Regulating Agricultural Biotechnology:
A Study of Multi-level Environmental Governance in China and the European Union

PhD(SLaw) Thesis

Newcastle Law School

Newcastle University

Naiyue Ma

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Abstract

As a developing country with relatively limited arable land, China has invested heavily in the development and use of genetically modified crops to boost agricultural productivity. Biotechnology is designated as a strategic emerging industry in China and the government has encouraged and supported extensive biotechnology research. The potential of this new technology, and the expectations of it in boosting agricultural production, are very high - but these are also mixed with public concern as to its safety and potential impacts on the environment in China. Important issues about biosafety and the need for appropriate regulation of the development and (then) release into the environment of agricultural genetically modified organisms (GMOs) have been prevalent in recent years. China has introduced legislation on biosafety management, but the regulatory system for GMOs has been criticized for being vague and lacking enforceability. A series of recent actions indicate that the Chinese government is aware of the need to revise its biotechnology regulatory system, but transforming the complex system of multi – level governance currently applied to agricultural biotechnology in China will be challenging.

The European Union has a precautionary approach to GMOs, and a comprehensive and integrated regulatory framework for managing the development and release of GMOs. The EU model has practical relevance to establishing the shape of legislative reforms in China. This thesis will survey the regulatory framework of agricultural GMOs in both China and the EU, specifically in the range of GM crops and GM food and feed. It adopts a comparative methodology, and provides a detailed analysis on the regulation of key issues: including risk assessment and the approval processes for developing new agricultural GMOs, their cultivation, marketing and safety assessment within the EU and China. The thesis identifies valuable lessons and precedents from the EU and considers how they might be adopted to provide possible solutions for legislative reform in China.

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everything possible, as they always do. Last but not least, I greatly appreciate their constant efforts on restraining themselves to probe when this thesis might be completed.

List of Abbreviations

ACRE—Advisory Committee on Releases to the Environment (UK)

AQSIQ--General Administration for Quality Supervision, Inspection and Quarantine of People's Republic of China

CAC--Codex Alimentarius Commission

EFSA--the European Food Safety Authority

GMOBC--National Genetically Modified Organisms Biosafety Committee of People's Republic of China

MEE--the Ministry of Ecology and Environment of People's Republic of China

MOA--the Ministry of Agriculture and Rural Affairs of People's Republic of China

MOST--the Ministry of Science and Technology of People's Republic of China

NHC--the National Health Commission of People's Republic of China (formerly the Ministry of Health)

NDPC--the National Development and Planning Commission of People's Republic of China

Table of Contents

Chapter 1 Introduction

1.1 Context

In the history of the development of human society, people constantly struggled with the population, the resources and the environment. The lesson we learned from the history is that each time the technical revolution may brought the solutions. Since 1980s, the development and application of the genetic recombination and transformation have boosted the development of biotechnology to a new generation and at the meanwhile, brought numerous interests to the economic. The genetically modified organisms result from genetic engineering experiment in which genetic material is transferred from one organism to another, so that the recipient organism will have a new trait. The genetic technique is expected to allow more cost-effective crops and herds with desirable characteristics that are not available using up-to-date breeding technology. The transgenic technique allows genetic material to be transferred between organisms that are altogether unrelated to each other.

The very first genetically modified organism—transgenic tobacco with antibiotic resistant gene indicates that the utilization modern biotechnology in a new stage and in 1994, the commercialization of transgenic long-shelved tomato could be seen as the beginning of large scale application of transgenic agricultural plants.[1] The industrialization of the biotechnology promotes the global trade of its products and especially the development and the application the agricultural biotechnology draws much attention. The development of Genetically Modified Organisms (GMOs) for use in arable crop production and the food production system have been considered as one of the great advances of the modern biotechnology.

Nowadays, the GMOs is no longer a novel concept to people since they have been widely used in agricultural production, food and feed production with the purpose of enhancing the

[1] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009), see the Foreword and p42.

economic benefits and human health.[2] Nevertheless, as the same as any new invitation in human society, the application of GMOs in agricultural production or narrowly speaking, the food production has been a controversial issue since the advent of this new technology. The foundation of the transgenic technology is the technology of recombination of DNA which breaks the biological barrier in the nature and allows scientists to artificially create new species which would not be existed under natural conditions. On the one hand, this breakthrough technology is regarded as the proof of human beings' increasing ability of controlling the environment which might benefit the environment as well as human ourselves. For example, the application of the pesticide-resistant crops might dramatically decrease the usage of pesticide and benefits the environmental protection; the crops with traits of insects-resistance, the drought-resistance or disease-resistance could lead to higher yields and benefits the farmers, especially the farmers in the developing countries.[3] On the other hand, there are concerns about the biosafety. Biosafety includes the concerns on the risks of cross-pollination and of the disruption to the cellular ecology of plants, the possible potential effect on the biodiversity and natural environmental as a whole and the unknown risk, for example the GMOs may provoke allergies for human beings as well as the animals,[4] and the possibility of unintended genetic drift between different species.[5] In a broader way, all the concerns shows that people's deeper and anxiety about the way which people change the world and the way people transform the environment.[6] The knowledge of the safety and the potential risks of the newly invited GMO products numerous research and study, obtaining a certain answer may needs examinations from generation to generation. However, regardless of all the concerns the new biotechnology, it has been widely used in various ways including medication, agricultural cultivation and food and feed production. The products of GMOs have commonly appeared in the field, on the market shelves and on people's tables.

Along with its rapid development and application, the transgenic technology has raises the new

[2] Lucia Roda, 'Risk Analysis and GM Foods: Scientific Risk assessment' (2009) 4 European Food and Feed Law 253. p 253
[3] Terri Raney, 'Economic Impact of Transgenic Crops in Developing Countries' (2006) 17 Current Opinion in Biotechnology 1
[4] Christopher Rodgers, 'Implementing the Community Environmental Liability Directive: Genetically Modified Organisms and the Problem of Unknown Risk' in Luc Bodiguel and Michael Cardwell (eds) *The Regulation of Genetically Modified Organisms : Comparative Approaches* (OUP 2010) p.200
[5] World Health Organization: *Modern food biotechnology, human health and development: an evidence-based study* (2005)
[6] Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar, 2008) p.1

challenges for environmental governance of issues such as risk assessment, the criteria and thresholds to be applied for risk analysis prior to the approval of new biotechnology products, strategies for increasing consumer awareness and choice, and legal issues of environmental liability. To establish a sound and perfect regulatory system for the new biotechnology used in agricultural production causes difficulties and contradiction to governments around the world. It might because that the perfect balance between the desire of considerable economic and social interests and worries about unpredictable consequences of growing and consuming GMOs in large scale to the environment and the human beings is almost impossible to achieve.

Legally administrating the release of GMOs into the environment and the consumption of GM food and feed pose important questions for policy makers. However, due to the scant and uncertain scientific evidence as to the potential risks to health and the wider environment arising from the use of GMOs and GM food products, there is no universal consensus on the optimum approach for the administrative regulation of GMOs and GM products. Governance of the environmental and health risks varies from country to country. The approach may vary according to the different countries' knowledge of GM technology and their national conditions. However, there is one constant factor-- designing appropriate governance structures to regulate the GM technology used in agricultural production and food production is a challenge in every country or region and there is a strong tension between the economic and social benefits that the technology may offers and protecting the environment and people's health to the greatest extent from its potential unforeseen consequences

China is a large agricultural country with the most population in the world, in spite of the economy rapidly develops in various aspects in the recent decades, the agriculture is always regarded as the most important pillar of the economy and the lifeblood of the nation. Under the pressure of the large population and relatively limited arable land, the modern technology has often been seen as an important and effective measure to increase crops yields and ensure national grain security.[7] The research and development of agricultural technology started from

[7] Wanhua Yang, 'Regulations of Genetically Modified Organisms in China', (2003) 12 (1) Review of European Community and International Environmental Law 99 p.99

the 1980s and government has invested heavily in the process and has been promoted several national research and development programmes. By the year of 2000, there were more than 90 research institutions participated into the research and development of agricultural GMOs.[8] The nature of centralized governance and financial system of China offers the research and development programmes of GMOs the reliable funding and stable base, the process of GMOs' scientific research and development is rapid.[9] China has one of the largest cultivated areas of transgenic agricultural crops compare to other the developing countries.[10] According to the previous study, China started promoting commercially cultivation of *Bt* cotton since 1997 with the growing area of 30,000 hm^2 which extended to 230,000 hm^2 in the following year. In 2004 this number has increased to 350,000 to 400,000 hm^2 which account for almost 2/3 of the total cultivation area of cotton.[11] Furthermore, China also relies heavily on imported GM crops. According to the statistics, China has been importing soybeans since 1999 mainly used in cooking oil production. In 2000 the gross of the imported soybean is less than 20 million tons which is almost as much as the total gross of domestic soybean production; while in 2008 this number has increased to nearly 38 million tons. Nearly 70 percent of the imported soybeans are transgenic, mainly from the US, Argentina and Brazil.[12]

The repaid development of biotechnology and increasing demands of GMOs products not only brings challenges to the scientists in the biotechnology field but also rises a legal issue—how China should build the legal framework of agricultural biotechnology in order to ensure its normal and orderly development as well as to protect the biosafety.

China is one of the counties with abundant biodiversity and because of the long history of agriculture there is very rich biological genetic resource, the Chinese government thus took great cautious attitude on safety management of genetically modified organisms. As early as 1993 the former State Science and Technology Commission (Now the Ministry of Science

[8] X Qing and J. Wade, GAIN Report No. CH0046, '*Current Status of Chinese GMO Development and Regulation*' Foreign Agricultural Service USDA 2000
[9] See n.8 p.99
[10] See n.3
[11] See n.1, the preface.
[12] Ibid.

and Technology) enacted the 'Administrative Measure on Genetically Engineering Safety Management'[13] which is the earliest legislation in the history related to GMOs safety. In order to regulate the constantly increased agricultural biotechnology research and environmental release, the State Council issued 'Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms'[14] in 2001 and the Ministry of the Agricultural issued three administrative measures as auxiliaries in the following year. The 2001 Regulation and its auxiliary measures constituted the regulatory framework of agricultural GMOs safety management in China and marked the start of the comprehensive safety management on each section of agricultural GMOs including the research and experiment, the production and process, the import and export as well as marketing.

The need of improving the current Chinese governance regime on GMOs is not triggered by the domestic situation but also by influence from international society. China signed the Protocol to accede to the WTO on November 11, 2001 and formally became the 143rd party of the WTO on December 11, 2001. The WTO membership of China triggered a process of amendment of existing domestic laws that were in conflict with the WTO rules. The process was completed when the membership started in 2001. To a certain extent, China is still at the stage of learning and getting familiar with the WTO rules.

WTO membership brings uncertainties for China's agricultural regulation in several ways. Firstly, there is no certainty whether China's current GMO regulatory framework is compatible with WTO rules. It is still too early to draw any conclusions as the US-EU GMO dispute on the EU regulation on GMOs is still pending at the WTO Dispute Settlement Body.[15] The outcome of this dispute shall produce an important impact on China's GMO policy and its regulatory framework. Whatever the outcome of the dispute will be, on one hand, the regulation of agricultural GMOs should not be used as a tool of discrimination and trade barrier; on the other

[13] Administrative Measure on Genetically Engineering Safety Management, Decree No.17 (1993) of the State Science and Technology Commission

[14] Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms, adopted at the 38th Meeting of the State Council on May 9, 2001, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001, and effective as of the date of promulgation.

[15] Hui Li, 'WTO Agricultural GMOs Trade Disputes and Review on EU's Administration on GMOs', (2007) 2 Global Law Review 35

hand, the increasing public concern on the potential adverse impact of the GMO on the environment and human health should not be overlooked or neglected. The consumer should be informed and should have choices. The Chinese consumers, especially those in the urban areas, are increasingly demanding more information on the food products they consume.

Secondly, since China's agricultural GMO regulation was to a certain extent pushed forward by the Biosafety Protocol, the relationship between the Biosafety Protocol and the WTO rules is relevant. The question is, in case of conflict, which one, the Biosafety Protocol or the WTO, may override the other. Hopefully the US-EU GMO dispute could give some hint on how to resolve this issue. However, since this thesis will mainly focus on studying the governance regime on GMOs biosafety in China and EU, the WTO aspect here as a less relevant aspect to the research and in the following content of the thesis it would not be discussed in further detail.

It is commonly agreed that in order to establish the rule of law, firstly there have to be laws and secondly, these laws have to be effectively implemented. At the present, China has more or less achieved the first step since laws and administrative regulations and measures have been issues in the last twenty years. In spite of some deficiencies still exist, the framework of the biosafety regulation has been achieved in great extent. However, the second condition is more difficult to achieve. The lack of effective implementation could be due to lack of clarity in the law and regulation, but clarity alone cannot guarantee effective implementation of a law. The political, economic, social and cultural environment behind the weak implementation is complicated.

The European Union and the US have highly developed multi-level governance arrangements for regulating agricultural biotechnology; these jurisdictions are two representative systems which present two inherently different attitudes to the regulatory approaches on biotechnology used in agricultural production and the food industrial production. However, there is at least one common factor between those two regulatory frameworks —they are both well developed and offer examples of different approaches to risk assessment, consumer choice and environmental protection that can be studied as comparators offering insights into the potential development

and refinement of the governance of GM biotechnology in China.

The writer chose the EU legal management framework as the object of study for the following reason. Even though the state conditions including the size of population, the land area, the governing method and the extend of genetic techniques used in agricultural production, are obviously different. However, the legislative idea of agricultural biosafety between China and the EU are very similar, for example they both regard the precautionary principle as the guiding principle and apply compulsory labelling requirements for GMO products. Overall, the European countries began to pay attention on biosafety issues from early 1980s and considered the management and risk assessment on environmental release of GMOs. The EU and its Member States then enacted a series of law and legal documents and issued detailed approval procedures and technical guidelines. Until today, the European Union is the region with the strictest management on biosafety that the GMOs products are totally banned from market and field trail in the some of the Member States. Also, the European Union implement a strict GMOs labelling method and product traceability system. Most importantly, the EU and China share the same opinion on the precautionary principle should be the conceptual foundation of legislation on biosafety. Therefore, the writer considered the EU's multi-level governance on GMOS and the legal framework as highly valuable and some of the approaches on GMOs management are feasible in China which should be learned from in order to develop a cohesive and comprehensive legal system on agricultural GMOs at the national level as well as the provincial level.

Therefore, this thesis will study and analyse the regulatory approaches on agricultural biosafety of the European Union and the China. The regulatory frameworks of EU and its member states could be seen as characteristic of a precautionary approach to biotechnology and its regulation. This research aims to analyse both of them and assess whether – and if so how - the valuable experience of the EU and its member states can offer guidelines and solutions for some of the problems facing Chinese agriculture and food supply in the future. There is one Chinese proverb saying that "To the country people is all-important; to the people foodstuff is all-important; to the foodstuff safe is all-important." Due to the fact that increasing use of

biotechnology in agricultural production may bring food safety issues, it is necessary and urgent to take preventive measures and to regulate as effective as possible on this controversial food source.

1.2 Research Questions

RQ 1 What can China learn from the EU in relation to the regulation of agricultural biotechnology?

RQ 1.2 What is the role of law in regulating agricultural biotechnology and its use in food production in the EU, and China?

RQ 1.3 What is the role of the precautionary principle in EU and Chinese law on agricultural biotechnology and its use in food production?

RQ 1.4 What principles are applied in undertaking risk assessments prior to authorizing the use of biotechnology products in food production in the EU, and China?

RQ 1.5 What are the principal differences between the regulatory regimes for agricultural biotechnology and its use in food production in the EU and China?

RQ 1.6 What can China learn from the EU and its member states, and from their regulatory approach to biotechnology and its use in food production?

RQ 2 To what extent, and how, can regulatory measures minimize the risk of environmental damage arising from the use of agricultural biotechnology, while also maximizing its potential benefits in food production?

RQ 3 .1 To what extent, and if so how, do regulatory measures in China promote and protect “organic” (‘green food’) food production?

RQ 3.2 Should China adopt coexistence measure for GM and non-GM production, and if so what model should be adopted for GM coexistence measures?

RQ 4 What reforms to the regulation of agricultural biotechnology are desirable and/or

necessary in order to protect the environment in the PR of China while also maximizing its potential benefits in food production?

1.3 Methodology

This research will use a comparative method in studying the regulatory framework on biotechnology (GM technology) used in agricultural food production between the European Union. The thesis will firstly examine the governance arrangements for the release of GMOs into the environment in China (Chapter 2). It will then examine the comparable arrangements in the EU and its member states (Chapter 3). It will be seen that both jurisdictions adopt a complex multi-level governance approach to the different issues involved in assessing risk, setting standards for public safety and environmental regulation, and then arranging for the labeling and traceability of food products containing GM material. This is inevitable: assessing risk, for example, is a scientific matter that must be undertaken by scientific experts; setting standards for the level of risk that is acceptable in the public interest is a matter for central or local government bodies (as the case may be); while overall policy on GM technology will usually be a political matter for the central government. A number of differing bodies will typically be involved in making decisions relevant to the governance of biotechnology products, their production and use: scientific committees, governmental level review panels, local or central government bodies, and (as to their use in production) landowners and farmers. These roles are allocated to different bodies in EU law and Chinese law. The thesis will draw comparisons between the governance arrangements within the EU and China (Chapter 4) and then conclude by offering suggestions for reform of the regulatory model for Chinese law (Conclusion).

The research was executed using a doctrinal study method. The research reviews all the relevant legislative provisions in China and in European Union law for the regulation of GM agriculture, and for the use of GM products in the food chain. Research was conducted in China to gather relevant legal and policy documentation, and the thesis uses Chinese legal literature to interrogate the issues that agricultural biotechnology raises for multi-level governance in the

Chinese context. The research methodology adopted was granted ethical approval by the Research Ethics Committee of the Faculty of Humanities and Social Sciences, Newcastle University, in October 2013.

This thesis will study the different regulatory approaches on agricultural biotechnology for food production adopted in the EU and China. The thesis will aim to evaluate options for guiding China to achieve a higher level in regulating agricultural biotechnology – both for the protection of the environment and for protecting food safety and food supply. The primary focus will be on studying the regulatory approaches on agricultural biotechnology for food production which are used in the European Union and China. In order to achieve this purpose, the writer will structure the thesis in the following order. In Chapter 2, there will be an introduction on the regulatory framework and management system of agricultural GMOs in China, the development of the agricultural biotechnology will also be included. At the end of this chapter, there will be a conclusion discussing the shortcomings of the current Chinese governance regime on agricultural GMOs and the necessity of learning advanced experience from other countries and governments. In Chapter 3, the EU's multi-level governance system on GMOs will be detailed discussed and in Chapter 4 there will be an analyse on the differences between two different governance regimes on the agricultural GMOs of the EU and China. In the final part of this thesis, the writer will state the main findings of the research as well as the possible improvements and development which the Chinese regime may take by learning the EU example.

Chapter 2 Regulation of Agricultural GMOs in China

2.1 Introduction

It is forecasted that in the near future the cultivation area devoted to genetically modified crops in developing countries will exceed that in industrialized countries.[1] However, the applications of agricultural biotechnology have been criticized because of their possible potential risks for the environment, human health and social economic consequences, particularly among the developing countries.

Over the past years, Chinese government made a large amount of investment and resources into the research and development programmes of the genetically modified technology and has become one of the largest growers of GM crops in the world. According to the survey report published by the International Service for the Acquisition of Agro-biotech Applications (ISAAA) in 2012, China has become the sixth largest producer of agricultural transgenic crops in the world by the total cultivation area of four million hectares.[2] The issues of biosafety in China is particularly significant due to the national factors and international factors. Domestically speaking, China has made great efforts on investment in biotechnology and the research and development be carried out inside the country has achieved great improvements. There are many biotechnological research institutes have been set up in the country, mostly funded by the government have developed a large range of GM crops varieties and innovated new varieties of GM crops, for example, the rice genome was decoded by a Chinese team.[3] Chinese *Bt* cotton competes with Monsanto's flagship Bollgard and according to many

[1] Peter Ho, Jennifer H. Zhao, Dayuan Xue and Jac. A. A. Swart, 'Biotech Politics in an Emerging Economy: Is China a Developmental Risk Society?' Heather Xiaoquan Zhang (ed.), *Rural Livelihoods in China: Political Economy in Transition* (Routledge 2015)

[2] Andrew Anderson-Sprecher and Ma Jie, 'Peoples Republic of China Agricultural Biotechnology Annual 2014' (Global Agricultural Information Network, United States Department of Agriculture, Foreign Agricultural Service 2014 GAIN Report Number: 14032)

[3] James Keeley, 'Regulaing Biotechnology in China: the Politics of Biosafety' IDS Working Paper 208, Institute of Development Studies 2003 http://www.eldis.org/go/home&id=14842&type=Document#.VlLq3HbhAdU accessed Oct 17, 2014

researchers and farmers that it performs well.[4]

In order to administrate the increasing biotech research and manage the safety of its product, in the year of 2001, Chinese State Council promulgated the Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms (hereafter referred as the 2001 Regulation).[5] This regulation aims to strengthen the safety management of agricultural GMOs, to safeguarding the health of human, protecting the ecological environment and to promote research of biotechnology, and it regulates the safety controls over the laboratory research, field testing, production, processing, marketing, and other applications of agricultural biotechnology. The auxiliary administrative measures issued by relevant agencies provided detailed explanation and implementation methods of the regulation.

This chapter aim to introduce the current status and development of the agricultural biotechnology research and commercialization, review the China's polices and legal framework governing both agricultural biotechnology research and its applications. In order to achieve these objectives, this chapter is organized as follows. The next section provides an overview of China's development of agricultural GMOs. The second to the fifth sections will focus on biosafety management and regulations respectively from the institutional aspect, the substantive aspect and the international aspect. Finally, the sixth section provide a brief summary of this chapter.

2.2 Overview of the Development of Agricultural GMOs in China

China used to face the predicament of unbalanced relation between the demand of agricultural products and supply. Since the implementation of the policy of reform and opening, this

[4] Ibid.

[5] Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms, adopted at the 38th Meeting of the State Council on May 9 2001, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001.

situation has been improved in great extent. The agriculture in China has entered into a new stage of the development and shall focus on adjustment of the agricultural structure, improvement of food quality, increasing of farmer income, improving ecological environment and implementation of the sustainable development of the rural area. The popularization of new scientific technology, especially the biotechnology and information technology in agricultural production is the solution designated by the government.[6]

2.2.1 *Goals and Strategies*

The research and development of agricultural GMOs in China started from the mid of 1980s. Due to the nature of China's central-planned economy, especially the centralized financial system, the research and development of agricultural GMOs in China, unlike that in the developed countries which private companies perform most of the agricultural biotechnology research, the research and development of GMOs heavily relied on public funding from the government. In order to achieve the multifaceted goals of the biotechnology development, China invested in various national biotechnology programmes.[7] The goals of the biotechnology development is defined by the Chinese government as to safeguard the nation's food security, to increase agricultural production efficiency and farmer income, to promote sustainable development of agriculture, to protect the environment and human health, and to enhance the competitivity of Chinese agriculture as well as the modern biotechnology itself in the international agricultural market and the international biotechnology research field.[8]

From the early 1980s, the plan of promoting the technology in general was firstly raised in the '7th Five-Year Plan' in section five.[9] in general the biotechnology has been promoted and

[6] 'The Outline of Agricultural Science and Technology Development (2001-2010)', the State Council, Decree No. 12, issued on April 28th 2001.

[7] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p2157

[8] Jikun Huang and Qinfang Wang, 'Biotechnology Policy and Regulation in China', IDS Working Paper 195, Institute of Development Studies 2003 < https://www.ids.ac.uk/files/Wp195.pdf> accessed Oct 17 2014

[9] The 'Five-Year Plan' is the crucial part of the long-term Chinese national economic plan, the main function of the Five-Year Plan is to set up goals and direction of national economic further development, and to guide the national major construction projects, productivity distribution, the proportions of national economy. The 7th Five-Year Plan is the plan of

incorporated into several national research and development programs for science and technology programmes, mainly for achieving the purpose of more rapid economic growth. The development process of the transgenic technology in China could be divided into two stages. The first stage is from 1986 to 2000 start with the launch of the '863 Plan' namely the National High-Technology Research and Development Programme. The main objective is this plan is to reach the world technology frontiers level, encouraging to learn from the advanced technology and the main research in the field of gene cloning and plan gene transformation as well as the early-stage industrialization.[10] There also were other significant programmes launched in the same period, including the '973 Plan', the Initiative of National Key Laboratories on Biotechnology, the Key Science Engineering Programme and established several special foundation projects including the Special Foundation for Transgenic Plants Research and Commercialization, the Special Foundation for High-tech Industrialization, Natural Science Foundation, and the Foundation for High-Tech Commercialization, etc.[11] For those projects approved by these projects, programs and plans, the government provided funding and relevant policies favorable to the research and development activities. In the early years of 21st century, China entered into the second stage of the biotechnology development which aimed to comprehensive and independent innovation and large-scale industrialization and ultimately establishing the agricultural biotechnology industry.[12]

2.2.2 *Agricultural biotechnology research institutions*

The national agricultural biotechnology research in China is mainly carried out by governmental departments and institutions instead of private sectors. The Ministry of

national economic and social development from 1985 to 1990. Currently China is taking its 13th Five-Year Plan.

[10] The '863 Plan' was a high scientific and technology development programme funded by the government and launched in March of 1986. The '863 Plan' included a large number of applications and basic research projects with a 10 billion RMB investment from the government (equivalent to 2 billion US dollars for the time). Biotechnology is one of the priorities of the program. The projects funded in biotechnology include two areas, the agriculture (47.28% of the biotechnology fund) and the medicine (52.72% of the biotechnology fund). See *Summary of the Biotechnology in the 863 Program of Our Country* , http://www.863.gov.cn/1/1/index.htm (Accessed Oct 19 2015)

[11] Jikun Huang and Qinfang Wang, 'Biotechnology Policy and Regulation in China', IDS Working Paper 195, Institute of Development Studies 2003 < https://www.ids.ac.uk/files/Wp195.pdf> accessed Oct 17 2014

[12] Zhen Zhu, 'Research Proceeding in the Development of GMOs in China' in Dayuan Xue ed., *Risk Assessment and Regulation of Genetically Modified Organisms: Proceedings of the International Biosafety Forum—Workshop 4 Beijing* (2011 China Environmental Science Press) p.8

Agriculture, the Chinese Academy of Sciences, the State Forestry Bureau and the Ministry of Education are the major authorities which are main responsible for agricultural biotechnology research.[13] Among the others, the role of the Ministry of Agriculture in the biotechnology research is the most important. There are three research academies affiliated to the Ministry of Agriculture which respectively are the Chinese Academy of Agricultural Science, the Chinese Academy of Tropical Agriculture and the Chinese Academy of Fisheries. Those research academies establish their own research institutes and laboratories to conduct biotechnology research programme.[14]

The agricultural biotechnology research is also carried out by institutes external to the Ministry of Agriculture's research system. For example, the research institutes affiliate to the Chinese Academy of Forestry and the State Forest Bureau as well as some universities directly affiliated to the Ministry of Education which are capable of the independent research, for example the Beijing University, Fudan University, and China Agricultural University.[15]

At the provision level, the institutional framework is similar to the national level and play an importation role of contribution to the agricultural biotechnology development. There are in total of 34 provinces[16] in China and each province have agricultural university and academy of agricultural science. Normally there would be institutes and laboratories of agricultural biotechnology research which funded by the local government or national government attached to the provincial agricultural universities and academies.[17] It is very obvious that Chinese government heavily invests resources on agricultural biotechnology research and has great ambition to achieve higher level of research ability and international competitiveness. According to the latest information available, China has now obtained more than 300 genes with important traits which could be used in various biotech crops in order to improve

[13] Jikun Huang and Qinfang Wang, 'Biotechnology Policy and Regulation in China', IDS Working Paper 195, Institute of Development Studies 2003 < https://www.ids.ac.uk/files/Wp195.pdf> accessed Oct 17 2014, p.6
[14] Ibid.
[15] Ibid.
[16] To be precise, there are 34 provincial-level administrative regions, including 23 provinces, 5 autonomous regions, 4 municipalities and 2 special administrative regions.
[17] Jikun Huang and Qinfang Wang, 'Biotechnology Policy and Regulation in China', IDS Working Paper 195, Institute of Development Studies 2003 < https://www.ids.ac.uk/files/Wp195.pdf> accessed Oct 17 2014, p.6

nutrition, resist drought, enhance salt and alkali tolerance.[18]

2.2.3 *The current situation of GM crops production in China*

Due to the importance of agriculture for China and the expected role of GM plants in agriculture, they have received much attention, support and publicity. China is one of the members of the six 'founder biotech crops countries' and now the sixth largest GM crops producer of in the world with a total cultivated area of 4 million hectares. According to the 2015 report published by the International Service for the Acquisition of Agro-biotech Applications (ISAAA), China has planted 3.7 million hectares of biotech crops: 3.7 million hectares of biotech cotton, 7,000 hectares of virus resistant papaya and 543 hectares of Bt poplar.[19] From 1994 to 2016, China has approved 60 biotech crops strains for cultivation and use in food and feed production which include 17 strains of maize, 12 strains of Argentina canola, 10 strains of cotton, 10 strains of soybean, 3 strains of tomato, 2 strains of rice, 2 strains of poplar, 1 strain of papaya, 1 strain of sweet pepper, 1 strain of sugar beet and 1 strain of petunia.[20] However, due to the concerns of the public opinion and the pressure from the domestic seed industry, only a few of the approved events are being commercialized today and the most widely planted GM crop in China is Bt cotton and virus resistant papaya.[21] The information of approved biotech crop event for commercialization could be found on the Ministry of Agriculture's official website.[22] The transgenic crops which are approved for commercialization need to firstly obtain a 'Safety Certificate' from the Ministry of Agriculture and currently the majority of the safety certificates are for the domestically developed varieties

[18] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p2157

[19] Biotech Country Facts & Trends—China 2015, Report from International Service for the Acquisition of Agro-biotech Applications (ISAAA) [https://www.isaaa.org/resources/publications/biotech_country_facts_and_trends/download/Facts%20and%20Trends%20-%20China.pdf] last accessed 08 Dec 2016

[20] ISAAA Brief No.52, 'Global Status of Commercialized Biotech/GM Crops: 2016 ', p.41 < http://www.isaaa.org/resources/publications/briefs/52/download/isaaa-brief-52-2016.pdf> accessed Oct 10, 2017

[21] Andrew Anderson-Sprecher and Ma Jie, 'Peoples Republic of China Agricultural Biotechnology Annual 2014' (Global Agricultural Information Network, United States Department of Agriculture, Foreign Agricultural Service 2014 GAIN Report Number: 14032)

[22] MOA's website <http://www.moa.gov.cn/ztzl/zjyqwgz/spxx/> last accessed 08 Dec 2016

of Bt cotton.[23]

At the present, the Bt cotton is the most widely planted biotech crop in China. In 2011, total cotton cultivation area of cotton is 5.45 million hectares and 71.5 of them is biotech cotton and in 2015 this number increased 3.8 million hectares. The virus resistant papaya is only planted in Guangdong Province, Hainan Province and Guangxi Province on approximately 8,550 hectares according to report of 2016.[24] In addition, in 2002 the State Forest Administration (SFA) passed commercialization permission of two GM forestry plants events, both are insect resistant poplar and according to the latest statistics available, the total grown area is 542 hectares.[25] Generally speaking, biotech crops cultivation must be approved on a provincial basis with one exception. The Bt cotton is approved by the Ministry of Agriculture which could be cultivated in three major cotton-producing areas covers various provinces and regions. These cotton producing areas include: the Yangtze River Reaches Area(covering Sichuan Province, Hubei Province, Hunan Province, Jiangxi Province, Zhejiang Province, most part of Jiangsu Province and Chongqing Municipality, Huainan City of Anhui Province, and Nanyang City and Xinyang City of Henan Province); the Yellow River Reaches Area (covering Shandong Province, Henan Province (except Nanyang City), Hebei Province, Beijing City, Tianjin Municipality, Shaanxi Province, and Shanxi Province, Huaibei City of Anhui Province, Xuzhou City of Jiangsu Province), and the Northwestern Inland Area (covering Xinjiang Province, Gansu Province, Ningxia Province, and Inner Mongolia Province).[26]

In spite of the heavy investments on the agricultural biotechnology research that Chinese government has been promoting, there is no genetically modified grains or staple crops have

[23] Concluded from the information provided by the MOA's website < http://www.moa.gov.cn/ztzl/zjyqwgz/spxx/201706/t20170614_5678550.htm> accessed Oct 10, 2017

[24] Biotech Country Facts & Trends—China 2015, Report from International Service for the Acquisition of Agro-biotech Applications (ISAAA) [https://www.isaaa.org/resources/publications/biotech_country_facts_and_trends/download/Facts%20and%20Trends%20-%20China.pdf] last accessed 08 Dec 2016, p41

[25] Joshua E. Lagos and Ma Jie, 'Peoples Republic of China Agricultural Biotechnology Annual 2013' (Global Agricultural Information Network, United States Department of Agriculture, Foreign Agricultural Service 2013 GAIN Report Number: 13033); and the note 19, p41

[26] Andrew Anderson-Sprecher and Ma Jie, 'Peoples Republic of China Agricultural Biotechnology Annual 2014' (Global Agricultural Information Network, United States Department of Agriculture, Foreign Agricultural Service 2014 GAIN Report Number: 14032)

been permitted for commercialization. In 2009, two transgenic crops varieties which are the insect resistant rice and a high-phytase maize both developed by Chinese domestic research institutes obtained the biosafety certificates for food and feed use from the Ministry of Agriculture for the first time. According to the seed variety registration regulation in the Seed Law[27], after obtaining the biosafety certificates, any new seed variety must complete the registration process before commercialization. However, the Ministry of Agriculture did not complete the final step toward the domestic commercialized cultivation before the biosafety certificates expired in 2014.[28] The future of these domestically developed varieties is now unclear.

Even though the information of ongoing biotech research and development is not published and provided by the competent authorities based on the consideration of confidentiality and intellectual property, it can be tell from the publications on approval information by the Ministry of Agriculture, major crops include insect resistant corn, high lysine corn, resistance to pre-harvest germination wheat, and insect resistant soybeans[29] are undergoing field trials which could be at the intermediary experimental staged or the environmental release stage.[30]

As mentioned above, China has heavily invested in biotech research and seed development programmes carried out by government funded research institutes and universities. In July 2008, the State Council approve the 'Special Project on Breeding New Biotech Variety' in 2008 and in the following 12 year a total amount of over 24 billion RMB of funding (the funding came from the national government, local government and companies) had been invested into the project.[31] As an important part of the 'Long and Mid Term National Development Outline

[27] 'Seed Law of the People's Republic of China,' adopted at the 16th Meeting of the National People's Congress Standing Committee on 8 July, 2000, amended at the 17th Meeting of the 12th National People's Congress Standing Committee on 4 November, 2015. Article 22

[28] These two insect-resistant risk varieties and the high phytase corn variety obtained the safety certificates again in Jan 2015.

[29] This information is available on the MOA official website < http://www.moa.gov.cn/ztzl/zjyqwgz/spxx/> (accessed on Oct 09, 2015)

[30] Global Agricultural Information Network (GAIN), Report No.CH15032, Agricultural Biotechnology Annual—China Considering Major Revisions to Biotechnology Regulations (USDA Foreign Agricultural Service, 21 December 2015)

[31] Andrew Anderson-Sprecher and Ma Jie, 'Peoples Republic of China Agricultural Biotechnology Annual 2014' (Global Agricultural Information Network, United States Department of Agriculture, Foreign Agricultural Service 2014 GAIN Report Number: 14032)

for Science and Technology (2006-2020)' , the project focuses on both agricultural biotech crop and biotech animal research and targets to develop varieties with new genetic traits in order to improve the ability of resisting insect, disease, and stress.[32]

On the contrary to the national programmes, the private investment is the biotechnology research is not only very limited but also strictly administrated and controlled. The foreign investment is banned from all the transgenic research and production activities but allowed in the production traditional or hybrid seed in the way of joint capital with Chinese companies control the share.[33]

2.3 The Legal Regime of Agricultural Biotechnology

In order to have a better understanding of how GMOs are regulated in China, it is necessary to have a brief overview of Chinese legal system: the organization and relationship among various laws. There are two aspects of relevance to the GMOs regulation: the horizontal relationship among different laws at the central level and the vertical relationship between national and local laws.

Since China is a unitary state, national laws are superior and override conflicting local laws: in the hierarchy of legal norms, the Constitutional provision regarding environmental protection ranks highest.[34] Second are the laws issued by the National People's Congress, for example,

[32] The Long and Midterm National Development Plan for Science and Technology (2006-2020) http://www.gov.cn/jrzg/2006-02/09/content_183787.htm (Accessed on 10 Nov, 2015)

[33] Andrew Anderson-Sprecher and Ma Jie, 'Peoples Republic of China Agricultural Biotechnology Annual 2014' (Global Agricultural Information Network, United States Department of Agriculture, Foreign Agricultural Service 2014 GAIN Report Number: 14032)

[34] See Ying, Song. "The Chinese environmental lawmaking framework.", Chinese Journal of International Law, Spring 2002 Issue. Constitution of the People's Republic of China, adopted at the 5th Meeting of the 5th National People's Congress and promulgated for implementation by the Proclamation of the National People's Congress on December 4, 1982. Provisions regarding environmental protection including:
Article 9 All mineral resources, waters, forests, mountains, grassland, unreclaimed land, beaches and other natural resources are owned by the state, that is, by the whole people, with the exception of the forests, mountains, grasslands, unreclaimed land and beaches that are owned by collective in accordance with the law. The state ensures the rational use of natural resources and protects rare animals and plants. Appropriation or damaging of natural resources by any organization or individual by whatever means is prohibited.
And Article 26 The state protects and improves the environment in which people live and the ecological environment. It prevents and controls pollution and other public hazards. The state organizes and encourages afforestation and the

the 2014 Environmental Protection Law[35] and the 2000 Fishery Law[36]. The third type will be the administrative laws, often in the form of a regulation issued by the State Council, for example, the 2001 Administrative Regulation on the Safety of Agricultural GMOs[37]. Fourth are the ministerial rules (usually in the form of 'administrative measures') issued by ministries, commissions and administrations or agencies. For example, the 2002 Administrative Measures on the Safety of the Import of Agricultural GMOs[38] by the Ministry of Agriculture.

Within the set of laws that is ranked second, some laws have more general objectives and targets, than others (for example, the "Environmental Protection Law" is more general than the "Marine Environmental Protection Law"). Laws ranked third and fourth often have very specific objectives and targets. With regard to the effect of each rank of legal norms, Article 63 of the 'Administrative Procedural Law'[39] provides that in handling administrative cases, the People's Courts shall in order take the law, administrative rules and regulations and local regulations as the criteria. Local regulations and applicable to those administrative cases within the local administrative region.[40] In comparison, with regard to the legal effect of those administrative rules issued by the ministries, commissions and agencies or by local municipalities, the People's Courts shall refer to them. In case of conflicts among these administrative rules, it is within the discretion of the State Council to make interpretation and decisions. In accordance with the Legislation Law[41], administrative regulations have higher

protection of forests.

[35] Environmental Protection Law of the People's Republic of China. Adopted at the 11th Meeting of the 7th National People's Congress Standing Committee on December 26, 1989, amended at the 8th Meeting of the 12th National People's Congress Standing Committee on April 4, 2014.

[36] Fishery Law of the People's Republic of China. Adopted at the 14th Meeting if the 6th National People' Congress Standing Committee on January 10, 1986, amended at the 18th Meeting of the 9th National People's Congress Standing Committee on October 31, 2000.

[37] A different translation in English is 'Regulation on Administration of Agricultural Genetically Modified Organisms Safety', adopted at the 38th Meeting of the State Council on May 9, 2001, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001, and effective as of the date of promulgation.

[38] 'Administrative Measures on the Safety of the Import of Agricultural Genetically Modified Organisms', promulgated by the Decree No. 9 of the Ministry of Agriculture on January 5, 2001, and amended by the Decree No. 38 of the Ministry of Agriculture on July 1, 2004.

[39] 'Administrative Procedure Law of the People's Republic of China', adopted at the Second Session of the Seventh National People's Congress on April 4, 1989, promulgated by Order No. 16 of the President of the People's Republic of China on April 4, 1989, and effective as of October 1, 1990; amended by the 28th Meeting of the 12th National People's Congress Standing Committee on 27 June, 2016

[40] Administrative Procedure Law, Art. 63.

[41] 'Legislation Law of the People's Republic of China', adopted at the 3rd Meeting of the 9th National People's Congress Standing Committee on March 15, 2000, amended at the 3rd Meeting of the 12th National People's Congress Standing Committee on March 15, 2015

legal authority than local decrees and administrative or local rules.[42]

2.3.1 *Historical evolution of GMO regulation*

The evolution of GMO regulation in China can be divided into two separate periods. The first period began with the 1993 MOST Genetic Engineering Measures and the second period started from the 2001 State Council Regulation and is ongoing.

The regulation of GMOs in China started in 1993 when the formerly State Science and Technology Commission (now has been changed into the Ministry of Science and Technology, hereinafter referred as the MOST) issued the 'Administrative Measures on the Safety of Genetic Engineering' (hereinafter referred as the 1993 MOST GE Measures).[43] An initial legal framework on GMO regulation was then established and the GMOs were regarded as a purely scientific matter. The 1993 MOST GE Measures provided standards and management regime for each stage in the process of genetic engineering including the laboratory operation safety and safety control measures,[44] from research in the laboratory and field experimentation in small scale, and pre-market production testing of the use of transgenic products. The main function of the MOST is to enhance the national research and development of science and technology, the 1993 MOST GE Measures thus designated the MOST as the competent authority of developing and supervising the national administration of genetic engineering[45]. A National Genetic Engineering Safety Committee under the MOST was established to supervise and coordinate overall administration of genetic engineering safety among different government agencies. Later the Ministry of Agriculture (MOA) issued the 'Implementation Measures on the Safety of Agricultural Genetic Engineering[46] (hereinafter referred as the 1996

[42] Ibid. Art 72 regulates that the People's Congress and its Standing Committee at the provincial level, of the municipalities, of the autonomous regions could legislate local regulations based on specific situation and actual demands. The local regulations shall not be conflicted to the Constitutional law, the law and the administrative regulations.

[43] 'Administrative Measures on the Safety of Genetic Engineering', Decree No.17 (1993) of the State Commission of Science and Technology

[44] Ibid. Art 4 and 5.

[45] Ibid. Art 4.

[46] 'Implementation Measures on the Safety of Agricultural Genetic Engineering' Decree No.7 (1996) of the Ministry of Agriculture (MOA Decree 7/1996)

MOA Measures) in 1996 and the State Tobacco Monopoly Administration issued the 'Administrative Measures on the Research and Application of Tobacco Genetic Engineering' [47](hereinafter referred as the 1998 Tobacco Measures) in 1998 to provide more detailed rules on Tobacco genetic engineering research and application. After these three administrative acts were issued, there were some discussions about whether a more comprehensive national law should be promulgated by the National People's Congress within the committees of the Congress, as consistent with Chinese legislative practice. But such an approach was dropped, mainly due to the resistance from the science community. The Congress agreed that the time was not ripe and there was no further legislative action for the GMOs afterwards until the year of 2001.

In May 2001, the State Council issued a new 'Administrative Regulation on the Biosafety of Agricultural GMOs'[48] (hereinafter referred as the 2001 State Council Regulation), which belongs to the third rank in the legal hierarchy. It repealed the 1996 MOA Measures on Agricultural GMOs. There are several points that are noteworthy about this change. To start with, it is a regulation instead of the ministerial administrative measures, which means that it is more comprehensive in nature. Secondly, although the regulation still deals with agricultural GMOs, it was not issued by the Ministry of Agriculture but by the superior authority, the State Council. This change enhanced the legal effect of the act and had institutional implications, which will be discussed later. However, the MOA was still the initiator and drafter of this regulation under the designation of the State Council.

The 2001 State Council Regulation could be seen as the basis of Chinese legislation on agricultural GMOs biosafety. It outlined the basic and comprehensive management system on GMOs from the objectives of laws to the institutions of management. In the Article 3 of the 2001 State Council Regulation, the definition of the agricultural genetically modified organism

[47] 'Administrative Measures on the Research and Application of Tobacco Genetic Engineering', promulgated by the State Tobacco Monopoly Administration on March 26,1998.

[48] 'Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms', adopted at the 38th Meeting of the State Council on May 9, 2001, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001, and effective as of the date of promulgation.

which is "…the subject of the regulation has been provided: the agricultural genetically modified organisms include: animals, plants, microorganisms and their products which genomic structures have been modified by genetic engineering technologies for the use in agricultural production or processing, which mainly include:

1) genetically modified animals, plants (including plant seeds, breeding livestock and poultry, aquatic fry and seeds) and microorganisms;

2) products of genetically modified animals, plants and microorganisms;

3) products directly processed from genetically modified agricultural products;

4) seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary drugs, fertilizers, additives and other products containing ingredients of genetically modified animals, plants and microorganisms or their products."[49]

The regulation also provide the definition of agricultural genetically modified organisms safety, which is "…the protection of human being, animals, plants and microorganisms and the ecological environment against the danger or potential risk arising from agricultural genetically modified organisms.[50] Any activities of research, experiment, production, processing, marketing, import and export related to agricultural genetically modified organisms within the territory of China must conform to the Regulations."[51]

The Article 4 entitles the competent agricultural administrative department of the State Council which is the Ministry of the Agriculture, "is responsible for the nationwide supervision and administration of agricultural genetically modified organisms safety. Also, the competent agricultural administrative departments of local governments at or above the county level are responsible for the supervision and administration of agricultural genetically modified organisms' safety within their respective administrative areas. The competent public health administrative departments of local governments at or above the county level are, in

[49] The 2001 Regulation, Article 3. The English translation of the Regulation is available on the official website of the Ministry of Agriculture, see < http://english.agri.gov.cn//governmentaffairs/lr/st/201301/t20130115_8106.htm> last accessed Oct 27, 2017

[50] Ibid, Art 3.

[51] Ibid, Art 2.

accordance with the relevant provisions of the Food Hygiene Law, responsible for the supervision and administration of the hygiene and safety of genetically modified food within their respective administrative areas."[52]

One of the greatest contribution of the 2001 State Council Regulation is that it establishes an Inter-Ministerial Joint Conference system for GMOs safety administration. The Inter-Ministerial Joint Conference is, according to the Regulation, "composed of responsible persons from the departments of agriculture, science and technology, environmental protection, public health, foreign trade and economic cooperation, inspection and quarantine, and the responsible person from other relevant departments." The conference is in charge of directing and creating China's comprehensive policy on GMO regulations and shall be responsible for the discussion and coordination of major issues involved in the administration of agricultural genetically modified organisms' safety.[53]

Most important part of this regulation is that it defined a full set of institutional system with matter of GMOs safety management. The first will be the class-based administration and evaluation system. The 2001 Regulation institutes a class-based administration and evaluation system for agricultural GMOs safety. Agricultural GMOs are classified into Classes I, II, III and IV according to the extent of their risks to human beings, animals, plants, microorganisms and the ecological environment. To be specific, Class I refers to no or unlikely risk; Class II refers to low risks; Class III refers to medium risks and Class IV refers to high risks. The specific standards for the classification are to be formulated by the competent agricultural administrative department of the State Council which the MOA.[54] Table 3.1 below illustrates the administrative requirements for different classes of GMOs and the in different stages.

[52] Ibid, Art 4.
[53] Ibid, Art 5.
[54] Ibid, Art 6.

Table 2.1 Administrative requirement for GMOs from laboratory research to production[55]

Management Stage	**Safety Class**	**Management System**	**Administration Authority**	**Accepted Authority**	**Authorized Document**
Laboratory Research	Class I, II	n/a	Institutional biosafety committee of agriculture	n/a	n/a
	Class III, IV	Report	Office of biosafety administration of agricultural GMOs (MOA)	Science and Technology Development Centre, MOA	n/a
Field Testing	Class I, II, III, IV	Report	Office of biosafety administration of agricultural GMOs (MOA)	Science and Technology Development Centre, MOA	n/a
Environmental Release Testing	n/a	Examination and Approval	Office of biosafety administration of agricultural GMOs (MOA)	Science and Technology Development Centre, MOA	Approval Documents
Productive Testing	n/a	Examination and Approval	Office of biosafety administration of agricultural GMOs (MOA)	Science and Technology Development Centre, MOA	Approval Documents
Application	n/a	Examination	Office of	Science and	Safety

[55] The detailed requirements are provided by Article 10 to Article 16 of the 2001 Regulation. See also Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p225

for Safety Certificate		and Approval	biosafety administration of agricultural GMOs (MOA)	Technology Development Centre, MOA	Certificate

Secondly, it establishes an evaluation system for agricultural GMOs safety. The competent agricultural administrative department of the State Council is in charge of formulating standards and technical norms for safety evaluation of agricultural genetically modified organisms.[56] The Ministry of Agriculture organizes National Agricultural Biotechnology Committee twice a year to dispose the application of safety evaluation on agricultural GMOs.[57] Thirdly, in the process of production and handling the GMOs products, it establishes a production and marketing licensing institution. A production license and a marketing license shall be obtained from the competent agricultural administrative department of the State Council for the production and marketing by any unit or person intend to produce or market genetically modified seeds, breeding livestock and poultry, or aquatic fry and seeds.[58] The 2001 Regulation also institutes a labeling system for GMOs and "the catalogue of agricultural genetically modified organisms subject to labeling administration shall be determined, adjusted and published by the competent agricultural administrative department of the State Council in consultation with the other relevant departments of the State Council."[59] The labelling requirement will be discussed later with more details. Furthermore, it institutes the application measures[60] and inspection and quarantine measures[61] for importing and exporting agricultural GMOs into/out of the territory of China.

In order to implement this regulation, the MOA subsequently issued the following more detailed ministerial acts. The first one is the 'Administrative Measures on the Safety of the Import of Agricultural GMOs'[62] (hereinafter referred as the 2002 MOA Import Measures), the

[56] Ibid, Art 7.
[57] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009). p 225
[58] Ibid, Art 19 and Art 26.
[59] Ibid, Art 8. The detailed requirements for GMOs labelling will be explained in the following sections.
[60] Ibid, Art 31, Art 32 and Art 33.
[61] Ibid, Art 34 and Art 35.
[62] 'Administrative Measures on the Safety of the Import of Agricultural Genetically Modified Organisms', promulgated by the Decree No. 9 of the Ministry of Agriculture on January 5, 2002, and amended by the Decree No. 38 of the Ministry of

'Administrative Measures on the Labeling of Agricultural GMOs'[63] (hereinafter referred as the 2002 MOA Labeling Measures) and the 'Administrative Measures on the Safety Assessment of Agricultural GMOs'[64] (hereinafter referred as the 2002 MOA Assessment Measures) in July 2002. These measures were supposed to be applicable from March 20 2002, but in fact, the entry into force was postponed till April 20, 2004.[65] On February 20, 2004, the MOA issued Ministerial Communication No. 349, which formally confirmed that the MOA should conduct 'normal' administration in accordance with the 2001 Regulation and three MOA Measures. It means that the 'normal' rules and procedures provided by the four administrative legal documents were applied as from April 20, 2004.

Apart from these specific laws on agricultural GMOs, other laws also have provisions relevant to the GMOs. After promulgation of three Administrative Measures to implement the 2001 State Council Regulation, the Ministry of Agriculture issued a 'Administrative Measures on Examination and Approval of Agricultural Generically Modified Organisms Processing'. [66] This Measure is formulated according to the relevant provisions of 2001 State Council Regulation, for the purpose of intensifying the administration of examination and approval of agricultural genetically modified organisms processing.[67] The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) issued the 'Administrative Measures on the Inspection and Quarantine of the Import and Export of GMO Products'[68] in 2004 (hereinafter referred as the 2004 AQSIQ Inspection Measures).

Another particular administrative measure is noteworthy that the Ministry of Health[69] issued

Agriculture on July 1, 2004.

[63] 'Administrative Measures on the Labeling of Agricultural GMOs' Decree No.10 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 10/2002)

[64] 'Administrative Measures on the Safety Assessment of Agricultural GMOs' Decree No.8 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 8/2002)

[65] Web Commentary "China's Regulation on the Trade of Agricultural Product GMOs", http://www.agri.gov.cn (last accessed Oct 17, 2015). MOA, Communication No. 349 (February 20, 2004), http://www.agri.gov.cn (last accessed October 17, 2015).

[66] 'Administrative Measures on Examination and Approval of Agricultural Generically Modified Organisms Processing', Decree No. 59 (2006) of the Ministry of Agriculture, issued on January 27, 2006 (MOA Decree 59/2006)

[67] Ibid, Art 1.

[68] Adopted at the meeting of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on September 5, 2001, promulgated by Decree No. 62 of the Director-General on May 24, 2004

[69] Formerly the Ministry of Health, in the reforms of 2013 the ministry has been dissolved and its functions integrated into the new agency called the National Health and Family Planning Commission (NHFPC), in 2018 the agency has been changed

the 'Administrative Measures on the GM Food Hygiene'[70] (hereinafter referred to as 2002 MOH GM Food Measures), based on the 'Law of the People's Republic of China on Food Hygiene'[71] (1995) of the National People's Congress. In the past decades, Chinese society has changed in various aspects, the Food Hygiene Law needed to be amended for adapting the current situation. In order to solve the food safety problems which occurred with the social development, the Food Hygiene Law was replace by the new 'Law of the People's Republic of China on Food Safety'[72] in 2009. However, the 2002 MOH GM Food Measures was repealed in 2007. GMO Foodstuffs are now subject to the 2001 State Council Regulation and currently there is no particular and separate legislation regulating GMO foodstuffs.

2.3.2 *Regulatory authorities and their competences*

As described above, the evolution of GMO regulation in China can roughly be divided into two periods: 1993 to 2001 and 2001 to now. It was the MOST that started the regulation of GMOs in China, with the 1993 MOST GE Measures, which covered all the stages and activities of genetic engineering: experiments, trials and industrial production, even though, at the time China was in fact only at the stage of research and development. At that time import or export of GMOs was not a considerable issue either internationally or domestically. The material scope was limited. It was a framework and administrative measures, providing general principles. Other relevant ministries or agencies were allowed to make more detailed rules. In 1996 the MOA and in 1998 the Tobacco Administration issued two relevant measures concerning GMOs within their respective competences. As there was a multi-agency regulatory system, the cooperation and co-ordination among the ministries and agencies was automatic, free from difficulties and without explicit and detailed procedural requirements.

into the National Health Commission (NHC) after the National People's Congress and the Chinese Political Consultative Conference which are convened once a year, usually in spring.

[70] 'Administrative Measures on the GM Food Hygiene', Decree No.28 (2002) of the Ministry of Health, issued on 8 April 2002

[71] 'Law of the People's Republic of China on Food Hygiene', adopted at the 16th Meeting of the 8th National People's Congress Executive Committee on October 31, 1995, abolished at 2009 and be replaced by the 'Law of the People's Republic of China on Food Safety', adopted at the 7th Meeting of the 11th National People's Congress Executive Committee on February 28, 2009

[72] Ibid.

The second period, starting with the 2001 State Council Regulation, made the situation slightly different. The Regulation came from the superior authority, the State Council, but the Regulation expressly delegated the regulatory competence on agricultural GMOs to the MOA. The MOA is responsible for the regulation of research, seeds and crops, field trials, production, environmental release and commercialization, consumer information of labeling on GM food, import and export of GMO agricultural products.[73] It is not responsible for health and safety regulation of GM food and inspection and quarantine of import and export of GMOs. The Ministry of Environmental Protection[74] is responsible for the environmental regulation and for the implementation of the Biodiversity Convention[75] and the Biosafety Protocol[76] in general, but it does not have a significant role in the regulation of agricultural GMOs. Currently, it is still multi-agency regulatory system, but the regulatory competence has been concentrated in the MOA.

The second period of the evolution of GMOs regulation in China shows one unique element regarding to the institutional setting of agricultural GMO biosafety management which is very different from some other countries and the EU with advances system of GMOs biosafety management regime. It is understandable that the policy makers designate the MOA to be in the center role of agricultural biotechnology management since the agricultural affairs are the fundamental duty of the MOA which should be more familiar to and has more expertise on the GMOs than other ministries. Furthermore, the environmental assessment in agricultural production regarding to the pesticide use is also carried out by the MOA as well. It seems the MOA is more than competent to fulfill the job of agricultural biosafety management. However, this system has brought many critics. The opponent argues that the MOA shall not be both the 'judgement' and the 'player' in the biosafety management, this institutional setting might cause

[73] See the 2001 State Council Regulation Art 8, Art 9, Art 19, Art 26, Art 31and Art 39.

[74] Formerly the State Environmental Protection Administration (SEPA), was upgraded to the Ministry of Environmental Protection in 2008; in 2018, the Ministry has been renamed into the Ministry of Ecology and Environment of PRC after the National People's Congress and the Chinese Political Consultative Conference which are convened once a year, usually in spring.

[75] China signed the Convention on Biological Diversity (CBD) in 1992, the Standing Committee of the National People's Congress ratified the Convention. In 1993 the CBD entered into force for China on December 29 of 1993.

[76] The 2000 Biosafety Protocol was adopted on January 29, 2000 in Montreal of Canada and entered into force on September 11, 2003. On August 8, 2000, China signed the Protocol and on April 27, 2005 has approved the Protocol.

lack of enough attention to the environmental risks of GMOs, or even involve potential conflicts of interests because the MOA is primarily responsible for agricultural production, with many biotechnologies developed under MOA's own research system and also, the MOA is the competent authority to formulate the relevant standards and technical norms of agricultural biosafety evaluation.[77]

The Ministry of Agriculture and Rural Affairs (MOA)

In accordance with the 1993 MOST GE Measures, the MOA is responsible for the safety aspects of agricultural GMOs. In fact, agricultural GMOs take a majority part of China's GMO research and development. Medical biotechnology is not included in the agricultural biotechnology. In comparison with the 1996 MOA Measures, the 2001 State Council Regulation gave a more active role and competence to the MOA. The MOA is directly affiliate to the State Council, and the State Council have the responsibility to the MOA to carry out supervision and management of agricultural GMO biosafety.[78] The main responsibility of the MOA includes the formulation of agricultural biotechnology policy, the approval of biotech agricultural crops for import and domestic production. Currently the MOA also take the place of the Ministry of Science and Technology in the management and distribution funding from central government to Chinese institutes and universities for the agricultural biotechnology research and development.[79] In principle, if any rules or institutional arrangements of 1993 MOST GE Measures are in conflict with the 2001 State Council Regulation, the latter will override the former because it is issued by the State Council, not by the MOA that is at the same level of the MOST.

The Inter-Ministerial Joint Conference for Biosafety of Agricultural GMOs is established within the State Council. The responsible person from the seven national level ministries and agencies including the Ministry of Agricultural, the Ministry of Environmental Protection, the

[77] Jikun Huang and Qinfang Wang, 'Biotechnology Policy and Regulation in China', IDS Working Paper 195, Institute of Development Studies 2003 < https://www.ids.ac.uk/files/Wp195.pdf> accessed Oct 17 2014, p12.
[78] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865, 870.
[79] USDA GAIN Annual Report 2014, supra note 2.

General Administration for Quality Supervision, Inspection and Quarantine, the Ministry of Science and Technology, the Ministry of Commerce, the National Development and Reform Commission and the National Health and Family Planning Commission shall participate. The Conference takes place irregularly and the main responsibility of the Conference members are to study, coordinate and decide on important issues concerning the safety of agricultural GMOs.[80] It shall be noticed that the Inter-Ministerial Conference do not actually make decisions on the agricultural biosafety relevant events, the coordination purpose of the Conference is more important when a biotech policy affects multiple ministries.[81]

Within the MOA, a National Agriculture GMO Biosafety Committee is established. This is a national level committee and it consists of 64 experts in the research, production, processing, inspection and quarantine, health and environment of agricultural GMOs.[82] The selection of the member is based on areas of their expertise. These members normally only work in the Committee for part time and they are mostly scientists study in the different discipline including agronomy, biotechnology, plant protection, animal science, microbiology, environmental protection and toxicology. For example, the first Committee was composed of 56 experts/scientific members, 29 of the members are responsible for making recommendation and decisions on GM plants; 9 members are dedicated to examining recombined microorganisms for plants; 12 members for transgenic animals and recombined microorganisms for animals; and 6 members for GM aquatic orgnisms. A few members also have positions within the MOA and other agricultural related government agencies.[83] The competence of MOA covers all the activities concerning agricultural GMOs, including research[84], intermediate trial[85] production and processing[86], marketing[87], imports and exports[88].

[80] See 2001 State Council Regulation Art.5.
[81] USDA GAIN Annual Report 2014.
[82] Ibid, Art 9.
[83] This introduction was referenced from Jikun Huang, Ruifa Hu, Scott Rozelle and Carl Pray, 'Development, Policy and Impacts of Genetically Modified Crops in China: A Comprehensive Review of China's Agricultural Biotechnology Sector'. Paper presented at the workshop held at Villa Bellagio, Bellagio, Italy, June 2005, Science, Technology and Globalization Project. The Committee now consists 64 experts and serve three-year terms, according to the interview with the vice-minister Taolin Zhang on October 8, 2015 http://www.agrogene.cn/info-2855.shtml (accessed on October 10, 2015)
[84] See 2001 State Council Regulation, Art. 9 to Art.12.
[85] Ibid, Art.13 to Art.18.
[86] Ibid, Art. 19 to Art. 25
[87] Ibid, Art. 26 to Art. 30

It seems that the MOA is the single and lead agency responsible for all activities of agricultural GMOs in China. Different ministries or agencies still collaborate on the issue of GMOs, but the MOA could be seen as the most important role being responsible for regulating agricultural GMOs.

The Ministry of Science and Technology (MOST)

Although the MOST was the first government ministry that initiated the regulation of GMOs in China in 1993, it is playing a more indirect role now. According to the 1993 MOST GE Measures, a National Safety Commission on Genetic Engineering was established within the MOST for the overall supervision and coordination of the safety of genetic engineering.[89] What is noteworthy is that the 2001 State Council Regulation does not make any reference to this Commission. Since the early stage of the biosafety management regime was set up in 1990s, whether the MOST or the MOA shall take the dominant position has been a consistent debate. Based on the current situation and the administrative system, Huang pointed out that it is very unlikely that the MOST will be dominate in the biotechnology management unless the government structure be reformed, which is unlikely to be happen in the short term.[90] At present, the MOA is responsible for all activities regarding agricultural GMOs, including imports and exports. Thus, in practice, the MOA has taken over much of the regulating competence of the MOST. The MOST used to in charge of managing and distributing funds from central government to research institutes and universities for the research and development of agricultural transgenic crops, however, since major part of the researches are about the agricultural biotechnology, the MOA has now in charge. It seems like that the MOST has only one role left in GMO regulation, namely to participate in the MOA dominated Inter-Ministerial Joint Meeting and the Agricultural GMO Biosafety Committee.

The Ministry of Ecology and Environment (MEE)

Currently there is no legislation or administrative measure promulgated by the Ministry of

[88] Ibid, Art. 31 to Art. 38
[89] 1993 MOST GE Measure, Art 4.
[90] Jikun Huang and Qingfang wang, supra note 4. 12.

Ecology and Environment (which is used to be named as the Ministry of Environmental Protection) regarding to the agricultural biosafety issues. It was designated by Chinese government to be the leading authority for the negotiation and implementation of the 1992 Biodiversity Convention and the 2000 Biosafety Protocol. The main responsibility of the MEP is environmental administration, however, regarding to the area of biodiversity and biosafety, the role of the MEP is not clearly defined by law. Originally, the MEP was mainly responsible with the matter of pollution, but for the past few years with the increasing environmental awareness, the scope of competence of the MEP has expanded. The 2001 State Council Regulation provides that experts of MEP participate in the Inter-Ministerial Joint Conference for Biosafety of Agricultural GMOs led by the MOA. In the area of testing of biotechnology products, the MEE and its affiliated testing institutes are in charge of testing for environmental safety assessment and developing national and industry standards for biotech testing.[91] The MEE clearly should be responsible for regulating the environmental implication of agricultural GMOs, but with the regulation of almost all activities related to agricultural GMOs in the hands of MOA, there is little left for the MEE.

However, the picture is not yet totally fixed for the MEE or the MOA. It was reported in 2011 that the MEE and the MOST are refining details of a new draft of law on GMOs biosafety including the GMOs food safety to be promulgated by the National People's Congress, which belongs to the second rank.[92] The aim and purpose of this draft law is to ensure the overall biosafety in a wide range of issue areas: agriculture, medicines, trade, and the environment. It is expected that the MEP will have a more significant role in GMOs biosafety management.

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

The AQSIQ set up inspection and quarantine offices nationwide and those offices are directly responsible to the AQSIQ. The main function of the AQSIQ and those offices is to examine and

[91] For example, the Ministry of Environmental Protection issued the 'Guideline for eco-environmental biosafety assessment of Insect-resistant transgenic plants' (HJ 625—2011), become effective on January 1st, 2012.
[92] See < http://scitech.people.com.cn/GB/13653570.html> (accessed on 10 Oct, 2015)

quarantine all the GM products when they entry and exit the Chinese territory. In accordance with the 2001 State Council Regulation, the AQSIQ has issued the 'Administrative Measures on the Inspection and Quarantine of Imports and Exports of GM products'[93], which entered into force on May 24, 2004. This measure regulates the procedure should be taken by the customs when carried out the examination and quarantine of importing and exporting biotech goods.

In general, the job of testing the biotechnology products is jointly carried out by the affiliated testing institutes of the MOA, the AQSIQ and the MEP. The AQSIQ does not testing all the GM products but only the products and foods imported or exported. To be specific, the AQSIQ examines imported products to prevent unapproved biotechnology events, the MOA supervised and conducts the domestic crops assessment and their safety assessment experiments, and the MEP carries out the environmental safety assessments in general. All of the MOA, the AQSIQ and the MEP have developed biotech testing standards both for national testing and industry production testing and the methods adopted in testing is the polymerase chain reaction (PCR) testing methodologies.[94]

The National Health Commission (NHC) (formerly the Ministry of Health, MOH)

The NHC is responsible for the hygiene of food in general. In 1995, the National People's Congress promulgated the "Law of the People's Republic of China on Food Hygiene" (it has been now replaced by the Law of the People's Republic of China on Food Safety in 2009, hereinafter the Food Safety Law[95]). This law conferred the competence of supervision and administration of food hygiene in general to the NHC. Other relevant ministries or agencies are responsible for the administration of food hygiene in as far as this is within their competence.[96]

The role of NHC in GMO food safety administration has changed dramatically in the past decade. First of all, in April 2002 the former MOH issued the 'Administrative Measures on the

[93] 'Administrative Measures on the Inspection and Quarantine of the Import and Export of GMO Products' Adopted at the meeting of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on September 5, 2001, promulgated by Decree No. 62 of the Director-General on May 24, 2004

[94] < http://www.china-cas.org/#>

[95] Supra note 51

[96] Ibid. Art.4

GM Food Hygiene' in accordance with the 1995 "Food Hygiene Law" and the 2001 State Council Regulation. These measures was not the only regulation regarding to the GMO foodstuffs promulgated by the former MOH at the time, but also it defined the leading role of MOH in administration on the GMO food safety and its risk assessment. However it was soon abolished in 2007 when the new 'Administrative Measures on New Resource Food'[97] issued by former MOH took effect. The GMO food was catalogued as a kind of new resource food in these new measures yet the words like "genetically modified organisms food' were not appear anywhere in the measures, it may cause confusion whether the former MOH was still in charge of the GMO food administration. Till the year of 2013, the reformed NHC issued 'Administrative Measures for the Safety Review of New Food Raw Materials'[98], the Article 23 clearly stated that the new food raw materials do not include the genetically modified food.[99] Currently, there is no specific legislation regulating GMO food products and the NHFPC has no more administrative competence with regard to the GMOs.

2.4 Substantive Regulations on Agricultural Biotechnology

The following section is a summary of the relevant substantive rules, standards and procedural requirements of agricultural GMOs in China.

2.4.1 *Regulations on research activities*

The 2001 State Council Regulation provides the legal framework for regulation of GMOs in China. The 2002 MOA Assessment Measures provide detailed procedural and substantive rules for the implementation of the 2001 State Council Regulation with regard to research.

The Regulation covers all the activities of research, field experiment, production, processing,

[97] 'Administrative Measures on New Resource Food', Decree No.56 (2007) of the National Health and Commission, issued on 1 December 2007

[98] 'Administrative Measures for the Safety Review of New Food Raw Materials', Decree No. 1 (2013) of the National Health and Family Planning Commission, issued and come into force on October 1, 2013

[99] Ibid. Art.23

sales, imports and exports of agricultural GMOs within the territory of China.[100] With regard to research, it applies to the research activities conducted by Chinese entities, joint entities and foreign entities[101]. According to the Regulation, in order to ensure the GMOs safety during the process of GMOs research and testing all units engaged in the relevant work GMOs are required to have competent facilities and safety measures commensurate with the safety classes. Furthermore, each unit should establish biosafety groups which will be responsible for the research and testing [102] The biosafety measures should be adequate to deal with the corresponding risk category (explained below) approved by the authority. Before a joint entity and a foreign entity conduct their research and field trial activities in China, they should obtain the approval for their research from the MOA.[103] For research activities in the risk Categories III and IV (medium risk and high risk), the approval from the MOA is required before the beginning of the research work.[104]

On the aspect of risk assessment, a 4-category system was initially provided in the 1993 MOST GE Measures and this system was adopted in the 2001 State Council Regulation. The Measures identified four categories of risk to human beings, animals, plants, microorganism and the ecological environment: Category I - no risk, Category II - low risk, Category III - medium risk and Category IV - high risk.[105] Each ministry or agency should set up its own detailed technical standards and environmental standards for these four categories and submit them to the National Safety Commission of the MOST for its records. Only the research, intermediate trial and industrial production, environmental release and utilization of GMOs falling into Category IV (high risk) were subject to the examination and approval of the National Safety Commission.[106] If the research and intermediate trial created risks of Category III, and risks of industrial production, environmental release and utilization of GMOs would fall into Categories of I to III, they were subject to examination and approval by relevant ministries and

[100] The 2001 State Council Regulation, Art 2.
[101] Ibid, Art 18.
[102] Ibid, Art. 11
[103] Ibid, Art. 18
[104] Ibid, Art. 12
[105] 1993 MOST GE Measures, Art. 6
[106] Ibid, Art. 14, Art. 15 and Art. 16.

agencies at the national level. If the risks of the research and intermediate trial would fall in Category I or II, the executive chief of the research entity (for example, a biotechnology institute) was responsible for the examination and approval (in practice this means that if the executive chief of the research unit is the researcher himself or herself, he or she has the authority to approve his/her own work). The 1993 MOST GE Measures itself did not provide any detailed standard on how to assess the risks. In other words, only the highest risks were subject to the National Safety Commission for approval.

The 1993 MOST GE Measures did not provide tight controls on GMOs. This might be because in 1993, GMO related activities were mainly at their early stage of research and development (public programs such as the "863 Program" were only launched in the late 1980s) and issues involving GM products did not cause direct challenges to the governmental regulation. Another reason for this situation may because that the scope of the overall competence of former the State Science and Technology Commission (now the MOST), responsible for these rules, was to regulate the scientific and technological aspect of GMOs, not the intended use of this science and technology. Sales, imports and exports of GMOs were clearly not within the competence of the Commission and were not mentioned at all in the 1993 MOST GE Measures. Another reason is that imported GMOs and GM products, for example, GM soybeans, did not cause serious concerns at that time; import and export of soybeans were more or less balanced before 1995.

In response to the above concern, the State Council decreed the 2001 State Council Regulation to replace the early 1993 MOST GE Measures. It still uses the four categories of risk assessment created in the 1993 MOST GE Measures, but all agricultural GMO related activities (including sales, imports and exports) of all risk categories are now regulated by the MOA. The 2001 State Council Regulation, however, does not refer to or even mention the 1993 MOST GE Measures or the National Safety Commission established with 1993 Measures. Instead, a Biosafety Committee is established which is responsible for safety evaluation of agricultural GMOs, including Category IV risk of GMOs.

The 2001 State Council Regulation divides up field trials in 3 stages: the intermediate trial, the environmental release and the production trial.[107] After the research activity is completed in the laboratory and moves on to the stage of field trials, the research entity should report to the MOA[108]. When moving on to the next stages of trial, an application should be sent to the MOA that will decide whether or not to approve. After the final stage of field trial (production trial) is completed, the unit engaged in trail may apply for a Biosafety Certificate of Agricultural GMOs from the MOA. According to the 2002 MOA Assessment Measures, the MOA will organize assessment for such certification twice a year. The two deadlines for application are March 31 and September 30. Within two months after receipt of the application, the MOA will decide whether to accept the application or not. Within three months after the acceptance of the application, the MOA shall notify the applicant about the result of the assessment.[109] From 2008, the MOA published an announcement stated that the National Agricultural Biotechnology Committee will conduct appraisal three times a year, the three deadlines for submission of safety evaluation documents respectively are in March, June and November. The Committee will make reply within 45 days after receiving the application.

2.4.2 *Regulation on production and processing*

The production and processing of agricultural GMOs is regulated in the third sector of the 2001 Regulation. A production permit or a production license measure has been introduced.[110] It requires all units or individuals producing GM seeds, GM breeding stock or GM aquatic fry should apply for a Production Permit from the MOA, and fulfill the conditions laid down by other relevant laws and administrative regulations.[111] In addition, according to the Article 19, any production unit or person who apply for the production license of genetically modified seeds, breeding livestock and poultry, and aquatic fry and seeds shall meet the following

[107] 2001 State Council Regulation, Art.13.
[108] Ibid, Art.14
[109] 2002 MOA Assessment Measures, Art.16.
[110] 2001 State Council Regulation, Art 19-Art.25.
[111] Ibid, Art.19 and Art.21.

conditions:

a. having obtained a safety certificate of agricultural genetically modified organisms and passed variety examination;

b. planting or breeding in the designated areas;

c. having adopted appropriate safety administration and precautionary measures and other conditions provided for by the competent agricultural administrative department of the State Council.[112]

They should also establish and keep production documents which include the information of production location, genes and their sources, methods of genetic modification and the whereabouts of the GM seeds, GM breeding stocks and GM aquatic fry.[113]

In addition, any production units or individuals conducting the production or processing of all other kinds of agricultural GMOs should obtain the approval from the MOA or the competent agricultural administrative department at the provincial level.[114] The detailed rules for the application of the approval shall be made by the MOA in due course. After they get the approval, they should periodically report to the local agricultural agencies at the county level the information on production, processing, safety administration and the destination of the product.[115]

2.4.3 *Regulation on marketing*

Pursuant to the 2001 State Council Regulation, units or individuals intending to market GM seeds, GM breeding stock and GM aquatic fry should apply for a Marketing License from the MOA, and fulfill the requirements laid down by other relevant laws and administrative regulations.[116] They should also establish and keep files that contain the information on the

[112] Ibid, Art 19.
[113] Ibid, Art 20.
[114] Ibid, Art.21.
[115] Ibid, Art.23.
[116] Ibid, Art 26.

sources, storage, transportation and sales of the seeds, breeding stock and aquatic fry.[117]

2.4.4 *Regulation on GMOs Labelling*

The 2001 State Council Regulation provides that it is prohibited to import or sell any agricultural GM products listed in the inventory of the 2002 Administrative Measures on the Labeling of Agricultural GMOs without a proper label. The GM label should be made by the unit or individual responsible for the production and packaging.[118] The label should clearly indicate the names of the main raw materials containing GMO ingredients in the product. If there is any special requirement on the scope of sale, the specific scope shall be identified and the product should be sold within that identified scope.[119] Any advertisements of agricultural GMOs should be examined and approved by the MOA before they can be published, broadcasted, set and posted to the public.[120]

More detailed requirements of GMOs labelling are provided by the 2002 MOA Labelling Measures. The Measures require all the approved agricultural GMOs products should be correctly labelled and aiming to prevent unlabeled or mislabeled GMOs products be imported or sale in the territory of China. It also provides that the agricultural agency at or above the county level is responsible for the supervision and administration of the GMOs labelling. The AQSIQ is responsible to check the GM labelling at the port of import.[121] If the labelling on the package is difficult (for example, at the fast food restaurant or retail business), the labelling may be made by special identification on price tag, separate GM tag, or special identification at the outside of the container.[122] The GM labelling should be in Chinese language and the GM labelling of imported agricultural GMOs should be sent to the MOA for approval and to the AQSIQ and Ministry of Commerce for record before it can be used. The time limit for the

[117] Ibid, Art 27.
[118] Ibid, Art.28.
[119] Ibid, Art.29.
[120] Ibid, Art.30.
[121] 2002 MOA Labelling Measures, Art.4.
[122] Ibid, Art.8

examination for GM labelling is 30 days.[123]

Unlike the European Union, Chinese law has not yet provided technical means or standards for GMO detection or a threshold for GM labelling. If any GM content is found by the agricultural agency at or above county level, a label needs to be used. The 2002 MOA Labelling Measures provides three kinds of labels for intentional release to environment. The first way is labelling GMOs and the products containing GMOs ingredient as 'genetically modified XX'. Secondly, the directly processed product of agricultural GMOs should be labeled as 'processed GM XX product' or 'processed from GM XX material'. Finally, if a product if processed from GM material however the GM ingredient of the product is no longer contained or detectable, it should be labeled as 'processed product from agricultural GMOs but the relevant GMOs may not be contained'. Labelling is not the only way available to put the GM products under control, but it is a common way for this kind of product in many countries. For example, both in the EU countries and China adopted mandatory labelling requirements. It is increasingly used by the government for reasons of administration and protection of consumer interests regarding to not only GM products but also to many other agricultural and industrial products in China. In the inventory annexed to the 2002 MOA Labelling Measures, 5 groups of GM products must be labelled before sale and most of them are major agricultural imports. The 5 groups of products which are subject to the mandatory labelling requirement include: Group 1: soybean seeds, soybeans, soybean powder, soybean oil and soybean meal; Group 2, corn seeds, corn, corn oil and corn flour; Group 3, rapeseed for planting, rape seeds, rapeseed oil, rapeseed meal; Group 4, cottonseed; and Group 5, tomato seed, fresh tomato, tomato sauce. This list since it was published in 2002 has not been updated since.

In October 2015, the newly implemented Law on Food Safety (promulgated by the National People's Congress Standing Committee) will incorporated existing regulations on biotechnology labelling into law and it also makes legally mandate GMOs labelling instead of referring to relevant regulations as discussed above. In other words, the 2002 MOA Labelling

[123] Ibid, Art 10, 11, and 12.

Measures requires the labelling of approved agricultural biotech products and prohibit the importation and sale of any unlabelled or mislabeled products. The 2015 Food Safety Law codifies into law existing biotechnology labelling regulations. For example, Article 69 states that producers will pay the penalty if GMOs products are not properly labeled.[124]

In addition to these new labelling requirements, the misleading advertisement have also recently become the subject of controlling measures. In January 2015, the Ministry of the Agriculture released the Notice Concerning Guidance for GMO-related Advertisements, which required the competent agricultural authorities at the provincial level to work with the local commerce authorities as well as the food and drug authorities to strengthen the supervision over advertisements related to GMOs. The Notice explicitly "prohibits the use of 'non-GMO' in advertisements of products made of crops where no genetically modified version has been approved for sale in China or where no genetically modified version exists."[125] Non-GMO labels can be used for products for which genetically modified versions are available, but the labelling must be accurate and cannot use misleading words such as 'healthier' or 'safer'.[126]

2.4.5 *Regulations on imports and exports of agricultural GMOs*

The rules laid down in the 2001 State Council Regulation are applicable to both agricultural GMOs developed in China and abroad. The MOA is responsible for the GMO regulation while the decision on specific import and export of GMOs is made by the Ministry of Commerce (formerly the Ministry of Foreign Trade and Economic Cooperation, MOFTEC).[127] In comparison with the domestic GMOs developed in China, the imported GMOs are subject to a separate and more stringent regulation, mainly provided by the 2002 MOA Import Measures.

[124] Law of Food Safety, Art. 69.
[125] Global Agricultural Information Network (GAIN), Report No.CH15032, Agricultural Biotechnology Annual—China Considering Major Revisions to Biotechnology Regulations (USDA Foreign Agricultural Service, 21 December 2015)
[126] Notice Concerning Guidance for GMO-related Advertisements http://www.moa.gov.cn/ztzl/zjyqwgz/zcfg/201501/t20150122_4346780.htm last accessed 10 December 2016
[127] Zhou Yu (ed.), *The Management Mode and the Regulations on Genetically Modified Food in Worldwide* (Beijing Military Medical Science Press, 2012) 66

For the purpose of research and field trials, the importing entity should apply to the MOA for approval.[128] The unit should possess the application qualification provided by the MOA, the prior corresponding research and field trial already conducted overseas and relevant safety administration and prevention measures. If the overseas companies export GM seeds, breeding stock, aquatic fry, agricultural pesticides, veterinary medicine, fertilizer and additives produced by agricultural GM technology or containing agricultural GM composition to China for the purpose of field trials, they should apply to the MOA for approval. In the application, they should provide information that:

- the proposed use and marketing has been approved by the exporting state or territory;
- scientific experiments in the exporting state or territory show that no harm has been caused to human, animal, micro-organism and eco-system;
- there are relevant safety administration and preventive measures.

After a successful completion of the production trial and safety evaluation, an agricultural GMO Biosafety Certificate will be issued.[129] With the GMO Biosafety Certificate and other relevant approvals, the importing entity or the overseas entity may go on with other procedures of evaluation, registration, quarantine and customs.[130] The time limit for the MOA and the AQSIQ to approve or reject the application for the Biosafety Certificate is 270 days.[131]

According to the 2002 MOA Import Measures, the Measures apply to any one of the three uses of agricultural GMOs, namely research, field trails, and production and processing.[132] For the purpose of research, the importing entity should apply to the MOA for approval with a list of documents. If the import is for the purpose of environmental release and production trial, the GMO Biosafety Certificate is required and the application should be sent to the MOA.[133] Production mainly refers to the import of seeds, breeding stock and aquatic fry for purpose of the production of GMO crops, stocks and fish in China. Before the production starts, the GMO

[128] 2001 State Council Regulation, Art.31.
[129] Ibid, Art.32.
[130] Ibid, Art 32, 33 and 34.
[131] Ibid, Art 36.
[132] 2002 MOA Import Measures, Art.4.
[133] Ibid, Art.5 to Art 8.

Biosafety Certificate is required and other relevant administrative rules also apply.[134] For the purpose of processing, the overseas exporting company should also first apply for the GMO Biosafety Certificate from the MOA.[135] If the imported processing GMO materials contain living GMOs, they should be segregated from other materials and guaranteed that all necessary measures are taken to assure that there is no release into the environment.[136] For the purposes of production and processing, the relevant import contract should only be signed after the GMO Biosafety Certificate is issued.

In comparison with domestic GMOs, the imported GMOs are subject to more stringent control from the stage of research. For the domestic GMOs, the research of below Risk Category III, no report to the MOA is necessary. For research at or above Risk Category III, only report to the MOA is necessary. But for the imported GMOs of whatever risk category, the importing entity should apply to the MOA for import approval. At the stage of field trials, for the domestic GMOs, report to the MOA is necessary when turning to the intermediate trial from the research stage. When turning from intermediate trial to environmental release or production trial, an application for approval from the MOA is required. While for the imported GMOs, no matter of what risk category, an application for approval from the MOA is required. Moreover, an application for approval from the MOA is required when turning from each stage of filed trials to the next stage. At the stage of production, if the overseas companies export GM seeds, breeding stock, aquatic fry, or seeds, or breeding stock, aquatic fry, agricultural pesticides, veterinary medicine, fertilizer and additives produced by agricultural GM technology or containing agricultural GM composition to China for the purpose of production, they should also apply to the MOA for approval. Besides, going through all stages of field trials in China and the Biosafety Certificate are required. For the importing GMOs used as processing materials, the oversea companies should apply for the Biosafety Certificate from the MOA and go through the safety evaluation procedure. If the same oversea company already holding the Biosafety Certificate for the same agricultural GMO, the application for a new Certificate in the

[134] Ibid, Art.11.
[135] Ibid, Art.12.
[136] Ibid, Art.16.

future is simplified. With the importing safety management registration form, a copy of the first Biosafety Certificate and a safety measure plan to be adopted by the oversea company in China, the oversea company may apply for the second Biosafety Certificate.

Export of Chinese agricultural GMOs is not as strictly regulated as import. Only at the request of an importing State, the AQSIQ will examine the products and issue a GMO-Free Certificate.[137] A GMO Biosafety Certificate is not compulsory for exporting Chinese agricultural GMOs.

2.4.6 *Regulations of liability and law enforcement*

The 2001 State Council Regulation delegates the enforcement authority to the MOA and local agricultural agencies at or above the county level. In case of violation of the above procedural and substantive rules, the enforcement measures include inquiry, an order for cessation of the wrongful act, sealing up, detainment, withdrawal of Biosafety Certificate, destruction of the dangerous agricultural GMOs and imposing fines. Most of the penalty provisions are targeting the violation of the administrative procedures, for example, failure to report to the MOA of Categories III and IV field trials.

Article 45 of the 2001 State Council Regulation provides that in the case of illegal production and application of agricultural GMOs without the approval after the production trial, the MOA shall order an immediate stop of the production and impose a fine of no less than RMB 20,000 (about 2,000 GBP) but no more than RMB 100,000 (about 10,000 GBP).[138] Article 50 provides that in case of import of agricultural GMOs without the approval of MOA, the MOA shall order to stop the import and confiscate the imported products and the income gained with the illegal activities. If the illegal income is over RMB 100,000, the MOA shall impose a fine of one to five times of the illegal income. If the illegal income is less than RMB 100,000, the MOA shall impose a fine of no less than RMB 100,000 but no more than RMB 100,000. On the

[137] 2001 State Council Regulation, Art. 37.
[138] The current exchange rate of RMB to GBP is about 10:1, last checked on Nov 2015.

aspect of damage to the environment or to non-GM crops caused by the release of GMOs, nothing is provided. It seems that the MOA administration, backed by penalties provisions, has the highest priority. Biosafety is not given the same amount of attention and is not backed by any provisions in the 2001 State Council Regulation. The logic might be that if all the agricultural GMO procedural requirements are met, biosafety is automatically secured.

In general, the agricultural GMO regulatory system seems complete, containing both substantive and institutional norms, and incorporating international regulatory approaches and techniques, but the real challenge to such a regulatory system is firstly whether China, the largest developing country has the capacity to implement and enforce the rules. Taking into the consideration the highly decentralized and fragmented character of public administration in China, limited administrative resources (both human and financial resources) and strong local protectionism by local governments and other elements, it is not surprising that incidents such as the illegal plantation of GMOs took place. According to the report by Greenpeace, 93 percent of samples taken in 2015 from corn fields in five counties in Liaoning province, part of China's breadbasket, tested positive for GMO contamination.[139] However, there is no genetically modified corn variety has been approved for domestic commercial cultivation in China. The Information Office of MOA claimed on news conference earlier this year that illegal planting of GM crops did happen in some cities, however, the severity was not as bad as above report claimed.[140] China is definitely shall improve the regulatory system and achieve one mode which is suitable and practical to the specific political, economic, social and cultural environment of the regulatory state.

2.5 International Aspect of the GMOs Regulations

Since the late 1970s, China started to participate in international efforts for the protection of environment. China has participated in some most important multilateral environmental

[139] Report from Greenpeace < http://www.greenpeace.org.cn/gecorn2015/> last accessed 9 December 2016
[140] News from the MOA < http://www.moa.gov.cn/zwllm/zwdt/201604/t20160413_5093642.htm> last accessed 13 December 2016.

treaties and bilateral agreement. For example, in 1996 China participated in the Vienna Convention on Nuclear Safety; in 2002, joined the Kyoto Protocol; and in 2009 participated in Copenhagen Accord and so forth. China's domestic environmental lawmaking was actually triggered by its participation in international efforts. The following part of this paper will focus on the international aspect of the China's regulation of agricultural GMOs.

2.5.1 *General overview of China and international treaties*

The relationship between international environmental treaties and domestic law is a matter of constitutional law. There are two major issues involved in this aspect. The first is the incorporation of international treaties into Chinese law. The second is the supremacy of the international treaties. The 1982 Constitution and the 2000 Legislation Law are both silent on these issues.

On the issue of incorporation of international norms into domestic legal system, at least three approaches may be identified. The first one is that an international treaty is directly applicable in China without any subsequent domestic legislative act by the legislature, for example the 1984 UN Convention against Torture. The second is that a subsequent domestic legislative act is made in order to transform international norms into domestic law, for example the 1970 Hague Convention on Hijacking. The third approach, which is most widely adopted recently, especially after the WTO membership, is the revision or annulment of existing domestic laws in order to be in line with China's international legal obligation.

On the issue of supremacy of international law, reference can only be found in national laws. A typical example is Article 46 of the "Environmental Protection Law" (1989), which provides that if an international treaty regarding environmental protection concluded or acceded to by China contains provisions differing from those contained in the laws of China, the provisions of the international treaty shall apply, unless the provisions are those to which China has announced reservations. Therefore, one could conclude that the supremacy of international

treaties is recognized by Chinese law.

2.5.2 *Convention on biological diversity and biosafety protocol*

1992 Convention on Biological Diversity

China signed the Convention on Biological Diversity (CBD) in 1992. In January 1993, the Standing Committee of the National People's Congress ratified the Convention. The CBD entered into force for China on December 29 of 1993. The SEPA was designated as the lead agency for the implementation of the CBD in China. Other ministries and agencies participated in the implementation efforts. On June 13 1994, the China Action Plan for the Protection of Biodiversity was published. In February 1998, the China Research Report of the State of Biodiversity was made public. Later China also published the following documents on biodiversity:

- the Administration of China Natural Reserve,
- China Protection of Biodiversity and Sustainable Use of Wetlands,
- State Report of Convention Implementation,
- China State Framework of Biosafety, etc.

In February 2014, the Coordination Office of the CBD Implementation (belongs to the MEP) published its 5th National report of the implementation progress of the CBD in China. According to the Coordination Office, China made tremendous efforts for the protection of biodiversity. The progress includes the following: establishment of the state coordination framework for the implementation of the CBD, led by the MEP; improvement of the regulatory and enforcement framework; strengthening of the protection of the habitats; improvement of public education and public awareness; and more active collaboration with the international community. On the aspect of challenges, the review identified the following: continuing degradation of the habitats and distinction of species; invasion of alien species; inadequate administrative framework of biosafety; inadequate protection and management of the genetic

resources; urgent need for protection of the biodiversity in the western provinces in China.[141]

2000 Biosafety Protocol

The 2000 Biosafety Protocol was adopted on January 29, 2000 in Montreal of Canada and entered into force on September 11, 2003. On August 8, 2000, China signed the Protocol and on April 27, 2005 has approved the Protocol.[142] The second COP-MOP[143] was held between in 2005 in Montreal, Canada. China participated in this COP-MOP.

After signing the Protocol, it took China about 5 years to ratify. This long delay caused concerns in the National People's Congress and the Political Consultative Conference. The Protocol, in their view, played a positive role in protecting China's biosafety and human health, stabilizing the agricultural production, promoting agricultural exports, ensuring the social stability and improving the living standard of the agricultural community in China. Moreover, the Protocol would help China to build and strengthen its administrative capacity. Therefore, it was in the interest of the country to approve the Protocol. The reason of the failure to ratify the Protocol was the coordination problem among ministries or agencies. However, the Coordination Office emphasized that this should not have become an obstacle to the final approval. National interests were more important than the interests and administration authority of individual ministries or agencies.

It seems that there has been institutional tension between the MOA and the MEE. As it was reviewed earlier in this paper, the current GMO regulatory framework delegated the regulatory authority on agricultural GMOs to the MOA, and as a result, the MEE is marginalized. But the designated agency responsible for the implementation of the CBD in China is the MEP. Therefore, the MEE logically believed that it should be able to regulate all the matters falling within the scope of the CBD, including all matters involving GMOs. As to the current regulatory framework, the MEP considered that it lacked the supervision on relevant basic

[141] The 5th National Report of the Implementation of CBD in China, the Ministry of Environmental Protection, 2014 February. https://www.cbd.int/doc/world/cn/cn-nr-05-zh.pdf (last accessed on December 2, 2015)
[142] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) 163
[143] COP-MOP stands for the Conference of the Parties serving as the meeting of the Parties to the Protocol.

research work and environmental release of GMOs. It claimed that the regulatory framework is not complete and has obvious gaps and is far from being a unified and coherent national supervision and management mechanism. Another argument was that the MOA cannot be both the player and referee at the same time. There is a conflict of interest in the current GMO regulation.

This is neither the first nor the last time that institutional tension affected the effectiveness of policy and law in China. And the regulation of GMOs is not an isolated problem in China, either. It has to be admitted that the regulation of GMOs demands to bring several ministries or agencies in. The complicated issues of GMO regulation (e.g. science, technology, human health, environment, economic, social, and etc.) easily go beyond the scope of competence of a single ministry or agency. Therefore, a workable and efficient regulatory framework has to deal with coordination issues first. It is strongly demanded that the MEE, together with the MOST in particular and other relevant ministries, would draft a new GMO Safety Law to be promulgated by the National People's Congress, which is superior to the State Council regulation.

a. China's overall view of the Protocol

China participated in the negotiation of the Protocol but the position of China was not clearly recorded in the negotiation documents of the Protocol. In general, China shared the position of the 'like-minded group of countries' and supported a strong Protocol.[144] According to the officials of the MEP, the present provisions of the Protocol more or less reflected the position of China, and they claim that early ratification would benefit the protection of biodiversity, eco-system and human health; and would prevent the potential risks caused by the import of GM products and environmental release and commercialization of living modified organisms or LMOs[145] in China. Other advantages of the Protocol are the legitimacy and justification of establishing a GMO regulatory framework in China and the support for capacity building of strengthening of the regulatory framework.

[144] Coordination Office (MEP), Brief Report on the Protection of Biodiversity and the Implementation of the CBD, < http://www.biodiv.gov.cn/lygz/lyjb/index.htm> (last accessed December 2, 2015)

[145] the term used in the Protocol for this group of GMOs, Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The 2001 Regulation of the State Council was issued one year later on May 23 of 2001. The following will show that on certain substantive aspects there are clear connections between these two legal documents.

b. Precautionary approach

The precautionary approach is the cornerstone of the protocol. It inherited the Art 15 of the Rio Declaration on Environment and Development, '…In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'.[146] In other substantive and procedural provisions, the precautionary approach is specified.

As it was mentioned earlier in this paper, the objective of the 2001 State Council Regulation was mainly focused on three aspects: to strengthen the safety management of the agricultural GMOs; to ensure the safety of human health, animal, plant and micro-organism and eco-system; and to promote the research of agricultural GMO technology.[147]

In general, GMO related activities are not banned in China, but the GM seeds, GM crops and GM food are regulated and treated substantially different from the conventionally produced seeds, crops and food. This differentiated treatment (not prohibited by the Biosafety Protocol) is not based on the evidence of actual harm but on the potential uncertainty and risks associated with GMOs. There are several regulatory tools, including safety assessment, Biosafety Certificate, compulsory labeling, import and export control and relevant liability scheme provided by the law. Basically, China adopted the precautionary approach.

[146] The United Nations Conference on Environment and Development, Rio Declaration on Environment and Development. Having met at Rio de Janeiro from 3 to 14 June 1992. Art. 15

[147] 2001 State Council Regulation, Art.1.

c. Advanced Informed Agreement (AIA)

The Protocol created an important procedural requirement for the exporters of LMOs, which is, to seek consent from the importing country (public authority) before the first shipment of LMOs which are meant to be introduced into the environment or for direct use as food or feed for processing. This is the so-called the Advance Informed Agreement (AIA).[148] The importing country (public authority) has 270 days to make a decision on the import request. The decision should be made available to both the exporter and to the Biosafety Clearing-House established under the Protocol.[149]

The 2001 State Council Regulation and the 2002 MOA Import Measures incorporated the same requirements,[150] but the scope of such consent is broader than what was provided in the Protocol. They cover the import of agricultural GMOs for research and experiment, for environmental release or production (e.g. seeds, etc.) and for materials for being processed. The application for export to China shall be made to the MOA and the AQSIQ, which shall, within 270 days of the receipt of the application, make a decision on whether to approve or to reject the application.[151] But before that, the exporter should apply to the MOA for the agricultural GMO Biosafety Certificate and other relevant documents issued by the MOA.[152]

d. Documentation

The Protocol requires bulk shipments of LMO commodities, such as GM corn or GM soybeans that are intended to be used as food, feed for processing, to be accompanied by documentation stating that such shipments "may contain" living modified organisms and are "not intended for intentional introduction into the environment".[153]

As described above, the 2002 MOA Labeling Measures provides three kinds of labels for intentional release to environment. The difference with the Protocol is that the Measures do not

[148] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Art.7-Art.11.
[149] Ibid, Art.12
[150] Chapter 5 of the 2001 State Council Regulation.
[151] 2002 MOA Import Measures, Art.18.
[152] Ibid, Art. 12
[153] Cartagena Protocol, Art.18

use the term “may contain”, but a clear ‘contain’ label.

e. Risk assessment

According to the Protocol, the importer may make the risk assessment or require the exporter to make such assessment.[154]

The MOA issued the Assessment Measures in 2002. The requirement of a risk assessment is not only applied to imported GMOs, but also to domestic GMOs. From what was provided by the Measures, the assessment is to be made on a scientific basis. However it has to be noted that neither the Protocol nor the Measures provided criteria (e.g. GMO threshold) or methods (e.g. PCR or ELISA) used for assessment.

f. Liability

The issue of dispute settlement and liability was not resolved when the protocol was signed. It was left for later the first COP-MOP.[155] By the time when the fist COP-MOP was held in Kuala Lumpur, China has already promulgated one 2001 State Council and three Administrative Measures. The 2001 State Council Regulation and relevant Measures all provided liability and penalty provisions in the form of fines and criminal penalties in case of forged documentation. As it was mentioned earlier, the liability provisions in the Regulation and Measures are targeted to strengthening the GMO administration, however not on the biosafety.

2.6 Conclusion

This chapter gave a general introduction of the regulation of agricultural GMOs in China. As the chapter shows, China embraced agricultural GMO technology with enthusiasm since the middle of 1980s, mainly out of economic and political reasons. Considerable public funds have been invested in this area. As a result, China has become the among the six largest agricultural GMO producers. Based on the consideration of the possible impact that the biotech products

[154] Cartagena Protocol, Article 15 and Annex III
[155] Ibid, Art.27.

might bring to the environment and human health, China, as many other countries and regions in the worldwide pays high attention to the biosafety management, especially on the agricultural sector. In summary, the legislative framework of agricultural biosafety is mainly constituted by the relevant regulations in the Environmental Law, specialized agricultural biosafety regulation, relevant legislation as well as technology norms. Among the others, the core content of the specialized agricultural biosafety includes: the Administrative Regulation on the Biosafety of Agricultural GMOs (2001), the Administrative Measures on the Safety Assessment of Agricultural GMOs (2002), the Administrative Measures on Safety of Import of Agricultural GMOs (2002), the Administrative Measures on Labelling of Agricultural GMOs (2002), the Administrative Measures on the Inspection and Quarantine of the Import and Export of GMOs Products and the Administrative Measures on Examination and Approval of Agricultural GMOs Processing (2006). This series of legislations provided the legal basis to the risk assessment, administrative system, labelling requirements, report system, licensing system, supervision and examination system. Furthermore, the scale of legislative framework also extends to the forestry, food safety, products inspection and quarantine related to the GMOs. In the past decades, this framework has a positive effect on enhancing the biosafety management, regulating import and export order of agricultural transgenic products and supporting the research and development of biotechnology. However, the current situation of the biotechnology development and the national conditions of China has greatly changed and is very different from the time when the biosafety legislative framework was established. The legislative framework is urgently needed improvement to cope with the challenges.

Nowadays Chinese government pay high attention on domestic biotechnology research and development as the recent national policy repeatedly emphasis that biotechnology is a strategic emerging industry. On the other hands, the commercialization of GMOs has been held back and till now there have been no licences for commercial planting transgenic staple crops granted. And Chinese government is also more cautious on importing transgenic crops. For example, in 2014, the MOA announced to delay the approval of one soybean varieties application for the reason of the public concerns. This is the first time the MOA refuses to

approve an import application based on non-scientific reason.[156] Furthermore, the biosafety certificates of Chinese domestically developed biotech rice and corn expired in August 2014 and the MOA did not complete the final approval for commercialization. All the actions taken by the government might look contradictory that supports and invests the biotechnology research strongly yet stalls the approval for commercialization of the domestically developed GM varieties and import of foreign imported GM crops. A comment by the President Xi in September 2015 might explain this confusing situation. He commented that *'…Biotech is a new technology, and a new industry with bright prospect. As a novel issue, biotechnology attracts social disputes and doubts, which is normal. For this issue, I want to emphasize two aspects, one is guaranteeing safety and the second is indigenous innovation. That is, we shall be bold in research, but cautious in commercialization. The industrialization and commercialization of genetically modified crops shall strictly follow the technical procedures provided by Chinese regulations; the industrialization and commercialization of genetically modified crops shall be steady and make sure no problem occurs, and all safety-related factors shall be considered. The research and innovation shall be bold, so we can take the commanding heights in biotechnology, and not let large foreign companies dominate the agricultural biotechnology product market.'*[157]

This is remarks made publicly for the first time by President Xi on biotechnology. These comments affirmed the official support for biotechnology research but with a cautious attitude on the commercialization. In the future, China will continue to pursue the development of agricultural GMOs because such technology is expected to ultimately become the solution to many existing problems of the Chinese agricultural sector, including production efficiency, food security, food safety and environmental protection.

The development of the Chinese regulatory framework for agricultural GMOs was triggered by many considerations, including domestic and international ones. Many competing interests are

[156] USDA Gain Report No. CH14032, p2

[157] Xi Jinping's speech on the Central Conference on Rural Work on December 23, 2013, released in September 2014, the English translation was cited from the USDA Gain Report, 2014 p.3

involved, both internationally and domestically. Internationally speaking, the EU and the US stand for two opposing sides on the regulation of the agricultural GMOs. The EU's precautionary approach is more influential in the design of the whole regulatory framework in China. The US is more influential in forcing China to remove the regulatory obstacles to American GM products into Chinese market. An obvious reason why China chose the EU model is that China, like the EU, is not a major exporter of GM products, but an importer. As an importer, the issues of biosafety and food safety all are currently existing and challenging. If the international rules (the Biosafety Protocol) and foreign rules (the EU model) provide ready and useful models for this purpose, China shall learn the lessons. Domestically speaking, the interests of the biotechnologists, GM crop farmers and the MOA, etc. are prevailing. The interests of other agricultural scientists, non-GM crop farmers and the MEP are neglected. The issue of biosafety is not given the importance it should have. The lawmaker of GM technologies does not seem to pay enough attention on the protection of non-GM crop farmers and taking precautionary measures to reduce the risk of gene pollution, for example. The issue of biosafety is expected to be given proper attention in the future GMO safety law.

As to the characteristics of the GMO regulation in China, the following features may be identified. Firstly, China used legal binding regulations, rather than the voluntary guidelines. Instead of revising the existing regulation, a new regulatory mechanism was created, limited to agricultural GMOs. Secondly, China took a multi-ministry approach so several ministries and agencies are involved in the regulatory framework. Thirdly, with China's accession to the WTO, the decision-making has become more transparent than before; relevant documents and information have been published on official websites. Fourthly, the MOA plays the leading role in this regulatory framework. In theory, biosafety and environmental considerations are considered, but the priority of the MOA is agricultural production. Therefore, a more active role of the MEE is definitely necessary in the GMO regulation. The relevant issues of agricultural GMOs are not only agricultural or economic issues, GMOs should be addressed and regulated in broader context and in the more neutral way.

From the above study on the Chinese governance of GM technology and agricultural GMOs products, it is fair to say that, after decades of efforts, China has established a comparatively thorough legal system on the GMO management from the laboratory research to marketing the final products of this technology. However, in order to streamline the regulatory process of agricultural biotechnology and bring the governance of GM technology into a higher level, further improvement is still needed. The aspects of the Chinese governance regime on GMOs which need to be improved and their shortcomings could be summarized as follows.

(i) First of all, among the current scattered regulations and administrative measures, a comprehensive law on GMOs biosafety is missing from the legal framework which could have made the legal system logically clearer. In order to largely enhanced the legal enforcement, the policy makers might need to consider to simplify the legal organization of the relevant laws, clarify the administrative responsibilities of the different governmental and public agencies involved in het development, licensing and commercialization of GM crops, and thereby made the enforcement of the relevant provisions more straightforward and effective. Moreover, as the development of research on GM technology is rapid and the utility of its products is increasing, the current dominating regulation on GMOs which is the 2001 Regulation on Biosafety of Agricultural Genetically Modified Organisms[158] could be considered as out of date. In respect of effective law enforcement and management, there are gaps and defects exist in the legal framework, for example, the comprehensive traceability measure, the co-existence measures and emergency management measure are absent.

(ii) Secondly, although with the accession to the WTO, the decision-making process on the GMOs issues has become more transparent than before; relevant documents and information could be found on official websites. However, the public participation mechanism is still absent from current Chinese legislation. The current regulations on

[158] Regulation on the Biosafety of Agricultural Genetically Modified Organisms, adopted at the 38th Meeting of the State Council on May 9, 2001, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001, and effective as of the date of promulgation.

GMOs management do not have stipulations or articles relating to public participation in the decision-making process of GMO authorisations or the GMOs safety management. The regulation of biosafety and/or GMOs might be considered as scientific issues which require professional scientific knowledge to understand and evaluate the technical scientific issues to which they give rise. However, it is important that the rights of ordinary citizens to participate in decision making on GM technology are not neglected.

(iii) Finally, the establishment of a regime for establishing liability for damage caused by GM cultivation and appropriate remedies is necessary for protecting and promoting biosafety. This has been ignored in the current GMOs biosafety management system. Environmental liability - and the establishment of remedies – should be one of the most important elements in building a future Chinese system for the governance of biosafety law and GM technology.

These issues will be discussed in more detail in the following chapters, and options for reform considered in the Conclusion.

Chapter 3 Regulatory Regime for Genetically Modified Organisms in the European Union[1]

3.1 Introduction

In the European Union, governments, the media, non-governmental organizations, consumers, and industry associations remain conflicted about the use of agricultural biotechnology. The controversies surrounding the use and cultivation of GMOs in the European Union concern the uncertainty of the safety, possible risks to human health and the environment, and the necessity of it to the society. Acceptance varies widely across countries. The EU produces very few genetically modified (GM) plants, however, with the increasing acceptance of biotechnology around the world by leading agricultural producers, the EU imports millions of tons of GM soybeans and corn products every year, mainly used as a feed ingredient in the livestock and poultry sector.[2] The most recent developments of GMOs legislation include a new directive[3] that allows Member States to ban cultivation of GM crops in their territories for non-scientific reasons and a legislative proposal on allowing Member States to prohibit or restrict the use of GM food and feed on part or all of their territory.[4]

Until the 1990's, the European Union was a leader in research and development of biotech plants. Nowadays, the EU is still active in agricultural biotechnology research however the

[1] This chapter is an updated and largely expanded vision based on the writer's LL.M dissertation, 'A Study on the EU Policy and Regulation of Genetically Modified food and its reference to China', submitted in Sep 2012. The idea and structure is from the work. Some of the references used in the LL.M dissertation have also been quoted in this thesis with updated information and adjustment.

[2] Global Agricultural Information Network (GAIN), EU-28 Agricultural Biotechnology Annual 2016, GAIN Report Number: FR1624 (USDA Foreign Agricultural Service , 12 June 2016) https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf accessed 10 May 2017 p10

[3] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member State to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. [2015] OJ L68/1

[4] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory (COM(2015) 177 final).

research is not likely to leas to commercialization of GM crops in the near future. The EU has multi-level governance arrangements allocating responsibility for decision making on different aspects between the Member States and EU institutions. The effect of this has in practice been to restrict development. As a result of strong regulatory constrains, the commercial cultivation of GM crops is very limited in the EU. The only GM plant cultivated on a large scale commercially is GM corn/maize which is grown on around 130,000 hectares, mostly in Spain, where accounts for 30 percent of the corn area.[5] The EU does not export any GM products but is a major importer of soybeans (around 30 million metric tons per year on average) and corn products (around 7 million metric tons per year on average), mainly used as animal feed in the livestock and poultry sectors. The proportion of GM products in total imports is estimated at around 90 percent for soybeans and less than 25 percent for corn.[6] With the growing adoption of biotechnology around the globe by leading agricultural producers, the EU is getting increasingly isolated internationally, and it is more and more difficult and expensive for EU companies to source non-biotech products.

In the worldwide, the regulatory approaches on the biotechnology research and the use of GMOs that the European Union has applied could be regarded as on an advanced and sophisticated level.[7] However, despite its advanced management regime and the rapid development of the transgenic technology, the general attitude of policy makers and general public to GMOs is still complicated and with a hint of refusal. The reason behind the advanced regulatory approaches and cautious attitude to the GMOs is actually deeply connected to the historical events and the social causes. The following section will introduce the background of the EU regarding to it legislative framework to the GMOs.

[5] GAIN Report Number: FR1624, p11.
[6] Ibid.
[7] Bernd van der Meulen, 'The EU Regulatory Approach to GM Foods' (2007) 16 Kansas Journal of Law and Public Policy 286

3.2 The Moratorium on Authorisation of GMOs in the EU[8]

The cautious attitude on the use of transgenic technology in the agricultural production and food production started almost as the same time as this new technology had been applied and this skepticism intensively increased throughout the period of time from the 1980s to the 1990s. Subsequently, this attitude has soon caused intense political awareness and interest around the issue. Discussions and debates emerged not only about the necessity and safety of the utilization of new technology in foods production and processing as well as their incorporation into the market from the scientific perspective, but also about the role of politics, science, and public concerns and participation in GMOs debate from the social perspective. The GMOs issue could not be simply sorted as merely a scientific issue or merely a social issue, it covers both. The motivation for formulating a legislative framework governing the GMOs in the EU is mainly driven by two factors: the scientific uncertainties of the GMOs based on its nature and the public concerns around the safety issue.[9]

3.2.1 *Previous food safety crises*

The food safety within the European Union is a long-running issue. Nowadays, the European Union enjoys the high reputation regarding to its strict management of food safety management, protection of public health and customer right. However, these achievements were not accomplished in an action. The food safety crises happened in the past and had seriously threatened the public health and the government reputation.[10] The Bovine Spongiform Encephalopathy (BSE) crisis could be seen as the most representative case which caused a reconstruction in the legal and regulatory approaches of the European Union's food law.[11]

[8] For more detailed literature discussing the moratorium on authorization of GMOs in the EU, please see for example, Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar Publishing Limited, 2008), p.2 'Introduction-The EU's moratorium on authorization of GMOs'

[9] D. R. Anderson, "Biotechnology Risk Management: the Case of Genetically Modified Organisms (GMOs)," (2001) 54 (4) CPCU Journal 219

[10] Bernd van der Meulen, P297.

[11] Ibid. In this article it also mentioned other food safety crisis which happened in the past, however, the BSE crisis was considered by the author as 'a catalyst for the recent developments in the field of EU food legislation'. Also see Community Legislation on BSE, *available at* http://ec.europa.eulfoodlfs/bselbseI5_en.pdf Last accessed in Jan 2017

At the early stage when the BSE crises outbroke, the government tried eliminate public concerns by suggesting that the problem was exaggerated by media and the scientific significant was little.[12] For instance, in order to ensure the safety of British beef to the public, the British Minister of Agriculture of the day feed his daughter a hamburger on television to reassure consumers.[13] However, as the fatalities of livestock caused by the BSE increased rapidly and the spread of the disease to human beings, the European citizens lost their trust on the government, the food industry and the scientific data published by the officials. The influence of the BSE crises was not only about risking public's health and caused damages and hazards but also it caused the collapse of EU citizens' confidence to the government with the way that the government and food industries handled of the disease. Just as it was stated in the Phillips Report of the (BSE) crises: '…When on 20 March 1996 the Government announced that BSE had probably been transmitted to humans, the public felt that they had been betrayed. Confidence in government pronouncements about risk was a further casualty of BSE.'[14]

As a consequence of government authorities' failure in handling of the BSE crises, many European citizens and customers lost their trust in reassurance by the government especially in the case of relating to the public health.[15] Therefore, when the biotechnology was used in the agricultural planting and food production, there was no surprise that the European citizens kept skeptical to this new biotechnology and its products—GMO food, 'Frankenstein Food' as branded by the media, as well as the scientific assurances and risk assessment results.[16] In this way, it appears that the strict management regime for the GMOs was a defensive strategy took by the European Union authorities to re-obtain public's trust and re-build the government credibility of the government for the time.[17]

[12] Ibid.

[13] To convince the population that there was nothing wrong with British beef, the Minister of Agriculture, John Gummer, fed his young daughter a hamburger on TV (May 16, 1990 BBC). Text, picture and video available at: < http://news.bbc.co.uk/onthisday/hi/dates/stories/may/16/newsid_2913000/2913807.stm> last accessed in Jan 2017

[14] G. Little, 'BSE and the Regulation of Risk' (2001) 64 Modern Law Review 730

[15] Bernd van der Meulen, p300

[16] It is a dramatic interpretation of GM food, see e.g. Fields of Gold shown by the BBC on 8-9 June 2002 (www.bbc.co.uk/fieldsofgold). Quoted from the article Michael Cardwell, 'The release of genetically modified organisms into the environment: public concerns and regulatory responses' (2002) 4 (3) Environmental Law Review156

[17] Bernd van der Meulen, p297

3.2.2 *The scientific uncertainty of GMOs*

The development and exploitation of GMOs might promise a variety of potential benefits, but also causes possible serious social, economic, and environmental concerns at national, international and global levels.[18] Except the public concerns and fears of the risks involved, the EU regulatory framework on GMOs is also influenced by the scientific uncertainty of GMOs. The public concerns and fears not only caused by the scientific uncertainty of GMOs and the possible risk to human health and the environment, but also caused by media reports with skeptical and nervous atmosphere regarding to implication of GMOs products on the market in the European Union.

However, the risks involved regarding to the GMOs are different from those of food crises which happened in the past because the nature of the GMOs and the former food crises are different. Specifically, the former kind of food risk, for example, the risk of the BSE is "grounded in identifiable and ultimately established risk"[19] which is practically identifiable and preventable. Also, the evaluation of the risk is not really a scientific issue. On the other hand, the risk involved within the GMOs are far more complex and potentially far reaching. Furthermore, the use of transgenic technology in agricultural production and its final products or products are much more uncertain than normal ones. The utilization of GMOs in human history started only a few decades ago however, the certain answer to the safety issue takes experience learned from long-term research and assessment in cultivation and production which might cost time from generation to generation. Despite the British Plain English Campaign awarded Mr. Donald Rumsfeld the prize for the most nonsensical remark made by a public figure to it, his quote actually provided a great explanation of modern society's general concerns to GMOs' risk. He said, "…as we know, there are know knows; there are things we know we know. We also know there are know unknowns; that is to say we know there are some things we do not know. But there are also unknown unknows—the ones we don't know we

[18] M Rosso Grossman, 'Genetically modified crops in the United States: Federal Regulation and State tort liability' (2003) 5 Environmental Law Review 86

[19] Lisa Carson and Robert Lee, 'Consumer sovereignty and the regulatory history of the European market for genetically modified foods' (2005) 7 (3) Environmental Law Review 173

don't know."[20]

From the scientific perspective, the methods used to identify a certain risk include multiple elements: the selected variables, the measures, the samples, the models and causal relationships.[21] The issue of the GMOs is more complex and the identification of its potential risks cannot only rely on short-term observations and a few variables. To what extent the GM technology and its products might impact the human society and the environment is still unclear based on the current scientific knowledge due to the complex nature of the GMOs. Therefore, there is no surprising that the arguments and debates around the issue of scientific uncertainty of GMOs has been ongoing. Furthermore, based on the consideration of the uncertain, unquantifiable and unpredictable nature of GMOs risks, it is reasonable that the Precautionary Principle was designed as the guiding principle of the EU's regulatory framework and penetrates into the whole management regime of GM technology and its products.[22]

3.3 The Regulation Regime of Agricultural GMOs in the EU

The history of regulation on GMOs in the European Union is not long.[23] The regulatory framework of agricultural GMOs in the EU in its initial stage was governed under the governance of the EU's General Food Law[24], and its core content include the Council Directive 90/219/EEC on the contained use of GMOs[25] and Council Directive 90/220/EEC on the deliberate release of GMOs into the environment[26]. The regulatory framework changed its focus from the previous predominantly market-oriented approach to consumer protection by

[20] Donald Rumsdeld: quoted in Rum Remark wins Rumsfeld and Award, 2 December 2003. Source: < http://news.bbc.co.uk/1/hi/3254852.stm > last accessed 24th April, 2017

[21] Karen Morrow, 'Genetically Modified Organisms and Risk', in Luc Bodiguel and Michael Cardwell (eds), *The Regulatory of Genetically Modified Organisms—Comparative Approaches* (Oxford, 2010) p54

[22] Miguel A. Recuerda, 'Administrative Authorizations, Risk and Biotechnology' (2009) 4 EFFL 251. P.252

[23] Michael Cardwell, *The European Model of Agriculture* (OUP, 2004) p.285

[24] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L31/1

[25] Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms [1999] OJ L117/ 1

[26] Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1990] OJ L 117/15

the trigger of the previous food safety crises,[27] This transformation was clearly stated in the Communication *Life Sciences and Biotechnology—a Strategy for Europe*[28] of the European Commission. In the first paragraph, the European Union Commission expressed its opinion that the EU's approaches to GMOs should be:

"[r]ather than passively accepting the advent of the new technology, it was preferable to develop proactive policies to exploit them in a responsible manner, consistent with the European values and standards."[29]

In the process of revising and improving the regulatory framework since 1990s, it could be seen that the European Union is trying to achieve the balance between the interest environmental protection as well as the human health and the valuable benefits to the social and economic development brought by the new technology. It has been concluded that, the purpose of the legislation is to safeguard the protection of health, the transparency of information to the public, and the protection of the environment, all shall not be achieved by sacrificing the chance of development the modern biotechnology sector could offer to the society.[30] Shortly after the release of the Communication, both of the 90/219/EEC Directive and 90/220/EEC were replaced,[31] a series of regulations were formulated and enacted which focused on the GM food and feed safety were adopted and enacted.[32] The Precautionary Principle of EU environmental law is a corner stone of the regulatory approach adopted through these instruments.[33]

[27] Bernd van der Meulen, 'Regulating GM food: three levels, three issues' in Han Somsen (ed), T*he Regulatory Challenge of Biotechnology—Human Genetics, Food and Patents* (Edward Elgar Publishing Limited 2007) p.139

[28] European Commission, *Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: Life Sciences and Biotechnology—a Strategy for Europe* COM (2002) 27 [2002] OJ C55/3

[29] Ibid, para.1

[30] Marine Friant-Perrot, 'The European Union Regulatory for Genetically Modified Organisms and its Integration into Community Food Law and Policy' in Luc Bodiguel and Michael Cardwell (eds), *The Regulatory of Genetically Modified Organisms—Comparative Approaches* (Oxford, 2010) p.80

[31] To be specific, the Directive 90/219/EEC was replaced by the Directive 2009/41; the Directive 90/220/EEC was replaced by the Directive 2001/18/EC.

[32] Specifically, the Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed [2003] OJ L 268/1; and the Regulation No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC [2003] OJ L 268/24

[33] Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms, Preamble(8)

The current EU regulatory framework follows a 'step-by-step' approach which was explicitly stated in the 2001 Directive: "…that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken."[34] There are three steps composing the EU regulatory framework which are the contained use of GMOs, the deliberate release of GMOs into the environment and placing the GMOs on the market including the cultivation and the use of GMOs in food and feed production.[35] Therefore, in order to have a thorough understanding on the system of current EU regulatory framework for GMOs, the following content will firstly study on the guiding principle—the Precautionary Principle and then respectively study on the regulatory regime for each step in the legal framework.

3.3.1 *The precautionary principle in the EU*

The Precautionary Principle, which famously acknowledges the place of scientific uncertainties at the center of decision making procedure, is also an important opportunity to open up space for broader perspectives on the regulation. The precautionary principle provides, at its most basic, that scientific uncertainty does not in itself preclude regulatory action. Depending on the approach which precautionary principle chosen, that regulatory action could be constrained by, for example, the severity or irreversibility of the risk, or by a cost-benefit analysis of regulatory action.[36] The precaution principle is the subject to vastly different interpretations and roles, also it is an important principle of EU law and hence of the regulation on GMOs.

The precautionary principle applies broadly in the EU, to the regulation of environmental protection, human health and safety.[37] The European Court of Justice (ECJ) and the Court of

[34] Ibid, Recital 24.

[35] Hans-Georg Dederer, 'The Challenge of Regulating Genetically Modified Organisms in the European Union: Trends and Issues' in Yumiko Nakanishi (ed.) *Contemporary Issues in Environmental Law: The EU and Japan* (Springer, 2015) p143

[36] See for example *Rio Declaration on Environment and Development* (United Nations Conference on Environment and Development, 1992); and European Commission, *Communication on the Precautionary Principle* COM (2000) 1 final; Regulation 178/2002 Laying Down the General Principles and Requirements of Food Law OJ 2002 L31/1.

[37] Article 191 (ex Article 174 TEC) of the Treaty on the Functioning of the European Union, applies the precautionary

First Instance (CFI) have both had a number of opportunities on which to consider the precautionary principle, and the Commission has published an important Communication on the subject.[38]

In the 1970s, the origin of Precautionary Principle was primarily proposed when the West Germany by the time set up the principle of *Vorsorgeprinzip*, which could also be referred as the principle of 'foreseeability'. [39] In 1992, the Rio Declaration provided the landmark specification for the principle in Principle 15:

"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[40]

In the following year, the concept of the Precautionary Principle was introduced for the first time by the Maastricht Treaty into European Union law. It was provided in the Article 191(2) TFEU (ex 174(2) EC) that:

"Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay…"[41]

The Precautionary Principle then has been gradually adopted into the EU environmental law and regarded as the guidance principle after the Maastricht Treaty. The status of the Precautionary Principle was consolidated by the *Communication on the Precautionary Principle* released by the EU Commission and in the *Communication* the Precautionary

principle to the environmental title of the Treaty.

[38] See European Commission, *Communication on the Precautionary Principle* COM (2000) 1 final

[39] Stuart Bell and Donald McGillivray, *Environmental Law* (7th edn, OUP 2008) p. 64

[40] Rio Declaration on Environment and Development (1992) 31 ILM 874, Principle.15

[41] The Treaty on the Functioning of the European Union Article 191(2)

Principle was designed as a "central plank" of Community policy in 2000.[42] Furthermore, the Court of First Instance described the Precautionary Principle in the subsequent *Artegodan* Judgment as a "general principle of Community law".[43] There is no doubt that in order to prevent the emergence of unpredictable and uncertain risks, the Precautionary Principle is a "safer option" to the policy makers.[44]

In addition to the environmental law in general, the EU General Food Law is a representative example of the Precautionary Principle applied in the EU legislative framework. Article 7 of the General Food Law lays down the Precautionary Principle as one of the general principles of the General food law: "…In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment."[45] Moreover, the EU General Food Law has established the risk analysis system to safeguard on human health, including objective risk assessment and risk management. The risk assessment is based on the existing scientific evidence and knowledge, while the risk management is based on the result of risk assessment and other factors.[46] Due to the accomplishment of comprehensive and thorough protection on public health, the General Food Law explicitly invokes Precautionary Principle:

"…following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk

[42] Veerle Heyvaert, 'Facing the consequences of the precautionary principle in European Community Law' [2006] 31 (2) European Law Review 185. P. 186. Joined cases: Case C-180/96, *United Kingdom v Commission*[1998] E.C.R. I-2265; Case T-199/96, *Laboratoires pharmaceutiques Bergaderm SA & Jean-Jacques Goupil v Commission*[1998] E.C.R. II-2805; for more recent case, Case C-165/08, Commission of the European Communities v Republic of Poland [2008] ECLI:EU:C:2009:473.

[43] Case T-74/00 R *Artegodan GmbH v Commission*[2002] E.C.R. II-4945, para. 184

[44] Miguel A. Recuerda, 'Administrative Authorizations, Risk and Biotechnology' (2009) 4 EFFL 251

[45] Regulation (EC) No 178/2002, Article 7

[46] Helle Tegner Anker and Margaret Rosso Grossman, 'Authorization of Genetically Modified Organisms: Precaution in US and EC Law' (2009) 1 EFFL 3 p8

assessment".[47]

The application of the Precautionary Principle have different effects on the EU' approaches applied for the contained use of GMOs and for the deliberate release GMOs into the environment.[48] The precautionary principle mainly applies to the administrative procedure of the approval of GMOs, the labelling of GMOs and the safeguard clause.[49] The Directive 2001/18 on the deliberate release of GMOs and Regulation 1830/2003 on Traceability and Labelling are also guided under the Precautionary Principle. The Article 1 of Directive 2001/18 on the Deliberate Release of GMOs stated "in accordance with the Precautionary Principle"[50] and Article 4 also stated "…Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs."[51]

It was pointed out by Michael Cardwell that the application of the Precautionary Principle in the Directive 2001/18 could be seen as an illustration of the *Communication on the Precautionary Principle*[52] which released in the year of 2000.[53] He summarized it as "…establishing a common understanding of the factors which would justify the invocation of the precautionary principle and of establishing guidelines for its application based on reasoned and coherent principles."[54] In addition, the *Communication* also suggested that the Precautionary Principle should play a fundamental role in regulating the food law in the EU.[55]

[47] Regulation No.178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, [2002] OJ L 31/1. Article 7(1)

[48] Marine Friant-Perrot, p.81

[49] in respect of 'safeguard clauses', EU directives and regulations often contain safeguard clauses, allowing Member States to take action to respond to problems emerging after authorization. The safeguard clasues used in the field of GMOs is headed in the Deliberate Release Directive and will be discussed in the next section.

[50] Directive 2001/18 Article 1.

[51] Ibid. Article 4

[52] Commission of the E*uropean Communities, Communication From the Commission on the Precautionary Principle* COM (2000) 1 Brussels, 2000

[53] Michael Cardwell,p.146

[54] Ibid.

[55] Ibid.

3.3.2 *The EU legislation for the contained use of GMOs*

Under the process approach of the EU, there is a horizontal approach applied to the contained use of GMOs and deliberate release the GMOs into the environmental, which means all types of GMOs are covered and regulated by two EU directives at their contained use and deliberate release stage. The contained use of GMOs is regulated by the Contained Use Directive (Directive 2009/41) while the deliberate use of GMOs is governed under the Deliberate Release Directive (Directive 2001/18).[56]

The risks exist in each stage related to the operation of GMOs from the laboratory research to use of transgenic technology in food production. One of major risks concerns policy makers is that "micro-organisms, if released into the environment in one Member State in the course of their contained use, may reproduce and spread, crossing national frontiers and thereby affecting other Member States."[57] Therefore the Directive on the contained use of GMOs is the first barrier provided by the EU regulatory framework regarding to the GMOs safety and to prohibit or minimize the chance of risk happening.

The origin of regulating the contained use of GMOs was the Directive 90/219[58] on the contained use of genetically modified micro-organisms which was subsequently amended by Directive 98/81[59] in 1998. The current concept of contained use of GMOs is defined in the Article 2(c) of Directive 2009/41, as "any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, used, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment."[60]

[56] See note 33,p144

[57] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms [2009] OJ L125/75 Preamble (17)

[58] Council Directive 90/219/EEC

[59] Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms[1998] OJ L330/13

[60] Directive 2009/41/EC, Article 2(c)

The Directive 2009/41 provided detailed requirements and procedures for proceeding the risk assessments on contained use of genetically modified micro-organisms which in the contained use facilities, for example, the laboratories or greenhouses, based on the perceived level of hazards of the genetically modified micro-organisms.[61]

Specifically, at the first stage of preventing the possible adverse impact of contained used of GMOs to human health and the environment, it is compulsory for the user to proceed the risk assessment.[62] This procedure of the assessment needs be recorded and kept in file and sent to the competent authority in an appropriate form as a part of the notification procedure or by request.[63] The risk level of the genetically modified micro-organisms will be divided into 4 classifications based result of the risk assessment. The 4 classifications a respectively are: Class 1—activities of no or negligible risk; Class 2—activities of low risk; Class 3—activities of moderate risk; and Class 4—activities of high risk.[64] Furthermore, the Annex IV explicitly lays down the different purposed for utilization of genetically modified micro-organisms in difference risk classification could imposed on.[65]

In addition, according to the Directive 2009/41, the unit or person who carries out the genetically modified micro-organisms research for the first time, need to notify the competent authority in advance by submitting a formal notification or application.[66] The competent authority will process the application differently depending on the classification of the genetically modified micro-organisms use belongs to. Specifically speaking, for the research on the Class 1 genetically modified micro-organisms, the unit or person only need to submit a summary of the risk assessment. Neither the prior consent from the competent authority nor the further notification of the research process is necessary.[67] As the risk of the use of genetically modified micro-organisms increase, the requirement and procedure of notification becomes

[61] Marine Friant-Perrot, p.82
[62] Directive 2009/41/EC. Article 4 (2)
[63] ibid. Article 4 (6)
[64] ibid. Article 4 (3)
[65] ibid. Annex IV
[66] Ibid. Article 6.
[67] Ibid. Article 7 and Annex V, Part A.

more complex and strict accordingly.[68] The strictest requirement and management applies to Class 3 and Class 4 uses of GM micro-organisms. According to the Article 17, each Member State is required to submit an annual summary report to the European Commission on the research programmes carried out on Class 3 and Class 4 use of genetically modified micro-organisms and in every three years, Member States should also submit a summary report on their experience with the Directive.[69]

Therefore, the European Union establishes its safety management procedure on the contained use of GMOs in the research facilities. Since the research activity of the contained used of GMOs is carried out in the laboratory and the risks are considered as controllable, the approval procedure relatively simplified compare to the authorization regime applied to the deliberate release of GMOs into the environment.[70] The following section will study on the EU approaches on managing the deliberate release of GMOs.

3.3.3 *The deliberate release of GMOs into the environment*

The Council Directive 90/220/EC was the first directive on the deliberate release of GMOs in the EU and was replaced by the Directive 2001/18/EC on deliberate release of GMOs (hereafter, the Deliberate Release Directive) which was considered as more 'rigorous' and 'comprehensive'.[71] Based on the Precautionary Principle, the Deliberate Release Directive requires an environmental risk assessment of GMOs to be proceeded before the application for authorization. The explicit reference to the precautionary principle is one of the major changes in this new directive. The Precautionary Principle was invoked in the Article 1 of the Deliberate Release Directive:

"…[i]n accordance with the precautionary principle, the objective of this Directive is to

[68] Marine Friant-Perrot, p.83
[69] Directive 2009/41/EC. Article 17 (1)(2)(3)
[70] Marine Friant-Perrot, P83
[71] Michael Cardwell, p.286

approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment."[72]

The precautionary principle implies that absence of full scientific proof of harm cannot be used to obstruct measures intended to prevent harm.[73] It could be disputable of the way to interpret this in real situations, yet in the Deliberate Release Directive, the precautionary approach is interpreted in the case-by-case approach stated in Article 4:

'Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.'[74]

Moreover, this Deliberate Release Directive sets up a new administrative management regime for both the deliberate release GMOs into the environment and the placing GMOs on the market, as it is stated at Preamble: "no GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use."[75] The two subjects should both follow the step-by-step procedure yet the procedure provided to two subjects are different and respectively stated in the Part B and Part C of the Directive.[76] It also requires each Member State of the European Union to establish appropriate measures on coexistence on the national level to prevent accidental presence of GMOs in other crops and products.[77]

[72] Directive 2001/18/EC Article 1
[73] 1992 Rio Declaration, Principle 15
[74] Directive 2001/18/EC Article 4
[75] Directive 2001/18/EC Preamble 25
[76] Michael Cardwell, p.145
[77] Christopher Rodgers, 'DEFRA's Coexistence Proposals for GM Crops: A Recipe for Confrontation?'(2008) 10 (1) Environmental Law Review 1 p1

In Part B of the directive there are articles about the deliberate release of GMOs for any purpose other than for placing on the market, and it extends beyond just research and development. This part covers experimental release, namely field trails, of GMOs which are used in order to study their performance, behaviour and interaction with outside environmental factors before applying for a market release of GMOs. The Part B also set out an authorization procedure specifically for the transgenic varieties of maize, oilseed rape, and potatoes.[78]

The authorization procedure will be started by the submission of a notification by the applicate which should include the technical information indicated in Annex III of the Deliberate Release Directive and an environmental risk assessment report to the competent authority of the Member State. According to the Annex III, the technical information should cover interactions between the GMOs and the environment, and plans for monitoring, control, waste treatment, and emergency.[79] The competent authorities must make a reply either to authorize or reject the application within 90 days after examine the application.[80] The result of risk assessment submitted by the applicate must clearly states any risk to human health or the environment to the competent authority.[81] In accordance to the Precautionary Principle, in case that there are any modifications or unintended changes of the GMOs which could have adverse consequences and risks to human health and the environment or new information and scientific knowledge becomes available on certain risks, the applicate must, the applicate should immediately measure those risks and revise the measures, even the notification has been examined by the competent authority of a Member State or has received the written consent for that authority.[82] In addition, Member States must make the information of all Part B releases in their territory available to the public, also the European Commission is responsible to inform the public about the information contained in the system of exchange.[83] Therefore, the Member States are

[78] Marine Friant-Perrot, P83
[79] Ibid. In particular, Annex IIIA, paras IV and V
[80] In the stage of examining, the consideration of any observations from other Member States should also be included under the exchange of information procedure established by the Article 11. See Directive 2001/18/EC Article 11 and Article 6(5)
[81] Ibid. Article 10
[82] Ibid. Article 8
[83] Ibid. Article 9 and 11

conferred more considerable powers under the Part B of the Deliberate Release Directive in order to enhance the environmental protection in the territory of the Union.

Part C generally covers articles for marketing authorizations of GMOs to be used on a commercial scale but also GMOs that are imported from non-EU countries and that will be used in the food or feed industries. Part C provides a procedure at the Community level for authorization of GMOs.[84] As Macmaoláin pointed out that, "it is clear from the outset that Directive 2001/18 is largely moulded by a vastly increased consideration for consumer concerns, an input that was largely missing from the provisions of Directive 1990/220."[85] Furthermore, the Part C constitutes the a most rigorous administrated procedural stage with preventive approaches to the application of the GMOs to be placed on the markets and public participation system with high degree.[86]

There are several amendments and improvements between the Directive 90/220 and the current Deliberate Release Directive. First of all, the most significant amendment might be the object of the risk assessment is expanded by the new Directive.[87] According to the Annex II of the Directive, the formerly stated "potential harmful effects" is expanded to include "indirect effects" and "delayed effects".[88] Therefore, the reasonable consideration on the risks and consequences to the economy and society brought by the deliberate release of GMOs into the environment need to be include to the risk assessment.[89] Specifically, the "indirect effects" means "effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interaction with other organisms transfer of genetic material, or changes in use or management"; and "delayed effects" is explained as "effects on human health or the environmental which may not be observed during the period of release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after the termination of the

[84] Marine Friant-Perrot, p.85
[85] C Macmaoláin, *EU Food Law: Protecting Consumers and Health in a Common Market* (Hart Publishing 2007) p.246
[86] Marine Friant-Perrot, p.85
[87] Michael Cardwell, p.147
[88] Directive 2001/18/EC Annex II
[89] Michael Cardwell, p.147

release".[90] Secondly, the Deliberate Release Directive requires the notifier to submit the monitoring reports and any new information on risks to the competent authorities of the Member State and the European Commission.[91] Under the transparency policy, the competent authorities of the Member State and the European Commission must make sure that the results of the monitoring to be available to the public,[92] while under the precautionary principle, the notifier must immediately take the protective measures and report to the competent authority, with further provisions for onward circulation of this information to the European Commission if there is any new information emerges which could have adverse effects to the environment and human health.[93]

Another significant amendment is that the Deliberate Release Directive strengthened the requirements relating to the approval procedure of placing imported GMOs products on the market. To be specific, in case of a GMO product is to be placed on the market for the first time, any importer or manufacture who intends to place an imported GMO on the European Union market must submit a notification to the competent authority of the Member State.[94] Within 90 days of the notification, the competent authority must prepare an assessment report which indicates whether or not the GMO in question should be placed on the market.[95] The assessment report must be then sent to the European Commission and to be forwarded to other competent authorities of Member States. If the prepared report prepared by the competent authority indicates to place the GMO on the market, the European Commission and other Member States have a period of 60 days to make reasoned objections; otherwise, the manufacture and importer will obtain a consent with a maximum duration of 10 years.[96] This 10-years consent was firstly proposed by the Deliberate Release Directive, [97] and the consent could be renewed after the first 10-years consent expires. The renewed consent should not exceed 10 years term in general and in specific cases it could be shortened or extended

[90] Directive 2001/18/EC Annex II
[91] Directive 2001/18/EC, Article 20
[92] Ibid. Article 20(4)
[93] Ibid, Article 20
[94] Ibid, Article 13(1)
[95] Ibid. Article 14(3)
[96] Ibid. Article 15
[97] Michael Cardwell, p.147

accordingly.[98]

In summary, release applications received are of two types depending on their intended purpose. Applications under Part B of the Deliberate Release Directive, for research and development trials, are submitted within the Member State and consent is given at a national level. Applications under Part C are for placing a GMO on the European Union market. Part C applications are initially assessed by one (lead) Member State in Europe which then forwards a summary to the Commission and other Member States for assessment.

To illustrate how this procedure works, let us take the Advisory Committee on Release to the Environment (ACRE) of the UK as an example. The ACRE is an advisory non-departmental public body composed of leading scientists, sponsored by the Department for Environment, Food & Rural Affairs. The Department for Environment, Food & Rural Affairs (Defra) is responsible for the control of the deliberate release of genetically modified agricultural products and for national, EU and international policy on the environmental safety of such products.[99] Defra is the competent authority that implements and enforces the Deliberate Release Directive. Defra provides the secretariat for the Advisory Committee on Releases to the Environment (ACRE).

The ACRE undertakes critical reviews of applications to release GMOs under the UK and European regulatory framework. The main function of ACRE is to give advice to ministers on the risks to human health and the environment from the release of GMOs and on the release of certain non-GM species of plants and animals that are not native to Great Britain. If government grants consent, the committee will also look at any monitoring outcomes and make further assessments if required. To be more specific, the responsibilities of the ACRE are providing advice to government on: issuing consents to release or market GMOs; limitations of consents issued, limitations of consents issued, including monitoring and any amendments needed;

[98] Directive 2001/18/EC Article 17(6)

[99] For further and the latest information, please see the official website of ACRE < https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment>, last accessed on August 7, 2018

issuing feed and costs of enforcing consents; evaluating new research findings and any science-based GM matter; research into risks of GMOs; releasing non-native animals and plants into the environment and regulations for releasing and marketing of GMOs.[100] In reviewing applications, the ACRE gives advice on whether or not the proposed release activities of the application present a significant risk to human health and the environment. The ACRE particularly pays attention to the environmental risk assessment and any risk management and monitoring conditions attached to proposed releases. If these are not sufficient, we indicate what is required to ensure adequate risk management. Further information or clarification on particular points is often requested from applicants.[101]

In the situation that there is an objection raised by a competent authority of Member State or the Commission as regarding the risks of GMOs to human health or to the environment, the Commission should consult with the relevant Scientific Committee(s)[102] which is composed of representatives of the Member States. After the official consultation, the Commission will subsequently submit a draft decision to a Scientific Committee. The procedure for the objections to the placing GMOs and the GMOs products which need to carried out by the Community is provided in the Articles 18 and 30(2).[103]

Thirdly, the Article 23(1), headed 'Safeguard clause', of the Deliberate Release Directive provides that:

"Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific

[100] Source https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment last accessed in May 2017

[101] The Advisory Committee on Release to the Environment Annual Report 2015 < https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/561272/acre-annual-report-2015.pdf> p14 last accessed in May 2017

[102] Directive 2001/18/EC Preambles(53), 'Provision should be made for consultation of the relevant Scientific Committee(s) established by Commission Decision 97/579/EC(7) on matters which are likely to have an impact on human health and/or the environment'; 97/579/EC Commission Decision of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety ; Directive 2001/18/EC, Article 15

[103] ibid Article 18, 30(2)

knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory."[104]

Therefore, the safeguard clause of the authorized consent was limited to the Member States regarding to the new available information emerging in relation to the risks to public health and the environment. Even if the Commission has granted the authorized consent to a GMO product which has been properly notified, any individual Member State still has the right to temporarily prohibited, restrict or impede this GMO product in its territory based on the reasonable consideration according to the safeguard clause.[105] However, at the meantime Article 23 states that "Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive".[106] If such a decision made by an individual Member State, it must immediately inform the Commission and the Commission will make a final decision of whether to continue to permit this prohibition.[107] As Michael Cardwell summarized that the consequences of establishing the new procedure does not only improve the information collected by the European Parliament, it rather seemed to address concerns at the powerful decision-making role of the European Commission which was expressed in the case of *Association Greenpeace France v. Minitère de l'Agriculture et de la Pêche*[108].

Finally, the Deliberate Release Directive provided tightened labelling requirements. According to the Deliberate Release Directive, all GMOs placed on the market as or in products must be properly labelled. To be specific, Article 12(2) provides that the notification should contain a proposal for labelling which complied with the detailed standard stated in Annex IV. The

[104] Ibid, Article 23
[105] Raymond O'Rourke, *European Food Law* (3rd end, Sweet&Maxwell 2005) p.178; see also Directive 2001/18/EC Article 23
[106] Directive 2001/18/EC Article 23
[107] Ibid.
[108] Michael Cardwell, p.147; Case C-6/99 *Association Greenpeace France v. Minitère de l'Agriculture et de la Pêche* [2000] ECR I-1651

Directive also requires that "the words 'his product contains genetically modified organisms' shall appear either on the label or in an accompanying document".[109] This clause could be seen as an interim step for the later regulation regarding to the labelling requirement. The later Regulation 1830/2003 concerning traceability and labelling of GMOs and traceability of food and feed products from GMOs has fully developed and improved the labelling management. In addition, the Regulation 1830/2003 made an exception to the labelling requirement by providing minimal threshold approach which exempt the labelling of products with GMO ingredients lower than 0.9 percent[110] in the case of adventitious or technically unavoidable traces of authorized GMOs. The products which fit the requirement could be placed on the market without labelling.[111] More detailed regulations on GMOs labelling will be discussed later in this chapter.

It is out of doubt that the Deliberate Release Directive greatly augmented the regulatory framework for GMOs in the EU. The Commissioner Byrne appraised the Deliberate Release Directive as "…an important point of departure' to be complemented by "a legislative package".[112] Therefore, the horizontal approach took by the EU in accordance with its process approach governs contained use and deliberate release of GMOs is completed by the Contained Use Directive and the Deliberate Release Directive. The authorization procedure and management regime of the GMOs foods and feeds are not provided in specific by the Deliberate Release Directive,[113] the full legislative package is completed by the Regulation 1829/2003 on Genetically Modified Food and Feed and the Regulation 1830/2003 on Traceability and Labelling.

3.4 The Regulation on GM Food and Feed

In order to protect consumer safety and facilitate customers' choice, the EU legislature established a regulatory framework specifically for GM food and feed which places heavy

[109] Directive 2001/18/EC.Article 12
[110] Ibid, Article 21(3), as amended by Regulation 1830/2003
[111] Ibid, Article 21
[112] MEMO/01/42, Commission Welcomes the Adopting of New Rules for GMOs, Brussels, 16 February 2001
[113] Marine Friant-Perrot, p.87

administrative burdens on both food business operators who deal with GM foods and those who do not.[114]

The first regulation on GMOs in human food and animal feed was the Council Directive 90/220.[115] In order to specifically govern the use of GMOs in food production, the Regulation 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients[116] was enacted in 1997. Subsequently, the European Commission *White Paper on Food Safety* was issued one proposal of it suggested the regulatory framework should adopt legislations on risk assessment, authorization, and labelling regarding to the novel foods with particular reference to GM food and feed and to enhance the authorization procedure provided by the Regulation 258/97.[117] Therefore two new regulations which were the Food and Feed Regulation and Regulation 1830/2003 on traceability and labelling were issued in 2003.

The Regulation on Food and Feed and the Regulation 1830/2003 on labelling and traceability together with the Deliberate Release Directive have contributed to the regulatory framework of the European Union in two main aspects: firstly, a single authorization procedure is provided and secondly the traceability and labelling regime is strengthened. The year of 2003 could be seen as the milestone of the development on regulating the use of GMOs in food and feed production. Thus, the pre-2003 legislative framework and post-2003 legislative framework will be studied separately below.

3.4.1 *The legislative framework before 2003*

The Regulation (EU) No. 258/97 concerning novel foods and novel foods ingredients regulates

[114] Bernd van der Meulen, p.153;
[115] Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms
[116] Regulation No. 258/97 of the European Parliament and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients [1997] OJ L 43/1; please note that the Regulation (EC) 258/97 has now been repealed by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2011 [2015] OJ L327/1
[117] European Commission, *White Paper on Food Safety* COM(1999) 719 final, Brussels 12 January 2000. Annex—Action Plan on Food Safety: Actions 6,50,51 and 52

the GM food while GM feed was partially regulated under the Deliberate Release Directive before the year of 2003. GM food and feed will be discussed separately in the following sections.

Within the meaning of GMOs indicated by Directive 90/220/EC,[118] the Regulation (EC) No.258/97 divided the GM food into two categories. The first category covers food, and food ingredients products from, but no longer containing GMOs; and the second category covers food and food ingredients containing or consisting of GMOs. Generally speaking, food containing GMOs or food produced from GMOs had to fulfill the requirements for all novel foods, which required not present any danger to the consumers; not mislead the consumers; furthermore, the GMO products shall not be differed from the products they intend to replaced, they should be substantially equivalent regarding to the nutrition of the products.[119]

There are different authorization procedures applied to the two categories of GM food. Two possible approaches were provided in the case of food produced from, but not containing GMOs. The first approach is that, under Regulation (EC) No 258/97, the applicant could notify the European Commission of the placing on the market of the product while the product was substantially equivalent to its traditional counterpart[120], then the European Commission was responsible to forward the notification to Member States within 60 days.[121] The substantial equivalence could be established based on either generally recognised scientific evidence and existing scientific knowledge, or on an opinion provided by food assessment institute of a Member State[122]. Secondly, the applicant had to submit a request to the competent authority of the Member State in which the product was to be placed on the market and also the applicant needed to forward a copy of this request to the European Commission. This was also the approach to foods and food ingredients which contain GMOs. In the request, information which

[118] According to Directive 90/220/EC, "a 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".
[119] Regulation (EC) 258/97, Article 3.
[120] Ibid, Article 3(2). Equivalence of the novel food in comparison to its tradition counterpart in terms of: composition, nutritional value, metabolism, intended use, level of undesirable substances contained.
[121] Ibid, Article 5.
[122] Regulation (EC) 258/97, Article 3(4).

demonstrate the product had fulfilled the general criteria had to be included. The general criteria requested the products shall not present a danger to the consumer; mislead the consumer; or, differ from foods or ingredients it intended to replace to the extent that normal consumption would be nutritionally disadvantageous for the consumer.[123]

The submitted notification shall also conclude a summary of detailed labelling rules and complete file of information. After receiving the request from the notifier, the Member State shall ensure a risk assessment to be carried out. It could be done by its competent food assessment institute which needed to be informed to the European Commission, or the Member State could ask the European Commission to designate a competent body of another Member State to carry out the assessment. The responsibility of the European Commission was to provide necessary recommendations from the scientific perspective in order to support the application and preparation of the risk assessment report.[124]

There was a period of three months for the initial risk assessment report to be completed. The report had to indicate whether an additional assessment would be necessary.[125] Then the report would be sent to other Member States through the European. Each Member State had the right to make comments or objection on the report within 60 days and the comments or objections would be circulated to other Member States within this period.[126]

After completing the above procedure, if there was no additional assessment was required and no objections from the Member States were received, the applicant would be informed and receive the consent that the product could be placed on the market. In case that the addition assessment was considered as necessary or any Member State objected the proposal, a further authorization decision would be necessary. Under this situation, the Standing Committee for

[123] Ibid, Article 3(1)

[124] Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council (Text with EEA relevance) (97/618/EC) [1997] OJ L253/1

[125] Regulation(EC) 258/97, Article 6

[126] Regulation (EC) 258/97, Article 5.

Foodstuffs was designed to make the further authorization decision. If no opinion was reached by the Standing Committee for Foodstuff, the European Council would make an authorization decision. The scope pf the authorization needed to be defined in the authorization decision, and the should establish: "1) the conditions of use of the food or ingredient; 2) the designation of the food or ingredient and its specification; and, 3) any specific labelling requirements."[127] Moreover, the authorization decision should also in accordance to the environmental safety requirements for GMOs which provided in Article 10 of Directive 90/220. The applicant would then be informed by the European Commission of the result. Throughout the process, the European Commission had to consult with the Scientific Committee on Foodstuffs regarding to any matter which could possibly bring adverse impact to human health.[128]

According to the labelling requirements, the labels of the GMO product shall indicate the presence of a GM organism and any characteristic which caused the product no longer equivalent to its counterpart product, for example the composition, nutritional value or effects and use of the food. The notification and method must be indicated in the label in the case of such a change in characteristics.[129]

Regulation (EC) No 49/2000[130] provided a labelling threshold of 1% for adventitious presence of GMOs in the product, while Regulation (EC) No 50/2000[131] extended the labelling scope to include additives and flavourings containing GMOs.

The Deliberate Release Directive replaced the Directive 90/220 and regulate all the activities related to the placing products containing or consisting of GMOs on the market. The Deliberate Release Directive does not provide provisions specifically for GM feed therefore the GM feed

[127] Ibid, Article 7.
[128] Ibid, Article 11.
[129] Ibid, Article 8.
[130] Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC [2000] OJ L6/13
[131] Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms [2000] OJ L6/15

was only partially regulated under the Directive. To be specific, if the GMOs are used directly as animal feed they are covered under the Directive and the Directive is applicable to all GMOs; while the animal feed which are proceed from GMO product are not regulated by the Deliberate Release Directive. Before 2003, the specialized authorization procedure for GM feed was absent.[132]

Moreover, a general notification procedure for GMOs being placed on the market has been establish the Deliberate Release Directive. According to the Article 13, the notification must attached with a list of documents including: 1) information required in Annexes III and IV of the Directive; 2) the environmental risk assessment and report; 3) conditions for the placing on the market of the GMO; 4) a proposed period for consent which shall not be exceed 10 years; 5) a monitoring plan; 6) a labelling proposal which must comply with labelling requirements; 7) a proposal of packaging; and, (8) a summary of the complete dossier.[133] This notification must be submitted to the competent authority of the Member State where the GMO is about to be placed on the market for the first time.

Within 90 days after receiving the notification, the competent authority must prepare an assessment report indicating a permission or objection on placing the GMOs in question on the market. The assessment report will be sent to other Member States and the European Commission; and other Member State and the European Commission have 60 days to make comments or objections. In case of outstanding issues, there was a period of 105 days permitted to resolve the issues.[134]

3.4.2 *The legislative framework after 2003*

As it has been discussed above, before the year of 2003 GM food products were generally

[132] European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain) p. 8 <https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_rep-stud_2010_report_eval-gm.pdf > last accessed in May 2017

[133] Ibid. Art. 13(2).

[134] Ibid. Art. 14(2).

regulated as novel foods under Regulation No 258/97. There was no specific authorisation procedure provided for GM animal feeds except the GMOs which directly used as animal feed were covered under the Deliberate Release Directive 2001/18/EC since the Directive is applicable to all GMOs. In order to achieve the ultimate goal of high level of protection of the public health and welfare, the environment and customers' benefits in relation to GM foods and feeds as well as the effective function of the internal market,[135] two regulations were formulated and enacted to specifically deal with the GM foods and feeds in 2003. The first of these, Regulation 1829/2003[136] (also known as the Food and Feed Regulation) provides the general framework for GM food and feed regulations, while the second legislation is the Regulation 1830/2003 (hereafter referred as the Labelling and Traceability Regulation), regulates traceability and labelling[137]. These two regulations replaced and expended the GM provisions laid out in Regulation 258/1997 with the main objectives to achieve higher levels of protection of human and animal health; to encourage the free movement of feed and food in the internal market; and to eliminate differences between authorities in the assessment of GM food and feed to prevent distorted competition.[138]

In general, the Food and Feed Regulation introduced a centralized risk assessment procedure which is arranged by European Food Safety Authority (EFSA), rather than individual Member States; and it operates together with the Labelling and Traceability Regulation which regulates the traceability and labelling of products containing GMOs and their products. The Food and Feed Regulation identifies two categories of GMO products. The first one is GM food and food which contains or consists of GMOs, food produced from or containing ingredients which produced from GMOs and GMOs for food use)[139]; the second category is GM feed and GMOs feed use, feed containing or consisting of GMOs, feed produced from GMOs and GMOs for

[135] Regulation (EC) 1829/2003, preamble (3).
[136] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance) [2003] OJ L268/1
[137] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
[138] Regulation (EC) 1829/2003, Article 1.
[139] Ibid, Article 3.

feed use[140]. In addition, in accordance with previous legislation, GM food has to be examined as safe, not misleading and must not be different from its counterpart origin products to the extent that their normal consumption would be disadvantageous to the consumer.[141] The GM feed is regulated under the same principles. Regarding to the environmental safety, products containing or consisting of GMOs have to be in accordance with the requirements of Deliberate Release Directive.

3.4.3 *The risk assessment*

The regulatory approvals process and risk assessment for GM food and feed comprise a number of steps. An application for authorising a GMO for food or feed uses must be submitted to a national authority. The application under the Food and Feed Regulation must also comply with the requirements set out in Commission Implementing Regulation 503/2013 on applications for authorisation of genetically modified food and feed.[142] It must include: purpose and scope; all relevant data, studies and analysis of the results; monitoring plan; labelling proposal; detection method; and, indication of confidential information. The national authority acknowledges receipt of the application within 14 days. It then sends the application to the EFSA for a risk assessment. EFSA makes the application summary available to the public.[143]

The EFSA core task is to independently assess any possible risks of GM plants to human beings and animal health and the environment. EFSA does not authorize GM products; its role is limited to giving scientific advice. EFSA's panel provides independent scientific advice on the safety of GM plants on the basis of Deliberate Release Directive and derived food or feed on the basis of Food and Feed Regulation. There is a guidance document published by the EFSA and its Panel to provide guidance for the preparation and presentation of applications submitted

[140] Ibid, Article 15

[141] Ibid, Article 4

[142] Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (1)

[143] If the application also covers cultivation, EFSA delegates the environmental risk assessment to an EU Member State which sends EFSA its Environmental Risk Assessment (ERA) report.

within the framework of the Food and Feed Regulation and the Deliberate Release Directive. This document therefore covers the full risk assessment of GM plants and derived food and feed.[144]

According to the Food and Feed Regulation, GM food and feed can only be placed on the market after the authorisation. To obtain the authorization, an application must be sent to a competent authority of the Member State which the applicants choose, the application should generally include the following documents: 1) name and address of the applicant; 2) the designation of the food and its specification (including events used); 3) information to demonstrate compliance with Annex I of the Cartagena Protocol; 4) a detailed description of the method of production and manufacturing; 5) copies of studies which demonstrate safety, that the product does not mislead the consumer and does not differ from food it is intended to replace; 6) either analysis supported by data to show that the characteristics of the product are not different from its non-GM counterpart, or a proposal for labelling; 7) either a reasoned statement that the food does not give rise to any ethical or religious concerns, or a suitable proposal for labelling; 8) the conditions for placing the product on the market; 9) methods for the detection, sampling and identification of the GM event; 10) positive and negative control samples of the food to be used for control purposes, plus information as to where the reference material can be accessed; 11) a proposal for post-market monitoring regarding the use of the food for human consumption (where appropriate); 12) a summary of the dossier.[145] In case of the GMOs and food containing or consisting of GMOs, the following documents should also be submitted accompanied to the application: a complete technical dossier related to the release into the environment of GMOs (as laid down in Annexes III and IV of the Deliberate Release Directive); and a monitoring plan for environmental effects (as provided in Annex VII of the Deliberate Release Directive).[146]

[144] EFSA Guidance document for the risk assessment of genetically modified plants and derived food and feed by the Scientific Panel on Genetically Modified Organisms (2006) < http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2006.99/epdf> last accessed in May 2017

[145] Regulation (EC) No. 1829/2003 Article 5(3) The documents listed here relate to food, those for feed are similar.

[146] Regulation (EC) No. 1829/2003 Art.5(5)

The national competent authority must forward the application to EFSA after receiving, and the EFSA must forward the application to the European Commission and Member States in turn. Within 6 months, the EFSA shall provide an opinion based on the assessment to the completeness of the dossier if it is considered as valid.[147] The EFSA could reasonably extend the time line if the supplementary information which shall be prepared and provided by the applicant is considered as necessary.[148]

The Food and Feed law provided a series of processes for the EFSA to take while it prepares the opinion. EFSA should firstly examine whether the submitted documents are in accordance with the guidance document provided by the EFSA for the risk assessment of GM plants and derived food and feed, and it should fulfill the general requirements for GM food. Secondly, during a three-months period, the EFSA shall ask the Member States for their voluntary comments on the dossier. Thirdly, the EFSA may designate a food assessment body of a Member State to carry out a safety assessment. Following this, the EFSA may ask a competent authority of a Member State to provide an environmental risk assessment. In case of the applications for GMOs cultivation, this process is compulsory. Moreover, the EFSA must send to the relevant community reference laboratories the samples and methods for detection to have a further assessment. Finally, the EFSA is obliged to examine the scientific data in order to ensure the GMOs food and its conventional non-GM counterpart is characteristically same.[149]

The final opinion shall in accordance with Articles 6 and Article 18 of the Food and Feed Regulation and a number of annexes and it must when complete be sent to the European Commission, the Member States and the applicant. In accordance to the public participation, the EFSA will publish the opinion on its official website and the specific arrangements for the public to comments on will be provided on the European Commission website. The public

[147] Ibid, Article 6

[148] European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain) <https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_rep-stud_2010_report_eval-gm.pdf > p12 last accessed in May 2017

[149] Regulation (EC) No. 1829/2003 Article 6(3)

comments and responses will be collected during a 30-days period.[150] Moreover, according to the Food and Feed Regulation, the applicant could ask the European Commission to delete the confidential information in relation to the intellectual property and personal data from the publicly published opinion for appropriate justification, for example, if the data is disclosed to the public, the competitivity of the applicant will be seriously harmed.[151]

3.4.4 *The single authorization procedure*

The single authorization procedure is one of the great contributions provided by the Food and Feed Regulation. The procedure is applicable to all genetically modified food and feed, including the food and feed produced from GMOs and consisting of GMOs.[152] The single authorization procedure conducted under the so-called 'one door—one key' principle at the European Union level which is applicable to both the GM food and GM food for industrial uses.[153] Furthermore, for the GMOs and GM products which are not intended to enter the food chain, the applicant can do the application on the basis of Part C of the Deliberate Release Directive; for GMOs and GM products are the food uses the application is made on basis of the Food and Feed Regulation.[154]

Before the GM food to be placed on the market, the applicant must submit an application to the competent authority of the Member State where the product is expected to be placed on the market.[155] Once they receive the application, the competent authority at the national level is obliged to forward the application together with the supplementary information provided by the applicant to the EFSA[156]. The food and feed must be examined and proved to not have adverse effects on human health, animal health, or the environment[157]. The EFSA shall then

[150] Ibid, Article 6(6)
[151] Ibid, Article 6(7)
[152] Regulation 1829/2003 Article 3
[153] Bernd van der Meulen, 2007 p142
[154] Marine Friant-Perrot p.90
[155] Regulation 1829/2003 Article 5
[156] The required information being set out in Article 5 (3) of the Food and Feed Regulation in the case of GM food and Article 17(3) in the case of GM feed
[157] Regulation 1829/2003 Article 4(1)(a) and 16(1)(a)

immediately forward the application and any supplementary information to the European Commission and other Member States, and a summary of the application must be made available for public comments.[158] The Deliberate Release Directive also requires a compulsory risk assessment regarding environmental protection.[159]

The European Commission needs to submit an initial decision to the Standing Committee on the Food Chain and Animal Health within three months of receiving the complete opinion prepared by the EFSA. This initial decision shall be in accordance with the opinion of EFSA, provisions in the EU law and any other legitimate factors. The European Commission shall apply an explanation in case the draft decision differs from EFSA's opinion. The Standing Committee on the Food Chain and Animal Health will the prepare an opinion on the initial draft of the European Commission indicating whether or not propose the authorisation. The European Commission will adopt the draft decision in case that qualified majority in favour is achieved; otherwise, the draft decision must be sent to the Council by the European Commission and the European Parliament shall be informed. Within three months, the Council shall response by qualified majority. If the qualified majority of Council opposes the decision, the European Commission could response by resubmitting the original draft decision; submitting an amended draft decision; or providing a legislative proposal. In case of no qualified majority in favour or object is obtained (including the case where the Council has not acted within three months), the decision must be adopted by the European Commission according to the Article 5(6) of the comitology decision process[160].

After any GMOs food and feed to be placed on the market, the authorization holder should fulfil the obligation as one of the condition of the authorization which is to submit the monitoring reports to the European Commission and if there is any new scientific evidence or information which could impact the original risk assessment on the use of GMOs in food and feed

[158] Ibid. Article 5(2)(b) and 17(2)(b)
[159] Ibid. Article 6(4) and 18(4)
[160] The comitology procedure is a horizontal decision making tool set out in Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC; European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain) p.14

production, authorization holder must alter the European Commission.[161] In case when the authorized GMOs products is proved by scientific evidence to be risky to human and animal health, or the environment safety, the Member State could take interim protective measures autonomously if the European Commission fails to take actions on time after being officially informed.[162] In addition, the period of the validity for the authorisation is 10 years which is renewable as appropriate. The application for renewal must be made no later than one year before the initial authorisation expires. The documents need to be submitted for the renewal must include: a copy of the original authorisation; a report on the results of monitoring (if specified in the original authorisation); any other new information relating to the evaluation of safety and risks to the consumer and environment; and, a proposal for amending or complementing the conditions of the original authorisation (where appropriate). Except the required documents are different, the decision procedure and timeline are identical as the origin authorisations.[163]

The Regulation on Food and Feed also enhanced the transparency of information and protection of customers' interests by informing and consulting the public. Therefore, the public is able to reach the information including the applications, supplementary information provided by the applicant, the EFSA's opinion, monitoring reports.[164] Nevertheless, the customers' right to know and right to choose is more directly protection and more effectively assured by the Regulation 1830/2003 on Traceability and Labelling.[165]

3.4.5 *Traceability and labelling regime*

The function of the traceability and labelling regime could be concluded as "to allow consumers to be informed of the history of the food concerned (such as the ingredients and additives used)

[161] Ibid. Article 9 and 21
[162] See Regulation No.178/2000 Article 53 and 54
[163] European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain) p.14
[164] Ibid. Article 6(7), 18(7) and 29
[165] Marine Friant-Perrot, p.89

and, thereby, to follow their preferences when choosing what to eat."[166] The Traceability and Labelling Regulation contributed great improvement to the management system of GMOs and also consolidated and extended the regulatory framework in the European Union.[167] It established a harmonised framework at the Union level for tracing and identifying GMOs, GMO food products and feed and covered all stages of through the production and distribution chains.[168] The Regulation is applicable to all GMOs placed on the market including: products consisting of, or containing GMOs, placed on the market in accordance with the Union legislation; food produced from GMOs, placed on the market in accordance with the Union legislation; and animal feed produced from GMOs, placed on the market in accordance with the Union legislation.[169]

Traceability

The general requirements of the traceability regulated under the General Food Law[170] that all food, animal feed, food-producing animals, and any other substance intended or expected to be incorporated into a food or feed shall be traceable at all stages of production, processing and distribution.[171] In other words, any person who supply food, feed, food-producing animal, or any substance intended or expected to be incorporated into a food or feed and the business operator who has been supplied to, must identify each other. The system and procedures shall be recorded and the related information shall be available to the competent authorities. The Traceability and Labelling Regulation provided more specific provision for the GMO food and feed to be placed on the market.

The Traceability and Labelling Regulation defines its objectives in the Article 1 as: "facilitating accurate labelling; monitoring the effects on the environment and, where appropriate, on health;

[166] ibid
[167] Michael Cardwell, *The European Model of Agriculture* (OUP, 2004) p.150
[168] Lisa Carson and Robert Lee, 'Consumer sovereignty and the regulatory history of the European market for genetically modified foods' (2005) 7 (3) Environmental Law Review 173 p.180
[169] Directive 1830/2003 Preamble (11)
[170] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
[171] Regulation (EC) No 178/2002, Art. 18

and implementing appropriate risk management measures including, if necessary, withdrawal of products. "[172] It defines traceability of GMOs as "the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market though the production and distribution chains."[173] This traceability regime is also generally called as 'from farm to fork' regime. The Traceability and Labelling Regulation also requires a paper trail for each GM food and feed to ensure traceability internally.

At the first stage of placing a product consisting of or containing GMOs on the market, the business operators who supply the GMO product must record in file of information which indicate that the product contains or consists of GMOs and provide the unique indentifier(s) assigned to those GMOs products. The file will be sent to the operator receiving the product. At every following stage, the same information must be passed on.[174]

In 2004, the European Commission devised a system of unique identifiers to be assigned to each GMOs and promulgated the Regulation (EC) No 65/2004 to establish this new system.[175] The Annex of this regulation prescribes the format of the identifier. The function of the unique identifier is that in any stage of the GMO product to be placed on the market from production to distribution, the information of the former supplier of the product and the next operator of the product (on step up and one step down) could be tracked through the information recorded in identifier. To the GMOs, the format of unique identifier is created by the Organization for Economic Cooperation and Development and it has been used for its Bio-Track product database and the Biosafety Clearing House.[176] The European Commission requires a document accompanied to each GMOs food and feed or GMOs for processing to indicate each GMOs ingredient the product concerns.[177] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity in Article 18(2) provides specific requirements for those accompanied

[172] Regulation (EC) No. 1830/2003
[173] Regulation (EC) No. 1830/2003, Art.3
[174] Ibid. Art. 4(1) and 4(2)
[175] Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms [2004] OJ L10/5
[176] Regulation (EC) 65/2004, Preamble.
[177] Ibid, Art. 2.

document of GMOs food and feed.[178]

The Commission requires the applicant must develop the unique identifier for each GMO food and feed as the condition in the authorization decision[179] and it shall be recorded in the relevant register.[180] The Commission shall ensure the unique identifier and relevant information to be forwarded to the Biosafety Clearing-House as soon as possible.[181]

As noted above, the unique identifier system was introduced in 2004 by the Regulation 65/2004, therefore for the GMOs product was granted to entry into the market before the Regulation 65/2004 would not have the unique identifier. Under this situation, the consent holders or the competent authority is obliged to consult with the Organization for Economic Cooperation and Development BioTrack product database and the Biosafety Clearing-House to affirm if a unique identifier has been created for that GMO product. [182] In case that GMO product has a unique identifier, the information shall be notified to the European Commission; for the GMO product has no unique identifier, the consent holder of the origin application and competent authority shall must develop one for that GMO. And the consent hold must inform the Commission about the details of the identifier within 90 days after the Regulation 65/2004 took effect.[183]

Labelling

The informed choice in one of the principles of European General Food Law and has been prescribed in the Article 8 that "…food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consumer. It shall aim at the prevention of: (a) fraudulent or deceptive practices; (b) the adulteration of food; and (c) any other practices which may mislead the consumer".[184]

[178] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.140
[179] Ibid, Art 3(a)
[180] Ibid, Art 3(c), 5(3)
[181] Ibid, Art 5(4)
[182] Ibid, Art 4.
[183] Ibid, Art 6.
[184] General Food Law, Regulation 178/2002, Art. 8

The Traceability and Labelling Regulation follows a similar authorization procedure applied to the food labelling only limits the objective to the scope of food and food ingredients consisting of, or produced from, GMOs. The Traceability and Labelling states that the labelling section shall apply to "foods which are to be delivered as such to the final consumer or mass caterers in the Community and which (a) contain or consist of GMOs; or (b) are produced from or contain the ingredients produced from GMOs."[185] Labels do not have to conclude of information on the use of GM processing aids and for the animal products, whether or not the animal was fed by GM feed does not need to be mentioned on the label.[186]

Regarding to the GM food, the customers will be able to be informed through the labels that the use of GMOs in the production of the food products they purchase in accordance with the principle of informed choice. Therefore, the Article 13 of the Food and Feed Regulation regulated that "the words 'genetically modified' or 'produced from genetically modified [name of the ingredient]" shall appear in the list of ingredients'.[187] These requirements have been further developed in Article 4 of the Traceability and Labelling Regulation that operators shall ensure that: " a)for pre-package products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified (name of organisms)' shall appear on a label; b) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified (name of organisms(s))' shall appear on, or in connection with, the display of the product."[188]

These labelling requirements apply to all products produced from GMOs including highly refined products with a few exceptions. The labeling requirement does not apply GMOs foods or feeds containing material which contains, consists of, or is produced from GMOs in a

[185] Regulation (EC) No. 1830/2003, Art. 12(1)
[186] Or generally speaking, processing aids do not need to be labeled. See Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [2000] OJ L109/32 at Art. 6(4)
[187] Regulation (EC) No. 1829/2003, Art 13
[188] Regulation (EC) No. 1830/2003, Art 4

proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.[189] The burden of proof is on industry regarding to "establish that the presence of this material is adventitious or technically unavoidable, operators must be in position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material."[190] It means in the whole production chain, the GM food production must be completely segregated from the conventional food production.

3.4.6 *The main changes between pre-2003 and post-2003 legislative framework*

The year of 2003 could be seen as milestone in the development of EU's legislation on GM food and feed. There are great changes and improvement contributed by the two regulations enacted in 2003. To start with, the GM food and feed were regulated in a single and specialized regulatory framework. Before 2003 the GM food was regulated as novel food, the feed which consist of or contains GMOs was generally regulated under the Deliberate Release Directive while the feed directly produced from GMOs was not covered by the legislation for GMOs.[191] Secondly, EU completed the centralized authorization procedure for GM food and feed which under the former system the EU was only partly involved in the procedure. If the result of the assessment which was carried out by one competent authority of one Member State granted the GM food and feed to be placed on the market, and within certain period of time there was no comments received from the European Commission or other Member States, the application would be approved. However, based on the centralized authorization procedure, the European Commission is involved in the whole process of every single case.[192] Moreover, the role of the EFSA in the assessment and evaluation was greatly enhanced. Before 2003, the competent authority of one Member State was in charge of processing the scientific evaluation. In case the

[189] Regulation (EC) No 1829/2003, Art 12(2) and Art 24(2). In case of a GMO that has not yet been authorized, a presence of 5% maximum is considered not to constitute an infringement provided that this GMO has benefited from a favourable opinion from the Community Scientific Committee or the European Food Safety Authority before the date of application of Regulation (EC) 1829/2003, Art 47.

[190] Regulation (EC) No 1829/2003, Art 12(3).

[191] European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain) p.15

[192] Ibid.

Member States objected, the scientific evaluation would have to be carried out by the Scientific Committee for Food of the European Union. After 2003 the EFSA was designed to independently complete all the scientific assessments.[193]

Furthermore, the labelling requirements of GM food product was used to be provided by the Regulation (EC) No 1139/98 [194] and Regulation (EC) No 49/2000 [195] while labelling requirement for GM feed or for food and feed produced from GMOs was absent.[196] The fourth main development after 2003 is that the labelling requirements have been systematized and applicable to all food and feed consisting, containing of or produced from GMOs. and a tolerance threshold was introduced into the system allowing unintended and technically unavoidable presence of GMOs. and finally, before the year of 2003 there was no requirement for the submission and validation of detection method included in the legal regulation at the EU level. After the Regulation No 641/2004[197] and Regulation No 1981/2006[198] came into force, applications for authorization should include the detection methods and identification of transformation event and control samples of the food and animal feed which must be validated by the Community Reference Laboratory before the authorization.[199]

3.5 Multi-Level Governance of GMOs in the EU

It is increasingly difficult to identify clear lines dividing national from European Union competences.[200] The EU has always been characterized by its multi-level governance, in which

[193] Ibid.

[194] Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produces from genetically modified organism of particulars other than those provided for in Directive 79/112/EEC.

[195] Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced form genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.

[196] European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain) p.15

[197] Commission Regulation (EC) No 641/2004 of 4 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presense of genetically modified material which has benefited from a favourable risk evaluation.

[198] Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms.

[199] European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain) p.15

[200] Maria Lee, 'Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy'

authority is not allocated in a straightforward way to either the EU or the Member States. Instead, authority is dispersed along a spectrum of more or less national-centralized control. Multi-level governance calls on institutions that enable collaboration, learning, and discussion in order to escape the limited solutions or deadlocks that occur when using harder-edged techniques of law and government.[201] Multi-level governance is not straightforward in respect of GMOs, however, the classic mechanisms of multi-level governance are present in the regulatory framework for GMOs. The regulation of GMOs provides plenty of opportunities for different levels of governance to intervene in decision-making, and the legislative framework generally avoids recourse to single levels of authority, as well as building in opportunities for early discussion. For example, the centralization implies by the role of the European Food Safety Authority (EFSA) in assessing risk is mediated by obligations of networking and consultation with national authorities, and special obligations of transparency in respect of disagreement.

The above sections introduced the comprehensive legal framework in the EU regarding to the authorization, traceability and labelling of GMOs. The Food and Feed Regulation provided legal basis for regulating the food, food ingredients, and containing, consisting of or produced from GMOs and it also regulates GMOs used as source material for food and feed production, for example the cultivation. The Deliberate Release Directive regulates all kinds of GMOs, in comparing to the GM food and feed, the Directive focus more on the cultivation of GM plants. The aim of the authorization procedure set out by both pieces of acts is to the products in questions placed on the market would not have adverse effect on human and animal health as well as the environment. From this perspective, the center of the authorization is the risk assessment based on the scientific evidence that every authorization should be justified on the ground of scientific assessment.[202] The EFSA plays a crucial role as it is designated by the

in Luc Bodiguel and Michael Cardwell (eds), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (OUP 2010), p101

[201] Governance also generally implies the involvement of civil society beyond 'government' although the focus here is particularly on the legal arrangement of EU and national contributions to decisions. Multi-level governance should also encourage consideration of the role and influence of sub-national regions and international bodies such as the World Trade Organization (WTO).

[202] Article 7 and Article 19 of the 2003 Regulation that the Commission may, take into account 'other legitimate factors relevant to the matter into consideration', in addition to the opinion issued by EFSA.

legislation to cooperate with competent authorities of Member States to process the scientific risk assessment.

According to the examination procedure provided in EU Regulation No 182/2011[203], the decision making on authorization of GMOs shall follow the form of implanting acts adopted by the Commission. Therefore, the authorization process is very much centralized to the European Union level while the Member State also plays a crucial role in the process. There are two stages the Member States involved in which could influence the decision making: the Member States could vote on the draft decisions provided by the Commission in the Standing Committee and in case the decision is unable to be reached at the Standing Committee level, the Member States could vote in the Appeal Committee. The decision can be made either based on the qualified majority in favour of or against to. The qualified majority in defined in the as "…votes representing at least 55 percent of the 28 Member States, and at least 65 percent of the EU population. Where there is no qualified majority in favour of or against the draft decision in the Appeal Committee, the result is "no opinion".[204]

The rules governing this procedure[205] provide that where "no opinion" is issued by the Appeal Committee, "the Commission may adopt the draft implementing act."[206] This wording in certain extent gives the Commission the discretion. While regarding to the decision making of GMOs cases, the Deliberate Release Directive, the Food and Feed Regulation together with the Traceability and Labelling Regulation reduced the "margin for manoeuvre" of the Commission significantly.[207]

The process for authorizing GMOs broke down at the end of the 1990s, in the face of

[203] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[204] European Commission, *Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions—Reviewing the decision-making process on genetically modified organisms (GMOs)*, COM(2015) 176 final, Brussels, 22.4.2015.

[205] Regulation (EU) No 182/2011

[206] Article 6(3) of Regulation (EU) No 182/2011.

[207] European Commission *Evaluation of the EU legislative framework in the field of GM food and feed* (2010) DG SANCO Evaluation Framework Contract Lot3 (Food Chain)

widespread public rejection of GM food and agriculture, and there were no authorizations between 1998 and 2004. The EU institutions and Member States ceased to apply the old legislation, and instead negotiated a new regulatory framework, composed of two key pieces of legislation, the Deliberate Release Directive and the Food and Feed Regulation. Since the entry into force of the Food and Feed Regulation in 2003, the Member States have not obtained a qualified majority in favour of or against a draft decision made by Commission on authorizing GMOs, including GMOs for cultivation or for GM food and feed. The result has always been "no opinion". This situation has consistently happened at all stages of the authorization procedure both in the Standing Committee and in the Appeal Committee, under the current rules, and in the Council in the past.[208]

The authorization process is complicated, varying according to the level of agreement or disagreement between the Member States, and according to the uses for which the GMO is to be authorized, in particular, according to whether the GMO (including a seed or other plant propagating material) is ultimately for food or feed use or not. The key steps are a risk assessment by the EFSA, on the basis of information submitted by the applicant, and a decision on authorization by the Commission and Member States through the examination procedure set out by the Regulation (EU) 182/2011.[209]

3.6 Public Participation in the EU Authorisation Procedures for GMOs

In 1972, the United Nations Conference on the Human Environment in Stockholm[210] (which gathered representatives from 113 countries (as well as numbers of international organisations and non-governmental organisations) laid down new principles of international environmental law and governance, including important recommendations regarding public participation in

[208] European Commission, *Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions—Reviewing the decision-making process on genetically modified organisms (GMOs)*, p4

[209] Maria Lee, 'GMOs in the Internal Market: New Legislation on National Flexibility' (2016) 79(2) The Modern Law Review 317. p318

[210] The United Nations Conference on the Human Environment had met at Stockholm, Sweden from 5 to 16 June, 1972, it is also known as the Stockholm Conference. The Declaration of the United Nations Conference on the Human Environment was adopted at its closing meeting, see http://www.un-documents.net/unchedec.htm (last accessed on May 21, 2018)

decision making. They have had an important impact on the governance of GMOs in the EU and elsewhere. In its closing meeting, the Declaration of the United Nations Conference on the Human Environment was adopted and the very first principle of the Declaration stated that, '[M]an has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations.'[211] The Declaration showed the commitment of the world community to solve global environmental problems and gave the rise to the enacting of international environmental agreements and national laws as well as stimulated the development of the environmental protection organization system.

If the Stockholm Conference brought the environmental protection issues to the attention of human society, the United Nations Conference on Environment and Development which was held twenty years later in Rio de Janeiro further appealed that the public should be empowered to participate in decision making and have a right to access information, as well as a right to environmental justice. The 10th principle of the Declaration on Environment and Development proclaims The Rio Declaration proclaims in principle 10 that: '[E]nvironmental issues are best handled with participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.' [212] The Rio Declaration has great significance because it appealed on countries and authorities to provide conditions for the public to access the information and justice as well as to participate into the decision-making process on environmental issues as they are the crucial links of basic human rights.

[211] Ibid.

[212] The United Nations Conference on Environment and Development was held in Rio de Janeiro, Brazil, from 3 to 14 June, 1992. See < http://www.un.org/geninfo/bp/enviro.html> (last accessed on 21 May, 2018)

3.6.1 *The Convention on Biological Diversity and the Cartagena Protocol*[213]

While at the same year, the Convention on Biological Diversity (CBD) took one step further which provide the public participation into the biosafety issues. The Article 13 of the Convention requires the Contracting Parties shall '…(a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes; and (b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.'[214] It has also mentioned in its Article 14 that '(the Contracting Parties) shall introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effect and, where appropriate, allow for public participation in such procedure.'[215]

Under the CBD, the Cartagena Protocol on Biosafety reinforced this obligation of the Contracting Parties with specific reference to the genetically modified organisms. The Cartagena Protocol specifically listed the 'Public Awareness and Participation' as its Article 23, that the Parties shall: '(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies; (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in

[213] The back ground information and further study of the UN Convention on Biological Diversity please see S. Jodoin & M. Cordonier Segger (Eds.), *Sustainable Development, International Criminal Justice, and Treaty Implementation* (Cambridge: Cambridge University Press,2013); for general idea of the Cartagena Protocol is inspired by Professor. Christopher Rodgers, "Environmental Risk, Environmental Liability and the Regulation of Biotechnology: Mediating Law and Biology?" Chapter 7 pp.95-115 in (Hocking ed.) *The Nexus of Law and Biology: New Ethical Challenges* (Ashgate, 2009)

[214] The Convention on Biological Diversity, < https://www.cbd.int/convention/articles/default.shtml?a=cbd-13> (last accessed on 21 May, 2018)

[215] Ibid. < https://www.cbd.int/convention/articles/default.shtml?a=cbd-14> (last accessed on 21 May, 2018)

accordance with this Protocol that may be imported.' Also, the Article 23(2) provides that the Parties shall, 'in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public'.[216]

3.6.2 *The Aarhus Convention*

It might need be addressed that neither the Declaration of the Stockholm Conference or the Rio Declaration has legally binding. There was no international document with legally binding specifically on public participation produced in the past until the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters were concluded in the 1998.[217] The Aarhus Convention was an important step taken by the international society to honor its commitment to protect the environment by enhancing the public awareness, promoting pubic participation and empowering the public the right access to justice in environmental matters.[218] Moreover, the Arhus Convention especially mention the agricultural biotechnology in its Preamble, where require the Contracting Parties to recognize 'the concern of the public about the deliberate release of genetically modified organisms into the environment and the need for increased transparency and greater public participation in the decision-making in this field.'[219] Later under the Almaty amendment in 2005, the legislations on GMOs was separated as a single area where the provision of the regulation were developed further.[220] The implementation of the Aarhus Convention started from October 2001 yet it was not ratified by the European Union until 2005.[221] Parties of the Aarhus Convention are mainly European countries, and till

[216] The Cartagena Protocol on Biosafety, see < http://bch.cbd.int/protocol/text/> (last accessed on 22 May, 2018)
[217] The Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matter (the Aarhus Convention), 1998. See < http://www.unece.org/fileadmin/DAM/env/pp/documents/cep43e.pdf> (last accessed on 1 June, 2018)
[218] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009), p.320
[219] Ibid. The Preamble.
[220] Michael Cardwell, 'Public Participation in the Regulation of Genetically Modified Organisms: A Matter of Substance of Form?' (2010) 12 Environmental Law Review 12 p.14
[221] Council Decision 2005/370/EC on the conclusion, on behalf of the European Community, of the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (OJ L124/1, 2005). Also see Michael Cardwell, 'Public Participation in the Regulation of Genetically Modified Organisms: A Matter of Substance of

the present days no Asian countries joint the Convention.

There are three pillars under the Aarhus Convention which are the access to information, access to justice and the public participation. According to the Aarhus Convention, the public participation should be involved in: firstly, the 'decisions on specific activities';[222] secondly, 'plans, programmes and policies relating to the environment';[223] and thirdly, 'the preparation of executive regulations and/or generally applicable legally binding normative instruments'.[224]

3.6.3 *Public participation in authorisation for GMOs in the EU*

The promotion of agricultural biotechnology and the GMO products in the European Union have encountered resistance from the European public since their introduction.[225] According to an analysis report, the reason behind this resistance from the European public to the GMOs was more because of social and cultural reasons than of lack of scientific knowledge and education or the negative publicity from the media.[226] On the other hand, the Public Participation in the legal framework and governance of the European Union plays an important role. The 2001 *European Governance—a White Paper*[227] could be seen as an evidence. It this document, the participation is identified as one of the principles of good governance, not only because 'the quality, relevance and effectiveness of EU policies depend on ensuring wide participation throughout the policy chain—from conception to implementation', but also that improvements in this area are 'likely to create more confidence in the end result and in the institutions which deliver policies'.[228] Later, in accordance to the Aarhus Convention, the European Union enacted the Regulation (EC) 1367/2006 to the make

Form?'(2010) 12 Environmental Law Review 12 p.14

[222] The Aarhus Convention, Article 6.

[223] Ibid, Article 7.

[224] Ibid. Article 8.

[225] Maria Paola Ferretti, Matteo Lener, 'Lay Public or Experts? E-Participation in Authorization for GMO Products in the European Union' (2008) 25 (6) Review of Policy Research 507 507

[226] Lujan, J. L.,&Todt, O. 'Precaution in the Public: the Social Perception of the Role of Science and Values in Policy Making'(2007) 16(1) Public Understanding of Science 97

[227] European Commission, *Good Governance—A White Paper* COM (2001) 428 (OJ C287/1)

[228] Ibid. p.7

sure that the publics' right on access to the information, public participation in decision-making process as well as access to justice in environmental matters be fulfilled.[229]

Regarding to the authorisations for GMOs, there are two directives governing the activities related to the GMOs which are the Deliberate Release Directive (Directive 90/220/EEC, later was replaced Directive 2001/18/EC) and the GM Food and Feed Regulation (Regulation 1829/2003/EC), they constructed two slightly different procedures for GMOs authorization and both of them provided provisions for public participation.[230] The early Council Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms[231] stated in its Preamble that 'it may be considered appropriate in certain cases to consul the public on the deliberate release of GMOs into the environment'.[232] The Article 7 especially required the Member State may provide that 'groups or the public shall be consulted on any aspect of the proposed deliberate release'.[233] Although this Directive was replaced by the Directive 2001/18/EC[234], the public participation were further emphasized and enhanced which allowed wider access to the regulatory process. Article 9 required the Member States shall 'consult the public and, where appropriate, groups', and they must 'lay down arrangements for this consultation, including a reasonable time period, in order to give the public or groups the opportunity to express an opinion', and 'comments by the public should be taken into consideration in the drafts of measures submitted to the Regulatory Committee.'[235] In Part C of this Directive which governs the GMOs which are about to be placed on the market, the Article 24 stipulates that the public may make comments on the summery and the assessment report submitted by the Commission and the Commission shall immediately forward the comments to the competent authorities in case of placing a GMO

[229] Regulation (EC) 1367/2006 of the European Parliament and of the Council on the Application of the Provisions of the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matter [2006] OJ L264/13

[230] See above Maria Paola Ferretti and Matteo Lener (2008), p.508

[231] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1990] OJ L 117/15

[232] Ibid. Preamble

[233] Ibid, Article 7.

[234] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC OJ L106/1

[235] Ibid, Article 9, Preamble (46)

product on the market.[236] In the GM Food and Feed Regulation[237] also have similar stipulation.

It could be concluded from the above instruction that the importance of public participation in the environmental matters are generally recognized from the international level and the national level. Moreover, along with the rapid development of modern network, the channels for the public accessing the information are numerous, therefore to guarantee the pubic have greater right of participating in the decision-making and legislative process is an irreversible trend. The provision regarding to the public participation in authorisations for GMOs in the European Union legal system are comparatively detailed. The public participation is not only necessary but also sustaining, sufficient period of time is provided for the public to express their comments which are guaranteed to be involved into the decision-making access.

Although development strategies on agricultural biotechnology are various from country to country, the practices of European Union in encouraging the public participation in environmental matters especially the GMOs matters have in certain degree proved its practicability and therefore could be studied and used for reference by Chinese policy makers in this area. The specific proposal for China to establish its public participation system in GMOs authorization will be discussed in the final chapter.

3.7 Co-existence Measures in the EU[238]

Agricultural production systems can be described in three categories: conventional, conventional using genetically modified crops, and organic. Conventional systems often use fertilizers and pesticides. Genetically modified systems use crops that have been genetically

[236] Ibid. Article 24.

[237] Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed [2003] OJ L 268/1, Article 6

[238] There are a large amount of literature on the co-existence issues, please see, for example, Maria Lee, 'The Governance of Coexistence Between GMOs and Other Forms of Agriculture: A Purely Economic Issue?' (2008) 20 (2) Journal of Environmental Law 193; Christopher Rodgers, "Coexistence or Conflict? A European Perspective on GMOs and the Problem of Liability" (2007) 27 *Bulletin of Science Technology and Society,* 233-250 and his 'DEFRA's Coexistence Proposals for GM crops: A Recipe for Confrontation?'(2008) 10 (1) Environmental Law Review 1

engineered to resist pests or disease or to tolerate herbicides. Organic systems, by contrast, do not usually use chemical fertilizers or pesticides, nor do they use GM materials in the production process.[239] These three types of agricultural production may occur in the same geographic region. When they do, producers who grow organic or conventional crops often want to avoid the adventitious presence of GM material in their crops.

Genetically modified crops make up an ever-larger proportion of the world's maize and soybeans, and the coexistence of these crops with other, more traditional varieties is a matter of increasing concern, especially in the European Union. In the EU, where GM crops have been viewed with suspicion, the goal of avoiding adventitious presence is particularly important. Of course, farmers in other nations often share the same concern.

According to the European Commission, the term 'coexistence' refers to "the ability of farmers to make a practical choice between conventional, organic and GM crop production, in compliance with the legal obligations for labelling and/or purity standards."[240] The European Association for Bio-industries (including 'green' or agricultural biotechnology) offered a more expansive definition: 'coexistence is about how crops intended for different markers can be grown in the same vicinity without becoming commingled and thereby possibly compromising the economic value of each other. Coexistence is based on the premise that farmers should be free to cultivate the crops of their choice using the production system they prefer, whether they are GM, conventional or organic'.[241]

Article 26a of the Deliberate Release Directive provides that: 'Member State may take appropriate measures to avoid the unintended presence of GMOs in other product'. This 'co-existence' provision in principle allows considerable flexibility in the Member States, with different approaches to respond to their diverse conditions, for example as to the size of farms,

[239] Pew Initiative on Food and Biotechnology, *Peaceful Coexistence Among Growers of Generically Engineered, Conventional, and Organic Crops* (Washington, DC: Pew Initiative on Food and Biotechnology, 2006) 7

[240] Commission Recommendation (EC) 2003/556 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming ('2003 Commission Recommendation') [2003] OJ L189/36, Annex, para 1.1

[241] ABE/EuropaBio, *Understanding Coexistence: Science, Principles and Practical Experiences* (2006)

different levels of commitment to organic farming and varied geographical and ecological conditions. Measures to ensure the co-existence of different forms of agriculture include staggered sowing, weed management and careful cleaning and maintenance of equipment. At the more interventionist end, separation distance or buffer zones between crops might amount to GM free zones on various scales.

Coexistence rules of genetically modified plants with conventional and organic crops are not set by EU authorities but by national authorities of Member States. At EU level, the European Coexistence Bureau organizes the exchange of technical and scientific information on best agricultural management practices for coexistence. On this basis, in July 2003, the European Commission issued its Recommendation[242] on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming.[243]

Countries which produce GM crops have enacted specific legislation on coexistence, except Spain where coexistence is managed by following the good agricultural practices defined by the National Association of Seed Breeders. In some parts of the EU such as Southern Belgium and Hungary, coexistence rules are very restrictive and strongly limit the cultivation of GM crops. Some countries are preparing coexistence rules. In Poland, the drafted legislation is expected to enter into force not earlier than in 2016. In the United Kingdom, rules will be implemented 'when GE crops are grown.' In France, several regulations are in place but the rules governing distances between GM crops and other fields have not been defined yet.[244]

3.8 Environmental Liability Regime in the EU

When the risks of GMOs research and development and other activities related to the GMOs,

[242] Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (2003/556/EC)
[243] Agricultural Biotechnology Annual, 2015 GAIN Report Number: FR9174
[244] GAIN Report, number FR9174 p26

for example, the production, transportation, environmental release, storage and marketing activities, turn into actual harm and damage, the problems of compensating the injured party as well as undertaking the corresponding legal liability for the damage to the biological environment are involved. 'Legal liability' under the biosafety law means legal consequences to the offender who violates biosafety law or breaks their contractual obligation while the 'redress' is the way or method to remedy the liability.[245] Damages are one of the most important parts in the biosafety legal system which are also comparatively controversial in the existing international biosafety legal system.

The European Union has started to consider to establish an EU community-wide environmental liability regime since 1993.[246] In April 2000, the European Commission published the 'White Paper on Environmental Liability'[247], and the Deliberate Release Directive explicitly refers to liability in its Recital.[248] The provisions provided by the Deliberate Release Directive shall not only be 'without prejudice to Member States' national legislation in the field of environmental liability', but also the 'Community legislations in this field needs to be complemented by rules covering liability for different types of environmental damage in all areas of the European Union.'[249] Moreover, the Deliberate Release Directive also anticipated the Commission to 'bring forward a legislative proposal on environmental liability' which will cover damage from GMOs.'[250] In 2004, a pubic liability mechanism at the Community level is provided by the EU's Environmental Liability Directive.[251]

The 2004 Environmental Liability Directive aims to prevent and remedy environmental

[245] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.255
[246] Ibid.
[247] White Paper of 9 February 2000 on Environmental Liability [COM(2000) 66-not published on the Official Journal], for general content, see http://europeanlaw.lawlegal.eu/environmental-liability-white-paper/#Document_or_Iniciative, last accessed on 4 June 2018
[248] Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar Publishing Limited, 2008), p.127
[249] Directive 2001/18, Recital 16.
[250] Ibid.
[251] Directive of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage [OJ L 143 of 30.04.2004].

damage and therefore establishes a framework based on the polluter pays principle. The polluter pays principle is set out in the Treaty on the Functioning of the European Union.[252] The provisions of the Directive apply for the remediation of pure ecological damage which is the 'environmental damage' and 'biological damage', therefore the Directive is based on the powers and duties of public authorities, which is different from the civil liability system for the economic loss and other commercial losses or property damage and they are not in the range of the remediation offered by the Directive.[253]

Before we can understand the liability regime provided by the Environmental Liability Directive, it is important to know the way the Directive defines the 'environmental damage' and 'operator'. There are three categories of environmental damage covered under the Directive. First of all, there is 'damage to protected species and natural habitats', which is any damage that has significant adverse effects on reaching or maintain the favourable conservation status of such habitats or species.[254] Secondly, there is 'water damage', which is any damage that significantly adversely affects the ecological, chemical and/or quantitative status and/or ecological potential, as defined in the Water Framework Directive 2000/60[255], of the waters concerned;[256] and finally, there is 'land damage', which is any land contamination that creates a significant risk of human health being adversely affected as a result of the direct or indirect introduction, in, on or under land, of substances, preparations, organisms or

[252] TFEU, Article 191(2)

[253] Christopher Rodgers, "Environmental Risk, Environmental Liability and the Regulation of Biotechnology: Mediating Law and Biology?" Chapter 7 pp.95-115 in (Hocking ed.) *The Nexus of Law and Biology: New Ethical Challenges* (Ashgate, 2009)

[254] 2004 Environmental Liability Directive, Article 2 (1)a. In addition, the 'favourable conservation status of a natural habitat' and 'the favourable conservation status of a species' have legal definition given in the Council Directive 92/43/EEC on conservation on natural habitats and of wild fauna and flora (1992). See Article 1(e), '… The conservative status of a natural habitat will be taken as "favourable" when: its natural range and areas it covers within that range are stable or increasing, and the specific structure and functions which are necessary for its long-term maintenance exist and are likely to continue to exist for the foreseeable future, and the conservation status of its typical species is favourable as defined in (i);' and Article 1(i), ' conservation status of a species…will be taken as "favourable" when: population dynamics data on the species concerned indicate that it is maintaining itself on a long-term basis as a viable component of its natural habitats, and the natural range of the species is neither being reduced nor is likely to be reduced for the foreseeable future, and there is, and will probably continue to be, a sufficiently large habitat to maintain its populations on a long-term basis'. For detailed study and discussion on the nature conservation law, please see Christopher Rodgers, *The Law of Nature Conservation* (OUP 2013).

[255] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy [2000] OJ L327/1

[256] 2004 Environmental Liability Directive, Article 2 (1)b

micro-organisms.[257]

In order to provide for effective liability, the establishment of a causal link between the activity and the damage is always required. Therefore, the Directive provides two different but complementary liability regimes which respectively applies for two different categories of damage. Firstly, the strict liability applies for the environmental damage caused by any of the dangerous activities (listed in Annex III) carried out by operators.[258] These activities include, among others, industrial and agricultural activities requiring permits under the 1996 Integrated Pollution Prevention and Control Directive, waste management operations, the release of pollutants into water or into the air, the production, storage, use and release of dangerous chemicals, and the transport, use and release of genetically modified organisms.[259] These activities are assumed to be high risk and therefore engage liability without proof of fault. Secondly, operators carrying out occupational activities other than those listed in Annex III are liable for fault-based damage to protected species or natural habitats (biodiversity damage)[260], which means an operator would only be held liable if the operator was at fault or negligent and if he has caused damage to species and natural habitats protected at EU level under the 1992 Habitats Directive[261] and 1979 Birds Directives.[262]

Under the liability regime provided by the Environmental Liability Directive, the public authorities play an important role since it is their responsibility to identify liable operators and to ensure them to undertake necessary preventive provisions or remedying measures stipulated by the Directive. Before the damage has actually occurred but there is an imminent threat of such damage, the operator shall immediately take necessary preventive action and inform the competent authority of all relevant aspects in certain cases.[263] While there is actual environmental damage has occurred, the operator shall, without delay, inform the competent

[257] Ibid, Article 2(1)c
[258] Ibid, Article 3(1)a.
[259] Ibid, Annex III.
[260] Directive 2004/35/EC, Article 3(1)b.
[261] Council Directive 92/43/EEC of 21 May 1992 in the conservation of natural habitats and of wild fauna and flora [1992] OJ L206/7
[262] Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds [1979] OJ L103/1
[263] Directive 2004/35/EC, Article 5.

authority of all relevant aspects of the situation and take: (a) all practicable steps to immediately control, contain, remove or otherwise manage the relevant contaminants and/or any other damage factors in order to limit or to prevent further environmental damage and adverse effects on human health or further impairment of services, and (b) the necessary remedial measures, in accordance with the relevant provisions of the Environmental Liability Directive (particularly in accordance with its Annex II).[264] In addition, public interest groups, for example the NGOs, will be able to require public authorities to act when necessary. The Directive also offers an additional safeguard when the decisions of the public authorities are deemed illegal, the public interested groups are able to challenge their decisions before the courts.

Regarding to the GMOs related issues, the Directive will also cover damages if the potential risks will cause damage to protected species, natural habitats, water and soil when the damage has occurred during the contained use of GMOs or their deliberate release into the environment. It might be worthy to point out that, regarding the damage the biodiversity, a public liability model would be more 'utility' in such cases. Certainly numbers of civil liability regimes may provide strict liability for hazardous activities, however they do not cover the unforeseeable harm. While a public liability model, it gives the public bodies power to carry out clean-up activities and then reclaim the financial cost from the operator – this avoids any need to 'value' the damage to the environment. It does not provide for financial damages to be awarded in the normal sense.[265]

3.9 The Recent Reform of the Rules for GMOs Authorized for Cultivation

The reform of the rule on GMOs cultivation authorization has been prepared for a long period.

[264] Ibid, Article 6.

[265] Christopher Rodgers, 'Implementing the Community Environmental Liability Directive: Genetically Modified Organisms and the Problem of Unknown Risk' in Luc Bodiguel and Michael Cardwell (eds), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (OUP 2010); see also , L Bergkamp, 'The Commission's White Paper on Environmental Liability: a weak case for an EC strict liability regime' (2000) 9(4) European Environmental Law Review 105 as there is a different oppoinion on the public liability model posited in the Environmental Liability Directive.

The Commission submitted a proposal of amendment on the GMO legislation to extend the grounds on which Member States could restrict or prohibit the cultivation of EU authorized GMOs on their territory.[266] In the explanatory memorandum of proposal, the Commission explained that "national, regional or local levels of decision making are considered to be the most appropriate frameworks to address the particularities linked to GMO cultivation". The proposed amendment has now been adopted into EU law as Directive (EU) 2015/412[267] ("The 2015 Directive"). The 2015 Directive claims "to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivated GMOs on their territory".[268] According to the Directive, the Member States of the European Union have the right to restrict or ban GMO cultivation within all or part of their territory based on non-scientific reasons.[269] This is a major development as the European Union shifts the power toward to the Member State and it allows Member States to make the decision on GMO cultivation on the basis of considerations of their own national situations as the priority. The provision applies to both the future authorizations and to GMOs which have already been authorized at EU level.[270]

The EU's action has been influenced by the awareness of the circumstance that the cultivation of GMOs is an issue which can be more thoroughly addressed at Member State level, since it has strong national, regional and local dimensions, given its link with land use, local agricultural structures and the protection or maintenance of habitats, ecosystems and

[266] Global Agricultural Information Network (GAIN), EU-28 Agricultural Biotechnology Annual 2016, GAIN Report Number: FR1624 (USDA Foreign Agricultural Service, 12 June 2016) https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf accessed 28 Oct 2017

[267] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L68/1). For a more thorough discussion on the value and impact of the Directive (EU) 2015/412, please see, for example, Dr. Mary Dobbs, 'Attaining Subsidiarity-Based Multilevel Governance of Genetically Modified Cultivation?' (2016) 28 (2) Journal of Environmental Law 245 and 'Genetically modified crops, agricultural sustainability and national opt-out: enclosure as the loophole?' (2017) 54 (4) Common Market Law Review 1093; Prof. Maria Lee 'GMOs in the Internal Market: New Legislation on National Flexibility' (2016) 79 (2) Modern Law Review 317

[268] Ibid, Recital 8.

[269] Global Agricultural Information Network (GAIN), EU-28 Agricultural Biotechnology Annual 2016, GAIN Report Number: FR1624 (USDA Foreign Agricultural Service, 12 June 2016) https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf accessed 28 Oct 2017

[270] Laura Salvi, 'The EU Regulatory Framework on GMOs and the Shift of Powers toward Member States: and Easy Way Out of the Regulatory Impasse?' [2016] 3 EFFL 201

landscapes.[271] The pivot and core of the modified structure of regulatory competence in this matter has been identified in the principle of subsidiarity, which constitutes the means to reconcile the objectives of harmonization at a European level with the need for flexibility related to the diversity of situations in the various European countries, in the framework of the correct and effective functioning of the European market.[272]

The directive formally confers Member States the right to adopt legally binding acts restricting or prohibiting the cultivation of GMOs on their territory, without however affecting the common procedure for marketing authorisation, which still remains firmly at the EU level. The objective appears to be twofold: improving the authorisation process of GMOs on one side and ensuring consumers', farmers' and operators' freedom of choice on the other, thus ensuring a greater degree of clarity to stakeholders regarding the cultivation of GMOs in the Union.[273]

In line with the aim of a proper and effective functioning of the internal market, the Directive also provides that the restrictions or prohibitions adopted pursuant to it should refer to the cultivation and not to free circulation and the import of genetically modified seeds and plants propagating material as, or in, products and of the products of their harvest. Generally, it is prescribed that compelling grounds conform with Union Law, in particular as regards the principle of non-discrimination between national and non-national products, the principle of proportionality, provisions on the free movement of goods set out in Articles 34 and 36, as well as in compliance with international obligations.[274]

According to the new directive, restrictions or prohibitions may be adopted by Member States either in the course of the authorisation procedure or thereafter, and independently from the measures that Member States cultivating GMOs are entitled or required to take by application of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products.

[271] Recital No 6 of Directive No 2015/412/EU

[272] Laura Salvi, 'The EU Regulatory Framework on GMOs and the Shift of Powers toward Member States: and Easy Way Out of the Regulatory Impasse?' [2016] 3 EFFL 201; This new directive relies on the Article 114 TFEU, which forms the legal basis for every harmonizing measure that has as its objective to establish and further the functioning of the internal market.

[273] Directive 2015/412/EU Recital No 6

[274] Directive 2015/412/EU Recital No 8

In case a State intends to exercise its powers to adopt restrictions or prohibitions during the authorisation procedure for a certain GMO or during the renewal of such authorisation, this intervention will take the form of the possibility to request that the geographical scope of the written consent or authorisation shall be adjusted to the effect that all or part of its territory is to be excluded from cultivation, at the latest 45 days from the date of circulation of the assessment report under Article 14(2) of Directive 2001/18, or from receiving the opinion of the EFSA under Article 6(6) and Article 18(6) of Regulation 1829/2003. The demand is then presented by the Commission to the other States and to the notifier/applicant, who may decide to adjust or confirm the geographical scope of its initial notification/application within 30 days.[275]

If no action is taken during the course of the authorisation procedure, or if the notifier does not answer the geographic adjustment request, the State may opt for the adoption of a comprehensive ban or restrictions of a GMO cultivation in its territory. This restriction may also involve a group of GMOs defined by crop or trait, which has already been authorised at the EU level. The Member State shall communicate a draft of those measures and the corresponding grounds invoked to the Commission, who may "make any comments it considers appropriate." This communication may take place before the GMO authorisation procedure has been completed under Part C of Directive 2011/18/EC or under Regulation (EC) No 1829/2003. For a period of 75 days starting from the date of such communication, the Member State concerned shall refrain from adopting and implementing those measures, and ensure that operators refrain from planting the GMO concerned.[276]

Besides, Directive 2015/412 allows Member States to adopt transitional measures in order to apply the provisions of the Directive to products which have been authorised or which were in

[275] Ibid, Article 26(c). In case the notifer/applicant confirms or does not respond within 20 days, the geographical scope of the notification/application shall be adjusted accordingly.

[276] Ibid, Article 26(b). On expiry of the 75-day period, the Member State concerned may, for the whole duration of the consent/authorisation and as from the date of entry into force of the Union authorisation, adopt the measures, as originally proposed or as amended in the light of comments received from the Commission and, eventually, it communicates without delay those measures to the Commission, the other Member States and the authorisation holder; see Article 26b, and Article 5 of Directive 2001/18/EC.

the process of being authorised before the act is enforced, signally, demanding that the geographical scope of a notification/application submitted, or of an authorisation granted under Directive 2001/18 or Regulation 1829/2003, is adjusted.[277]

With regard to the reasons Member States may put forth to justify restrictions on cultivation (the so-called "compelling grounds"), the Directive specifies that they must be distinct from and complementary to those assessed according to the abovementioned acts. Member States may demand that the cultivation of a certain GMO or of a group of GMOs is banned or restricted on the ground of "environmental policy objectives" (different from and complementary to the assessment of risks to health and the environment which is carried out by the EFSA or other competent authorities),[278] "land use," "town and country planning," "socio-economic impact,"[279] "agricultural policy objectives," "coexistence" and "public policy".[280] Whether such reasons are invoked individually or in combination, they shall in no case conflict with the environmental risk assessment carried out in the EU context by EFSA.[281] That is to say, a Member State will not be able to base a restriction or a prohibition on cultivation in its territory on risks that EFSA has already assessed.

It should be noticed that the 2015 Directive applies to GMOs for cultivation only, the GM food and feed are not yet the object of the Directive. The Commission, in the view of above consideration, proposed to amend the Food and Feed Regulation in the same way as to allow Member States to restrict or prohibit the use, on part of all of their territory, of GM food and feed authorized by the EU for compelling reasons other than the risk to human or animal health or to the environment—that is, criteria other than those assessed by EFSA in its risk

[277] Directive 2015/412/EU Recital No 26, and Article 26(c)

[278] Ibid, Recital No 14. For example, the maintenance and development of agricultural practices which provide a better potential to reconcile production with ecosystem sustainability, or maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features, as well as specific ecosystem functions and services.

[279] Ibid, Recital 15. As it states, there should be the possibility for Member States to adopt measures restricting or prohibiting cultivation of authorized GMOs in all or part of their territory under the Directive related to the high cost, impracticability or impossibility of implementing coexistence measures due to specific geographical conditions, such as small islands or mountain zones, or the need to avoid GMO presence in other products such as specific or particular products.

[280] Ibid, Recital 13.

[281] Ibid, Article 26b.

assessment.[282] However, this proposal was not carried through.

3.10 Conclusion

After persistent efforts and practices, the European Union has now established a 'farm to fork' regulatory framework governing the GMOs comprehensively from evaluation, authorization, production, tracing and marketing. It is generally recognized that the EU's approach regarding to the GMOs and genetic technology management at the most developed level in the worldwide. The whole legislative framework is constituted by number of Regulations and Directives which created a 'safety net'[283] to ensure the higher level on protection of human and animal health as well as the ecological environment safety. In spite of arguments and opposition along the way of the development of the regime, the EU contributes greatly in expansion the content of international GMOs legislation and plays a role as exemplification to other countries. As it has been introduced in Chapter 3, the current comparatively weak management on GMOs in China is urgently needed to be improved. The EU provided valuable and resourceful model to Chinese legislation especially regarding to (but not limited to) the multi-level government on GMOs, the traceability and labelling regime, the transparency of information as well as the public participation regime. The next chapter would comparatively study on the EU legislative framework and Chinese legislative framework and take one step forward to discuss the feasibility and necessity of adopting EU approaches into the Chinese context.

[282] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory (COM (2015) 177 final).

[283] Michael Cardwell, The European Model of Agriculture (OUP, 2004) p.150

Chapter 4 Multi Level Environmental Governance of GMOs: Comparative Aspects

Chinese government has heavily invested in biotechnology research and the biotechnology plays a critical role in the national development strategy. The amount of total investment on biotechnology research and development from the Chinese government is estimated to be 12 billion Yuan (approximately $1.9 billion) since 2008, with a matching investment from private industry.[1] The amount far exceeds any other country's public investment in biotechnology.[2] It is expected that Chinese government expenditure on agricultural biotechnology will accelerate in the near term.

In September 2014, the President Xi Jinping released his remarks on the agricultural biotechnology publicly for the first time, he affirmed the governmental support for the agricultural biotechnology research to prevent the foreign companies "dominating the agricultural biotechnology product market", yet emphasized the commercialization should be carried forward with cautious attitude and approaches.[3] In February 2015, the Chinese Communist Party pledged in its annual high-level policy paper on agriculture that 'to strengthen research, safety management, and public outreach on biotechnology'.[4]

[1] USDA Foreign Agricultural Service, GAIN Report No. CH16065, 'Agricultural Biotechnology Annual—China Moving Towards Commercialization of Its Own Biotechnology Crops'; all the published GAIN reports by USDA Foreign Agricultural Service could be found on < https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Forms/AllItems.aspx>, last accessed on August 7, 2018

[2] Ibid.

[3] Ibid.

[4] This high-level policy paper is so called 'the No. 1 Document'. It is the first policy document issued by the Chinese Communist Party each year. The document is reserved for important issues, such as agriculture.) The document built on the comments President Xi Jinping made on biotechnology during a major policy speech on agriculture in December 2013 at the Central Conference on Rural Work by the Central Committee of the Communist Party. He stated, '*Biotech is a new technology, and a new industry with bright prospect. As a novel issue, biotechnology attracts social disputes and doubts, which is normal. For this issue, I want to emphasize two aspects, one is guaranteeing safety and the second is indigenous innovation. That is, we shall be bold in research, but cautious in commercialization. The industrialization and commercialization of genetically modified crops shall strictly follow the technical procedures provided by Chinese regulations; the industrialization and commercialization of genetically modified crops shall be steady and make sure no problem occurs, and all safety-related factors shall be considered. The research and innovation shall be bold, so we can take the commanding heights in biotechnology, and not let large foreign companies dominate the agricultural biotechnology product market.*' USDA Foreign Agricultural Service, GAIN Report No. CH16065, 'Agricultural Biotechnology Annual—China Moving Towards Commercialization of Its Own Biotechnology Crops'

The government of China is in the process of revising laws and regulations governing biotechnology. In July 2016, the Ministry of Agriculture (MOA) released the "Revised Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms"[5], which was earlier notified to the WTO SPS Committee (SPS notification 881)[6]. The regulations defined in MOA Decree No.7 (2016) revises MOA Decree No. 8 (2002), the previous regulations governing biotechnology. The amendments remove timelines for approvals, extend the National Biosafety Committee's term from three years to five years, and emphasize that entities engaging in GMO research and experiments are accountable for safety management. On several occasions, MOA officials have revealed that they are revising labelling requirements for GMO products and plan to establish minimum threshold levels for labelling, which is expected in the next two or three years. In 2015, MOA reported that it is exploring the feasibility of establishing a public solicitation mechanism to enhance public involvement in the agriculture biotechnology review and decision-making process.

The 13th Five-Year Plan for National Science and Technology Innovation (13th FYP)[7] issued by the State Council in August 2016 revealed that China will push forward the commercialization of key products, including the new generation Bt cotton, Bt corn, and herbicide-tolerant soybeans. The 13th FYP also pledges to establish the technical system for biosafety evaluation to guarantee safety of GE products. In 2016, MOA revealed a roadmap for the commercialization of GE crops in China, starting with cash crops "not for food use"; followed by crops for input for feed and industrial use; food crops; and finally staple food crops (rice, wheat, and soybeans).

In summary, China has made great efforts in the development of various areas including science, technology and legislation since the Reform and Opening-up Policy took place in the late 1970s.

[5] "The Decision on Revising 'Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms'" Decree No.7 (2016) of the Ministry of Agriculture.

[6] WTO Committee on Sanitary and Phytosanitary Measures, Notification G/SPS/N/CHN/881, 2 Jun 2015. available on file:///C:/Users/qd/Downloads/NCHN881.pdf, last accessed in May 2017

[7] 'The 13th Five-Year Plan for National Science and Technology Innovation', issued by the State Council, July 28th , 2016, available on < http://www.gov.cn/zhengce/content/2016-08/08/content_5098072.htm>, accessed in May, 2017

At present, China is moving towards commercialization of its own biotechnology crops and the government is also in the process of revising laws and regulations governing biotechnology. It obviously would be a long way and it could be difficult during the process. Regarding to the legislations, some of Chinese laws regulating agricultural biotechnology followed example of other countries in certain aspects, but in many areas new legislation and policy guidance needs to be formulated, drawing on the valuable lessons and practical experience of other countries in the management and development of agricultural GMOs.[8] China and the EU share many characteristics in common for GMOs legislation - for example, both explicitly follow the precautionary principle, and both have adopted mandatory labelling requirement. On the other hand, China and the EU as two very different countries/regions, choose different strategies and map out the legal and mechanisms based on their own conditions including state situation, economic development level, biotechnology development level and trend as well as the need for biosafety protection. Simply 'copying and pasting' the EU legislative model into the Chinese system is not only unlikely to be productive but also not practically possible. Notwithstanding, the EU system of multi-level governance for GM technology in agriculture is a model that can offer valuable insights for the development of appropriate governance arrangements in China.

4.1 General Background Comparison

Since the regulation of GMOs was first established in the early 1990s globally, countries have gone through initial formation, gradual modification and evolution of their own rules.

4.1.1 *Governance on GMOs biosafety in the EU*

If there is any country or region would be a paradigm for a cautions and conservative approach to the regulation of new GMOs, it must be the European Union. Since 1980s, European

[8] Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons From the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465 p 470

countries began to pay attention to biosafety issues, such as the environmental assessment and managing the release of Genetically Modified Organisms. Since then, the European Union issued a series of legal documents which were also absorbed by EU member states into their own national biosafety-related legal documents, and they developed more detailed examination and approval procedures as well as technical guidance. The European Union is considered as the strictest in biosafety management and some members even totally ban on the sale of certain GM products as well as field tests and conduct strict GM foods labelling systems. The precautionary principle is an important concept for biosafety legislation.[9]

In the European Union, biosafety management is based on the classification of biosafety regulations. Biosafety regulations in the EU are divided into two categories. The first category is horizontal legislation, which involves the use of genetically modified micro-organisms in a closed facility, deliberate release of GMOs and occupational safety of labors exposed to biological agents. The second category is product legislation, which includes pharmaceutical products, animal feed additives, plant protection product, novel food and plants seeds.[10] While GMOs in the EU are regulated at two authoritative levels: The European Commission (EC) and European Food Safety Authority issue harmonized rules on GMOs; EU member states have individual rules and regulatory agencies within their territory.[11] Companies hoping to sell and market their GMO-containing foods in a certain European country must apply for approval at the country level first; if approved, the company can proceed by notifying other countries via the European Commission. If there is any objection from other member states, additional evaluations will be conducted by the EU. A draft proposal is then submitted from the EU and voted on by representatives from EU member states. If vetoed, the proposal must be submitted to the EU for another round of votes.[12]

The EU's cautionary attitude on GMOs is due to several different economic, political and societal reasons. Economically, limiting the sale of GMOs protects domestic agricultural business by setting a higher trade barrier for large GMO exporters. In European politics,

[9] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009), p.183
[10] Ibid. p.184
[11] p.184
[12] Han, Y et al. 2013. "Evolution of GMO Regulations in the European Union and Indications for China." *Zhejiang Agric Sci* 11:1482–1489.

environmental and often "anti-GMO" groups have been taking a larger role in policymaking at regional, state or even European levels. Finally, the rising consumer demand for "natural" or "organic" food, which is often manipulated by social media, has led to a culture of distrust of GMOs. Some environmental groups and lobbies are reported to be active in attacking GMOs, trying to protect their own claims of being "natural" and "healthy." Politicians, like those who passed a bill to ban foods directly containing GMOs from school lunches in Taiwan,[13] are often very sensitive to the opinions of their electorates. They carefully avoid any public rejections of these controversial issues, trying to stay aligned with their electorates for the benefit of their political careers. The impact of the EU's restrictive policy on GMOs not only increases costs for manufacturers but also delays the development of modern biotechnology. Further, other countries considering the EU as a potential export market must wait and see, hoping to mirror policies from these large countries/regions with whom they heavily trade. Some of these "wait-and-see" countries choose to follow the EU as a model, whereas others may choose to mirror the U.S., a representative of a GMO "soft"-regulating country, to maximize benefits from exporting their crops.[14]

4.1.2 *GM Governance in China*

With the passing and implementation of the updated Food Safety Law in October 2015, China would now probably be categorized as falling on the stricter side of GMO labeling. The new law in China specifically includes an article on GM food that requires mandatory GMO labeling. Those who violate the labeling requirements will be punished with fines or even suspension of their license. However, specific rules on how to label GMOs with regard to the font size and

[13] < www.foodnavigator-asia.com/Formulation/Unraveling-the-reasons-behind-Taiwan-s-ban-on-GMOs-in-school-meals> accessed May 2017

[14] Cantley, M. 2012. "European Attitudes on the Regulation of Modern Biotechnology and Their Consequences." *GM Crops Food* 3(1):40–47. It might be worth to mention that, in the United States, if a food product is not produced from GM materials or contain any GM ingredient, the manufacturers could label the product as "not genetically engineered," "not bioengineered," or "not genetically modified through the use of modern biotechnology"; and food products derived from GM materials which meet 'the same safety, labeling, and other regulatory requirements' which apply to all foods regulated by FDA did not have be labelled as 'GM food'. However, in 2016 the 'The National Bioengineered Food Disclosure Standard 'was signed by the President, which means the United States may also establish requirements on labelling human foods derived from genetic technology. For further information, please see, 'Labelling Food Derived from Genetically Engineered Plants' < https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/ucm346858.htm> (last accessed July 2018)

other detailed requirements have still not been announced. China is also well aware of the variances in other countries on GMO labeling: The U.S. represents countries requiring only voluntary labeling; most European countries require mandatory labeling once the GMOs exceed a certain threshold in a product; Japan requires mandatory labeling only on certain processed foods.[15]

Surveys conducted from 2007 to 2008, and in 2010, showed that the majority of Chinese consumers are not opposed to purchasing GM foods. Most Chinese people have heard about GMOs, but consumer awareness is not high. Consumers with higher income or greater knowledge of GMOs are more willing to purchase them.[16] However, in one specific case in Hunan, China, in 2012, fear mongering, rather than scientific media coverage of a Golden Rice experiment, fueled a long-lasting debate about GMO safety in China and resulted in unnecessary worries, concerns and even fear among Chinese consumers.[17]

China's GMO regulations could date back to the early 1990s, covering each process of genetic engineering from research and development to premarket testing of the use of GM products. By the end of 2000, China had approved about three-fourths of the 443 applications for the biosafety review of GMOs submitted for approval by research institutes and producers of GMOs. In 2002, China started to require that all food products containing GMOs receive a safety assessment and go through an approval process, in addition to being labeled accordingly. However, these labeling requirements were not fully executed, and there was criticism from Chinese academic researchers in the early 2000s regarding the loopholes in the GMO laws and regulations that were not well coordinated between different authoritative agencies.[18] With the increasing need for GMO regulation brought by biotechnology development and rising consumer demands for mandatory labeling, China made updates to its GMO regulations in October 2015. However, it is not yet clear how the chnges to GM governance they will

15 < news.sohu.com/20151109/n425680807.shtml> accessed May 2017

16 Han, F et al. 'Attitudes in China about Crops and Foods Developed by Biotechnology' 2015 PLoS One 10(9):e0139114

17 Yang, J et al. 2014. 'The Rejection of Science Frames in the News Coverage of the Golden Rice Experiment in Hunan, China.' Health Risk Soc 16(4):339–354

18 Yang, W. 'Regulation of Genetically Modified Organisms in China' 2003 *Rev Eur Commun Internat Environ Law* 12(1):99–108

implement are to introduced. Meanwhile, there is also a need for the Chinese government to better communicate with consumers and the media so that the public will be better informed and educated about the science on such controversial issues.

4.2 Multi-level Governance and Agricultural Biosafety

Despite bringing new opportunities that biotechnology in agricultural production offer worldwide, the uncertainty surrounding whether the use of GMOs may negatively affect the environment, food safety and ecosystems has always been a major concern for the Chinese government when making the decisions. Around the world, especially in the developing countries which is populous and heavily relied on agricultural productions, the legislation on agricultural biosafety has been drawing increasing attention from the government. The establishment of the legislative framework has always been a key point of governmental work in China and so far a series of key legislations have been enacted regarding to the GMOs management and administrative regime. However, there are still challenges to the country due to the agricultural GMOs biosafety management in the practices and the implementation.[19] The sector will explain the current situation of the agricultural biosafety governance and in the EU and China.

4.2.1 *Multi-level governance and the politics of agricultural GMOs in the EU*

The EU legislation on GMOs has been designed and structured to ensure a difficult balance between safety concerns and the safeguard of health and the environment, premises upon which the entire European legal order is built, and interests related to the construction of an efficient and competitive internal market: a balance between trade and risk.[20]

The first regulatory intervention carried out by the EU in the area of GMOs took place in the

[19] Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons From the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465

[20] Marjolein B. A. van Asselt, Esther Versluis, Ellen Vos (eds), *Balancing between Trade and Risk. Integrating Legal and Social Science Perspectives* (Routledge, 2013)

early 1990s, with the adoption of Directives 90/219/EEC[21], on the use of genetically modified microorganisms in a confined environment and 90/220/EC, on their emission in the environment for experimental purposes and GM products market placement.[22]

The legal framework established by these instruments was soon considered fragmentary and incomplete. Therefore, after several years, and following some serious food scandals, a deep reform process occurred in the area of GMOs, mainly resulting in the adoption of Directive 2001/18/EC on the deliberate release of GMOs into the environment,[23] which basically concerns the cultivation of GMOs, and so affects agriculture and environment, and of Regulation (EC) No 1829/2003 on marketing and labelling of GM food and feed,[24] whose objectives pertain to quality of life, human health, animal welfare and consumer protection. These two pieces of legislation are both built in the light of a precautionary approach and provide that any GMO shall not be cultivated (or marketed) within the Union unless previously assessed by EFSA for what concerns its potential risks for health or the environment and, then, authorised by the EU Commission.

Based on the analysis of the consolidation process of EU governance of GMOs, two different and opposing trends may be observed. On the one hand, the EU has moved towards a "communitarisation"[25] of the matter, through a centralization of decision-making at the EU level as regards the procedural arrangements granting scientific assessment and marketing authorisation of GMOs,[26] in accordance with a "one door one key" approach. On the other hand, since the reduction of regulatory powers held by the Member States, the EU has had to deal with the numerous national pressures and instances aimed to acknowledge further

[21] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms, OL J117, 8.5.1990

[22] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms OL J117, 8.5.1990

[23] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC OJ L106, 17.04.2001

[24] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed OJ L268, 18.10.2003

[25] Maria Lee, "Multi-level governance of GMOs in the European Union: ambiguity and hierarchy", in Luc Bodiguel and Michael Cardwell (eds.), *The Regulation of Genetically Modified Organisms: Comparative Approaches* p101

[26] Nicolas de Sadeleer, "Marketing and Cultivation of GMOs in the EU: An uncertain balance between Centrifugual and Centripetal Forces", (2015) 6(4) *European Journal of Risk Regulation* 532 558

flexibility and discretion for Member States, specifically with regard to the cultivation of GMOs.

In March 2015, the European Commission (EC) released a proposal that would allow Member States to refuse to approve new licenses for the development and release of GMOs for cultivation for non-scientific reasons. The adoption of Directive 2015/412/EU[27] fits into the long and complex evolutionary, and somehow also regressive, process which has witnessed EU harmonization initiatives, on the one hand, and nationalist efforts to reassign regulatory powers to the Member States, on the other.[28]

It has been observed that the adoption of Directive 2015/412/EU nearly carries a symbolic value when studied within the European integration process. In- deed, it appears to be the first and most significant act through which the Union has set a re-transfer of powers from the European level to the national level, thus embracing a reverse trend to the one that has been characterizing the integration process for years.

The directive formally confers on Member States the right to adopt legal binding acts restricting or prohibiting the cultivation of GMOs on their territory, without however affecting the common procedure for marketing authorisation, which still remains firmly at the EU level. The objective appears to be twofold: improving the authorisation process of GMOs on one side and ensuring consumers', farmers' and operators' freedom of choice on the other, thus ensuring a greater degree of clarity to stakeholders regarding the cultivation of GMOs in the Union.[29]

In line with the aim of a proper and effective functioning of the internal market, the Directive also specifically pointed out that the Member States adopted the restriction or prohibition measures should refer to the GMOs cultivation rather than the circulation and import activities

[27] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory OJ L68, 13.3.2015

[28] Laura Salvi, The EU Regulatory Framework on GMOs and the Shift of Powers towards Member States: an Easy Way Out of the Regulatory Impasse? (2016) *European Food and Law Review* 11(3) 201

[29] Directive 2015/412/EU, Recital No 6

of GM seed and plants contain GMOs. Generally, it is prescribed that compelling grounds conform with Union Law, particularly in accordance of the non-discrimination principle between national and non-national products, the principle of proportionality, provisions on the free movement of goods set out in Articles 34 and 36 of the TFEU, as well as in compliance with international obligations.[30] Currently, there are nineteen Member States have 'opted out' of approving GM crops for cultivation for all or part of their territories. Additionally, the Directive requires those Member States in which GM crop cultivation takes place to take appropriate measures aimed at preventing possible transboundary pollution into adjoining Member States in where cultivation of GM crops is prohibited.[31] This effectively means that cultivating Member States bear the responsibility and liability associated with cultivating GM crops.

The Member States that want to restrict or prohibit GM crops cultivation have two options. The first option is: during the authorization procedure, a Member State may ask to amend the geographical scope of the application to exclude part of or all its territory. The manufacturer of the GM plant has 30 days to adjust or confirm the scope of the application. If the manufacturer does not answer, the scope is adjusted according to the Member State's demand. Member States are allowed to ask for their territory to be reintegrated into the geographical scope of the authorization after it has been granted. And the second option is that after a GM variety has been authorized for cultivation in the EU, a Member State may adopt national opt out measures, by invoking grounds such as environmental or agricultural policy objectives, town and country planning, land use, coexistence, socio-economic impacts, or public policy. These opt out measures may restrict or ban the cultivation of a GM variety or of a group of GM varieties defined by crop or trait.[32]

[30] Ibid Recital No 16

[31] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member State to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. [2015] OJ L68/1

[32] USDA Foreign Agricultural Information Service, GAIN Report No: FR1624 'EU-Agricultural Biotechnology Annual 2016' available on < https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf > last accessed in May 2017

4.2.2 *The governance of agricultural GMOs biosafety in China*

The legal framework governing the agricultural GMOs biosafety in China is composed of four 'pillars' which refers to four types of laws.[33] The following section will introduce each one of them separately.

The Environmental Protection Law,[34]as the fundamental law regulate all issues relating to the environmental protection and the protection of specific habitats, therefore, in certain degree, it provides the biosafety protection the legal basis. Article 17 of this law states that the "people's governments at various levels shall take measures to protect regions representing various types of natural ecological systems, regions with a natural distribution of rare and endangered wild animals and plants, [and] regions where major sources of water are conserved . . . ."[35] This wording provide the agricultural GMOs biotechnology management the legal ground at the level of the law.[36]

The second pillar include specific legislations addressing agricultural GMO biosafety issues. China has enacted the following regulations and administrative measures in order to achieve better governance on agricultural biosafety: Administrative Regulation on Biosafety of Agricultural GMOs (2001);[37] Management Measures on Agricultural Safety Assessment (2002)[38]; Management Measures on GMOs Labeling (2002)[39]; Management Measures on Safety of Agricultural GMO Import (2002)[40] and Approval Measures on Processing

[33] Wenxuan Yu, Canfa Wang, 'Argo-GMO Biosafety Legislation in China: Current situation, Challenges, and Solutions' (2012) 13(4) Vermont Journal of Environmental Law 865,866

[34] 'Environmental Protection Law of the People's Republic of China', adopted at the 11th Meeting of the 7th National People's Congress Executive Committee on December 26, 1989, amended at the 8th Meeting of the 12th National People's Congress Executive Committee on April 4, 2014

[35] Ibid, Article 17.

[36] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p.866

[37] Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms, adopted at the 38th Meeting of the State Council on May 9, 2001, promulgated by the Decree No. 304 of the State Council, revised in Aug 2011.

[38] Administrative Measures on the Safety Assessment of Agricultural GMOs' Decree No.8 (2002) of the Ministry of Agriculture, issued on 5 January 2002, revised in 2015

[39] Administrative Measures on the Labeling of Agricultural GMOs Decree No.10 (2002) of the Ministry of Agriculture, issued on 5 January 2002

[40] Administrative Measures on the Safety of the Import of Agricultural Genetically Modified Organisms, promulgated by the Decree No. 9 of the Ministry of Agriculture on January 5, 2001, and amended by the Decree No. 38 of the Ministry of Agriculture on July 1, 2004

Agricultural GMOs (2006)[41]. Among them, the 2001 Regulation which issued by the State Council plays the leading and fundamental role the rest of them provide the specific rules and requirements in accordance to the 2001 Regulation regarding to classification-based administration and evaluation, [42] labeling, [43] licensing for production [44] and business operations, [45] and examination and authorization procedures. [46] Therefore, the above legislations constitutes the legal framework for managing agricultural GMOs research, production, and processing; business operations; import and export; supervision; and examination.[47]

There are also regulations were enacted to address other relevant biosafety issues including the genetic engineering safety management, forestry biological safety, genetically modified food safety and the cross boarder movement of genetically modified products.[48] For example, the Administrative Measure on Genetically Engineering Safety Management (1993) [49] provides requirement on taking risk management and safety measures during the genetic engineering research in the laboratory; The Administrative Measure on Examination and Approval of Developing Forestry Transgenic Engineering Activities (2006)[50] governs the biosafety of transgenic engineered forests; The Administrative Measures on Inspection and Quarantine of Import and Export GMO Products (2004) [51] regulates the inspection on transboundary movement of GM products for both import and export activities.

The last but not the least, the legal framework of biotechnology framework is completed by a

[41] Administrative Measures on Examination and Approval of Agricultural Generically Modified Organisms Processing Decree No.9 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 9/2002
[42] The 2001 Regulation on Biosafety of Agricultural GMOs, Article 6
[43] Ibid, Article 8
[44] Ibid, Article 19 to Article 23
[45] Ibid, Article 26
[46] Ibid, Article 39 to Article 42
[47] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p867
[48] ibid
[49] Administrative Measure on Genetically Engineering Safety Management, Decree No.17 (1993) of the State Commission of Science and Technology (SCST Decree 17/1993)
[50] Administrative Measure on Examination and Approval of Developing Forestry Transgenic Engineering Activities, Decree No.20 of the State Forestry Administration, issued on May 11, 2006
[51] Administrative Measures on the Inspection and Quarantine of the Import and Export of GMO Products', issued by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, promulgated by Decree on May 24, 2004

series of technical standards and norms set up for the agricultural GMOs biosafety evaluation. The Ministry of Agriculture, the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and the Ministry of Environmental Protection are the main department who responsible for the testing and assessment on the safety of agricultural GMOs and the risks to the environment, the specific job is carried out by the testing institutes affiliated to the departments mentioned above.[52]

In order to fulfill the legislations and strengthen the implement of the law, the Chinese government have designed different competent authorities or agencies to be specifically responsible for management of GMOs biosafety in their correspondent area. At the national level, the Ministry of Agriculture play the leading role on the biosafety management in general of agricultural GMOs related activities under the supervision of the State Council. In addition, the Inter-Ministerial Joint Conference for Biosafety of Agricultural GMOs is established within the State Council which mainly deal with the significant issues regarding to the agricultural GMO biosafety.[53] The local competent agricultural agencies and health departments above the county level shall be involved in the management and supervision on agricultural biosafety and GM food safety.[54] Also the Ministry of Agriculture is in charge of the examination, supervision and management of GMO labellings at the national level together with the General Administration of Quality Supervision, Inspection, and Quarantine which is in charge of the inspection, testing and verification the labelling process of GMOs.

Regarding to the risk evaluation, the National Agricultural GMOs Biosafety Committee established by the Ministry of Agriculture is responsible for the evaluation on the agricultural biosafety which is constitutes by the specialists and experts from different disciplines including agriculture, medicine, sanitation, food industry, environmentology and detection and inspection. In 2016, the specialists and experts from the field of bioinformatics, genomics, biophysics and genome editing technology have also been invited to the group of committee members in

[52] These standards are on file with China's Standardization Committee; see also Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p868

[53] Ibid, Article 5

[54] The 2001 Regulation on Biosafety of Agricultural GMOs, Article 4

accordance with the development of the new technology.[55] The risk evaluation shall strictly follows the classification based administration and evaluation system which has been established under the 2001 Regulation[56] which shall cover all stages related to GMOs including research, experiments, production, processing, and business operations that import and export of GMOs.[57]

According to the 2001 Regulation, the research and field experiment, production and processing, business operation, import and export, and transboundary movement of GMOs and their products shall obtain licensing accordingly from the competent authorities at the national and local level.[58] The competent authorities including the Ministry of Agriculture, the Ministry of Environmental Protection are in charge of issuing the relevant licenses including the Certificate of Agricultural GMO Biosafety,[59] Certificate of Non-Genetically Modified Agricultural Produce,[60] Permit of Agricultural GMOs Processing,[61] Inspection and Verifying Approval Document of Agricultural GMOs Labeling,[62] Approval Document of Importing Agricultural GMOs,[63] Permit of Transboundary Movement of Genetically Modified Products.[64]

4.3 Risk Assessment

It is fair to say that differences between diverse administrations on GMOs safety adopted by different countries around world are not merely about the various measures and approaches,

[55] Information provided by the Ministry of Agriculture, 'the State have established the 5th National Agricultural GMOs Biosafety Committee' < http://www.moa.gov.cn/zwllm/zwdt/201609/t20160908_5269516.htm> last access, Oct 26, 2017
[56] The 2001 Regulation on Biosafety of Agricultural GMOs , Article 7
[57] Administrative Measures on the Safety Assessment of Agricultural GMOs, Article 2
[58] The 2001 Regulation on Biosafety of Agricultural GMOs; see also Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p871
[59] Ibid, Article 33
[60] Ibid, Article 37. In certain degree, these licenses allow consumers to make informed purchases by disclosing products that contain GMOs.
[61] Administrative Measures on Agricultural GMOs Safety Assessment, Article 15
[62] The MOA Labelling Measure, Article 12
[63] The Administrative Measures on the Safety of the Import of Agricultural GMOs, Article 5
[64] 2001 Regulation on Biosafety of Agricultural GMOs, Article 35; see also Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p871

but the guiding principle of GMO safety evaluation behind.[65] It could be very obvious that the countries heavily relied on the production and export of agricultural GM products are mostly less cautious regarding to the safety administration.[66] For example, the United States adopted the substantial equivalent principle as its conceptual foundation on biosafety management regime.[67] The core point of this principle is that if a GM food could be proved as substantially equivalent to its counterpart conventional food, then the GM food shall be treated no differently from the conventional food. It is, however, the biotechnology itself and the process of research and production shall be strictly regulated and examined.[68] Therefore, the GMOs and the products in the US are assessed based on risk analysis and sound science principle.[69] As major grower country, Canada, Brazil and Argentina also adopted similar principle to the US on the GMOs biosafety management system.[70]

On the contrary, EU's attitude towards the GMOs are very cautious and the general public in the EU also hold skepticism to the safety of GM products.[71] As a large importing country, the safety administration measures on GM product at all stages in the EU is very strict while the safety evaluation which carried out in the final products of GMOs is considered as the strictest in the worldwide. The logic behind the attitude to the GMOs is that although currently there is no scientific evidence could prove the GMOs are hazard to human and animal health and the environment, the potential risk and long-term impact of GMOs are uncertain. Therefore, the European Union adopted the Precautionary Principle as the fundamental principle guiding the legislative framework and safety administration on GMOs. Each Member States also established their own GMO safety administration system in accordance with the principle. Around the world, the EU could be considered as the region that implements the strictest

[65] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p.2158

[66] Jikun Huang and Qingfang Wang, 'Agricultural Biotechnology Development and Policy in China' (2002) 5 (4) AgBioforum 122

[67] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.189

[68] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p.2158

[69] Li Y H, Liu J. 'The safety management model exploration of agricultural GMOs' (2011) 2 Quality and Safety of Agro-Products 43

[70] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p.2158

[71] Ibid.

administration on GM products.[72]

4.3.1 *The EFSA and risk assessment in the EU*

In the European Union, the primary concern for GMO planting and cultivation is the environmental protection and ecological safety.[73] The applicant's environmental monitoring plan need to be thoroughly examined and evaluated by the EFSA GMO Panel as a part of the risk assessment. The European Food Safety Authority (EFSA) is the keystone of European Union risk assessment regarding food and feed safety, animal health and welfare, nutrition, plant protection and plant health. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent and transparent scientific advice and clear communication on existing and emerging risks associated with the food chain. On request from the European Commission, European Parliament or Member States or on its own initiative EFSA provides scientific opinions on issues falling within its remit.[74]

EFSA and the Scientific Panel on Genetically Modified Organisms (GMO Panel) provide independent scientific advice on the safety of: GMOs such as plants, animals and micro-organisms, on the basis of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms; Genetically modified food and feed, on the basis of Regulation (EC) No 1829/2003 on genetically modified food and feed.

EFSA and the GMO Panel carry out risk assessments in order to provide scientific opinions and advice for risk managers. Its risk assessment work is based on reviewing scientific information and data in order to evaluate the safety of a given GMO. This helps to provide a sound foundation for European policies and legislation and supports risk managers in taking effective

[72] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p.2158

[73] Regulation 1829/2003 Article 5(5)

[74] European Food Safety Authority (EFSA), Irina Olaru, Elisabeth Waigmann Annual report of the EFSA Scientific Network for Risk Assessment of GMOs for 2016 available < https://www.efsa.europa.eu/en/supporting/pub/1208e> last accessed in May 2017

and timely decisions. Most of EFSA's work on GMOs is carried out in the context of authorisation applications, since all GM food and feed products must be evaluated by EFSA before they can be authorised in the EU.

As part of its work on the safety assessment of GMOs, EFSA assesses for all GM applications not only possible adverse effects on human and animal health, but also the impact on the environment. This arises from the legal framework for the release of GMOs into the environment. EFSA's GMO Panel evaluates the Environmental Risk Assessment of GM plants and GM microorganisms, carried out by companies asking for a market authorisation.

The GMO Panel considers, for example, if GM plants have adverse effects on non-target organisms; if they are more persistent and/or invasive than their conventional counterparts, or what their impact on the biodiversity would be. The GMO Panel developed a guidance document for the risk assessment of GM plants and derived food and feed which assists applicants in the preparation of their applications.[75] The GMO Panel has updated its guidance with respect to environmental risk assessment in 2010, strengthening the requirements for GM applications submitted to EFSA for evaluation with respect to data generation, collection and analysis.[76] In addition, specific guidance has been developed on the evaluation of possible effects of GM plants on non-target organisms.

The GMO legislation requires applicants to monitor for possible environmental effects associated with the cultivation of GMOs following their introduction in the EU and to report findings on a regular basis to the Member States and the European Commission. During the pre-market risk assessment phase, EFSA's GMO Panel looks at the scientific quality of the post-market environmental monitoring plan proposed by the applicant. Such a plan must be part of the application for a GMO intended for cultivation in the EU.[77] For those GMOs which were approved for cultivation, EFSA's GMO Panel will also be able to assess the annual reports containing information gathered from the monitoring of GM plants authorised for cultivation in

[75] EFSA Panel on GMOs, *Guidance on Risk Assessment of Food and Feed from Genetically Modified Plants*, 2011 EFSA Journal 9(5)

[76] EFSA Panel on GMOs , *Guidance on the environmental risk assessment of genetically modified plants,* 2010 EFSA Journal 8(11)

[77] Ibid.

the EU.

EFSA endeavours to develop networking and stronger cooperation with the Member States, and to strengthen its relationship with institutional partners (European Union and international) and stakeholders, as recommended by EFSA's Management Board. In accordance with EFSA's strategy for cooperating with Member States, the EFSA Scientific Network for Risk Assessment of GMOs (the GMO Network) was established in 2010. Since its inaugural meeting in November 2010, the GMO Network has met once per year.

Members of the GMO Network are organisations nominated through the EFSA Advisory Forum contact point from the Member States: one Member Organisation for molecular characterisation / food-feed safety area of competence and one Member Organisation for environmental risk assessment (ERA) area of competence. The Member Organisations appoint selected experts (and alternates) to attend meetings in light of the topics on the agenda. A maximum of two experts per country are invited to the annual meetings.[78]

4.3.2 *GMOs safety evaluation system in China*

The transgenic biotechnology is designated as a strategic emerging industry regarding to the national development plan. China has adopted a safety evaluation procedure for GMOs based on the following principles, which are: the principle of substantive equivalence, the principle of prevention, the principle of case-by-case analysis, the principle of staged evaluation, the principle of science-based analysis and the principle of familiarity.[79] According to the 2001 Regulation and its auxiliary administrative measures[80], any activities relating to the

[78] EFSA Annual Reports 2016.

[79] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p.2162

[80] Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms, adopted at the 38th Meeting of the State Council on May 9, 2001, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001, and effective as of the date of promulgation; the Ministry of Agriculture subsequently issues three administrative measures in order to support the implement of the 2001 Regulation by providing detailed requirements in the relevant area, which are: Administrative Measure on Safety Assessment of Agricultural Genetically Modified Organisms, Decree No.8 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 8/2002); Administrative Measure on Safety of Import of Agricultural Genetically Modified Organisms, Decree No.9 (2002) of the

agricultural GMOs including research, field trail, production, processing, import and export within the territory of China shall be the object of the safety evaluation in order to prevent possible hazard or risks to human and animal health and the environment.[81] The agricultural GMOs safety evaluation is carried out by the combination of graded approach and multi-staged approach. The graded approach divided the GMOs into Classes I, II, III and IV according to the extent of their risks to human beings, animals, plants, microorganisms and the ecological environment. To be specific, Class I refers to no or unlikely risk; Class II refers to low risks; Class III refers to medium risks and Class IV refers to high risks;[82] while the multi-staged approach refers to research in laboratory, intermediate test, environmental release, pre-production test and the issue of safety certificate.[83]

All the applications for the GMOs authorization need to pass the safety evaluation and shall be submitted to the National Agricultural Biosafety Committee which is formed by the Ministry of Agriculture.[84] The members of the Committee are the scientists and experts from different disciplines and mainly recommended by the members of the Inter-Ministerial Joint Meeting. The Inter-Ministerial Joint Meeting system is established by the State Council and constituted by the head of relevant departments which are the Ministry of Environmental Protection, the General Administration for Quality Supervision, Inspection and Quarantine, the Ministry of Science and Technology, the Ministry of Commerce, the National Development and Reform Commission and the National Health and Family Planning Commission.[85] The members of the National Agricultural Biosafety Committee meet 3 times a year and make decisions on the applications based on the result of safety evaluations of the agricultural GMOs.[86] The Ministry of Agriculture shall, based on the demand of safety evaluation of agricultural GMOs, entrust the competent technical testing institutions to carry out the safety evaluation and provide scientific

Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 9/2002); Administrative Measure on Labelling of Agricultural Genetically Modified Organisms, Decree No.10 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 10/2002) and; Administrative Measure on Hygiene of GMO Foodstuffs, Decree No.28 (2002) of the Ministry of Health of People's Republic of China, issued on 8 April 2002

[81] Administrative Measure on GMOs Safety Assessment, Article 5

[82] The 2001 Regulation, Art 6.

[83] Ibid, Article 19

[84] The 2001 Regulation, Art 9.

[85] Ibid, Art. 5

[86] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.227

ground to the safety evaluation and management.[87]

The agricultural GMOs biosafety evaluation and management system include the report regime and approval regime. The report regime is applicable to the research on GMOs belong to safety Class III and IV and intermediate test; and the approval regime is applicable to the environmental release, pre-production test and the application of safety certification.[88] Regarding to the report regime, any unit who intend to be engaged into research and experiment of GMOs belong to the safety Class III and IV, and intermediate test of all agricultural GMOs shall submit the safety evaluation report of agricultural GMOs and provide relevant technical data and document; the agricultural GMOs biosafety group within the unit is responsible to examine and verify the safety evaluation report and provide examination report. The unit will submit the report to the Ministry of Agricultural. Then the Office of Agricultural GMOs Biosafety Administration within the Ministry of Agriculture will preliminary examine the report, record the report into register, consult with the National Agricultural Biosafety Committee and provide the feedback in written form. Furthermore, the agricultural GMOs biosafety group within the research unit need to report to the Ministry of Agriculture annually on the implementation situation of biosafety management.[89] As to the approval regime, any unit intending to apply for environmental release, pre-production test and safety certificate, shall fill in the agricultural GMOs safety evaluation application form and provide relevant technical document. The agricultural GMOs biosafety group within the unit shall review the application form and technical document then submit them together with the review comment to the competent agricultural authorities at the provincial level where the testing will be carried out.[90] The competent agricultural authorities shall then record the application of safety assessment of agricultural GMOs into record and ensure the basic condition of testing site is true and the precautionary measures are feasible.[91] A written examination suggestions shall be

[87] Administrative Measure on Safety Assessment of Agricultural Genetically Modified Organisms, Decree No.8 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 8/2002) amended by the Decree No.7 of the Ministry of Agriculture in 2016 Art.7

[88] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.224

[89] The 2001 Regulation, Art.12 and Art 13; see also Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.225

[90] The 2001 Regulation, Art. 21.

[91] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.226

provided thereafter. Applicants submits application to the Office of Agricultural Biosafety Administration and the Office shall make decision on whether or not accept the application within two months after receiving. The Ministry of Agriculture then organizes National Agricultural Biosafety Committee to carry out safety assessment. The approval of the safety assessment and the safety certificate of agricultural GMO are signed by the minister, and a copy of the approval and the safety certificate will be sent to the competent agricultural administrative department of the region where the test will be carried out or the safety certificate will be used.[92] Both of the production license and business license issued by the Ministry of Agriculture need to be obtained in case of the production and markering of genetically modified plant seeds, breeding livestock and poultry, aquacultural breeding, and the producer and business operator are obliged to report to the local agricultural administrative department at regular intervals about the relevant situation of production and business.[93]

In addition, regarding to the imported agricultural GMOs, the examination and approval will be various depending on the different purpose of use of the imported agricultural GMOs. The imported agricultural GMOs are divided into 3 categories regarding to their purpose of use, which are: agricultural GMOs for research and test; agricultural GMOs for commercialization; agricultural GMOs to be used for processing raw material.[94] The Office of the Agricultural Biosafety Administrative shall make respond within 2 months on whether or not to accept the case; within 270 days, the MOA and the national inspection and quarantine department shall make the decision on approving or disapproving the application and inform the applicant the result.[95]

[92] Ibid.
[93] Ibid.
[94] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.227; see also Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157 p.2161
[95] Administrative Measure on Safety of Import of Agricultural Genetically Modified Organisms, Decree No.9 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 9/2002) Art.4; Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.227

4.4 Co-existence Policy

'Co-existence' implies two or more things existing in the same place at the same time; and in an ideal world, coexistence should be regarded as essentially passive.[96] Co-existence is not a new issue. Co-existence measures have long been used in the seed industry for production of high purity conventional stocks. Within a farming community, growing similar crops for different markets in the same farming region is not a new challenge. For many years, what might be considered as incompatible crops – for example specialty maize grown for human consumption and waxy maize grown for the starch industry – have been grown in the same areas or even on the same farm. Different types of wheat, barley and rice are similarly grown in close proximity and channelled to different uses. Farmers can follow simple but effective procedures to achieve agreed standards of quality and purity in their harvested product. The introduction of GM crops has however provided a new challenge in finding the appropriate co-existence measures and it has become a critical issue because global cultivation of GM crops has increased rapidly since their introduction in 1996.[97]. It is important to bear in mind that coexistence always refers to GMOs that have passed the very strict authorisation process, including comprehensive assessments of health-related or environmental risks. Therefore, environmental or health-related risks do not concern the formulation of coexistence rules.

As early as 2006, the EU Commissioner for Agriculture and Rural Development noted that the complex issue of coexistence often reflected conflicting goals among producers and consumers. Some farmers focus on enhanced competitiveness and see an important role for GMOs, while others prefer traditional practices. Some European consumers value 'quality production' and products 'linked to traditional practices and geographic origin'.[98] These values are consistent

[96] Luc Bodiguel, Michael Cardwell, Ana Carretero Garcia, and Domenico Viti, 'Coexistence of Genetically Modified, Conventional, and Organic Crops in the European Union: National Implementation' Luc Bodiguel and Michael Cardwell eds, *The Regulation of Genetically Modified Organisms: Comparative Approaches* 2010 Oxford 163

[97] Margraret Rosso Grossman, 'Coexistence of Genetically Modified, Conventional, and Organic Crops in the European Union: The Community Framework', Luc Bodiguel and Michael Cardwell eds, *The Regulation of Genetically Modified Organisms: Comparative Approaches* 2010 Oxford 125

[98] Speech by Mariann Fischer Boel, Member of the European Commission responsible for Agriculture and Rural Development, "Co-existence of genetically modified crops with conventional and organic farming at the Conference on Co-existence in Vienna. < http://eu-un.europa.eu/speech-by-commissioner-fischer-boel-co-existence-of-genetically-modified-crops-with-conventional-and-organic-farming/> accessed in May 2017

with the European model of agriculture that balances socio-economic, as well as environmental and territorial considerations. Other consumers value food produced by organic farmers or with traditional methods; some believe that GMOs are not compatible with traditional production. Many producers and consumers prefer to avoid mixing GM and other crops.

However, it might not only be about people's preferences. Friends of the Earth Europe asserted that: 'GMO contamination is a new type of pollution created by industry. It involves living and replicating organism, and because it involves the building blocks of life (genes), is irreversible as well as increasing over time. It can occur at any stage along the food chain as a result of natural processes and human intervention: from seed production, to crop growing, to harvesting, to storage, to transport, to processing and packaging'.[99]

There is no doubt that the very concept of 'coexistence' and its effectiveness is controversial and has engendered years of continual debate. And the issue the co-existence of GM crops and non-GM crops has caused attention from the major developed countries and regions for a time. The United States, Japan and the EU have all already set up policies and regulations on the co-existence of GM crops and non-GM crops.

However, China does not have a co-existence policy. As China is the sixth largest producer of agricultural biotechnology crops in the world by area,[100] this omission is surprising and could cause potential problems in the management of GMO crops and concerns as to the protection afforded by the GM governance arrangements to both farmers and consumers. By contrast, the EU has focused on co-existence from the early stages of its legislative process of GMOs.

In the EU, the European Council, European Parliament, and various committees have considered the issue and the European Commission published a set of guidelines in July 2003

[99] Friends of the Earth Europe, *Contamination or Legislate? European Commission Policy on 'Coexistence'* Friends of the Earth Europe Position Paper April 2006 < http://stopogm.net/sites/stopogm.net/files/contaminatelegislate.pdf> accessed in May 2017

[100] International Service for the Acquisition of Agro-Biotech Applications (ISAAA) 2015 Report

about the coexistence of GM and non-GM crops.[101] The guidelines are based on the principle that coexistence is about providing farmers and consumers with a practical choice between conventional, organic or GM food and feed production. These guidelines for Member States suggest best agricultural practices to follow when growing GM and non-GM crops so as to enable the farming community to continue growing non-GM crops without exceeding the labelling threshold. Since the publication of the Commission guidelines, a number of Member States (e.g., Denmark, Netherlands, and Spain) have developed country-specific guidelines and/or legislation that provide rules for the growing of GM crops. While some argue that Community-level legislation should govern co-existence, others believe that Member States should develop measures and implement them. In the end, policy-makers decided that it is for the best interest of various Member States to regulate coexistence to ensure that critical 'geographical, ecological and climatic conditions' that affect crop production can be considered.[102]

Article 22 of Directive 2001/18 states: "Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this directive." At the same time, Article 26a says "Member States may take appropriate measures to avoid the unintended presence of GMOs in other products."

In order to meet the requirement of being "appropriate", any co-existence measures taken by Member States must be: Aimed at avoiding economic loss to other farmers; proportionate to the legitimate objective (ensuring that non-GM products adhere to GM content less than the 0.9% labelling threshold); and compatible with basic principles of EU law (especially free movement of goods).

In March 2015, a research project, which was funded by the EU, called 'Practical

[101] Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.

[102] Speech by Stavros Dimas, Member of the European Commission, responsible for Environment: "Co-existence of genetically modified, conventional and organic crops: Freedom of choice. Conference on GMO co-existence. < http://eu-un.europa.eu/speech-by-european-commissioner-dimas-co-existence-of-genetically-modified-conventional-and-organic-crops/> accessed in May 2017

Implementation of Coexistence in Europe' (PRICE) released its conclusions. It involved a research consortium consisting of fourteen universities, agencies and firms under the co-ordination of the Technical University of Munich, Germany. The main results are the following:

> The current measures implemented to ensure coexistence of GM and non-GM crops in the EU are practically feasible, both at farm level and along the supply chain. However, they come with additional costs, which are currently met partly by consumers and partly by other supply chain stakeholders.
>
> Over a two-year period, field trials with GE corn were conducted in Spain, applying buffer zones or different sowing dates resulting in asynchrony in flowering. In this study, researchers concluded that the current isolation distances set up by most member states were disproportionate and may lead to unnecessary costs and burden. For a wind-pollinated plant such as corn, separation distances of about 20 meters are sufficient to ensure coexistence without cross pollination of non – GM crops by GM plants.
>
> Another team developed a decision-making tool that evaluated the effect of specific buffer zones or of a difference in flowering time on the probability of cross-pollination for corn. It thus makes it feasible to implement proportional coexistence measures.[103]

The EU's policy on co-existence could be seen as a successful co-existence of GM and non-GM crops in the worldwide. Because it is not just possible in theory, it is a practical reality. Since 1998, growing numbers of European farmers have chosen to plant approved GM varieties on their farms, and have demonstrated that they are fully capable of managing the farm-level practices that allow them to do so in harmony with their neighbours and with their own non-GM

[103] GAIN 2015 EU Report p26

crops. The key to this success is a regulatory and political environment which provides European farmers the freedom to choose their agricultural practices and which is based on principles of proportionality and non-discrimination.

The coexistence of transgenic and non-genetically modified crops in the European Union laid a theoretical foundation which China could learn as a reference for the establishment of a practical, feasible and sound coexistence legal system. Moreover, the legislative practice and operational experience of European Union's coexistence police provide a practical basis to China's coexistence regime. The decision makers shall explore the proper mode and measure of coexistence on the basis of China's specific national conditions.

4.5 Labelling and Traceability

The purpose of labelling regulation is to protect the consumers' right to know by providing the true information so they could make informed choices, while the traceability enables GMOs products especially GM foods and feeds can be traced and under the supervision at all stages of the supply chain. Traceability also makes labelling of all GMOs and GM food and feed products possible. It allows for close monitoring of potential effects on the environment and on health. Where necessary it can allow the withdrawal of products if an unexpected risk to human and animal health and to the environment safety is detected. Currently, there are numbers of countries have adopted labelling approaches for GMOs which are various based on the different national conditions. Among them, the United States, Argentina and Canada as the major producer and exporter country of GM crops, apply voluntary labelling approaches on GMOs,[104] while the EU and China have adopted mandatory labelling requirements.

The legislation on GM products labelling adopted by China is similar to the EU yet have some differences. To be specific, the EU and China both adopted mandatory requirements to products which contain, consist of GMOs, or produced from GMOs. One of the major

[104] Guillaume P. Gruère, A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule, *The Journal of Biotechnology Management and Economics* 2007 10(1) 51 p.52

differences between EU and China's labelling legislations is the requirement on traceability. The Food and Feed Regulation of the EU established a comprehensive traceability regime for GM food and feed products which ensures at each stage of related to the GM food and feed production and processing, the relevant information is available to be obtained by the operators and the comprehensive traceability regime will also facilitate the labelling requirements to be fulfilled in accordance to the legislation.[105] The labelling legislation of GMOs in China is also follow the process-based principle, the traceability mechanism provided in the legislations is comparatively incomplete and lack of feasibility.[106]

Another key element in the EU Food and Feed Regulation is the threshold approach applied to the labelling requirement.[107] Accordingly, this approach tolerances adventitious and technically unavoidable GMO presence in the final GM products and it set the threshold as 0.9% of the food ingredients considered individually or food consisting of a single ingredient. GM Labelling will be exempted if the GMO presence is lower than 0.9% in the final GM food and feed. However, China has not yet adopted a similar approach. Furthermore, the labelling legislations in the EU provide very specific requirements on labelling and the range of products covered by the legislations is broad.[108] In comparison, the GM labelling requirements in Chinese legislation is mostly vague and lack of feasibility, also the subject of the GM labelling (which was listed-out in the Administrative Measure on Labellings of Agricultural GMOs) is comparatively limited and needed to be updated.[109]

It is generally agreed that the labeling rules are unclear in China and enforcement is weak and inconsistent, the EU's GM food labelling regulation will be a valuable model to China in order to improve the legislations on GMOs labelling and therefore achieve a higher level of

[105] Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons From the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465 p.473
[106] Ibid.
[107] EU 1830/2003, art 7: "not apply to traces of authorized GMOs in a proportion no higher than 0.9% or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable"
[108] EU 1830/2003, Article 2—scope and Article 4--Labelling
[109] Administrative Measure on Labelling of Agricultural Genetically Modified Organisms, Decree No.10 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 10/2002) See Appendix; see also Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons From the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465 p.469

agricultural biosafety management.

4.5.1 *Review of the EU's legislation on GMOs labelling and traceability*

From the perspective of the legislative principle and legislative concept, the Chinese legislation on GM food labelling is similar to the EU's. The GM labelling and traceability regime which constructed by the Regulation 1829/2003[110] and the Regulation 1830/2003[111] is regarded as the most comprehensive management regime on GMOs and will be very valuable to China and also will help China to avoid similar problems that the EU already have encountered.[112]

The history of EU's establishment of GMOs labelling could be traced back to 1990s. The first legal requirement on GM food labelling was stated in the Regulation (EC) No. 258/97.[113] From that time on the EU has made persistent efforts on reviewing and improving the legislation on GM labelling.[114] Subsequently the Regulation 1139/98[115] expended the range of labelling varieties which included the GM maize varieties and GM soy varieties. The following Regulation 50/2000 include the all GM additives and GM flavoring in to the object of GMO labelling requirement.[116] In 2003, the Regulation 1829/2003 and Regulation 1830/2003 were enacted and the current GMOs labelling and traceability management regime was therefore completed. The Regulation 1829/2003 applies to both foods and animal feeds which produced from GMOs or contain ingredients produced from GMOs while the

[110] Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed [2003] OJ L 268/1

[111] Regulation No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC [2003] OJ L 268/24

[112] Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons From the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465 p.470

[113] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients OJ L43/1

[114] Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons From the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465 p.474

[115] Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC

[116] Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms; See also Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons From the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465 p.474

Regulation 1830/2003 provide legal requirements for traceability and labelling of GMOs. These regulations apply to products originating in the EU and imported from third countries. Bulk shipments and raw materials must be labeled, as well as packaged food and feed.

In the EU, the products exempt from labeling obligations are: Animal products originating from animals fed with GM feed (meat, dairy products, eggs); Products that contain traces of authorized GM ingredients in a proportion no higher than 0.9 percent, provided that this presence is adventitious or technically unavoidable; products that are not legally defined as ingredients according to Article 6.4 of Directive 2000/13/EC[117], such as processing aids (like food enzymes produced from GE microorganisms).

Labeling regulations for food products are presented in Regulation (EC) No 1829/2003, Articles 12 to Article 13:

> Where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified [name of ingredient]' must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GE component should be labeled "contains [name of ingredient] produced from genetically modified [name of organism].";
>
> Where the ingredient is designated by the name of a category (e.g., vegetable oil), the words "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]" must be used;
>
> The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients.

[117] Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. OJ L109/29

> Where there is no list of ingredients, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must appear clearly in the labeling. For example, “genetically modified sweet corn;” or “containing caramel produced from genetically modified corn” for a product with no list of ingredients.
>
> In the case of products without packaging the labels must be clearly displayed in close proximity to the product.

Labeling regulations for animal feed are presented in Regulation (EC) No 1829/2003, Articles 24 and Article 25:

> For feed containing or consisting of GE ingredients, the words “genetically modified” or “produced from genetically modified [name of the organism]” must follow in brackets immediately after the name of the feed.
>
> For feed produced from genetic engineering, the words “produced from genetically modified [name of organism]” must follow in brackets immediately after the name of the feed.
>
> Alternatively, these words may appear in a footnote to the list of feed. They shall be printed in a font of at least the same size as the list of feed.

In addition, the traceability rules defined in Regulation 1830/2003 require all business operators involved to transmit and retain information on GM products in order to identify both the supplier and the buyer of the product.[118] Operators must provide their customers with the following information, in writing: an indication that the product, or certain ingredients, contains, consists of, or is obtained from ‘GMOs’; information on the unique

[118] Regulation 1830/2003, Art. 4

identifier(s) for these 'GMOs'; in the case of products consisting of or containing mixtures of 'GMOs' to be used only as food or feed or for processing, this information may be replaced by a declaration of use by the operator. It has to be accompanied by a list of the unique identifiers for all those 'GMOs' that have been used to constitute the mixture.[119] In addition, for a period of five years after every transaction within the supply chain, every operator must keep a record of this information and be able to identify the operator from whom they bought the products and the one to whom they supplied them.[120]

The unique identifier approach is a great contribution by the European Union regarding to the implement of traceability regime. In 2004, the European Commission devised a system of unique identifiers to be assigned to each GMOs and promulgated the Regulation (EC) No 65/2004 to establish this new system.[121] The Annex of this regulation prescribes the format of the identifier. The function of the unique identifier is that in any stage of the GMO product to be placed on the market from production to distribution, the information of the former supplier of the product and the next operator of the product (on step up and one step down) could be tracked through the information recorded in identifier. To the GMOs, the format of unique identifier is created by the Organization for Economic Cooperation and Development and it has been used for its Bio-Track product database and the Biosafety Clearing House.[122] The European Commission requires a document accompanied to each GMOs food and feed or GMOs for processing to indicate each GMOs ingredient the product concerns.[123] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity in Article 18(2) provides specific requirements for those accompanied document of GMOs food and feed.[124] The Commission requires the applicant must develop the unique identifier for each GMO food and feed as the condition in the authorization decision[125] and it shall be recorded in the relevant register.[126]

[119] Ibid.
[120] Ibid.
[121] Commission Regulation (EC) No 65⁄2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms [2004] OJ L10/5
[122] Regulation (EC) 65⁄2004, Preamble.
[123] Ibid, Art. 2.
[124] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.140
[125] Regulation 65⁄2004, Art 3(a)
[126] Ibid, Art 3(c), 5(3)

4.5.2 *A review of Chinese legislation on GM food labelling*

The 2001 Regulation is not only the core regulation of the biosafety management in China but also it firstly established the mandatory labelling requirement to GMO products.[127] The GMOs labelling is currently regulated under the 2002 Administrative Measures on the Labelling issued by the Ministry of Agriculture in accordance to the 2001 Regulation issued by the State Council.[128] According to the Measures, there are three categories of GM products are required to be labelled mandatorily: the genetically modified animals, genetically modified plants and genetically modified micro-organisms; products directly processed from genetically modified agricultural products; and products produced from agricultural genetically modified organisms or products consisting of genetically modified organisms ingredient, while the products that are made using GMOs but where the presence of the GM material is no longer detectable in the final product.[129] There is also a range of specific GM products listed out in the Appendix of the Administrative Measure of Labelling which are the subject to the mandatory labelling requirement: soybean seeds, soybeans, soybean powder, soybean oil, and soybean meal; maize seeds, maize, maize oil, and maize powder; rapeseed for planting, rapeseeds, rapeseeds oil, and rapeseed meal; cotton seed; tomato seed, fresh tomato, and tomato paste.[130]

The Administrative Measure issued by the Ministry of Agricultural specifically targets GMO labelling. According to the Measure, the Ministry of Agriculture under the State Council is designated to be in charge of examination and approval as well as the supervision on GMO labellings in the nationwide.[131] The department of agricultural administration of local government above the county level shall be responsible to supervise and manage the

[127] Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001, and effective as of the date of promulgation, Article 28.
[128] Ibid
[129] Administrative Measure on Labelling of Agricultural Genetically Modified Organisms, Decree No.10 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 10/2002) Art. 6
[130] Ibid, see the Appendix.
[131] Administrative Measure on Labelling of Agricultural Genetically Modified Organisms, Article 4.

compliance of GMO labeling requirements, including the review and approval of GMO labeling for imported products.[132]

It seems that the GMOs labelling legislation in China is already in place and could provide the implementation of the labelling requirement a legal ground. However, after nearly 15 years of legal practice, the current situation of GMO labelling enforcement is not promising.[133] The lack of compliance and enforcement of the labelling requirement is caused by many reasons, mainly because of the loopholes existing in the current legislation.

First of all, the labelling requirements are not explicit. Take the GM soybean oil as an example, according to the 2001 Regulation, the GM soybean oil should be labelled as it is the "products directly processed from genetically modified agricultural products"[134]; however, if this GM soybean oil be mixed with other oil and processed as a new cooking oil, whether this re-processed products or other deep-processed products need to be labelled as GMOs products is not regulated by the current legislation.[135]

Secondly, the scope and coverage of labelling requirement causes confusion since it is both widely defined in the 2001 Regulation which are three categories (the genetically modified animals, genetically modified plants and genetically modified micro-organisms; products directly processed from genetically modified agricultural products; and products produced from agricultural genetically modified organisms or products consisting of genetically modified organisms ingredient, while the products that are made using GMOs but where the presence of the GM material is no longer detectable in the final product) and narrowly listed in the Administrative Measure on GMO Labelling which are 5 groups of GM products (soybean seeds, soybeans, soybean powder, soybean oil, and soybean meal; maize seeds, maize, maize oil, and maize powder; rapeseed for planting, rapeseeds, rapeseeds oil, and rapeseed meal;

[132] MOA Labelling Measures, Article 4. See also Yu Zhuang, Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law in China with Lessons From the European Union' (2013) 14(3) Vermont Journal of Environmental Law 465, p.468

[133] Yu Zhuang, Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law in China with Lessons From the European Union' (2013) 14(3) Vermont Journal of Environmental Law 465, p.469

[134] The 2001 Regulation, Art.3

[135] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p247

cotton seed; tomato seed, fresh tomato, and tomato paste).[136] In addition, the legislation of GM labelling in China does not provide requirement to GM feed which is not appropriate since there are large amount of GM feed imported into Chinese market and the meal of soybean seed, cotton seeds and rapeseed after oil pressing are mostly used for animal feed purpose.[137] Thirdly, the standardized format requirements of GM labelling including the pattern, character font, character size and colour are not provided by the legislation. Therefore, some producers or business operators may take the advantage of this loophole and use vague and obscure language in the labelling or make the labels less obvious. According to a survey carried out about the consumers' attitude on GM foods, there are half of the interviewed consumers found it difficult to recognize the GM labeling on the package of the product.[138]

Furthermore, the threshold approach allows adventitious or technically unavoidable presence of GM material in the final products and could enhance the feasibility and enforceability of the GM labelling legislation. China has not yet adopted a threshold approach regarding to the GMOs labelling and this "zero percent tolerance without a reasonable adventitious presence threshold is both unrealistic and misleading."[139] Lack of setting threshold in the current Chinese labelling system, it is difficult to handle pollution caused by adventitious or technically unavoidable presence of GMOs and the 'zero threshold' is neither scientifically practicable nor legally reasonable.[140] The last but not least, the current legislation is lack of one important element that it does not specifically emphasis on implementing the traceability of GMO products, or in other words, the current regulatory framework does not require tracing GMOs and its products at all stages from research to marketing through the distribution chain.[141]

The above discussed shortcomings of Chinese GM product labelling is not new issues to the legal scholars and experts of the relevant field, the appeal to the government of amendment on

[136] Yu Zhuang, Wenxuan Yu, p.469
[137] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p250
[138] See Dayuan Xue, p.248
[139] Yu Zhuang, Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law in China with Lessons From the European Union' (2013) 14(3) Vermont Journal of Environmental Law 465, p.470
[140] Dayuan Xue, p.248
[141] Yu Zhuang, Wenxuan Yu, p.470

GM products labelling has been ongoing in the recent decade. In May 2015, after a long period of waiting, the newly revised Food Safety Law[142] which is China's highest-level food law, was promulgated and came into force in October, 2015. It explicitly provides that the 'production and distribution of GM food must label prominently pursuant to law'[143] and stipulates correspondent administrative punishment for law-violation.[144] The 2015 Food Safety Law unfortunately fails to address certain critical issues, such as what constitutes GM food and the labeling methods deemed to be 'prominent'. Although the 2015 Food Safety Law provides a legislative basis for mandatory labeling of all GM food for the first time, it still lacks the detailed rules sufficient to command compliance and to be enforced.

4.5.3 *Possible improvements for the GM labelling legislation in China*

It is obvious that the Chinese legislative framework on biosafety management has been impacted by the EU biosafety management regime in several aspects, in regard to the GMOs labelling approach, the EU also set up a valuable module for China to learn from. However, China is different from the European Union in many aspects regarding to the political regime, national conditions, economic development. Therefore, China shall consider about its own national situation while adopting the GMOs labelling regime of the EU, for example, in China the consumers may comparatively have less knowledge about GMOs safety in food production than the European consumers, and generally speaking Chinese customers have less income, therefore, the food price might take a more important role in customers' choice in China.[145] Also, there are great numbers of private and individual-owned business of food production and processing which cause practical difficulties in management and supervision of the GM food labelling.[146] Therefore, China shall adopt EU's approach in a customized way regarding to its own social conditions in order to achieve a more effective and enforceable management on

[142] 'Law of the People's Republic of China on Food Safety', adopted at the 7th Meeting of the 11th National People's Congress Standing Committee on February 28, 2009, amended at the 14th Meeting of the 12th National People's Congress Standing Committee on April 24, 2015.
[143] 2015 Food Safety Law, Article 69.
[144] 2015 Food Safety Law, Article 125.
[145] Yu Zhuang, Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law in China with Lessons From the European Union' (2013) 14(3) Vermont Journal of Environmental Law 465, p.470
[146] Ibid.

GMOs products labelling.

Based on the analysis of both the EU and China's GM labelling legislations, there are some valuable experiences which China could learn from the EU in order to improve the GM food labelling legislation. Firstly, the range of labelling on the GMOs and its products needs to be largely broadened and the labelling on animal feed shall also be considered;[147] secondly, specific and detailed requirements on the format of labellings on GMOs products should be provided in the legislation; thirdly, a threshold regime needs to be adopted in Chinese GMO labelling system; and finally, in order to enhance the traceability, the unique identifier system shall be introduced into the current labelling system. The detailed proposal for improving the Chinese legislative framework will be discussed in the following chapter.

[147] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p880

Chapter 5 Conclusion

5.1 Introduction

It is not surprising that debates around the safety of GMOs to the environment and human beings continued for nearly thirty years since the agricultural transgenic crops have been commercialized. The transgenic technology is very new and its utilization in agricultural and food production is relevant to every one of us as consumers, and because of its environmental implications. It is also a process for different countries and international society to explore and develop the legislation regime of biosafety. Given the increasing cultivated area of GM crops, and public concern over the safety of transgenic technology and products, the regulation of agricultural biotechnology presents challenges for environmental governance for public authorities around the world, and these must be addressed.

Different countries choose strategies and map out the legal regime and mechanisms based on their own conditions including the biotechnology development level and trend as well as the need for biosafety protection. Yet from the perspective of the legislation and management, the biosafety legislation in general could be divided into two representative types. The first one is 'technology-based management', mainly adopted by the European Union and its member states. Under the technology-based management, the policy maker considers the modern biotechnology has potential and unforeseen risks and the precautionary principle is regarded as the fundamental principle of the legal framework. Thus, any research activity and products related to the modern biotechnology should be assessed and managed. The other one is 'product-based management' represented by the countries including the US and Canada. Under this legislative and management mode, the transgenic technology is considered as neutral and has no substantial difference from the traditional biotechnology; therefore, following the substance equivalent principle the legislation and management should be focus on the product itself instead of the technology.[1]

[1] Dayuan Xue (ed.), Biosafety and Regulation for Genetically Modified Organisms (Beijing Science Press, 2009) p183

China has now become the world's largest importer of genetically modified crops and one of the largest producers of GM cotton. At the same time, the Chinese government has made great efforts to develop a robust legal framework for the regulation of the development, risk assessment and marketing of GM products and foodstuffs containing GM ingredients. A new and comprehensive administrative framework for the regulation of GM crops and food has been established since 2001. This thesis has attempted to present a survey of the current legislative framework in China on GMOs. One of the principal objectives of this thesis is to provide proposals to address unsolved problems relating to the development, approval and marketing/commercialization of agricultural biotechnology for the future in China.

The study of GMO politics and regulations in this thesis is an example of how contemporary conceptions of biotechnology are an outcome of social, political, economic, and scientific interpretations and strategies deployed by various actors involved in the regulation of that specific technology. One conclusion that might be derived from the investigation presented in Chapters 3, 4 and 5 is that the designing of regulatory framework for agricultural GMOs could be influenced by many considerations, including domestic and international ones. Many competing interests are involved, both internationally and domestically.

Internationally speaking, the EU and the US represent the two opposing philosophies shaping the regulation of agricultural GMOs worldwide. The survey presented in Chapters 2 and 3 showed that the EU's precautionary approach has been very influential in the design of the whole regulatory framework in China. The thesis elaborated upon the regulation and administration on agricultural biotechnology in the EU and China and concluded in Chapter 4 that there are some similarities, but also some differences, between the two legislative regimes. The reason for choosing the EU as the model and the comparator for interrogating potential changes to, and improvements in, GM governance in China are many. To start with, the EU and China share common points in regulating agricultural biotechnology, for example, both follow the precautionary principle, and both have adopted mandatory labelling requirements for food products contain GM material or ingredients. Moreover, the EU is well known as its high level

of legal protection for human health and the environment and is experienced in GMOs legislation. The earliest regulation on GMOs of the EU could be traced back to 1990s, and the challenges and the solutions which the EU has developed over that period since 1990 could be a valuable reference point for evaluating the performance of the governance arrangements for GM releases and food production and marketing in Chinese law. Another obvious reason to adopt the EU governance model as a comparator is that China, like to the EU, is not a major exporter of GM products, but an importer. As an importer, the issues of biosafety and food safety are challenging. For these reasons, the EU was chosen for its well-developed and useful legislation model.

Considering the domestic factors, the use of transgenic technology offers benefits and opportunities to the agricultural development and agricultural production. Some countries in the aspect of agricultural production and trade has already be benefited from the application of agricultural biotechnology. For example, the US is the most successful country in the world in using transgenic technology as the core in the agricultural technology; Brazil and Argentina respectively became the second and third largest soybean exporters after developing major GM soybean production and export. South Africa changed from being a net corn importer into a net corn exporting market after GM maize was introduced and grown. The similar story happens to other countries because of the adoption of GM technology and the extensive planting of new varieties of GM crop. It could be seen that many countries especially the developing countries have chosen the GM technology as the strategic priority in order to improve their competitiveness of agricultural production in the worldwide.[2]

China has embraced agricultural GM technology with enthusiasm since the middle of 1980s, mainly for economic and political reasons. Considerable public funds have been invested in this area. In the future, China is expected to continue pursuing the development of agricultural biotechnology because the technology is expected to ultimately become the solution to various existing problems of the Chinese agricultural sector, including production efficiency, food

[2] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157, 2163

security, food safety and environmental protection.

There is no doubt that China is in the process of rapid development which is bracing yet stressful. China has to deal with problems left over by the boom of industrialization and urbanization, for example the difficulties cause by huge population, limited arable land and resources. The national food security and sufficient agricultural products supply is the priority of Chinese government and also the fundamental policy concern likely to underpin all the development in the future. Under the multiple pressure, merely rely on traditional agriculture will limit the possibility of increasing the total grain output and enhancing the quality of the grain, therefore, the promotion of research and development programmes on agricultural GMOs become an important and even imperative strategic option to the Chinese government in order to ensure the food security.[3] To certain extent, agricultural GM technology is in itself potentially neutral in its effects on the environment and public health: genetically modified seeds, for example, pose no threat to human health or the environment unless they are planted, and much will then depend on how the resulting crops are managed while growing *in situ*, and how the produce subsequently derived from the harvested crops is processed and then marketed in the food chain. In other words, whether the technology is safe or not depends on both ways of how it is used and how it is developed and used within agricultural production. The identification of deficiencies in the governance arrangements for GM agriculture in China, and the means to adapt and improve the regulation of GM crop development and use, is therefore a matter of some importance for the development of a strong, safe and successful agricultural sector in China.

Recommendations for improvements to the governance arrangements for the development, approval and marketing of products that use agricultural biotechnology are made in section 5.4 below. These are based on three fundamental governance principles:

1. *Transparency of Decision Making,* that is the need to introduce requirements for all relevant scientific and governmental decisions as to (for example) risk assessment and product authorizations to be published in a manner that makes them available to citizens,

[3] Ibid, p2163

2. *A Robust Scientific Evidence Base for Decision Making,* including where necessary peer review of all recommendations on risk assessment by appropriate expert bodies. This is necessary to underpin and strengthen public confidence in decision making on GM products, and
3. *A Recognition of the Importance of Measures to Maximize Public Choice* in using GM and non-GM products e.g. by ensuring that the labeling of food products that contain GM ingredients is robust and appropriate to inform consumer choice in the market place.

5.2 Research Questions and Main Findings

The thesis took as its principal focus the analysis of the way in which multi-level governance operates somewhat differently in China and the EU in the governance of the development, marketing and production of agricultural products using biotechnology. This inquiry was organized around the following research questions:

RQ 1 What can China learn from the EU in relation to the regulation of agricultural biotechnology?

RQ 1.2 What is the role of law in regulating agricultural biotechnology and its use in food production in the EU, and China?

RQ 1.3 What is the role of the precautionary principle in EU and Chinese law on agricultural biotechnology and its use in food production?

RQ 1.4 What principles are applied in undertaking risk assessments prior to authorizing the use of biotechnology products in food production in the EU, and China?

RQ 1.5 What are the principal differences between the regulatory regimes for agricultural biotechnology and its use in food production in the EU and China?

RQ 1.6 What can China learn from the EU and its member states, and from their regulatory approach to biotechnology and its use in food production?

RQ 2 To what extent, and how, can regulatory measures minimize the risk of environmental damage arising from the use of agricultural biotechnology,

while also maximizing its potential benefits in food production?

RQ 3 .1 To what extent, and if so how, do regulatory measures in China promote and protect "organic" ('green food') food production?

RQ 3.2 Should China adopt coexistence measure for GM and non-GM production, and if so what model should be adopted for GM coexistence measures?

RQ 4 What reforms to the regulation of agricultural biotechnology are desirable and/or necessary in order to protect the environment in the PR of China while also maximizing its potential benefits in food production?

In order to interrogate these questions, the thesis has adopted a comparative approach as its methodology. By mapping out the regulatory framework in both the EU and China, the range of key questions which were identified in the beginning of this work have been answered while this studied was carried out chapter by chapter.

Chapter 2 introduced the regulation and the management regime of agricultural biotechnology in China. It firstly provided an overview of the development of agricultural biotechnology and identified the goals and strategies of GMOs research and development and the early stage of biosafety legislation. The following section mainly focused on the institutional aspect of the GMO regulations in China. It explained the Chinese legal hierarchy and the historical evolution of GMO regulation as the background knowledge. Furthermore, this chapter in detail illustrated the substantive aspects of the GMO regulation, including the regulation of GMO research, regulation of production and processing, regulation of marketing, regulation of GMO labelling and regulation on imports and exports of GMOs. As it has been stated in the chapter, there is no 'law'[4] specifically regulates the GMOs in China. The current regulations on GMOs are enacted by the State Council in 2001 and its three auxiliary Administrative Measures are enacted and implemented by the Ministry of Agricultural. The subject of the current GMO regulations in China mainly include the research relevant activities, evaluation, production, processing,

[4] The legal hierarchy is divided into five levels according to their legislative body and effect. The 'Law' is usually enacted by the National People's Congress and the National People's Congress Standing Committee.

marketing and import and export activities within the territory of China. Finally, this chapter summarized the international influence on reforming the regulatory framework on biotechnology in China.

As to the characteristics of the GMO regulation in China, the following features may be identified. Firstly, China used legal binding regulations, rather than the voluntary guidelines. Instead of revising the existing regulation, a new regulatory mechanism needs to be built up specifically target to regulate the agricultural GMOs. China has made a series of regulation and administrative measures on GMOs safety management and the competent authorities and their responsibilities are confirmed.[5] According to the current regulations, all GMO products need to pass the safety evaluation and obtain permission for processing and production before entering market.[6] Also, the labelling requirement is compulsory for all kinds of GMOs products. There is also an import approval management mechanism has been set up regarding to import activities of agricultural GM products. In addition, a technical supportive system for standardizations including safety evaluation specifications, trial specifications and criteria specifications is also available.[7] Thus, the current regulatory system governances and regulates all research activities and processing and production related to agricultural GMOs in China.

Secondly, China took a multi-ministry approach, and as a result several ministries and agencies are involved in the regulatory framework. The regulation of GM technology in agricultural is , in China, a good example of multi-level governance in which key decisions about differing aspects of the research, development, testing, safety appraisal, market release, then production, of GM crops are taken by different public bodies, scientific panels and governmental agencies Nevertheless decision-making has on the whole become more transparent, as relevant documents and information can be found on official websites or as its official publications. The Ministry of Agricultural plays the leading role in this regulatory framework. Biosafety and environmental considerations are, in theory, taken into account, but the overriding priority of

[5] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157, p2161
[6] Ibid. p.2161
[7] Ibid. p.2161

the MOA is increasing agricultural production. Arguably, the introduction of a more active role for the Ministry of Environment is necessary if environmental protection issues and concerns are to be addressed effectively in the governance arrangements for GM agriculture in China.

Chapter 3 introduced the European Union's regulatory regime for GMOs. This chapter analyzed the historical reason of EU's current cautious attitude to the adoption of the use of GMOs in agricultural production. Then a detailed introduction of the role of the precautionary principle in the EU's environmental legislation system had been provided. The study of the legal frame work has been divided into two main sections: the regulations on contained use and the deliberate release of GMOs, and then the regulation of GM food and feed. The three guiding principles of EU laws on the commercial use of GMOs could be summarised as safety (for human and animal health and the environment), freedom of choice for consumers, farmers, and businesses (rules on coexistence, labeling and traceability), and case-by-case evaluations. Based on the development timeline of regulation, the study on GM food and feed was presented respectively as the legislative framework pre-2003 and post-2003.

This chapter also highlighted some key issues with strong EU characteristics including the multi-level governance of GMOs in the EU and the coexistence policy. The multi-level governance has always been considered a unique feature of the EU's character in its policy making – although our analysis of Chinese legislation and decision making on biotechnology in Chapter 3 showed that it, too, displays strong traits of multi-level governance (albeit organized in a different manner from those in the EU)[8]. The EU's agricultural biotechnology regulations occur at three levels which are the EU level, internally with individual member states and externally within international conventions, in other words, the agricultural biotechnology regulation is the subject of at least three 'layers' of multi-level governance. Profound and long-lasting disagreement over the proper role for agricultural biotechnology led to legislation that attempts to share authority and avoid hierarchical decision making within the EU.

[8] Referenced from the Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar Publishing Limited, 2008)

The multi-level governance in the EU requires institutions which enable collaboration, learning and discussion in order to escape the limited solutions or deadlocks that might occur when using harder edged techniques of law and government. Another highlighted factor in the EU's agricultural biotechnology regulation is the coexistence policy. Under normal agriculture and climatic conditions, the possibility of the adventitious presence of authorised GM material (for example GM genes) in 'non-GM' crops grown in proximity to GM crops cannot be excluded e.g. as a result of cross pollination of non-GM crops by wind drift or by insects. Therefore, suitable coexistence measures will be necessary during cultivation, harvest, transport, storage and processing to ensure the coexistence of GMOs with conventional and organic crops. The necessity for the adoption of an effective coexistence policy is based on several reasons. First reason is to avoid unintended presence of GMOs in non-GM (for example 'organic') crops. The objective of coexistence measures is to avoid unintended presence of GMOs in other products, preventing the potential economic loss and impact of the admixture of GM and non-GM crops. Moreover, the coexistence policy could protect consumer's choice since the choice of the consumers between genetically modified and non-genetically modified food is possible with a functioning traceability and labelling system, and an agricultural sector producing the different types of products. Thirdly, the coexistence policy allows EU countries have flexibility with regard to their national, regional and local needs for GMO cultivation to achieve the lowest possible level of GMOs in organic and other crops.

A comparison study was addressed in the chapter 4. In this chapter, different aspects of environmental governance of GMOs have been compared between EU and China. The chapter attempted to identify and assess the similarities and differences between the two regulatory regimes. It also sought to evaluate the extent to which the Chinese regulatory framework and governance regime of agricultural biotechnology could be reformed using best practice evident in the EU regulatory approach. There is no doubt that the EU's regulatory regime on GMOs provides the strictest rules and comprehensively protects the human-being's health as well as the environment. However, because of the different national conditions, national development strategies, demands on agricultural productivity, and the existing legal framework, China may not able to adopt the entire EU model and use it to revise the current regulatory framework of

agricultural biotechnology. Still, the European Union's model laid theoretical foundation and practical experience which China could learn from as a reference.

5.3 Limitations of the Research

The aim of the research is to supply different solutions for regulating the agricultural genetically modified technology in China in order to minimize the risk of environmental damage arising from the use of agricultural biotechnology while also maximizing its commercial benefits both to farmers and the country.

The case studies on GM agriculture in Hu Bei Province and Guang Dong Province were informed by gathering extensive Chinese scientific and legal research papers and policy documentation from NGO's, scholars in law and policy study, agricultural biotechnology scientists, and from discussions with governmental officials with a role in authoring GMOs for use in agriculture. A very important factor that this disclosed was the evident mistrust by the public of assurances of the safety of GM products by public officials and scientists. This could be traced back to the year of 2012, the illegal planning of Bt rice (the Golden rice) in China significantly discouraged Chinese people's confidence on GMO safety management. Even though the variety of the GM plant was not assessed as risky to human or the environment, it caused the public to have the low acceptance to GMOs.[9] The subsequent effects were serious. Till the recent days, the articles of demonizing GMOs and even the 'GMOs conspiracy theories' are still widely spread through media and internet in China. It potentially deepens the fear of general public to unfamiliar technologies, and it turns the fear into distrust to the government whom encourages the development of such a new technology and to the scientists whom have been involved into the transgenic research.

[9] Yunhe Li, Yufa Peng, Eric M. Hallerman and Kongming Wu, 'Biosafety Management and Commercial Use of Genetically Modified Crops in China' (2014) Plant Cell Rep 33 565 p.572

5.4 Prospects and Proposals

Biotechnology is considered as a strategic emerging industry by the Chinese government and offers great resources and funding in biotechnology research and development.[10] Recently the MOA revealed a roadmap for the commercialization of GM crops in China, starting with cash crops "not for food use"; followed by crops for input for feed and industrial use; food crops; and finally the staple food crops.[11] This shows the cautious attitude of Chinese government on promoting the commercialization of GM crops. It had also been specifically emphasized in the No.1 Central Document[12] in 2016 that '…the research and supervision of agricultural transgenic technology should be enhanced and be cautiously promoted on the basis of safety.'[13] The commercialization of transgenic agricultural crops needs to be cautiously promoted based on China's own national situation including the biotechnology ability, the economic demand and the public opinion and the process needs to be steady. The foundation of the commercialization of the agricultural GM crops is the safety of GMOs which requires in great amount of scientific researches and resource. The current scientific programmes related to the GMOs research funded by the national government covers the security isolation for variety GM crops, long-term environmental monitoring and toxicological and allergenicity evaluation of newly expressed material in GM crops.[14] The domestic academics recommended that the governmental funding should also cover the further research on the safety evaluation of new variety of GMOs and the assistant technical support for the evaluation.[15]

The purpose of biosafety regulation is to ensure any new agricultural technology to meet certain

[10] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157, p2157

[11] Vice-minister of the Ministry of Agriculture Taolin Zhang, response to the journalists in the 5th Meeting of the 12th National People's Congress, March 7th 2017 < http://www.china.com.cn/lianghui/news/2017-03/07/content_40423393.htm> last accessed in May 2017

[12] The No. 1 Central Document is the very first government document issues each year by the Central Committee of the Communist Party of China; in 1982-1986 and 2004-2017 the No.1 Central Document constantly focus on the work deployment of agricultural development and rural area construction thus the No.1 Central Document is commonly seen as the government document of agriculture and rural area.

[13] The No. 1 Central Document, available on the official website of the Ministry of Agriculture, lase assessed on Oct 7th 2017 < http://www.moa.gov.cn/ztzl/2016zyyhwj/2016zyyhwj/>

[14] Jianping Kou, Qiaoling Tang, Xianfa Zhang, 'Agricultural GMO Safety Administration in China', (2015) 14(11) Journal of Integrative Agriculture 2157, p2163

[15] Ibid.

standards in order to protect human and animal health and environment. By the analysis of the current situation of biosafety regulation and commercial use of GM crops in China with comparison with the European Union, it could be concluded that China have constructed the basic legal framework for GMOs management, however the further improvement needs to be made in order to streamline the regulatory process of agricultural biotechnology and bring the governance of GM technology into a higher level by taking into account of the following aspects.[16]

5.4.1 Proposals for strengthening the environmental governance of GM technology

The first proposal is to establish a new comprehensive law on GMOs biosafety to replace the current related regulations and administrative measures. This is also the constant appeal from domestic scholars in the field of environmental law over the years.[17] The development of GMOs' research is fast and the utility of its products in China is increasing, the current situation is entirely different from the time when the 2001 Regulation was enacted.[18] The agricultural biosafety is an essential and indispensable part of the biosafety legislation framework. Compare to other legislations on the GMOs biosafety, the agricultural biosafety legislation in relatively complete however there are still some gaps and defects, for example the lack of comprehensive traceability and the co-existence measures are absent. A comprehensive legislation on biosafety would not only provide the agricultural biotechnology regulations a legal basis with in the legal hierarchy, or normative order, for the environmental governance of GM technology in China, but also will benefit the implementation of the management on agricultural GMOs.

After years of the legal practice of the current regulatory framework, the shortcomings of the lack of a comprehensive law on GMOs biosafety is obvious. The current legal framework is

[16] Yunhe Li, Yufa Peng, Eric M. Hallerman, and Kongming Wu, 'Biosafety Management and Commercial Use of Genetically Modified Crops in China', Plant Cell Reports, 2014

[17] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p876

[18] Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms, State Council Decree No. 304, May 21, 2001

not effectively systematic, comprehensive or appropriately coordinate with the other areas of the environmental regulation in a Chinese context. The existing regulation and administrative measures are enacted by different government departments which merely focus on certain aspect of the GMOs biosafety on the basis of departments' responsibilities. In case of the GMOs safety emergency happens which beyond certain department's responsibility, the current legal framework may lead to management failures.[19] The current biosafety management is mainly undertook by the Ministry of Agriculture, at the mean time the departments of science and technology, hygiene, forest, commerce, environmental protection, quality supervision and inspection also share the corresponding responsibilities. Because of the lack of comprehensive legislation on GMOs biosafety, it is inevitable for the overlapping, conflict and omission to happen regarding to the function of administration.[20] To draft and promulgate a comprehensive legislation will be great opportunity not only effectively for remedying the defect exists in the current regulation system but also clarifying the responsibility and cooperation between different government departments in order to strengthen the management on biosafety in each step from the research to the production of the GMOs.

Secondly, the public participation mechanism needs to be established and safeguarded in the biosafety especially the agricultural biosafety legislations. The 2001 Regulations and its three auxiliary administrative measures did not have articles relating to public participation in the decision-making process of GMO authorisations or the GMOs safety management. However, in the wider context, common environmental and resource protection regulations in China usually include articles of encouraging public participation in management and supervision in general provisions.[21] It is also commonly required in international biosafety legislations. For example, the Article 13 of Convention on Biological Diversity requires the contracting parties to "promote and encourage understanding of the importance of, and the measures required for,

[19] Guihong Wei, 'Research on Legislation Issue and Advice for GMOs-Safety in China' in Dayuan Xue (ed.) *Risk Assessment and Regulation of Genetically Modified Organisms: Proceeding of the International Biosafety Forum—Workshop 4 Beijing.* (China Environmental Science Press, 2011) p192

[20] Ibid. p193

[21] For example, Article 6 in the Environmental Protection Law, Article 5 in the Water Pollution Prevention and Control Law, Article 4 in Marine Environmental Protection Law, etc.

the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes."[22] China is a party of CBD and the Biosafety Protocol, the national legislation on GMO biosafety management should fully reflects the requests of international laws. The reason behind the lack of encouraging public participation in current agricultural GMOs regulation might because that the policy makers considered the public is not interested and this kind of issue is too complicated and involves expertise.[23] Although the biosafety might be considered as a scientific issue which is requires professional scientific knowledge to participate and not directly relevant to ordinary citizens, public right of participation shall not be differed since GMO products are closely related to human health and the environment. Therefore, the competent authorities shall be involved to produce the relevant information including risk assessment and other relevant documents in a non-technical format which enable the general public to read and understand. The Ministry of Agriculture or the Ministry of Science and Technology would be the appropriate authority to undertake this job.

To establish mechanisms of public participation in biosafety, the first step to empower the public with the right to information on the environmental and public health risks associated with GMOs for which an authorization has been applied, and a right to make representations to the public bodies making a decision on their approval for release and development. The public participation could play a valuable role in the biosafety protection primarily based on the right to know the true situation of the environmental release, commercial production of GMOs and the GMO products on the market. As an important part of the environmental right, the right to know is mainly guaranteed by legal procedures and is a restriction on the administrative right of government.[24] The public will be able to participate into the decision making only after knowing their living circumstances, consumed food and market management. The right to know is the most basic right in public participation. The second right is the right to participate in decision making. The right to participation empowers the public to participate in environmental

[22] Convention on Biological Diversity https://www.cbd.int/convention/articles/default.shtml?a=cbd-13 last accessed Oct 27, 2017
[23] Dayuan Xue (ed.), Biosafety and Regulation for Genetically Modified Organisms (Beijing Science Press, 2009), p328
[24] Ibid.

risk assessment and policy making process at all stages of GMOs research, field experiment, commercial production and marketing. The public will only understand the current issues and object of policy making by completely participate at all stages, and thus provide sound suggestions. The concept of the public shall cover not only the ordinary citizens, but also scientists and experts in various disciplines, related administrative authorities and Non-Governmental Organizations. Wide comments are helpful in making right decisions. In order to protection public's right to participate in the decision making, the information disclosure and access need to be available to the public.[25] This would greatly assist the building of public trust in biotechnology in its application to GMOs administration processes in China. Furthermore, the 'public' should include ordinary individuals, groups and NGOs related or affected by certain program such as event, dialogue or proposed plan of action. Authorities includes competent agencies managing the programs shall connect to the public. There are two types of ordinary public participation: negotiation and intervention. The difference between the two types is the degrees of the influence, sharing, control and decision public participation is caused in policy making. Methods of public participation should include information exchange such as asking for comments, interview, questionnaire survey, hearing, seminar, feasibility study meeting.[26]

The GMOs safety emergency management system is another comparatively weak link in the Chinese legal framework on biosafety management. From the scientific perspective, there are potential risks in each activity related to the GMOs including the laboratory research, test, environmental release, commercialization, transboundary movement and the waste disposal. The groups and individuals involved into the related activities as well as the supervision departments should adopt the precautionary measures in order to cope with the risks. In order to minimize the damage to the personal and property security and the ecological environment when the potential risks become the real accident, the precautionary and preventive measure should be arranged in the legal system in advance.

[25] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865, p882

[26] Dayuan Xue (ed.), Biosafety and Regulation for Genetically Modified Organisms (Beijing Science Press, 2009), p336

The emergency management is an important part of the current Chinese legal framework. The existing emergency management legal regime involves the war state law, the general emergency law, the terrorist events law, the turbulence law, the disaster law and the accidental emergency law; the environmental emergency management is usually contained in the accidental emergency law.[27] The GMOs emergency management method is provided by four administrative regulations and measures. First of all is the very first biosafety protection legislation—the Administrative Measure on Genetically Engineering Safety Management.[28] Article 21 of the Measure stated that the units engaged into the genetically engineering should formulate emergency measures against the accidental emergency. On the one hand, the Article 21 is a milestone that it introduced the substantial emergency measure plan for the first time into the biosafety management; however, on the other hand, the further detailed provision of implementation is absent. The second regulation is the Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms[29] which clarified the responsibility of the competent authorities under the emergency situation. The Article 39 of the Regulation states that the agricultural administrative departments are entitled to keep the GMOs used for illegal research, test, production, processing, operation or import and export sealed and detained. The third regulation is the Administrative Measure on Safety Assessment of Agricultural Genetically Modified Organisms.[30] The responsibility of the unit which engaged into the agricultural GMOs test and production to set up the emergency plan for the accident is regulated in the Article 35. However, neither the Article 39 in the 2001 Regulation nor the Article 35 in the Administrative Measure on Safety Assessment of Agricultural GMOs provide the further detailed content of the emergency plan and caused the lack of operability for those regulations. The fourth regulation is the Administrative Regulation on Biosafety of Pathogenic Microbe Laboratory issued by the State Council did offered the detailed emergency plan[31] however the legal object of the regulation is merely the laboratory

[27] Ibid, p310

[28] Administrative Measure on Genetically Engineering Safety Management, Decree No.17 (1993) of the State Commission of Science and Technology

[29] Regulation on the Biosafety of Agricultural Genetically Modified Organisms, adopted at the 38th Meeting of the State Council on May 9, 2001, promulgated by the Decree No. 304 of the State Council of the People's Republic of China

[30] Administrative Measure on Safety Assessment of Agricultural Genetically Modified Organisms, Decree No. 8 (2002) of the Ministry of Agriculture

[31] Administrative Regulation on Biosafety of Pathogenic Microbe Laboratory, Decree No. 424 (2004) of the State Council; see Article 40, 45 and 48.

management of pathogenic microbe.

Based on the analysis of the current emergency management system and existing problems, the policy makers need to consider of learning from other countries' experience and follow the example commonly adopted by the international environmental law. Additional efforts should be focus on laying down detailed and feasible emergency plan which should include but not limited to the personnel placements, the emergency fund arrangement, information disclosure plan, the duties of competent authorities and the entity or individuals engaged into the GMOs related activities.[32]

The final proposal that this research project suggest is the establishment of a new law establishing a governing liability for environmental damage arising from the cultivation of GM crops and a suite of remedies to ensure the biosafety of products that include (or are produced using) GMOs. Even the most comprehensive preventive measure and the emergency response system could not guarantee the zero loss once the risks of GMO research and development, production, transportation, environmental release, storage and marketing activities turn into real harm, and when it happens it is necessary to compensate the injured party and bear the corresponding legal liability for the environmental damage. The liability and remedy is one of the most important elements in the biosafety law system and the relevant section in Chinese biosafety law is still at early stage that only three provisions directly regulate damages related to biosafety. These include the Article 28 in the 1993 Administrative Measure on Genetically Engineering Safety Management[33] which provides "in the case of damage resulting from a violation of this law, the entities and individuals that are liable shall cease infringement, eliminate pollution and compensate for losses. In serious cases, the persons responsible shall be subject to criminal sanction. Serious cases include 1) seriously pollute the environment; 2) harm or affect the public health; and/or 3) seriously damage ecological resources and affect the ecological balance." This provision follows the principle of fault liability in accordance

[32] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865, p881.

[33] Administrative Measure on Genetically Engineering Safety Management, Decree No.17 (1993) of the State Commission of Science and Technology

with the environmental protection law. However, the definition of some core concept, for example “serious pollution”, “affects public health” and “serious damage to ecological resources” are not explicitly interpreted. The Article 54 of the 2001 Regulation stipulates that “in the case that research, testing, production, processing, storage, transport, sale or import, export of agricultural GMOs in violation of this law causes damage, the responsible entities and individuals shall take the responsibility.” This stipulation also follows the principle of liability for fault. However, it is difficult for practical implement due to the lack of explicit provisions on subject of compensation, amount of compensation, liability exemption conditions. Thirdly, the Article 57 of the Administrative Regulation on Biosafety of Pathogenic Microbe Laboratory[34] provides that “if the legislate rights and interests of a party concerned are damaged by an approval decision in violation of the law, then the administrative department of health or the administrative department of veterinary who made the approval decision shall be liable for the compensations.” This provision is also vague regarding to the critical concept. It is thus evident that scattered provisions, on one hand, is lack of operability in the practice and on the other hand, could not comprehensively cover the range of the biosafety law.

The establishment of the liability regime is still a difficult issue in the whole international biosafety legal system.[35] The Convention on Biological Diversity is an international law document on bio-diversity conservation as well as a guide used to establish a comprehensive global legal framework, which only provides very general authorization provisions on biosafety damages liability remedies: the conference of the parties shall examine the issue of liability and redress based on the studies to be carried out, the examination shall include restoration and compensation for damage to biodiversity, except when such liability is a purely internal matter.[36] The relevant negotiation between the contracting parties is still also

[34] Article 57 in the Administrative Regulation on Biosafety of Pathogenic Microbe Laboratory, Decree No. 424 (2004) of the State Council. See also Christopher Rodgers, “Environmental Risk, Environmental Liability and the Regulation of Biotechnology: Mediating Law and Biology?” Chapter 7 pp.95-115 in (Hocking ed.) *The Nexus of Law and Biology: New Ethical Challenges* (Ashgate, 2009); Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar Publishing Limited, 2008) p136

[35]. Dayuan Xue (ed.), Biosafety and Regulation for Genetically Modified Organisms (Beijing Science Press, 2009) p255

[36] Article 14 of the Convention on Biological Diversity 1992, last accessed on 5th October 2017 < https://www.cbd.int/convention/ >

ongoing. To the Chinese policy maker in order to improve the legislative work on biosafety liability shall learn from the legal principles, mechanisms and regimes from the current international environmental and biosafety law as well as follow the progress made on related international negotiations. The experience from other countries and regions shall also be considered. Based on the analysis of current domestic legislative situation on the GMOs damages liability, the legislative work shall be focused on the principle of liability fixation, liability of joint damage, liability exemption condition and the environmental damage compensation regime.

5.4.2 Labelling and consumer choice

The GMOs labelling is currently regulated under the 2002 Administrative Measures on the Labelling issued by the Ministry of Agriculture in accordance to the 2001 Regulation issued by the State Council.[37] According to the Measures, there are three categories of GM products are required to be labelled mandatorily: the genetically modified animals, genetically modified plants and genetically modified micro-organisms; products directly processed from genetically modified agricultural products; and products produced from agricultural genetically modified organisms or products consisting of genetically modified organisms ingredient, while the products that are made using GMOs but where the presence of the GM material is no longer detectable in the final product.[38] Based the analysis on the shortcomings of labelling legislation in China which was provided in Chapter 5, the labelling system could be possibly improved in the following aspects.

To start with, the range of labelling on the GMOs and its products needs to be extended. The current labelling requirement mainly focus on the raw material and directly processed

[37] Administrative Regulation on the Biosafety of Agricultural Genetically Modified Organisms, promulgated by the Decree No. 304 of the State Council of the People's Republic of China of 2001 on May 21, 2001, and effective as of the date of promulgation

[38] Administrative Measure on Labelling of Agricultural Genetically Modified Organisms, Decree No.10 (2002) of the Ministry of Agriculture, issued on 5 January 2002 (MOA Decree 10/2002) Art. 6

products of agricultural GMOs (the labelling requirements are applicable to GM soybean, GM maize, GM rapeseed, GM tomato, GM cotton and their primary processed products.) In compare to the EU labelling regime, the range of GM products should be expanded largely. For the GMOs which already entered into the market, not only the GMOs product and its primary processed products (for example the GM soybean and the soybean oil directly processed from the GM soybean) but also the re-processed and deep-processed products of GM products (for example, the soy sauce brewed by GM soybeans or mixed cooking oil which consist of soybean oil processed from GM soybeans) need to be included in the range of labelling requirements. In other word, any food for consumption which is produced from GMOs, contains GMOs ingredients or consists of GMOs should be included in the scope of labelling regulation. Furthermore, the labelling on animal feed shall also be considered.[39] At the present, there is a large proportion of animal feeds contain GMO ingredients that the meal of the GM soybeans, rapeseed and cotton seed after pressing oil are mainly used as animal feeds, also the quantity of directly imported GM feeds is expected to be increased.[40] Therefore, China should, it is suggested, adopt EU's approach which not only to enhance the labelling management on GM foods but also shall apply labelling requirements on GM feeds to achieve a comprehensive management on the labelling of GMOs.

Secondly, a threshold regime needs to be set in Chinese GMO labelling system. From perspective of the practical experience, in the process of production, transportation and processing of GMOs and their products, it is very likely to have minor traces of GMO materials presented in the non-GM products due to the adventitious or technical unavoidable factors. Under the current Chinese labelling legislations, products with any traces of GMOs need to be labelled as products containing GMOs despite the fact that some operators' originally have no intention of using GMO product, the 'contamination' of their products with GM material is often adventitious or accidental. Furthermore, China signed the CBP in 2000 and became a Party of the Protocol in 2005. The handling, transport, package and labelling of GMOs in transboundary movements has been a core agenda of the Biosafety Protocol, this

[39] Wenxuan Yu and Canfa Wang, 'Agro-GMO Biosafety Legislation in China: Current Situation, Challenges and Solutions' (2012) 13 (4) Vermont Journal of Environmental Law 865 p880

[40] Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.250

'0% threshold' methods also cause difficulties to export and import activities.[41] In order to make the labelling more manageable from the scientific perspective considering the adventitious or technically unavoidable presence of GMOs, numbers of countries in the worldwide has adopted reasonable threshold in accordance with their own national situation. The EU adopted the threshold as 0.9% which set up by the Food and Feed Regulation[42]; in Australia the threshold is 1%, in Japan it is 5% and in South Korea, the threshold is 3%.[43] Considering about China's own situation, domestic scholar Xue suggest that China shall adopt 1% as the threshold for GMOs labelling.[44] His recommendation is made on the basis of the assessment of the domestic technology level as he stated that, China has reached the international research level in detection of agricultural GMOs and able to carry out the qualitative detection and quantitative detection of major GM products. The sensibility of quantitative detection is 0.5% and the qualitive detection is 0.1%.[45] Including the tolerance on the differences due to detective sensibility of different facilities, 1% is considered as reasonable. Therefore, labelling will be exempted to the product if the GMOs traces it contains is lower than 1%. Furthermore, the adoption of the 1% threshold which is similar to the mainstream in the worldwide is expected to promote the international trade of Chinese agricultural GMOs products and non-GM agricultural products. Moreover, accompanied with the labelling requirement, China shall follow the example of the EU and considers adopting the unique identifier method in order to strength the management on the traceability. The provision of the unique identifier will bring the management of GMOs products to a higher level after they are placed into the market. The purpose of the traceability is every single GMO product, or each GM ingredient contained by the product could be traced back to its origin in order to enhance the management during the marketing process and to protect the consumers' right to know and right to choose. The unique identifier method introduced by the European Union is regarded as the most effective way to the traceability management,[46] it is also the foundation of the development of the whole traceability regime.

[41] See Dayuan Xue, ibid. p251-252

[42] Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed [2003] OJ L 268/1

[43] Ibid.

[44] See Dayuan Xue (ed.), *Biosafety and Regulation for Genetically Modified Organisms* (Beijing Science Press, 2009) p.252

[45] Ibid.

[46] Ibid, p251

Lastly, the format of the GMO labels should be regulated towards a consistent and proper pattern. According to a survey carried out about the consumers' attitude on GM foods, there are half of the interviewed consumers found it difficult to recognize the GM labeling on the package of the product.[47] Since the ultimate aim of the labelling regulation is to provide the information to the customers and to ensure they make the informed choice. Without a visible and standardized label, it is impossible to achieve the goal of the regulation.[48] Therefore, the Chinese labelling regulation shall apply explicit requirements on the format of GM labels, for example, the location of the labels, the size and colour of characters. In addition, the relevant requirement shall be regulated under the law rather than guidelines provided by the competent agency to ensure the effective implement.

5.4.3 Co-existence of GMOs and non-GM agriculture

Co-existence is not a new issue since the co-existence measures have been used in the seed industry for production of high purity stocks, neither it is a new challenge within agricultural production for growing similar crops for different markets. In the conventional farming, farmers could follow procedures to achieve ideal standards of quality and purity in their products. The introduction of GM crops, however, raises new challenges in setting up the appropriate co-existence measures. The co-existence relevant regulation is absent in Chinese legal framework. Considering about the present situation in China that GM crops (especially GM cottons) are growing in large area while more GM varieties are expected to obtain the commercialized cultivation permission in near future, the adoption of co-existence measure is urgent to China. In the European Union, 'the Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.'[49] This wording gives the

[47] See Dayuan Xue, p.248

[48] Yu Zhuang and Wenxuan Yu, 'Improving the Enforceability of the Genetically Modified Food Labelling Law of China with Lessons from the European Union' (2013) 14 (3) Vermont Journal of Environmental Law 465, p483

[49] Art 26(a) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC OJ L106/1

Member States certain discretion on prohibiting, restricting or impeding the GM products in their own territory both at farm level and along the supply chain. China is conducted by 34 provinces and each province is different regarding to the farming conditions and agricultural production target. Therefore, China shall follow the example of the EU which allow considerable flexibility in the provinces, with different approaches to respond to their diverse conditions, for example as to the size of farms, different levels of commitment to organic farming and varied geographical and ecological conditions. Measures to ensure the co-existence of different forms of agriculture include staggered sowing, weed management and careful cleaning and maintenance of equipment; separations distance or buffer zones between crops might amount to GM free zones on various scales.

5.5 Conclusion

From the study executed in this thesis, the EU's comparatively sound and advanced governance regime on agricultural biosafety has various aspects which could be referenced by Chinese policymakers in the process of improving the current Chinese system on managing GMOs: for example, as to the public participation in decision-making processes, the design and implementation of co-existence measures as well as the GM product traceability system. Nevertheless, China is a large agricultural country in rapid development and designated the biotechnology as the development strategy for agriculture which have a very different state condition from the EU in respect of agriculture and economy, the EU model does not provide all the answers to the Chinese situation.

On the other hand, the safety issues around the GMOs involves extensive aspects including the genetic engineering technology, the assessment on GMOs food safety, the evaluation on the ecological risk, the environmental detection and supervision, the risk administration of GMOs, the social-economic impact, the international and domestic biosafety law and management regime as well as the public participation. The biosafety of the GMOs is not only a scientific issue but also a social issue. The policy maker might be in pursue of a rigorous and perfect legal system and powerful implementation however, it is not all the meaning the

biosafety legislation. No matter how powerful the administration is or how perfect the legal system is, whether or not the use of modern biotechnology in agricultural production is safe cannot be answered by law and the law can never take the place of science to find the answer. The law in the biosafety management should play a role on maximizing the effective and rational administrative on all links from research to marketing; protecting the right and benefit of each subject involved into the issue; building efficient response mechanism in order to minimize the impact of possible hazard and damage and; safeguard the ecological environment and sustainable development of the human society.

In the meantime, while the agriculture biotechnological research is widely promoted, the establishment of a comprehensive biosafety legal framework is out of synchronization. Under the current situation, the legislative work of improving the current regulations and filling the legislative gaps is urgently needed and the reform of the legal framework is expected to take place as soon as possible. The proposed solutions that this research project has concluded on the Chinese legislation and governance for agricultural biotechnology would contribute to improving the effectiveness of multi-level governance and the robustness of decision making in Chinese law.

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