



Genetically Modified Foods in China: Regulation, Deregulation, or Governance?

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Abstract

Whether to regulate or deregulate genetically modified food is an international debate, and each country or region has put forward specific policies and legislation based on its own special needs. When it comes to China, technological innovation, economic development, and food security and safety are significant considerations during the decision-making process. This chapter will outline these considerations and examine their influences on the formulation of policies and legislation on genetically modified foods and then point out the trend of government regulations and regulatory debates in China before ending with a conclusion.

Keywords

Regulation · Governance · Genetically modified food · China

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1 Introduction

Generally speaking, state intervention in the form of regulation¹ is to provide legal rules to modify the economic behavior of individuals and firms in the private sector, such as the research or marketing of genetically modified foods (GM foods). Thus, the reasons for regulation can be as diverse as the correction of market failure, maximization of economic efficiency and consumer choice, promotion of human rights, etc.² To these ends, licensing, standard setting, and requirements of information disclosure are important regulatory tools. Given the continually changing economic and societal contexts, nations take various actions to reorganize or reform regulations.

For one thing, the expansion in the use of rule-making by the state has led to the regulatory state, in particular as a response to socially harmful acts. In this aspect, there is evolution from economic regulation to social regulation, in order to address the safety concerns of the society, such as public health, in addition to economic efficiency. Moreover, risk regulation puts the emphasis on government's intervention in market or social processes to control potential adverse consequences. Given the challenges in the characterization of risks and hazards, it calls for professional engagement of experts to carry out scientific work. Deregulation is also introduced to reduce or eliminate excessive state regulation, for the purposes of lifting the burdens on business to increase their competitiveness and promoting self-regulation or private regulation on the basis of market mechanisms to achieve market relevancy.

Whether regulation or deregulation should be preferred depends on the economic sector and varies from state to state. The shift from deregulation in the 1990s to better regulation in the 2000s in the UK has provided insight into the importance of public participation and deliberation to promote an evidence-based and transparent process of public administration. That is to say, in addition to the role of the state, cooperation and commitment of different stakeholders are also needed. Noteworthy is the trend toward governance, which is broader in scope than state intervention that emphasizes the importance of private and public sector cooperation as well as public participation. From the above, a rough structure for the state intervention models can be generalized as below.

¹According to one definition, regulation is one of the governmental actions with legal power to impose rules backed by the use of penalties that are intended specifically to modify the economic behavior of individuals and firms in the private sector. See Organization for Economic Co-operation and Development, Glossary of industrial organization economics and competition law, available at <http://www.oecd.org/regreform/sectors/2376087.pdf>, p. 73.

²Tony Prosser, *The Regulatory Enterprise, Government, Regulation and Legitimacy*, Oxford University Press Inc., 2010, pp. 11–18.

The state intervention models

Models	Characteristics	Tools
Regulation	Economic regulation	Licensing
	Social regulation	Standards
	Risk regulation	Information disclosure
Deregulation	Lifting of regulatory burdens	Expert participation
	Self-regulation	Information disclosure
	Private regulation	Participation
	Better regulation	Participation
Governance	Regulation as large subset of governance	Information disclosure and communication
	Private-public cooperation	Participation
	Public participation	Cooperation

As far as GM foods are concerned, the most important regulatory purpose considered is food safety and thus human health. In this aspect, the essential role of state regulation is to deal with public risk, which is largely outside the individual risk bearer's direct understanding and control.³ That is to say, as the purpose of regulating food safety is to control potential adverse consequences to health, food safety regulation in general, and GM food regulation in particular, can be regarded as a typical example of risk regulation. The newly emerging technological risks involved in GM food have increased the uncertainty in terms of safety. The involvement of experts and their advice can provide scientific evidence for regulatory measures in order to decrease such uncertainty. However, whether scientific rationale is adequate to support public decision-making in the case of GM food is disputable.

On the one hand, a harmonized international rule provided by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) requires that members shall ensure that any sanitary or phytosanitary measure is based on scientific principles and is not maintained without sufficient scientific evidence.⁴ Moreover, in the scientific assessment of foods derived from biotechnology, it is also preferable to apply the principle of substantial equivalence. Accordingly, if a new or modified food or food component is determined to be substantially equivalent to an existing food, it can be treated in the same manner as its analogous conventional counterparts.⁵ In other words, once its substantial equivalences have been established, a food that is produced from biotechnology can be put on the market without the requirement of procuring extra licenses.

On the other hand, there is also exception to the scientific principle, since the SPS Agreement on its own provides that in cases where relevant scientific evidence

³Huber, P., Safety and the second best: the hazards of public risk management in the courts, *The Columbia Law Review*, 1985, No. 85 (Arcuri 2011), p. 277.

⁴Agreement on the Application of Sanitary and Phytosanitary Measures, Article 2.2.

⁵OECD, Safety evaluation of foods derived by modern biotechnology, concepts and principle, 1993, p. 14.

is insufficient, a member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other members.⁶ In such circumstances, members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. As far as how scientific uncertainty can justify the government's action rather than inaction in waiting for sound scientific evidence, a precautionary principle has been further introduced in the risk regulation regime of environment and food in order to allow the government's action and prioritize the public interest, like health, in the case of scientific uncertainty. Taking environmental protection as example, the United Nations Conference on Environment and Development has contributed to internationalizing this precautionary approach as a principle by proclaiming it in the Rio Declaration on Environment and Development in 1992 as: "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."⁷

In practice, the United States (USA) and the European Union (EU) represent different models regarding the state intervention in the case of GM foods. Generally speaking, the US model is relatively more "favorable" to the GM foods and has no license and labeling requirements for such tech-foods on the grounds of scientific assessment and substantial equivalence. The reason for such deregulation is to advance the biotechnology and international competitiveness of the USA. In contrast, the regulation of GM food in the EU may be characterized more as being precautionary, which has at its disposal regulatory tools that include license, labeling, and traceability. Notably, to support the regulation of scientific uncertainty in the case of GM foods, one important legal rule, the precautionary principle, is stipulated by the so-called General Food Regulation⁸ in the EU. Accordingly, 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.⁹

Despite the current regulatory arrangements in the USA and the EU, how to regulate GM foods is still an ongoing dispute within these regions. For the USA, there are calls for re-regulating GM foods in certain states, in particular the labeling requirement to protect consumers' right to know. Taking Vermont as example, it was

⁶Agreement on the Application of Sanitary and Phytosanitary Measures, Article 5.7.

⁷The Rio Declaration on Environment and Development of 1992, Rio de Janeiro, June 3–4, 1992, The United Nations Conference on Environment and Development, Principle 15.

⁸Regulation (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, Official Journal L 31, 01.02.2002.

⁹General Food Regulation, Article 7.

the first state in the USA to adopt a law requiring labels for GM foods, which went into effect in July 2016. For the EU, there are also controversies between the EU and member states and between member states as well. For example, when the EU authorized MON 810 maize based on the risk assessment, member states like UK and France approved its access to their markets, while Italy forbade its introduction. For such derogation, the application of the precautionary principle has been the rationale for the Italian regulation, and thus derogation has been supported by the European Court of Justice.¹⁰

It should be emphasized that the regulation of GM foods is also closely linked to more general regulation of biotechnology and its products. Notably, a transparent and efficient regulatory system in this field not only protects public health and the environment based on the best available science but also prevents unnecessary barriers to innovation and competitiveness, as the development and application of a technology need to go through various barriers, including technical challenges, economic costs, government regulations, and social responses.¹¹ It is therefore these multiple interests or even their conflicts that add complexity to government's regulation of GM food. That is to say, balancing multiple interests involved in the formulation of policies and legislation relating to the subject matters of food, biotechnology, and GM food poses a tremendous challenge. In China, for example, decision-makers have to consider the promotion of scientific and technological advancement, regulation of risks resulting from novel science and technology, the engagement of scientific experts and the public, and a myriad of other stakeholders. Therefore, whether GM technology can be transformed from laboratory results into commercial profits is decisively dependent on government's regulatory model, which in turn depends on the understanding of the safety of GM technology. In this respect, the regulatory approach to scientific uncertainty and the degree of response to public perceptions of risk, as well as other economic and cultural considerations, have further shaped the regulatory differences between the USA and the EU in GM foods.

In the meantime, government intervention in GM foods in China not only takes reference from the American and European experiences but also takes into consideration national condition from the political, scientific, economic, and societal perspectives. Comparatively speaking, national specialty in food regulation also contributes to the complexity of GM food regulation in China. Nowadays, food safety has become an urgent concern due to a series of food safety scandals, such as faked powdered milk and the so-called gutter oil (illicit reuse of cooking oil). Melamine-contaminated milk in 2008 received the most attention. Nevertheless, food regulation in China is not just about food safety. High on the agenda is also food security, given its large population. As a result, there is a host of disputes on whether to deregulate GM foods to ensure sufficient food supply or to regulate GM foods in a precautionary way that would highlight food safety and public health. Additionally, it is also important to mention the importance of governance promoted in the food safety domain of China. As provided by the *Food Safety Law* after

¹⁰Case C-236/01, Monsanto Agricoltura Italia (2003) ECR II-8105.

¹¹Suk et al., Dolly for dinner? Assessing commercial and regulatory trends in cloned livestock, *Nature Biotechnology*, 2007, No. 25.

revision in 2015,¹² social co-governance is one of the legal principles, and numerous institutional requirements are outlined for the subjects, content, and tools of governance.¹³ For example, risk communication from the perspectives of information disclosure and public participation was introduced for the first time to encourage participation by experts and the public.

In view of the above, this chapter first aims at outlining China's policies and legislation in relation to biotechnology regulation, with the purpose of highlighting the role of government in promotion of science and risk prevention. Secondly, by discussing GM food regulation, this chapter also addresses the challenges on how to consider scientific advice and public perception of risks during state intervention. In conclusion, the chapter will revert to the question raised by the title of the chapter and attempt to provide an answer on regulation of GM foods in China.

2 Biotechnology: Promotion of Science and Risk Prevention

2.1 Scientific and Technological Advancement

It is trite to acknowledge that advances in science and technology are crucial for economic and social development, and it is self-evident that scientific and technological progress has contributed considerably to improvement in the quality of life. As popularly accepted in China, science and technology are the first production force. Similarly, the USA also puts emphasis on the fact that a nation's economic performance and security depend on its ability to achieve world leadership in science and its innovative capacity of engineering, among others. The government, with its overarching responsibilities for planning, budgeting, and review, is uniquely suited to promote—though not manage—this process.

However, the government has an additional role to play in the research and application of biotechnology, which not only calls for public support for its further development but also government intervention to address safety, health, and environment-related concerns. As a matter of fact, in the risk society that we are now living in, together with benefits come risks, which are likely to be manifest in physical, chemical, or biological harms. Moreover, these risks have attracted public attention amidst environmental disasters and food safety concerns emanating from events such as the BSE (bovine spongiform encephalopathy, or mad cow disease) crisis.¹⁴ Therefore,

¹²Food Safety Law of the People's Republic of China, as revised and adopted at the 14th session of the Standing Committee of the Twelfth National People's Congress on April 24, 2015.

¹³Chinese Food Safety Law, Article 3. For a more detailed introduction to food safety governance in China, see Lepeintre Jerome and Sun Juanjuan (eds), *Building food safety governance in China*, Luxembourg Publications Office of the European Union, 2018, downloadable freely at https://eeas.europa.eu/sites/eeas/files/building_food_safety_governance_in_china_0.pdf

¹⁴The first diagnosed BSE in cattle was in the UK in 1986. However, the UK government did not take immediate action to protect consumers from contaminated meat products, as there was no sound scientific evidence to prove the risks to human health. The BSE crisis totally changed consumers' perception of food and food safety regulation. The failure to deal with food safety issues

while it is a national prerogative to support the research and development of science and technology, it is also vital to regulate its application in actual practice, in order to hold people and institutions engaged in these activities accountable and to protect public interests such as public health and environmental safety.

The emergence of biotechnology from laboratory to industrial application was welcome in the USA and the EU alike at the beginning. However, as it later turned out, the USA is in favor of GM food, while the EU is against it, as mentioned above. Additionally, it is also important to note that the research and development of this kind of science and technology as well as its application do include the food field but are not limited to it. For example, biotechnology can also be employed in the pharmaceutical industry. In view of this, biotechnology is a strategic research tool, and government's priorities in intervention can differ from sector to sector.

In the case of China, biotechnology has been applied in many specific fields, such as agriculture and food production and transgenic animal(s) in medicine and pharmacology. Although the legislative framework is still under development, many of the concerned departments have provided rules to mitigate the conflicts between the technological and economic benefits and safety concerns. Legal hierarchy in China accords precedence to laws enacted by the National People's Congress and thereafter to administrative regulations issued by competent authorities, which are followed by departmental rules. Therefore, the introduction of legislation with respect to biotechnology would establish general principles of law and provide binding guidance to competent authorities.

2.2 Promotion of Biotechnology from a Scientific Perspective

Biological processes have traditionally been utilized to improve the quality of human life, as in the case of food production and preservation with biological fermentation. Biotechnology has been regarded as one of the important scientific breakthroughs in China from the late 1970s. Since 1986, increased resources have been poured into research and application at the national level via in particular the "Seventh Five-Year Plan" of the National Key Scientific and Technological Project and the National High Technology Research and Development Program 863.

Therefore, early rules on biotechnology were promulgated by the State Scientific and Technological Commission¹⁵ to promote the research and development of biotechnology, taking the assurance of safety, including human health and environmental safety as well as the ecological balance, into account. It is indubitable that high-risk investment is of necessity during the research and development of biotechnology, which is faced with the challenges of raising large-scale monetary support, a lengthy research period, as well as unpredictable barriers or burdens caused by new regulation. Furthermore, experience has shown that broad application of

led not only to economic suffering but also to political mistrust and even loss of legitimacy of public authorities. To regain consumers' confidence in food business and official control, the EU food safety regulation went through radical reform.

¹⁵This national agency has been transformed to the Ministry of Science and Technology in 1998.

biotechnology will lead to considerable commercial value, such as genetic engineering, plant biotechnology, and pharmaceuticals, to name a few.

The national support for biotechnological research and development has enabled Chinese scientists to achieve a number of breakthroughs on novel gene identification in crops, leading to development of GM crops. Plant biotechnology and its application have contributed to reducing the threats posed by pests and diseases and limited resources like land and water and thus to improvement in productivity, most notably in the field of GM cotton and rice. For the former, it was a miraculous result,¹⁶ since Bt cotton is resistant to the bollworm and thus reduces use of insecticide and increases yields. For the latter, two strains of Chinese GM pest-resistant Bt rice, Huahui No. 1 and Bt Shanyou 63, obtained biosafety certificates in 2009.¹⁷

2.3 Legal Protection Mechanisms for Biotechnology

Intellectual property protection is implemented with the objective of incentivizing the research and development of biotechnology as well as its application. In this aspect, one of the typical examples is the development of plant biotechnology and protection of new varieties of plants. To this purpose, either a patent system or plant variety protection system based on the International Convention for the Protection of New Varieties of Plants (UPOV) can be applied. For the former, patent law has continued to develop and evolve in keeping with scientific and technological advancement, which with the emergence of biotechnology challenges the idea of non-patentability of living matter, as it proved to be incompatible with the biotechnological inventions surrounding plant varieties or human genes. As a result, patent regime in the USA was amended to extend patent protection to newly created microorganisms, genes, living animals, and plants. In relation to plant variety protection, the UPOV provides general rules for its member states to grant and protect breeders' right(s), which allows breeders to authorize acts such as production and sale of the propagating material of the protected variety.¹⁸ Notably, the exceptions to

¹⁶There are more than 300 species of cotton pests in China, and there are frequent outbreaks in large areas, causing serious losses in cotton production. Besides, the use of chemical pesticides has led to the emergence of some cotton pest resistance, which seriously threatens cotton production and also worsens environmental pollution. In this aspect, insect-resistant and herbicide-tolerant genetically modified cotton provides a new means for controlling pests, and China has started to commercialize GM cotton since 1997. See Liu Chenxi and Wu Kongming, Current progress in research and development of transgenic cotton and a strategic prospect for China, *Plant Protection*, 2011, 37 (*Alimentarius*, 2001), pp. 11–17.

¹⁷However, these two strains of approved GM rice did not get authorization for commercialization before the biosafety certificates expired on August 17, 2014.

¹⁸International Convention for the Protection of New Varieties of Plants (UPOV), 1991, Article 2: each.

Contracting Party shall grant and protect breeders' rights.

the breeder's right(s) are acts done privately and for noncommercial purposes or for experimental purposes.¹⁹

From a comparative perspective, a plant breeder's right is a specialized form of protection limited to new varieties of plant(s), while patent includes but is not limited inventions in the field of plant biotechnology. In view of the coexistence of these two systems as well as the interaction between them, a common understanding has been reached, that is, the promotion of plant biotechnology can be realized by combining these two systems.²⁰ Therefore, after several revisions, the 1991 Act of the UPOV recognizes that both of these systems can be applied to the same plant variety.^{21,22} However, application in practice differs by country, as each country gets to choose the protection afforded by either of the systems or two protections under both systems after the ban on "double protection" was lifted.²³

As far as China is concerned, the Patent Law was enacted in 1984. However, it clearly provides that no patent right shall be granted to plant varieties. There was no specific law for protecting new varieties of plants at that time either, which led to a legal vacuum in the protection of new plant varieties until the Regulation on Protection of New Varieties of Plants was introduced by the State Council in 1997. That is to say, China has chosen a special model rather than patent protection to grant and protect breeders' rights. It is interesting to note that the introduction of such regulation was a result of both internal and external pressures. For the former, it was the call for protection of breeders' rights from scientists engaged in the research of plant breeding. For the latter, it was the pressure from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) after China's accession to the World Trade Organization (WTO) and UPOV. Accordingly, members of the WTO are required to provide for protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.²⁴ However, the *sui generis* system in China, namely the 1997 Regulation, was based on the 1978 Act of the UPOV Convention, which has limited scope and extent of protection compared

¹⁹According to Article 15 of UPOV, the breeder's right shall not extend to acts done privately and noncommercial purposes.

²⁰For more information, see WIPO-UPOV Symposium, http://www.upov.int/en/documents/Symposium2003/intro_index.html. 2003

²¹Compilation of the 2002 & 2003 Joint Symposia Document of the World Intellectual Property Organization and the International Union for the Protection of New Varieties of Plants, UPOV publication No. 792(E), 2005, p. 16.

²²Comparatively, Article 2.1 of 1978 Act provides that each member State of the Union may recognize the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species. However, Article 2 of the 1991 Act deleted such double protection.

²³For more information, see UPOV 78 to UPOV 91, <http://www.apbrebes.org/content/upov-78-upov-91>

²⁴TRIPS, Article 27(3)(b).

Category of rules	Title	Year of taking effect and revision
Regulation	Regulation on Protection of New Varieties of Plants issued by the State Council	1997 (revised in 2013)
Departmental internal rules	Rules for the Implementation of the Regulation on the Protection of New Varieties of Plants (Agriculture Part) issued by the Ministry of Agriculture	1999 (revised in 2014)
	Rules for the Implementation of the Protection of New Varieties of Plants (Forestry Part) issued by the Bureau of Forestry	1999
	Rules for Review of New Varieties of Plants by Reexamination Committee under the Ministry of Agriculture	2001
Judicial interpretation	Interpretation of the Supreme People's Court on Several Issues Concerning the Trial of Dispute Cases on New Varieties of Plants	2001
	Regulations of the Supreme People's Court on Some Issues Concerning the Application of Law in the Trial of Cases Involving the Disputes over Infringement upon the Rights of New Plant Varieties	2007

Chart 1 Summary of current legal provisions on new plant varieties in China

to the 1991 Act of the UPOV as well as legislative updates in other regions, such as the EU.²⁵

Despite the weakness in the legal protection of breeders' rights in the 1997 Regulation,²⁶ some detailed rules have emerged (Chart 1): two rules for the implementation of the 1997 Regulation have been put forward in 1999 to satisfy the practical needs for implementation of the Regulation and for dispute settlement due to the quick development of the domestic plant breeding industry. One is for agriculture and the other for forestry. Additionally, a detailed rule for carrying out reexamination when rejecting applications was issued in 2001. There are also judicial

²⁵Chen Chao, Zhan Jinpeng, The challenges on the protection of new varieties of plants in China with the application of genetically modified technology, *Intellectual Property*, 2006, 6, p. 44.

²⁶For example, the legal requirements are confusing, while coordination between related regulations is missing. See On choice of legal system for protection of new varieties in China, available at <http://www.iolaw.org.cn/showArticle.aspx?id=4255> (last access on 2 July 2018).

interpretations and regulations from the Supreme People's Court to solve disputes over infringement of the rights over new plant varieties.

More importantly, increased attention has been paid to the protection of new varieties of plants due to China's ambition to develop a modern crop seed industry. As stated in the National Plan for Developing Modern Crop Seed Industry in China from 2012 to 2020 issued by the Office of the State Council,²⁷ the crop seed industry is a national strategic and core industry and also the foundation for promoting long-term stable development of agriculture and for ensuring national food security. For this purpose, the Regulation on Protection of New Varieties of Plants was revised in 2013. The most important change relates to the increase of fines in case of infringement of others' new plant variety rights (1–5 times the value of the infringing goods or RMB 250,000 when no value of goods is available or the value of goods is below RMB 50,000).²⁸

However, as analyzed in Chap. 14, the exiting legislative contents are from ideal arrangement due to the overall lower level of protection, serious disconnect between new plant varieties, and agricultural and forestry production.

2.4 Biotechnology in the Field of Agriculture and the Regulation of Its Biosafety

Agricultural biotechnology involves modification of living organisms such as plants by using scientific tools and techniques, including genetic engineering. However, not only benefits but also risks come with such development, such as risks relating to biosafety.

The Ministry of Agriculture (MoA)²⁹ in China has formulated rules for applying agricultural biotechnology. In 1996, the MoA issued Implementation Rules on Safety Administration of Agricultural Biological Genetic Engineering according to the Rules on Safety Administration of Biological Genetic Engineering promulgated by the State Scientific and Technological Commission in 1993, which are applied specifically to genetically modified organisms in the field of agriculture, such as plants and animals. Government intervention in biotechnological development not only promotes research and development but also addresses safety-related concerns over the environment and human health. Accordingly, experimental research, pilot tests, environmental release, and commercial production should be regulated while taking into account the risk levels.³⁰ On the other hand, China became a contracting

²⁷Office of the State Council, National Plan for Developing Modern Crop Seed Industry in China from 2012 to 2020 [2012] No. 59, available at http://www.gov.cn/zwgk/2012-12/31/content_2302986.htm

²⁸Regulation on Protection of New Varieties of Plants, Article 39.

²⁹Notably, after the reform of organizational arrangement in China in 2018, the Ministry of Agriculture has been expanded to the Ministry of Agriculture and Rural Affairs.

³⁰According to the Implementing Rules on Safety Administration of Agricultural Biological Genetic Engineering, genetically modified agricultural organisms are classified into Classes I, II,

party of the Convention on Biological Diversity in 1993. As a part of the Convention, the Cartagena Protocol on Biosafety regulates the safety of handling, transport, and use of genetically modified organisms (GMO), which has an impact on the regulation of GMO for both internal biosafety and transborder biosafety. For example, a National Coordinating Group was established by the department responsible for environment to implement the Convention in 1993 with specific measures, such as the China National Biosafety Framework. Accordingly, it has clarified the framework of policy and legislation on biosafety management, technical norms for risk assessment and risk management of GMOs and their products, and requirements for national capacity building on biosafety management.

In addition to the abovementioned regulatory experiences, the increasing quantity of imported GM food (corns, beans, etc.) without appropriate regulation and unauthorized plantation of GM crops also called for stricter regulation.³¹ As a result, the Regulation on Safety Administration of Genetically Modified Agricultural Organisms was promulgated in 2001 by the State Council. Compared with the Implementation Rules issued by the MoA, the Regulation has more legal importance, as it provides the legal basis for all the rules made by the relevant competent authorities. More importantly, the definition and scope provided by this Regulation regarding GMO includes not only animals and plants produced by this new technology but also products produced from these raw materials or products, such as seed, pesticide, and additives. To strengthen the official control and operators' obligation for biosafety, this Regulation lays down requirements for the licensing for production, distribution, recording, and labeling. Among these requirements, a safety certificate is required as an essential condition to obtain variety approval, and a license for production, distribution, and commercial applications is also mandatory. To make the Regulation more practicable, the MoA has further established detailed rules, namely, Administrative Measures on the Safety Assessment of Transgenic Agricultural Products, Administrative Measures on the Safety of Imported Transgenic Agricultural Products, Administrative Measures on the Labeling of Transgenic Agricultural Products in 2002, and Administrative Measures on Authorization of Processing Transgenic Agricultural Products in 2006.

Regrettably, the application of rules and measures of the MoA on agricultural biotechnology has been criticized for lack of transparency. According to the Top 10 Food Safety Events published by the Research Center for Food Safety Law under the China Law Society in 2015,³² one lawsuit was brought by a lawyer against the MoA on the ground of the MoA's failure to publish administrative information with

III, and IV pursuant to their risks to human beings, animals, plants, microorganisms, and the ecological environment. More detailed information can be found in the Administrative Measures on the Safety Assessment of Transgenic Agricultural Products (infra Chart 2).

³¹For more information, see the explanation for the adoption of stricter regulation by the State Council, <http://law.npc.gov.cn/FLFG/flfgByID.action?flfgID=42320&showDetailType=QW&zlsxid=23>

³²For more information, see the report Top 10 Food Safety Events in China 9, December 16, 2015, p. 10, available at <http://epaper.legaldaily.com.cn/fzrb/content/20151216/Article10003GN.htm>

respect to assessment and legal enforcement regarding GM food. Worse still, scandals involving illegal production and distribution of GM rice and its products have been consecutively exposed. For example, the EU imposed in 2011 and 2013 emergency measures governing the importation of specific rice products originating or consigned from China due to unauthorized GM rice.³³ In addition, CCTV reported the illegal production of GM rice in Hubei province in 2014. As a result, heightened nationwide enforcement of regulation on GM crops has been introduced. According to the Notification on the Strengthening of Official Control for GMO issued by the MoA, in 2016,³⁴ the frequency of inspection and testing as well as the strictness of accountability in case of non-compliance with agricultural biotechnology shall be increased. Further, when the Seed Law was revised in 2015, specific traceability requirements regarding the use of seeds produced from biotechnology and harsh punishment for illegal production and sale of GM seeds were introduced.

3 The Regulation of GM Food in China

3.1 Evolution for GM Food Regulation

Although general regulation is applicable to agriculture when biotechnology is involved, there is no specific rule applicable to GM food. The rules provided by the MoA are mainly concerned with the safety of primary production, and there is a lack of regulation on safety assessment and testing methods if GM organisms are to feed human beings. In view of this, the Ministry of Health (MoH),³⁵ as the competent authority for implementing Food Hygiene Law, decided to fill this legal lacuna in 2001. As a result, Rules on Hygiene Administration of Genetically Modified Food were issued by MoH in 2002. The rules were aimed at protecting consumers' right to health and information and hence require all food produced from genetically modified plants and animals as well as microorganisms to be assessed for safety and nutrition and also labeled with information identifying them as GM foods. However, the rules were repealed by the Rules on Administration of Novel Food Materials in 2007, resulting in a legal lacuna for regulating GM foods. As a remedy, the revised Food Safety Law in 2015 put emphasis on labeling requirements in the production and sale of GM foods.³⁶ In case of violation of the labeling

³³ Commission Implementing Decision (EU) No. 2011/884/EU in 2011. However, due to the continual notifications from member states for food and feed concerning unauthorized genetically modified rice in rice products originating from China, the Implementing Decision 2011/884/EU has been updated by the Commission Implementing Decision of June 13, 2013. Accordingly, other products which may contain rice were added to the scope of Implementing Decision 2011/884/EU. Besides, additional sampling protocols were also added to address processed products which were not covered by the previous decision.

³⁴ Notice on further strengthening regulation of GMO, 2016, available at http://www.moa.gov.cn/zwllm/tzgg/tz/201604/t20160417_5096932.htm

³⁵ Notably, after reform in 2018, MoH has become the National Health Commission.

³⁶ Food Safety Law of 2015, Article 69.

Legal provision	Department	Purpose	Year of taking effect and revision
Regulation on Safety Administration of Genetically Modified Agricultural Organisms	State Council		2001, revised in 2011
Administrative Measures on the Safety Assessment of Transgenic Agricultural Products	Ministry of Agriculture	Process for authorization of safety certificate	2002, revised in 2016
Administrative Measures on the Labeling of Transgenic Agricultural Products	Ministry of Agriculture		2002
Administrative Measures on the Safety of Imported Transgenic Agricultural Products	Ministry of Agriculture		2002
Administrative Measures on Authorization of Processing Transgenic Agricultural Products	Ministry of Agriculture		2006
Rules on Hygiene Administration of Genetically Modified Food	Ministry of Health	Strengthening regulation of GM food and protecting consumers' health and right to know	2002, repealed in 2007 by the Rules on Administration of Novel Food Material
The Food Safety Law	NPC Standing Committee	Production and distribution of GM food shall be clearly labeled.	2009, revised in 2015

Chart 2 Legislative evolution on genetically modified agricultural organism and genetically modified food

requirements, consumers can claim punitive damages in an amount equivalent to ten times the price paid for GM foods.³⁷

In view of the above, from agriculture to food, a legislative evolution is summarized in Chart 2. Notably, the listed departments for rule-making also provide a regulatory system for GM food regulation in China.

3.2 Key Mechanisms to Ensure GM Food Safety

According to the abovementioned laws and regulations, the regulation of GM food safety is supposed to be precautionary. Because there is a license requirement for GMO, and if an approved GMO is used for food production, labeling is further required for the final product. Notably, even for imported GMO used as food or GM food, labeling is necessary to indicate its GMO status. During this process, as a risk regulation, the regulation of GM foods relies also on the following important institutional arrangements to ensure GM food safety: risk assessment, GM food labeling, and risk communication.

3.2.1 Scientific Assessment

As mentioned above, GM foods are regarded as a kind of tech-food and rely on scientific assessment to prove their safety. In this sense, scientific assessment is also a basic principle that enables the application of biotechnology in practice and the implementation of food safety regulation. It is generally acknowledged that the introduction of Food Safety Law in 2009 provided the legal basis for food safety regulation in China, and one of the progresses achieved is to establish a scientific rationale for food safety by introducing risk assessment as well as risk monitoring. In the case of agricultural food, as early as in 2001, the safety assessment for transgenic agricultural products was established. More importantly, greater progress at this stage of primary production was the establishment of the Expert Committee on Agricultural Food Safety Risk Assessment in 2007 by the MoA according to the Law on Quality and Safety of Agricultural Products.³⁸ Notably, to be approved for commercialization, after obtaining safety certificates, there are still a variety of review, production, and sale licensing processes to be complied with.

3.2.2 Labeling

Generally, food labeling is the primary means of communication between the producer and seller of food on the one hand and the purchaser and consumer on the other. From a regulatory perspective, labeling is an essential tool to deal with

³⁷ Food Safety Law of 2015, Article 148.

³⁸ Law on Quality and Safety of Agricultural Products, Article 6. Although the Food Safety Law is aimed to unify food safety regulation in China, the regulation of safety and quality of agro-food at the stage of primary production is still separate. See Sun Juanjuan, Review of the “Law of the People’s Republic of China on Quality and Safety of Agricultural Products”, *Journal of Resources and Ecology*, 2018, 9 (Alemanno, 2012), pp. 106–113.

information asymmetry, in order to ensure an informed choice by consumers. In view of this, the requirement of food labeling in the case of GM foods provided under Article 69 of the Food Safety Law is closely linked to the need to protect the consumers' right to know. More importantly, the labeling provision has been further implemented by a national mandatory food safety standard, namely, GB 7718 on General Standard for the Labeling of Pre-packaged Foods.³⁹ In practice, consumers' claims for compensation due to the lack of GM food labeling have been supported by courts.⁴⁰ As mentioned earlier, the provision of punitive damages in the Food Safety Law also encourages consumers to participate in the fight against GM food that violates labeling requirements.

3.2.3 Risk Communication

Food scandals in China have not only pushed the reform for food safety regulation but also raised the public's awareness of food safety. As far as GM foods are concerned, a tussle between the popular celebrities Fang Zhouzi and Cui Yongyuan also attracted considerable attention thanks to the power of new media such as Weibo. Briefly, Cui Yongyuan is a well-known television personality who has engaged in the fight against GM foods for a long time. Among others, he criticized an article in favor of genetically modified foods written by Fang Zhouzi, who is a prominent biochemistry blogger. Fang then accused Cui of spreading unfounded rumors that hindered the development of China's national agriculture program. As a result, these disputes further raised public concern and mistrust on food safety of GM food.

Given the decline of public trust in food safety regulation, a communicative, participatory, and deliberative risk decision-making process can garner not only legitimacy but also public acceptability of protection levels. Therefore, in 2015 the Food Safety Law introduced risk communication among risk assessors, risk managers, consumers, industry, the academic community, and other interested parties, to encourage the interactive exchange of information and opinions throughout the risk assessment and management process concerning risk, risk-related factors, and risk perceptions, including the explanation of risk assessment findings and the basis of risk management decisions. Since then, increasingly, scientific experts have engaged in risk communication about GM foods. For instance, the 2016 Specific Project of Cultivation of New Varieties of GMO is one of the Major National Science and Technology Programs for the "Thirteenth Five-Year Plan". In addition to "hard science" research, two "soft science" research studies have begun in 2017, one dealing with science popularization and risk communication on GM technology and its development, the other exploring and implementing new approaches to risk

³⁹GB 7718–2011 is available at <http://bz.cfsa.net.cn/staticPages/9058ADC5-AFC3-4586-9798-D0170F6F879C.html>

⁴⁰For example, in a civil case decided by Beijing Haidian People's Court, (2017) Jing 0108 MinChu No. 29455, an imported food product was not labeled as GM food in line with its original labeling in English, and the court supported the consumer's claim of ten times compensation since it is legally required to be labeled. More information can be found at <http://wenshu.court.gov.cn/content/content?DocID=5716fdee-a38b-44ab-ab46-a85600f04aa8&KeyWord>.

communication on innovative technologies of strategic importance and public controversy.⁴¹

3.3 Ongoing Debates on GM Food Regulation

Although there are international obligations for the WTO members to base their food safety regulations on sound scientific evidence, the disagreements between the USA and the EU have shown that the regulatory differences in relation to GM foods are shaped by their differing economic and cultural specialties, public perceptions of risk, and scientific uncertainty. Therefore, to create the right regulatory environment for GM foods in China, government regulation should take into account the following factors.

3.3.1 National Condition

Comparatively speaking, the light regulatory touch for GM food in the USA is aimed at promoting new technology and economic value, since it is conducive to technological innovation and commercialization, thereby increasing national competitiveness. Benefiting from such light touch regulation, American biotech companies have taken leading positions in the field of biotechnology research and application and in turn become promoters of such light touch regulation of GM food. In contrast, the EU has paid more attention to public interest, since it had an urgent need to recover public confidence after the BSE crisis. Furthermore, listening and responding to public concerns also consolidated its democratic foundation as a Union and smoothed legislation at the EU level. In view of this, national specialty is an essential context for understanding the regulatory environment for GM food regulation.

As far as China is concerned, food security and food safety are both of great concern to the state and the public. Indubitably, the challenges of food security and the possible ways of overcoming such challenges are major concerns in China. However, issues like the surge in the import of staple foods, the drop in self-sufficiency rates of food supply, the reduction of cultivated land, and pollution of the environment all raise the expectations for the potential contribution of GM technology in improving yield.

Also as a special condition in China, public concern over GM foods exerts huge pressure on the commercial production of GM rice even after the granting of a safety certificate. Ongoing food safety problems have not only seriously affected consumer confidence in the government's credibility but also have an adverse economic impact on China's food industry and food trade. In this regard, the current situation in China is similar to that of the EU after the BSE crisis. That is to say,

⁴¹News, project of scientific education and risk assessment of biotechnology was officially launched in Tsinghua, 2017-01-05 (in Chinese), available at <http://www.biotech.org.cn/information/144802> (last accessed on July 2, 2018).

there is a strong need in China to restore consumer confidence in food administration and food industry through the strengthening of food safety regulations.

3.3.2 Scientific Assessment and Public Perception

Undoubtedly, scientific assessment provides sound evidence for food safety regulation. However, it is still questionable whether scientifically favorable opinion is adequate to support the government's decision to release GMO into the environment and use it for food production. As a tool to communicate with the public, risk communication is used not only to inform the public but also to involve them in the decision-making. Certainly, the lack of knowledge may lead to misunderstanding among the public, and rumors may find a way to exacerbate the situation. Therefore, education and communication are needed to change and improve public perception. Moreover, transparency with respect to decision-making also matters and can be achieved through the involvement of stakeholders and the public. In so doing, the decision-makers can have adequate information to undertake risk-taking or risk-avoidance decision(s), and public's tolerance of the risk can also increase.

Admittedly, participation of scientists and their opinions is necessary for decision-making during risk management in food safety regulation(s). However, lay people usually hold a different opinion from that of experts on technological risks. As shown by research,⁴² the ranking of risk among the ordinary public is based not on the statistics utilized by experts but on qualitative dimensions, such as whether risk is voluntarily or involuntarily taken, happens chronically or catastrophically, is known or unknown to science, and is controllable or uncontrollable. Furthermore, people tend to overestimate the probability of unfamiliar, catastrophic, and overly publicized events. Despite the subjectivity of the public's attitude toward risk, the public's perception of risk usually transforms into public concerns and, in turn, affects decision-making and eventually crystallizes into regulations. Therefore, the involvement of the public is also a mechanism to increase the social acceptance of a given risk.

3.3.3 Scientific Certainty Versus Scientific Uncertainty

Although science brings about certainty in public decision-making, it also entails uncertainty, which may result from indeterminacy, ignorance, or scientific controversy. As shown in the lessons from the BSE crisis, the failure to consider a scientific controversy may lead to an underestimation of a newly emerging risk as well as irreversible damage to human health. This is why the so-called precautionary principle was introduced in the EU as a legal principle for food law. Generally speaking, the precautionary principle was put forth to enable appropriate action against scientific uncertainty, with the purpose of dealing with irreversible damage in a proactive manner. Notably, the precondition for a precautionary action is still scientific assessment. In this respect, as a structured decision-making process, risk assessment is the

⁴²For more information about this research and finding, see Zhang Jie and Zhang Taotu, Risk communication researches in the USA: academic evolution, core proposition and key element, Public Relationship Research, 2009, 9, p. 98.

first step to provide scientific certainty, while precautionary action should be taken to handle scientific uncertainty.

Yet, as a weak principle, the application of the precautionary principle is subject to review by continued scientific assessment as well as principles such as proportionality, consistency, etc. Besides, in spite of an ongoing debate on whether being precautionary is a principle or an approach or an exception to scientific assessment, protective action with precaution has already been applied in the regulation of food safety. When it comes to China, the Food Safety Law provides risk prevention as a legal principle. However, without detailed rules to concretize this principle, it is difficult to discern whether it plays a role akin to the precautionary principle in European food law or not.

4 Conclusion: Governance Over Regulation

GM foods are specific foods produced through biotechnology. The regulation of such foods is undertaken with an aim of preventing technological risk and protecting public health and safety. Although international obligations and American practices have emphasized the role of scientific assessment in regulatory decisions in this area, precaution is also needed to deal with scientific uncertainty, either through the exception of the safeguard clause provided by the SPS Agreement as mentioned above or the precautionary principle promoted by the EU. All of these constitute a controversial background against which China may build its own regulatory system. As far as GM foods are concerned, there are only regulations on transgenic agricultural products in general and labeling requirements provided by the Food Safety Law in particular. The lack of detailed legislation reflects China's evasive attitude toward this issue.

In the end, a balanced approach to risk management regarding GM foods depends on the various stakeholders. While regulation was introduced as a form of government intervention in the case of market failure, self-regulation or co-regulation has also been introduced to promote cooperation between the government and market players. As in the case of traceability of GM food, the role of the government is to impose necessary obligations and undertake inspections through documentation. However, it is still the food business operators that have an advantage in recording and sharing the traced information, since they are best suited to do so at the production line. In addition to these important stakeholders, the participation of experts and the public are also important to guarantee science-based regulatory decisions and their social acceptance.

Therefore, this author is of the opinion that "governance" is a more preferable way to delineate a balanced regulatory environment for GM food. According to the definition proposed by the Commission on Global Governance⁴³ in *Our Global*

⁴³The Commission was established in 1992 with the full support of [United Nations Secretary-General Boutros Boutros-Ghali](#). One of its contributions was to make a standard definition on global governance.

Neighborhood in 1995, “governance” is the summation of many ways in which individuals and institutions, public and private, manage their common affairs, as well as a continuing process through which conflicting or diverse interests may be accommodated and cooperative action taken. By replacing regulation with governance, the emphasis is shifted to the engagement and coordination among different stakeholders. In this respect, food safety regulation, including regulation on GM foods, in China has yet to keep pace with the tendency of favoring governance over regulation.

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