, from transgenic plants to a transgenic mosquito, Aedes aegypti, used to combat the dengue disease, which is seriously affecting the country. The Brazilian Biosafety Law is internationally recognized for its technical accuracy, institutional predictability and good relationship with applicant agents.

This success is mainly attributed to the decision to focus the entire risk assessment process in one agency: CTNBio. All steps are supervised by the SSP, under the approval of CTNBio, which contributes to the fluidity and agility in the investigation.

Also considered as beneficial points are:

i) The law's functionality and clarity, or the basis of well-defined criteria, strictly followed.
ii) A majority of technical decision-making, with little or no political influence.
iii) Good popular reception of genetically modified products, or high acceptance of the technology, especially by farmers.
iv) Significant weighting of agriculture on the national GDP.

In particular, it is part of the charter of the regulator to exercise its responsibility with great effectiveness, since the health of public finances depends largely on the export of agricultural commodities.

According to the Ministry of Agriculture, Livestock and Supply (MAPA) data (MAPA, 2016), in the first half of 2016 the agricultural sector accounted for approximately half of total Brazilian exports, a performance similar to the previous two years. In addition, in the past two decades, the sector was one of the only areas to close financial years with a surplus result, something around R$ 80 billion, while several others presented systemic deficit balances.

Brazil is a powerful net exporter of agricultural commodities. The domestic products account for approximately 10% of its total exports. Still, there is criticism of the way Brazilian government deals with the issue, with several protectionist measures that end up discouraging the industry. Private initiatives call for a more Ricardian interpretation, which would allow market players to have the backing of the law to optimize the use of resources and domestic strategic advantages.

However, for biotechnology, it is believed that the regulatory function has reached a satisfactory stage, with few adjustments to standards. 2015 was a key year, which saw a silent revolution for the sector. About 20 new GM crops were approved, mainly soybean, corn and cotton tolerant to herbicides, an absolute record for CTNBio.

One can observe an increased synchronization between the content delivered in the applicant's files and the data required by CTNBio, in addition to the public reception of new products. In terms of the comparative system parameters, the country has achieved the highest grades in the institutional, regulatory and technical themes (Figure 3), considering mainly the composition and competence of the evaluating body, approval process and time, consistency between agencies and the executive power and unlikely power interference from other non-technical spheres, on the decision to approve each case.

Brazil, which at first mirrored the US law to regulate the use of GMOs internally, now offers the same level of access to biotechnology given to major players like the United States, Canada, Argentina and others with laws just as sophisticated.

3.2.1 Institutional framework and legal basis for the approval of GM events in China

Despite the historical barriers to the use of GMOs in China, the country is influential in research in agricultural biotechnology. It is estimated that public investment has doubled every three or four years in the last decade (Huang et al., 2010).

In the same period, the country analyzed and selected about 50 functional genes with appropriate rights of independent intellectual property and important genetic value for future releases of transgenic products (James et al., 2015). Observing the need to regulate this emerging sub-sector of agriculture, the Chinese Ministry of Agriculture initiated the coordination and decision-making on the release of GMOs in the domestic market.

The country's regulatory framework, developed and implemented in the 1990s, consists of:

1) The State Science and Technology Commission issued, in December 1993, the Security Control Measures of Genetic Engineering.

2) The Ministry of Agriculture promulgated, in November 1996, the Security Control Implemented Measures of Agricultural, Biological and Genetic Engineering.

3) The Administrative State of China, through its Tobacco Monopoly issued, in March 1998, the Administrative Measures for Research and Application of Genetic Engineering of Tobacco.

In a more focused action, and congruent to the present framework, the Chinese State Council promulgated, in May 2001, the Administrative Regulations on the Safety of Agricultural GMOs (usually referred to as "Regulation"), incorporating, once and for all, the safety management of GMO agriculture in the national regulatory framework. The document underwent minor changes in 2011, but no significant changes were made to the conceptual basis.

Starting from coordinates of the Regulation, the Ministry of Agriculture issued three administrative notes in 2002 as procedures:

i) Administrative measures for assessing the safety of agricultural GMOs.
ii) Administrative measures for assessing the safety of imported agricultural GMOs.
iii) Administrative measures for the labeling of agricultural GMOs.

In parallel, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) issued, in September 2001, administrative measures for the inspection and quarantine of GMO products that are pending in China. However, this law only came into force in May 2004.

In October 2010, the Ministry of Agriculture issued two technical guidance bulletins on safety assessment, being the Guidance for Plant Safety Assessment of Genetically Modified and the Orientation for Microorganisms Safety Assessment of Genetically Modified Animals, clarifying, therefore, procedures to request specific GMO safety assessment.

In 2012, the Ministry of Agriculture developed the Guide for Field Testing Safety Inspection of GM crops, strengthening the safety supervision in GMO field tests. To date, it is estimated that the Ministry has stipulated about 140 standards on understanding and use of agricultural biotechnology in China. According to the Regulation, is the Ministry of Agriculture's responsibility to ensure the supervision and management of national agricultural safety of GMOs in the country. It is also a rule to specify the determination of a political group responsible for holding inter-ministerial joint meetings to facilitate and coordinate the responsibilities between numerous government departments.

Starting from the China People's Republic as the central power, the following agencies are an extension of work in the regulation of transgenic products in Chinese territories:

1) **Inter-ministerial joint meeting group**: the safety management of agricultural GMOs joint meeting is composed of 12 departments, including the Ministry of Science and Technology, the Chinese Food and Medicine Administration, the Health and Family Planning National Committee, the Ministry of Commerce and others. The group is responsible for studying and coordinating the key issues related to the safety management of agricultural GMOs;

2) **Ministry of Agriculture**: the ministry is the authority which is responsible for the safety certification of agricultural GMOs and also the leader of the inter-ministerial group. It established the Agricultural GMO Safety Management Office to assess the safety, supervision and management, system establishment, examination and approval and import management labeling of agricultural GMO products.

3) **National Biosafety Committee**: based on information from members of the inter-ministerial group, the Ministry of Agriculture defines the National Biosafety Committee, responsible for the systematic safety assessment and scientific scope of GMOs. The Commission has a mandate of three years and must be multidisciplinary (agricultural experts, environmental scientists, etc.).

4) **Agricultural Safety Management Standardization of Genetically Modified Organisms National Technical Committee (referred to as Standardization Committee)**: a specialized technical organization under the Ministry of Agriculture in charge of research, development and review of technical standards and safety regulations. By 2014, more than 130 standards had been issued on standardization in the adoption of GMOs in China.

5) **Test institutions**: about 40 organs for GMO testing and verification of food and environmental safety in China that have acquired national mediation certification issued by the Ministry of Agriculture. These institutions provide technical support for the safety assessment of the Security Committee and examination and supervision of administrative services (Huang et al., 2010).

According to the Regulation and other peripheral rules, any research, experimentation, production, processing, distribution, import and export of agricultural GMOs in Chinese territory shall be subjected to security scrutiny of the Ministry of Agriculture, in order to mitigate any risks to living beings and the environment.

The National Biosafety Committee is in charge of the safety assessment of GMOs, and establishes a procedural judgment with this goal. Such multistage approach consists of five evaluation phases:

i) Laboratory research
ii) Small scale tests
iii) Release into the environment
iv) Pre-production testing
v) Security Certificate issued.

For admission criteria, the Ministry of Agriculture divides agricultural GMOs into three categories, namely:

1) Agricultural GMOs for research and testing;
2) Agricultural GMOs for commercialization;
3) Agricultural GMOs as raw material to be processed.

Agricultural GMOs imported for research purposes require entry application submission and must fit the requirements established throughout the testing process until approval. GMOs to be imported and processed must obtain two certificates:

1) The Agricultural Safety Certificate of GMOs for use as raw material and
2) The Agricultural Import Safety Certificate, valid for a single application and issued by the Ministry of Agriculture.

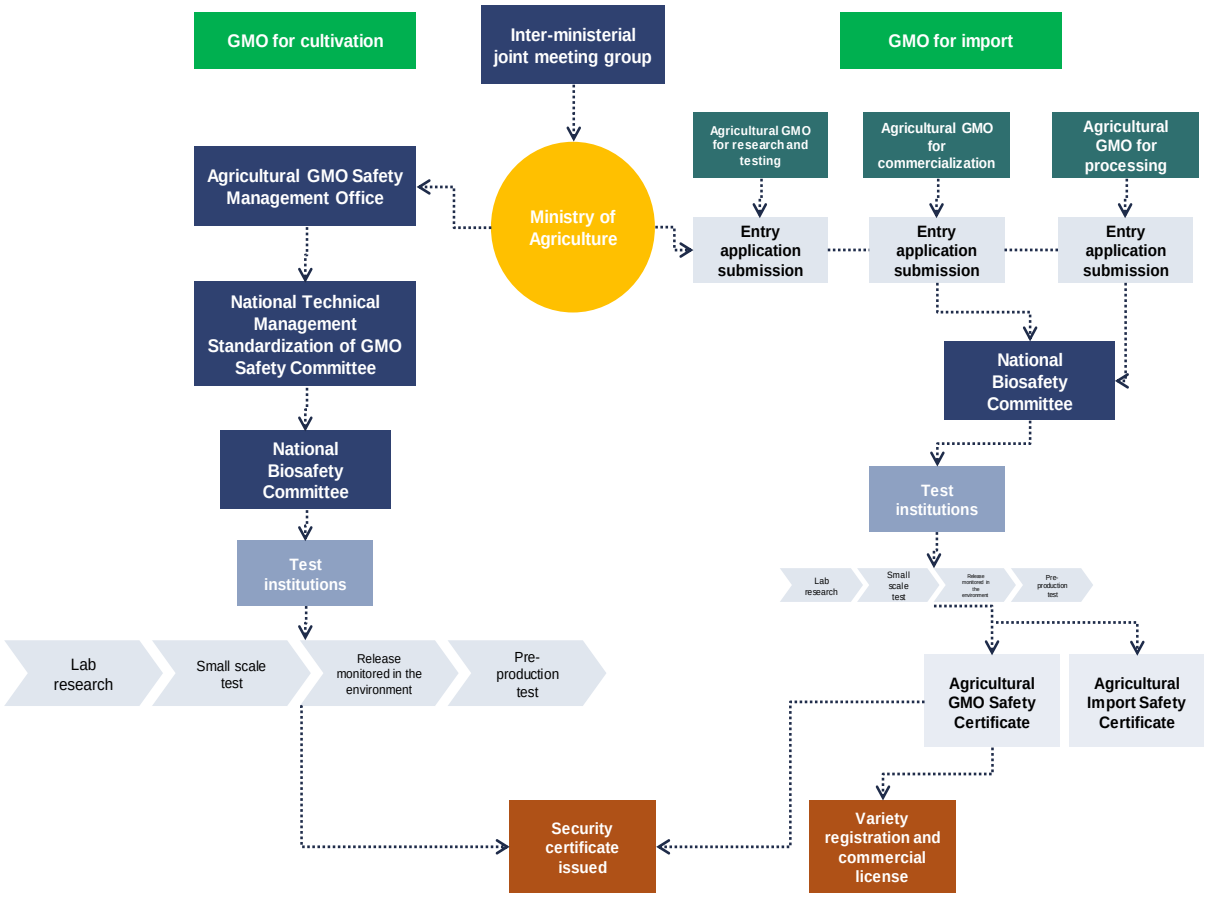
Items that will be directed to commercialization must be submitted to an application to enter the country, then subjected to small-scale testing, environmental release and pre-production tests. The third stage consists of verification and monitoring of outsourced testing institutions.

The National Biosafety Committee performs the final safety assessment and, if approved, the product receives the Agricultural Safety Certificate of GMOs for production use. If it is intended to be commercialized, a plant registration and commercial license are also needed, according to requirements of the Seeds Act.

China adopts mandatory labeling for genetically modified products, a procedure called Agricultural GMO Labeling Management Methods. To date, only transgenic papaya and cotton have been approved for domestic cultivation and labeled as such, while other crops, although abundant in Chinese agriculture, can only be imported as raw material for processing, such as soybean and corn.

The adoption of transgenic products scheme in the country is, therefore, illustrated in Figure 7 below.

Figure 7 – Approval process of GMOs in China



3.2.2 Idiosyncrasies of the Chinese approval process

The first genetically modified plant was developed in the early 1980s, in the form of an antibiotic resistance gene introduced in tobacco plants. The first permits for experimental planting took place in China, which released the product commercially, later banned by the government.

China has one of the most traditional research lines in agricultural biotechnology in the world, and the absence of a large number of domestic transgenic varieties available is explained by a mix of public insecurity, the global trading nature of interested parties and protectionism, among other factors.

The 1980s were marked by a sharp drop in national cotton production due to pest attacks, the most common being the army worm (*Helicoverpa armigera).* A decline of approximately 30% in yield was observed and the situation continued with worsening outbreaks between 1992 and 1993. In this period, it is estimated that crop yield losses totaled US$ 630 million, which resulted in a 15% area retraction across the country.

The first transgenic cotton with insertion of the Bt gene against *Bacillus thuringiensis* was introduced in 1997; until then, farmers tried to combat pests with conventional pesticides. The problem was temporarily mitigated and yields recovered, bringing margins higher than before the outbreak.

Since then, the frequency of food security discussions in China gained momentum, with government becoming aware that possible future crises, as faced in cotton, might endanger food supply to a booming population. This action culminated in the launch, from the Chinese State Council in 2008, of a national project worth US$ 3.5 billion aimed to support genetic breeding of the most popular crops to China.

It was concluded that the first commercial insertion of transgenic material in China happened out of necessity, an immediate demand that solved the cotton supply crisis, and the benefits have been recognized and supported by the population. Han et al. (2015) investigated, for about ten years, consumer habits and receptiveness of the Chinese population to transgenic products, with the following conclusions:

i) The opposition to GM food and to the production of transgenic meat is markedly higher than that of non-edible transgenic products, and meat derived from GMOs is the most rejected.
ii) Interestingly, acceptance of genetically modified rice is distinguished from other foods, with a positive perspective close to the acceptance of non-GM food crops.
iii) The Chinese population has great confidence in internally developed science (approximately 90% of positive responses), and in policy makers and government managers (about 70%), relying considerably less (about 50%) on the private sector, and the biotechnology industry;
iv) Most Chinese farmers who have grown Bt cotton (approximately 90%) had a positive attitude to the cultivation of genetically modified crops;
v) 56% of the Chinese scientific community supports the development of GM food, but also a large portion (40%) abstained from giving an opinion.
vi) Consumers' willingness to buy GM food is directly proportional to their socioeconomic status. Buyers in more developed regions are more receptive than the ones in less developed regions. The coefficient "income" is the most significantly correlated in all cases analyzed;
vii) Most Chinese consumers interviewed had some basic knowledge of genetically modified foods, but their general cognitive level is not high;

Therefore, it is speculated from the analysis of the GMO approval process in China, and the research conducted by Han et al. in 2015, that the law development has, until now, assumed a more reactive than pro-active posture. In addition, contrary to what common sense says, the absence of new transgenic product launches is not the result of exclusively popular resistance to it, but mostly to the low investment in the technology.

China wants genetically modified foods developed and manufactured domestically, giving great credibility to the internal scientific society, while showing significant distrust of private enterprises, mainly foreign, seeking to enter the domestic market with products developed abroad.

Moreover, as stated earlier, Bt cotton has emerged in China in view of the urgent need to address the serious infestation of pests in crops across the country. With a strong network of trade agreements between China and foreign markets, well supervised grain stocks and satisfactory

provision of domestic production, many consumers do not see why the current conventional production should be replaced by GMOs.

Yet in this matter, the Chinese government, which supports a strong manufacturing industry, and exports various technologies, has great interest in maintaining imports of agricultural commodities in exchange for tax exemption and distribution rights in overseas exporting countries. Currently, the country has free trade agreements with the Association of Southeast Asian Nations (ASEAN), Pakistan, Chile, New Zealand, Singapore, Peru, Costa Rica, Iceland, Korea and Australia, and is in negotiation with several others. For these reasons, an unusual situation has developed, which combines a well-structured and functional regulatory system, a scientific community with distinct knowledge of biotechnology, a high-income population, relatively receptive to products of this nature, yet with few cases of approval of GMOs for cultivation in China.

In addition, two important factors must be taken into account when improving the Chinese regulatory framework:

1) Information dissemination: this is a 1.4 billion-people country, which makes changes in communication and understanding of the law by the whole population costly and slow. This contributed to China's unsatisfactory performance on the regulatory theme, as its legislation does not guarantee an effective disclosure of information about GMOs, with access limited to a particular social/economic group of citizens.

2) Technical exclusivity in the decision-making process: many stages on the Chinese trial are still influenced by political decisions, which may have other, non-scientific motivations when analyzing GMOs.

As a reflection, the grades awarded in the institutional and technical themes were considerably below the average, especially with such good results regarding Brazil and the United States (Figure 3). China's bottlenecks on biotechnology add up to a mix of technical expertise with a limited freedom of operation, difficult international interaction in benchmarking the technology, confused political positioning and, therefore, very few approvals and the dispersal of outdated GM products to Chinese farmers.

3.3.1 Institutional framework and legal basis for the approval of GM events in the United States

The regulatory process for biotechnology use in the US was, from the beginning, formally open and transparent, being democratic, one can say, and subjected to the questioning of several organizations that were participants in the construction of the laws. Decisions by regulatory agencies were public and open to any required revisions.

The regulatory framework on the use of GMOs was established in the mid-1980s, through the Coordination Framework for Regulation of Biotechnology. This Regulation guides and coordinates the US regulatory agencies in the legal use of their authority to review the safety of products developed with genetic engineering, in the same way conventional breeding products are analyzed. It was decreed, therefore, that a new regulation for the evaluation of GMOs was

unnecessary, since the existing laws provided sufficient legal authority to understand biotechnology. As the main defense, it was argued that the product arising from the genetic modification was the main basis for decision-making, and not the process by which it was obtained.

The national system for this type of evaluation is composed of a central triad of regulatory agencies, investigating different aspects of product propositions to be launched, and the different biosystems which may be affected. These are:

1) **US Environmental Protection Agency (EPA)**: responsible for ensuring that pesticides do not present excessive risks to human health or the environment. The EPA scrutinizes pesticides expressed in transgenic crops. Developers of plants resistant to pests cannot carry out field tests in over ten acres without prior authorization from EPA, and must not commercially promote a product until the agency declares proven that the particular material does not present any excessive adverse effect on the environment.

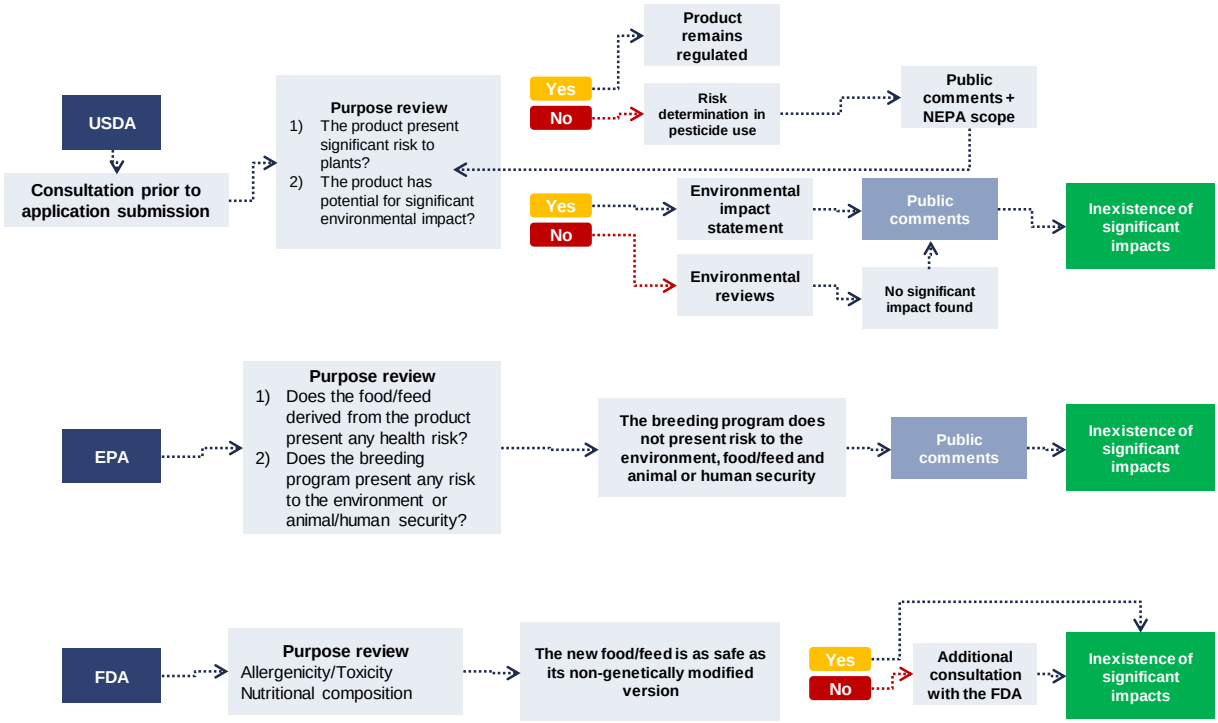
2) **US Department of Agriculture (USDA)**: responsible for examining the characteristics of plants and pests and with potentially adverse environmental effects. Regulation of GMOs from the department is done by the Animal and Plant Health Inspection Service (APHIS), whose mission is, also, to protect and promote agricultural health of the United States, and to administer the Animal Welfare Act. In short, the agency deals with issues surrounding food, agriculture, natural resources and other related areas;

3) **Food and Drug Administration (FDA)**: responsible for food safety analysis. The body bases its decisions on the Federal Food, Drug, and Cosmetic Act, having the authority to release, seize and/or recall products from the market, considering the recognition of food security. The institution observes that practices used by plant breeders in the selection and development of new varieties have historically been proven to be reliable in ensuring food security. There is not, therefore, a routine security check for absolutely all food launched in the US market. Many have a long history based on the development of food security in similar products, which may be considered in the specific case (FDA, 1996).

The way a product is regulated depends on its potential for impact and how it is used (food, medicine, pesticide, etc.). Depending on the genetically modified characteristic, one or more agencies are involved in the analysis. This is always done simultaneously by the relevant agencies. If the three are required to evaluate a product, the three will synchronously issue an opinion, without one's power surpassing the others.

The approval process of a GMO on US soil follows, therefore, the expressed order in Figure 8 below.

Figure 8 – GMO approval process in the United States



Source: Monsanto Company.

3.3.2 Idiosyncrasies of the American approval process

The first genetically modified crop approved for human consumption in the world was the Flavr Savr tomato, produced by the Californian Calgene, in 1994. The product was certified by the FDA in 1992, that claimed it to be a tomato as safe as that produced by conventional means. The United States were breaking, at that moment, an historical barrier between science and its practical application in relation to genetic engineering. The production of the Flavr Svr tomato ceased in 1997, but the American pioneering spirit never waned.

More than 20 years later, the country has about 100 approved traits (though not all sold), of main national agricultural crops, with more than 90% of the area containing transgenic material, and a receptive and loyal international market for their products.

It is reasonable to conclude that years of living with agricultural biotechnology justifies public acceptance of GM products, or that the regulatory system operates as effectively as possible. A brief review is enough to understand the structural problems present in the legislation and serious consequences to the technology advancement in America.

It is estimated that the process, from design to approval of a genetically modified variety (not necessarily transgenic), in the United States takes from 10 to 14 years to be completed, and requires no less than US$ 100 million (potentially reaching US$ 140 million) of invested capital. Factors such as isolation of the gene and efficacy, ensuring that its inclusion does not change any other essential characteristic of the plant, followed by years of cultivation and years of literature review, consume much of this decade for approval of the product.

In addition, once all tests have been performed, the process itself extends over two or three years until the regulatory agencies finally reach a final conclusion.

The precautionary principle is the starting point to address all relevant issues to the commercial release of GMOs, and the scientific basis for decision-making is solely defended as the only one acceptable. Most of the process is evaluated by the agencies, which means that a significant part of the safety testing of products is carried out by them, consisting of procedures previously evaluated in other releases of GMOs.

This critical analysis is expected to prove that all the technology possible to measure risks was used, and were unable to find potential threats to animal health, human and plants. So, the idea that to submit the GM material to the same evaluation given to a conventional product facilitates its adoption does not hold in practice. In fact, the evaluation of GMOs requires a long and repetitive process.

Another factor that contributes to the slowness of the approval procedure is the frequent legal battle between companies that develop GMOs. Other competing non-governmental organizations and/or organic or conventional production companies can also prevent the commercial release of some transgenic crops for different reasons. As an example, Roundup-Ready alfalfa (RRA), developed by Monsanto and approved by the USDA/APHIS in 2005, only got clearance for commercialization in 2010. This followed a legal dispute brought to the Supreme Court of the United States requested by the companies Geertson Seed Farms and Trask Family Seeds. It was alleged that the sale of large-scale new transgenic variety of alfalfa by Monsanto would lead to cross-pollination with conventional varieties, and consequently to their disappearance (US Supreme Court, 2010).

This situation reinforces the perpetuation of an approval system that requires heavy investments in research, considerably narrowing the number of companies capable of developing and introducing genetically modified varieties into the North American market. Dr. Barbara Glenn, CEO of the National Association of State Departments of Agriculture (NASDA), summarized this phenomenon in one sentence: "*We built the monster ourselves*", which denounces the GMOs evaluation system itself as a major cause of injury to the sector's competitiveness.

When the private sector invests in the development of a new variety, the most significant financial burden is focused on data production, or test stages. The dossier presented to regulatory authorities proving the safety of the new product is voluntary, but done in every case in an attempt to minimize the possible obstacles during the evaluation procedure.

Investment levels of US$ 100 million to US$ 140 million for a new GM variety to be approved means market selectivity. The approval process makes the technology exclusive to:

i) **Certain crops**, since investments are only justified for crops with a large coverage area (soybean, corn, cotton, etc.). Crops planted in small areas, or specific to certain regions (fruits, vegetables, flowers, etc.) are a higher risk, so are unlikely to attract heavy investment.

ii) **Certain companies,** due to the huge investment, and the solid and extended scientific basis required to develop each product.

Public certification is expensive. The faster a product is released on the market, the cheaper it is to develop, and certainly there are ways to make it happen without impairing the security guarantee.

Based on interviews, it was concluded that the USDA estimates that the understanding and acceptance of GMOs in the scientific community is approximately 80%, while in the social sphere it is no more than 60%. Working to reduce this information gap will potentially result in a decrease in the number of lawsuits filed every year against companies that launch GMOs and which delay product approvals.

Overall, the US have lost the first position to Brazil in the ranking of the comparative model mainly due to penalties in the institutional theme, with long periods required for the approval of a GM event, and in the technical theme, in the confused general understanding of the analytical process of approving new transgenic products in America (Figure 3).

Many interviewed authorities predict, however, an optimistic short-term change to this scenario. In July 2015, the White House Administration declared that it would update the way the government regulates genetically modified crops and other biotech products. They claim that the present assessment system, nearly 30 years old, has become obsolete and confusing, besides not fostering public confidence (Pollack, 2015). It is believed that although significant changes in the law are not observed at the moment, there is a movement toward it. USDA scientists interviewed in this study already speculate on significant changes within three years, considered to be a short term in legal parameters.

It is clear to the US government that the country's attitude towards biotechnology can generate only two possible outcomes:

1) Regulatory agencies simplify the approval process of GMOs and biotechnology research gains new momentum, or
2) Agencies, in the interests of absolute security, legitimize the complexity of the approval process, and biotechnology will continue to progress, but in the background, making room for companies to focus energy and resources on technologies with greater potential returns.

3.4.1 Institutional framework and legal basis for the approval of GM events in the European Union

Being a bloc of countries, not a single state with homogeneous legislature, the European Union characterizes the approval of genetically modified traits in its territory on two fronts:

1) Release of GMOs into the environment under the Directive 2001/18/EC;

2) GMO positioning in the food and feed market under the Regulation number 1829/2003. This provides the general framework for the regulation of GMOs in food and feed in the European Union.

The Directive's main objective is to protect human and environmental health in relation to the release of GMOs into the ecosystem. The indirective governs experimental releases of GMOs, for example, in the field-testing phase of a new product, and in the market positioning of GMOs, especially in commercial cultivation of transgenic seeds, import and processing of GM crops on European soil. On the other hand, the Regulation also defines the principles and regulates the market positioning of food and feed with genetically modified content, but, mostly, it aims to ensure clear labeling of those products, given consumers concerns, allowing them to consciously choose the product from its source.

The main difference between the Directive and the Regulation is in their geographic scope. The first, for experimental purposes, is relevant to a specific country that starts an impact evaluation around the application of a certain trait, while the Regulation, authorizing the commercial placement of a transgenic product, is at a Community level, or involves all Member States of the European Union.

Having the two main documents governing the environment legislation of GMOs in the EU, the approval process itself goes through various procedural stages.

The application, called notification, is first presented to the competent national authority of the Member State which originated it, who subsequently issues a final written authorization allowing the product access to the Community market.

The notification includes the following (included in the Directive):

i) Detailed information about GMOs.
ii) Environmental risk assessment.
iii) Proposed consent period not exceeding ten years.
iv) Post-market monitoring plan.
v) Proposed labeling, including the words "*This product contains genetically modified organisms"*.
vi) Notification summary.

Being notified, the relevant national authority issues an opinion, which takes the form of an "evaluation report". In case of favorable opinion on the market placing of GMOs, the Member

State, after receiving the notification, directs the report to other Member States through the European Commission.

This, in turn, prompts the issue of an opinion by the European Food Safety Authority (EFSA), composed of independent and highly qualified scientists. EFSA is responsible for assessing the environmental risks of the particular product, under guidelines of a GMO panel, such as:

i) Identification of any characteristics of the GMO that may cause adverse effects.
ii) Evaluation of the potential consequences of each adverse effect.
iii) Evaluation of the probability of each potential adverse effect.
iv) Risk estimate presented by known characteristics of the GMO.
v) Implementation of risk management strategies resulting from the deliberate use or placing of the GMO on the market.
vi) Determination of the overall risk of the GMO.

In the case of a positive determination to the use of GMOs by EFSA, the European Commission presents a draft decision to the Regulatory Committee, composed of Member State representatives, which will issue a new opinion. From this, three options for taking action are:

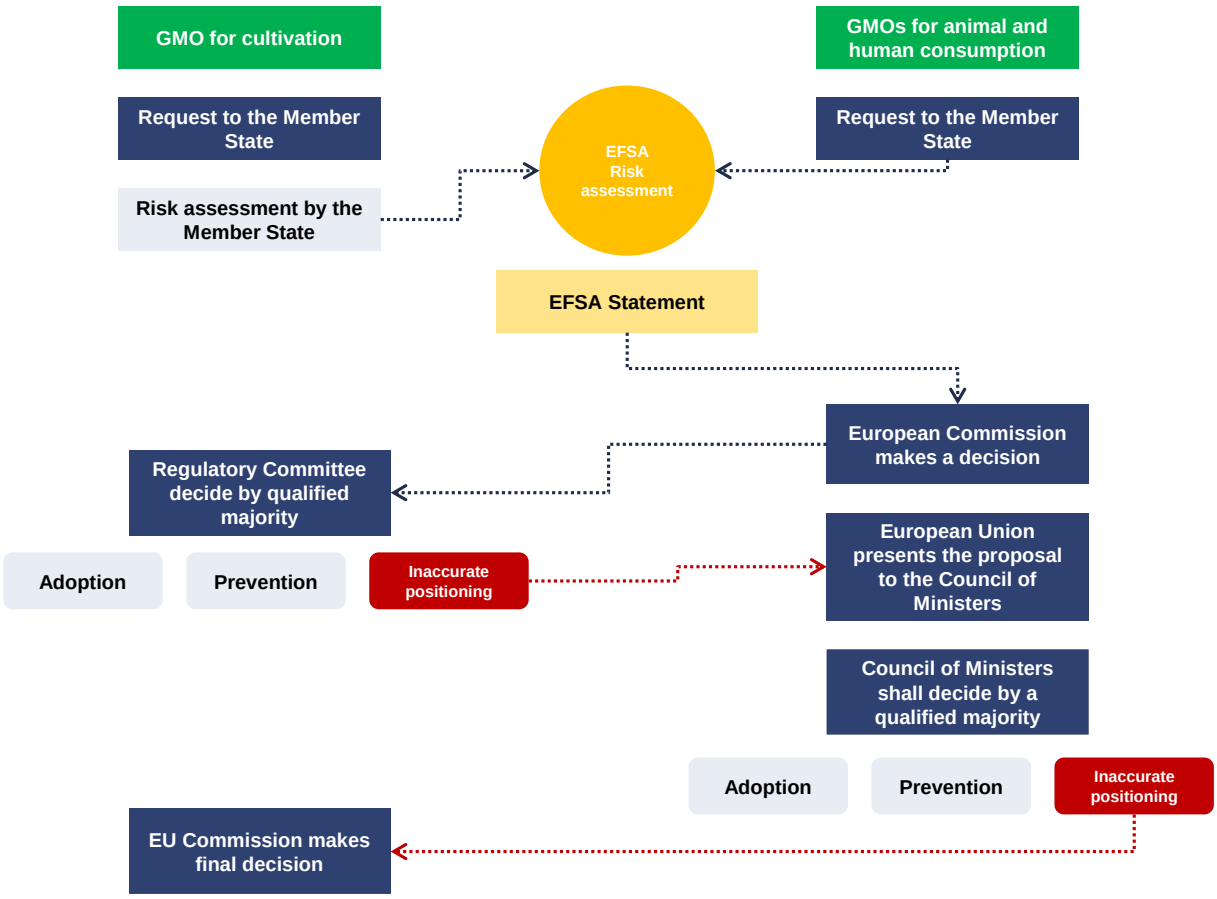
1) Committee is favorable to the proposal by qualified majority, the Commission adopts the decision.
2) Committee does not obtain a qualified majority, and the decision is presented to the Council of Ministers for adoption or rejection by a qualified majority.
3) Decision transferred to the Council is not manifested within three months and falls back to the European Commission.

Final authorization is valid throughout the Community, but thanks to a safeguard clause, a Member State may provisionally prohibit, on its territory, the placing of an approved GMO. Such a ban should be based on new security information, and require new decision-making by the European Union (consultation is repeated with EFSA and vote of Member States).

During the authorization process, the general public is informed and has access to the data provided by the notifier, such as the assessment reports of the competent national authorities and subsequent opinions.

The approval process can be summarized with the following diagram in Figure 9 below.

Figure 9 – GMO approval process in the European Union



Source: National Academies of Sciences, Engineering, and Medicine.

3.4.2 Idiosyncrasies of the European approval process

Of the four countries analyzed in this study, the European Union, together with Brazil, holds one of the most simplified GMO approval systems. This can be summarized in two stages: the preparation by the applicant of the safety dossier, and the presentation to EFSA. The second phase begins with the presentation of the draft decision to the Regulatory Committee, and possibly the Council of Ministers. In this second stage, many years of barriers in the European approval process can be identified.

Contrary to common sense, the adoption of biotechnology is vast and advanced in terms of research in the bloc. It is its agricultural division, however, that restricts the share and causes numerous problems in the domestic market. EuropaBio (2009) estimates that there are currently 300 biotechnology companies operating in 14 Member States, of which about 180 are involved in service provision, 30 in the development of therapeutic compounds for human use, and the rest distributed among various other segments. The agro-biotechnology sector covers only 3% of the total, potentially reflecting the serious mismatch between the scientific society and the political leadership of Member States groups.

Unlike what is observed in other decisions that are under the Regulatory Committee, the determination for authorization of agricultural GMOs cultivation has always reflected

opposition by the Commission, as explained in item 3 above, ie, *"3) Decision transferred to the Council is not manifested within three months and falls back to the European Commission"*.

The present framework requires that Member States justify their decisions strictly based on scientific arguments, and it is known that the majority of votes are based on considerations that reflect the debate on social and territorial levels. With the impossibility of justifying such motivations, a majority of Member States abstains from voting, and waits for the Commission's position.

The system is flawed, since the Commission's role, set by its own rules, is:

i) To propose legislation that is followed by co-legislators, namely the European Parliament and the Council of Ministers.
ii) To ensure the compliance of the European law (if necessary with help from the Court of Justice of the European Union).
iii) To establish annual objectives and priorities for action in work programs and to work towards their realization.
iv) To manage and implement EU policies and the EU budget.
v) To represent the EU abroad (negotiating trade agreements with other countries, etc.).

However, what is demanded is that it puts forward the Member States aspirations with regard to agricultural biotechnology. The body is in a delicate position with significant differences between the Member States in the process. The Commission works hard, with responsibility in data provision, and in legislating the GMOs usage throughout the bloc. This was one of the main reasons why the European Union had the lowest score in the qualifying table of the present study (Figure 3). The European regulatory framework is simple, but not functional. There is great confusion in the definition of roles and responsibilities of different agents involved in approval processes, with limited power of those in decision-making and strong political interference. Therefore, the bloc got the lowest grade in the institutional theme.

In search of solutions to the issue, the body proposed, in April 2015, amendment of the regulation on foodstuffs and genetically modified feed to allow Member States to decide to restrict or prohibit the use of GMOs based on non-scientific considerations.

According to an official declaration, Member States may adopt exclusionary measures if GMOs have been authorized in the European Union level. Such measures cannot be justified for reasons that go against the risk assessment carried out by EFSA, being, effectively, based on other non-scientific criteria (European Commission, 2015).

The proposal is currently being analyzed by the Parliament and Council of Ministers. In October 2015, the first attempt was rejected by the Parliament, and as the Executive community decided not to withdraw the declaration, the discussion at a legislative level has continued.

Although the overwhelming majority of the Parliament has rejected the Commission proposal, the authorities interviewed during this study were optimistic that the bloc is close to a resolution, or at least that different measures will be taken in the short term, due to the unsustainability of

the current situation. In the long-term, Member States manage an even greater challenge, and with little perspective of change: that is the public opinion on GMOs.

The adoption of the first Roundup Ready soybean (GTS-40-3-2 variety) in the mid-1990s, produced by Monsanto in the United States, was quick and won the wide acceptance of American farmers. They understood the technology, and communication between the business and public spheres was fluid. Based on this success, Monsanto and other big companies developing agricultural genetic engineering have tried a similar approach in Europe, not expecting that the public mindset would be so distinct, generating a completely adverse reaction to the biotechnology suggestion. The "Frankenstein food" term emerged in the UK at the time, and is still popular, a good metaphor for what Europeans think about GMOs.

The inflexibility in decision-making in the adoption of genetically modified products, or second step in the EU approval process comes, mainly, from the opposition of Member States to allow GMOs to be grown in their territories. Even under a favorable diagnosis of scientific security from EFSA, most Member States opt for neutrality, due, as already explained, to the fact that their motivations are social rather than technical.

Member States favorable to GMOs include: Finland, Netherlands, Spain and Portugal; Germany and the UK are divided by opinions. Austria, Greece, France, Ireland, Hungary and most others are against it.

The European Union scored exactly half of the ranking on the historical score compared with United States and Brazil, precisely because of the major opposition to biotechnology by consumers and farmers, and significant censorship of the Executive Power in complying with EFSA’s resolutions.

Many arguments attempt to explain the majority rejection to the technology, or why Monsanto's approach in the 1990s did not repeat the same success factor as in the US. Some include:

1) The European Union is one of the wealthiest regions in the world, where consumers can afford to choose between alternative production sources (GM, conventional or organic), where one is often considerably more expensive than others. A cost premium for certified organic goods in the EU is more acceptable than anywhere else in the world.

2) The European labeling system is sometimes inconsistent. Labeling on animal feed is required, but not on the meat, while those animals that grow the meat consume transgenic grains. Information transmission to consumers is, therefore, unclear. A premium is paid for the organic factor, but the meat consumed has, as raw material, feed that is mainly imported from countries with more than 90% of their agricultural area composed of GM grain crops.

3) The only transgenic cereal already approved in Europe for cultivation about 20 years ago consisted of the Bt176 and MON810 corn varieties by Syngenta and Monsanto, due to a stiff legislation regarding field trials of GM crops, and caution from the private sector to investing in research that may face reprisal and vandalism from organizations opposed to biotechnology. European farmers are unaware of genetically modified seeds developed especially for the climate and soil of their particular region. They do not know, therefore, the real and potential

benefits of agricultural transgenes, which contributes to the skepticism that such seeds would present results as good as or even better than those available today.

For these and other reasons, it is believed that the European resistance to agricultural biotechnology will not change in the near nor distant future. It is expected, though, that exogenous factors may, in the long term, confront the public perception. Global warming, increasingly periods of long drought, slowdown in global expansion of arable land, and predatory exploitation of the soil, among others, will invariably affect yield levels and farmers' margins, not only in Europe, but around the world, obliging all to take a second look at current options to combat the fundamental problems of agriculture.

As in China with the cotton crisis in the 1930s, it is believed that the paradigm shift in Europe will come out of need, and not as an organic change in society's mindset.

Chapter 4

Future perspectives on the use of biotechnology in selected countries

The biotechnology pipeline for global agriculture is promising. All of the investigated countries are involved with important research on the launch of revolutionary processes and innovative products. The discussion about the technology, however, should go beyond its agricultural application, but also cover opportunities arising from the flaws present on the maintenance of the science. The slowness of approval of new GMOs, the lack of clarity of the analysis process and quantification of the resulting added value are some of the main factors that make the regulatory framework the central point in this discussion.

This chapter is about the possible innovations on agricultural biotechnology for each of the examined agents, alongside new opportunities that appear with the holes in laws directed to genetic engineering around the world. The purpose, however, is not to make a list for new approved varieties or new releases. Since these are information readily available in the public domain in every country analyzed, they can be easily accessed. The question asked of the interviewees focused on processes that could revolutionize the biotechnology industry, not products.

4.1 Brazil

Under this premise, the most mentioned subject during data collection was gene editing. In the United States and Brazil, interviewed agents from different spheres mentioned the development of this biological tool, with many application possibilities for agriculture.

The highlight was the Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR), a system that allows bacteria to recognize and fight viral invaders. An RNA molecule guides, with surgical precision, a protein that cuts DNA molecules at specific points and activates repair. Its great differential lies in the manipulation of the genome itself, that is, without the need of insertion of external material. Since 2012, scientists from all over the world have applied the technique, with significant results already in evidence, especially in embryonic medicine.

Big corporations in agribusiness are already working on genetic editing with CRISPR, with estimated release of seeds developed under the technology in five to ten years. In October 2015, for instance, North-American company DuPont announced a partnership with Caribou Biosciences, from California, to cultivate new crops of corn and wheat edited with CRISPR on greenhouses, with field tests to be initiated in 2016. The product must be a variety resistant to droughts, and the hybrid reproduction of crops that still need self-pollination, such as wheat.

As biotechnology, CRISPR allows infinite interactions. Science is expanding studies on soybean, rice, potato and tomato, with the latter being the subject of recent Japanese research intended to deactivate maturing genes on fruits, a result that could take years to be reached via

conventional methods. The insertion of a genetic variant through this method is fast and considerably less expensive than other techniques on biotechnology.

The sector believes that this mechanism is the trigger to a new era of products and profitability, accelerating the creation of plants via simplification of procedures and allowing access to the technology for agents that, for whatever reason, could not invest in research and development of biotechnology.

It is expected, mostly, that the crops edited with CRISPR would be free of regulation, or close to that. To support that expectation, USDA and CTNBio are studying exemption of judgement on these plants, since they do not contain genes from another species. As to the framework of other important players, such as the European Union and China, the judicial approach to these products is still not clear. There is caution about the ethics of medicinal application, mainly because genome editing is a sensitive subject and that requires great supervision.

Another relevant step towards dissemination of biotechnology in Brazil was made in October 2015, when CTNBio authorized the commercial liberation of the Dengvaxia vaccine against the dengue disease, from the French laboratory Sanofi Pauster. Anvisa also approved the product in December 2015, with commercialization expected to start in 2016.

It is believed that in 2015 more than 1.5 million cases of dengue were confirmed in the country, almost 180% more than in 2014, and 15% above 2013 statistics. The outbreak in contamination and death risk demanded extreme agility and effort from the regulatory agency on the product liberation, and it was done on an emergency deadline of three months after the analysis request. The development of this vaccine opened new precedents on genetic mutation research on animals in Brazil. In this case Brazil responded to a developing threat the public health by pioneering a new application of animal biotechnology.

Lastly, 2016 should mark the release of the first genetically modified product developed entirely by the public sphere. It is a variety of bean launched by the Empresa Brasileira de Pesquisa Agropecuária (Embrapa), related to MAPA, that was developed under the premises of CRISPR, and had commercialization approved by CTNBio in 2011. The plant can resist the golden mosaic virus, transmitted by the white flea, and responsible for the productive loss of 90 to 300 thousand tons of beans every year, enough to feed from six to 15 million people (James et al., 2015). It is emphasized that beans are the most popular item in the Brazilian diet, eaten with white rice at least once a day.

Embrapa’s success marks the beneficial result of an investment project from public initiatives on agriculture. Until this product was released the public sector had not been as successful in inserting developing biotechnology for new agricultural varieties. Transgenic beans, when commercialized, could be the answer to a more focused approach by the institution, with emphasis on smaller areas and crops, which are not as competitive as soybean or corn, though no less important to domestic consumption.

4.2 China

The Stifel Nicolaus index, one of the oldest follow-up series of commodity price variation in the world, has concluded that the last two centuries were based on several super-cycles. The triggers for a super-cycle have diverse natures: military conflicts, financial crisis, industrialization processes, supply frustration, etc. The last super-cycle, observed from early 2000, had the lack of oil and rapid Chinese growth as major factors relevant to the index variation. The present moment is a downturn since the last peak (2011), with a growth of 3% per year, compared to the previous 10% average.

This deceleration could be due to full commodity storages and the maturation of the Chinese market, correlated to a Chinese repositioning in the world market, from being a major consumer to an exporter. With demand growth decelerating, maintenance of high grain stocks was required, and the country is currently going through changes from an extremely dependent-demand profile to a more sophisticated consumer market, internally directed.

China largely contributed to the ascension of the last commodities super-cycle, derives its strength and relevance to global trading with an infinity of products. China started to import soybean as animal feed in the late 1990s, triggering one of the most impressive agricultural transformations in the world. From the supply side, about 30 million hectares across America were converted to soybean in response to this growing demand. In the meantime, the Chinese workforce became the most expensive on the Asian continent, with an urban population surpassing the rural one for the first time in history, and per capita income jumping from US$ 970 at the beginning of the 1990s to current US$ 11,860, according to the World Bank (2016). This maturity stage has direct influence on the importance of GMOs to agriculture. It has become possible to understand that the future of biotechnology in Chinese agriculture is not only probable, but it is about to happen. Still, in the last commodities super-cycle, China emerged at a crossroad that is typical during the maturation of developing countries: the accelerated rural exodus demanding urgent measures in agricultural modernization, resulting in rising yields balancing with a reduction of the rural workforce.

The Chinese agrarian structure is highly segmented, and most of the agricultural production is done on more than 200 million small properties. It is believed that the expected modernization will only be viable with the concentration of rural properties and the formation of larger units. Zou Lixing, manager of the Chinese Development Bank, recently said that the long-term objective (30 years) is that 85% of the country's rural production be provided by 7% of the workforce (Zou, 2015); in the United States, 1.5% of the workforce is responsible for almost the entire national agricultural and livestock production (Miranda, 2016).

In the 1950s, China started a process of collectivization of its agriculture, under the influence of the Soviet regime, in which many farming families transferred their lands to a collective entity of higher responsibility. Later, the Household Responsibility System guaranteed the extension of the farmers' rights to use of land they possessed

In August 2002, the Rural Land Contract Law was approved, and its objective is to increase the size of rural properties. Until then, leasing contracts was informal, with the value often being

part of a crop's production. The implementation of the new agricultural reforms attracts large corporations and groups to the leasing of these areas, and, consequently, speeds up the productive concentration process (Miranda, 2016).

In 2003, the Chinese government started a subsidies policy to buy agricultural products under a minimum remuneration price, stimulating the national grain production and guaranteeing that the population still in rural zones do not feel impelled to migrate to urban centers.

After more than a decade of minimum price incentives, corn on offer in China surpassed demand, resulting in surplus stocks that could easily guarantee the country's consumption for almost a year, which is very costly to the government. In an attempt to solve this problem, the government announced, in March 2015, that prices of every agricultural crop, besides wheat and rice, would become market driven. Public supply companies should, from now on, hold responsibility for operational results and eventual financial losses.

Many market agents started speculating on the real chance of China starting to export part of its corn stock, especially when considered that major corn importers, like South Korea, Japan and Taiwan, are in the same continent, a geographic advantage to China. If that is the case, there is still a second phase in the market liberation of Chinese agriculture, which is the possibility that the country joins the group of elite exporters, a phenomenon that would transform the structure of global markets.

Biotechnology's positioning in this structural revolution of Chinese agricultural commodities is positive and promising. As a result of the government's change in policy, Syngenta, one of the biggest seed and agrochemical multinationals in the world, was sold in February 2016 to Chinese State company ChemChina, in a transaction worth more than US$ 40 billion. This acquisition marks a new stage of Chinese access to high-end technology in seed development. And to Syngenta, the agreement brings great capitalization possibility and a guarantee of accessing the Chinese market.

Besides, maturation of the Chinese economy also brings a better living standard to its residents, and as seen on Han et al (2015), the increase of per capita income brings several precedents to the population instruction and edification in acceptance of biotechnology. It would be as if the consumers' mentality is being modified gradually towards the assimilation of the technology and its benefits.

The current change is important to both the Chinese government and population, and for all countries that interact with them. This is the bridge everyone was waiting for in capitalising on the extensive scientific base China has in biotechnology. The country feeds 20% of global population with less than 10% of land available for cultivation, and sooner or later this must alert public powers to the need for innovative practices in agriculture. Biotechnology, a resource currently at hand, is the best tool to guide the future of agriculture in China, and is perceived as such.

4.3 United States

In the last few years, a significant resource concentration is being observed in the development of cattle genetic engineering in the US, something that certainly influences the way the national regulatory framework evaluates GMOs in animals. Using gene editing, advances in research for the creation of hornless cattle, especially in milking breeds, are significant, which would make the animal less dangerous to humans and to other cattle. Besides, if successful, that process would extinguish the painful process of cutting and burning of horns in animals, which highlights to the regulatory authorities the benefits of genetic engineering in terms of animal welfare.

For such, the "no horn" gene would be extracted from breeds in which the characteristic is natural, and inserted in breeds to be genetically modified, without transfers between different species. The extraction would happen in an animal whose meat is already part of human diet, so there would be no question in the security of human consumption.

An important movement in the United States food industry, happening right now, is impacting drastically the way North-American consumers are dealing with the presence of transgenic material in their food. This change can be specified in the Act 120, approved in May 2014 by the Legislative Powers in the state of Vermont. It obliges the labelling of genetically modified food, and prohibits the use of the term "natural" on the label.

The Court, in the first instance, denied requests from the Grocery Manufacturers Association (GMA), together with others, to block the implementation of the law, and the same was appealed at the Supreme Court. The Senate has been unsuccessful in going forward with a voluntary labelling project for GMOs against the Vermont law. The states of Connecticut and Maine also approved laws that oblige the labelling of GMOs, with measures under "trigger clauses", which means that the law would only become valid if other states follow suit.

With that, it was believed that the North-American Legislative would demand the FDA to create national rules for labelling, which has happened. Concomitant with Act 120, in July 2016 President Barack Obama signed Senate Bill 764 (S.764) into law, which requires food manufacturers to disclose the presence of genetically modified ingredients on labels.

The measure implements Law 114-216 (Genetically Modified Organism Labels Measure), which establishes a national labelling system for food products that have or do not contain genetically modified ingredients. It requires disclosure in food packaging under three options: on a text label, a symbol or an electronic or digital link (a QR code), that can be scanned by mobile devices, informing the consumer of transgenic content in any product.

Under this new rule, it is the USDA's responsibility to establish the mandatory standards by defining the amount of bioengineered substance needed in a particular product for it to be considered genetically modified. This way, S.764 surpasses Act 120 and operates at a national level, replacing state determinations involving the labeling of GMOs.

For the scientific community, the implementation of the Act 120 and the S.764 are a reversal in the adoption of GMOs in the United States. These laws assume an emphasis on the technology,

and not on the development process of products, which means that, in the end, the most important message left to consumers is if such product is transgenic or not, and not if it was produced under the security guidance of regulatory agencies.

When stated previously that it has come to the point in time that the North-American government has to decide between the simplification of the approval process of GMOs, or the legitimacy of the current complex method, one gets the impression that before being revised to take into account the power of the newer processes, such as gene editing, the regulatory framework is about to become even more complicated.

Facing obligatory labelling and a subsequent cost increase in the GMO approval process, biotechnology companies are encouraged to look for other techniques and technologies that would allow the same market coverage, but more diligently and via less expensive procedures, like gene editing, and on a management perspective, using data science.

The technology, concentrated in crop management, gained public interest in 2013 when Monsanto confirmed the acquisition of Climate Corporation, a San Francisco company that combines high resolution climatic monitoring, agronomic data modelling and high resolution climatic simulations, resulting in information and insurance to farmers, with the intent of mitigating risks associated to climate variations.

The application developed by Climate Corporation, Climate FieldView, covers more than 30 million hectares in the United States, and is in test phase in other locations, like Brazil, where it assisted the progression of the 2015/2016 soybean crops in major producing states.

The investment is an answer to the generalized skepticism that biotechnology will be the greatest contributor to any rise in world production, which will need to feed nine billion people in 2050. The technology encapsulated in seeds is already, by itself, a major progress in sustainable yield growth, but the ideal environment for the crop to be developed to its best capacity is as fundamental.

Data science, as declared by Chief Executive Hugh Grant in November 2015, is part of Monsanto’s long-term projection in the expansion to new markets, which potentially predicts a move towards technology company acquisitions that are not directly tied to the development of seeds or agrochemicals, but to services in precision agriculture.

4.4 European Union

The present European legal scenario is delicate, as already explained in this study. The Commission entered, in 2015, with a request for revision of the law coordinating the adoption of GMOs in the bloc, and does so with a solid reason. The current system does not work and the Commission is taking important decisions on behalf of Member States, which did not reach a majority of votes in all GMO approval requirements evaluated so far. Both legislators and Member States are not happy, since the latter refrain from positioning themselves on GMO introduction, especially because they cannot argue the ban on the entry of transgenic products in their territories on scientific grounds alone.

The possible long-term impacts in a post-adoption phase of the Commission proposal would transform the feed market dramatically. European meat and milk production is highly dependent on the exports of major players like the United States, Brazil and Argentina, who plant more than 90% of their soybean area with GM varieties. It is estimated that the EU bloc consumes 35 million tons of soybean more than it can produce, as both oil and meal.

The bloc is top five in world beef, pork and poultry production, and a direct prohibition on the import of GM crops by most Member States that are currently resistant to the use of biotechnology in agriculture is not compatible with the needs of the local animal protein market. There would not be enough domestic feed, nor organic and/or conventional suppliers around the world able to meet the European demand.

The opinions on the possibility of approving the revision of the European regulatory framework are balanced. Some agents believe it will never be approved, while others say it is just a matter of time. If the Commission's proposal is adopted, the decision-making autonomy of Member States might result in domestic commercial turmoil and the end of the single market. This might start a new era of European trade liberalization, which would bring great benefit to global trading and competition, but would also worry the European farmers.

Marie-Cécile Damave, market and innovation manager in saf agr'iDées in Paris (August, 2015), spoke brilliantly about a possible future of improved biotechnology receptivity in the European Union, although not in the expected circumstances. The unlikely acceptance of GMOs does not prevent the bloc making use of agricultural biotechnology in ways other than focusing on field results.

Having begun in 2014 and valid until 2020, the Horizon 2020 project, successor of the 7th Framework Program for Research and Technological Development (FP7), is the largest collaborative research and innovation program developed in the European Union, with a fund equivalent to € 80 billion, reserved for research and several scientific projects. Biotechnology has been declared by the European Commission as one of six technologies that will boost the European economy in the future, ensuring that the bloc keeps or increases its current position in global markets, its competitiveness and excellence in scientific research.

It is known that the multinational company's approach to Member States, when presenting new agrochemicals and genetically modified seeds, has not been successful in the past, and that

popular opinion on GM products in certain regions is too inflexible, but it does not necessarily mean that people refute the use of biotechnology in areas not related to the agriculture.

Horizon 2020 has directed significant investment in the bio-economy, allergen-free food, general health and healthy aging population, and biotechnology could be a solution offering the scientific basis to support it. Examples of managed projects making use of the technology include:

1) *FutureAgriculture*: proposes a method of improving photorespiration efficiency in plants, that leads to lower CO_2 loss and consequent yield decrease. New enzymes are used to bypass the photorespiration and potentially increase the photosynthetic efficiency of plants, generating higher crop yields.

2) *Human Brain Project (HBP*): aims to put in place a scientific research infrastructure based on the information and communication technology (ICT), which will allow researchers and industry to raise awareness in the field of neuroscience, computer science and medicine related to brain functions.

3) *Mara*: consists of the construction of autonomous DNA and molecular robots programmed to detect and destroy unwanted cells. Bacterial pathogens resistant to multiple drugs will be used as template for the first proof of concept tests, considering that alternative treatments of infectious diseases are essential in controlling disease outbreaks in the future.

4) *Symbiotic*: seeks to develop a light autonomous electrochemical biosensor, disposable and of low cost, using synergistically the host receiver element in a fuel cell of containing methanol (DMFC). The proposed electrochemical biosensor will be completely autonomous, operating at room temperature and using the oxygen available in the atmosphere.

These are some of the Horizon 2020 projects that include biotechnology in the improvement of various solutions to Europe's future, from agriculture to medicine, or fuel production, etc. It is believed that, although Member States will never reach a consensus on agricultural GMOs, either by social motivation and/or policy, biotechnology has a promising future of possibilities in the bloc, with potentially greater chances of public acceptance, which will be able to find the immediate beneficial impact of its use for the community well-being.

Conclusion

This research was undertaken in order to develop a comparative system, designed to examine the impact of biotechnology in countries relevant to global trading of agribusiness, namely Brazil, the United States, the European Union and China, from a legal perspective, that is, addressing their regulatory frameworks.

The findings pointed to a situation that denies the perpetuity of the countries' global positioning, considering the technology. Each, in its own sphere, is in a time of transition.

Brazil, in a silent revolution, in 2015 approved a record of about 20 transgenic materials, showing an increasingly synchronized coordination between the private sector, which produced almost all GM products launched in the country, and CTNBio, responsible for advising the Federal Government in the formulation, approval and implementation of the National Biosafety Policy related to GMOs. With clear and organized safety procedures, based on a highly technical framework with orders aligned with the agencies involved, Brazil scored the highest grade in the technical aspect of the comparative system.

At a time of deep recession in the country, marked by political interference and corruption investigations, CTNBio stands out among other public agencies, working efficiently and effectively in the analysis of transgenic material. Biotechnology was one of the factors that underpinned the external competitiveness of Brazilian agribusiness, and agriculture was the only sector that in recent years posted positive contributions to the Brazilian trade balance. It is, therefore, in everyone's interest that the regulatory agency and companies continue to work together, supporting a model that has generated good economic results for the country, which earned good grades for the country on the historical aspect of the analysis.

The European Union is divided between public and private sphere agents that believe that the bloc is approaching a turning point in allowing the planting of genetically modified material, despite those that believe in the continuity of the present situation, i.e. divergence of opinions between Member States and those with the European Commission. The optimists rely on the full approval of a law that decentralizes the decision to adopt agricultural transgenes from the Commission, and which allows complete freedom of choice for each Member State. The proposal, which covers grains for human consumption and animal feed, frustrates major trading partners of the European Union, mainly the United States, that want Europe to open its doors fully to GM crops within a free trade pact. The impasse extends to farmers, who take dualistic views on the question. On one hand some farmers favour the approval and consequent power to choose to farm GM varieties; on the other hand many are against biotechnology, based on concerns about the biosafety of these products. This complex behavior is observed throughout the entire GM industry in Europe, from the legislature to the consumer's table, which results in the lowest historical grade among the countries analyzed.

In addition, the European position in the overall ranking was significantly affected by the unsatisfactory performance of its institutional aspect, due to a clear confusion in defining roles assigned to each agency involved in the evaluation process of adopting GMOs. As a result, the

bloc has very few transgenic events approved, making the European institutional grade 30% lower than China, with the next lowest grade.

China experienced a number of paradigm breaks for the use of biotechnology in agriculture. This country, the primary contributor to the rise and fall of the last commodities super-cycle, which had its heyday in 2011, has most of its population favorable to the consumption of GM products, and is in the process of developing its own genetically modified varieties. It was questioned, then, what was preventing the wide commercialization of GM products in Chinese crops right now. The investigation led to the important role of business interests, and the need for greater scientific improvement, which should be achievable, mainly through benchmarking. The acquisition of Syngenta by ChemChina is an example of the acquisition of expertise in the field. The country is going through a delicate moment of transition, internationally recognized, from lack of resources in the past to exponential growth of current consumption, and increased supply of manufactured goods. China's dependence on agricultural imports opens several opportunities for the country to export more products within free trade agreements. Despite a growing popular acceptance of transgenic commercialization, the greater possible independence it would bring to the domestic market could hurt trade agreements with countries that currently provide grains to China. It is not in China’s interest, in other words, to harm international access to Chinese products, which are sold in some sort of exchange for the right to import various agricultural goods into China.

On the other hand, the incentive offered by the price-support mechanisms in place for specific agricultural commodities, such as corn, raises the possibility that China could become a major grain exporter, which could deeply transform the current framework of international trade agreements.

Expectations about China’s transformative potential are ambitious, but for now the Chinese situation with GMs reveals a country that is still learning how to deal with the technology. China’s history and development point to strong interferences from its political powers which govern how biotechnology, especially agricultural biotechnology, is handled domestically. With this, and a low number of GM events approved, the country performed poorly in the institutional theme.

As to the regulatory aspect, the difficulty in bringing knowledge of the law to the largest population in the world, and a still very premature structure of risk management involving GMOs contributed to an unsatisfactory grade, placing China at a level better than the European, but still far behind the Brazilian and the American grades

Finally, the United States, the great pioneers in research, development and biotechnology management, are crossing an important period that will transform the way the world deals with transgenic agriculture in the near future.

The US are experiencing an attempted deconstruction of its own regulatory framework, searching for more efficient ways to approve new varieties. Currently, the commercial launch of a new product takes on average ten years to be consolidated, and no less than US$ 100 million in investments, articulated jointly by the three main regulatory agencies: USDA/APHIS, FDA

and EPA. The recycling approval process will potentially shorten the analysis time, targeting every proposal towards the most relevant agency for evaluation. This ability, keeping the same parameters and quality control, has great impact on the high costs carried in research and development, and reduces the need for repeated procedures. Shorter analysis intervals and simplified steps result in substantial drop in initial investments, setting precedents that may allow smaller agribusiness companies to become competitive accessing biotechnology. It is possible to list, today, the few companies capitalized enough to drive a minimum of US$ 100 million in the launch of a single GM product. Thus, to simplify the approval process is to popularize the technology among a larger group of companies experimenting with GMOs; this means improved accessibility.

The American overall performance, although excellent, was positioned behind the Brazilian performance, mainly due to flaws in the institutional criteria, which extend the long process required to have a new GM product approved in the country. The same factors also result in a reduction in the technical performance, since it is believed that the American regulatory framework has, over the years, become complex and sometimes confusing.

As noted, each country is experiencing a revolution in transgenes, from a lesser to a greater degree. Analysis in loco and qualification of the regulatory frameworks make it possible to conclude that society is far from enjoying a homogeneous and unified market in the approach to biotechnology, but it can be asserted that there is optimism that major changes are imminent, and that there is much to change, even in the short term.

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Plain English Compendium Summary

Project Title:	The adoption of genetically modified organisms and legal implications: a comparative analysis
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Objectives	To qualify, under a same comparative perspective, the countries Brazil, China, the United States and the European Union with regard to the regulatory framework approving the commercial release of genetically modified organisms (GMOs).
Background	Since agriculture was established ten thousand years ago, the Earth has been changing. It is obvious that agriculture, and food production, has had a great impact in solving great social problems (especially overpopulation and food security. Meanwhile, biotechnology is the development which is most likely to remedy issues related to sustainable production, food security and conservation of the terrestrial biome. It is essential to include it in any long-term plans projecting a new order for global markets.
Research	Professionals from various parts of the agribusiness chain that deal directly and indirectly with agricultural biotechnology were interviewed, and given advance notice of the questions to be asked. The people were approached during interviews in each of the countries analysed (Brazil, China, US and EU). The literature available and pertinent to the topic was also reviewed.
Outcomes	Although Brazil does not hold the most traditional regulatory framework that evaluates GMOs, it is, currently, the most advanced in the world regarding it, followed by the United States. China is going through a turning point in its international position and market trading changes that will transform, in a very near future, the way the country deals with agricultural biotechnology. The European Union seeks alternatives to the use of the technology to non-agricultural fields, hoping that, in the future, public acceptance in these other areas make it easier to assimilate the use of biotechnology in agriculture.
Implications	As an extremely important factor in the development of food security and in the future of science as a whole, the present time is appropriate to study the reception and interaction of different nations to biotechnology. In this report, genetic engineering is investigated from a legal perspective, in an attempt to understand how each target nation is embracing, in legal terms, this complex and relevant innovation in agribusiness, and how communication is established with the public. It also analysed the likely development of transgenes in the future.