Study on the safety of genetically modified food biotechnology based on the legal system of food safety

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With the development of genetically modified biotechnology, genetically modified food (GMF) is stepping into our life. While the contribution of GMF to the economy is undeniable, its risk has also drawn the attention of the government and the public. Currently, the legislation of food safety is still imperfect in China. Therefore, GMF safety is an urgent issue which requires the improvement of legal system regarding GMF safety. In this paper, firstly, we point out the concerns about GMF safety. Next, we introduce the current legislation situation of genetically modified technology in China, followed by the analysis on the deficiencies of the GMF safety legal system. Then, we list the legal systems of GMF safety in the EU, the US and Japan. At last, based on the national situation of China and the guidance of foreign legislation of GMF safety, we propose suggestions to perfect the existing food safety system regarding the basic principles, GMF safety legislation and GMF safety system, aiming to guarantee GMF safety and protect the health of consumers.

Keywords: genetically modified food; food safety; legal system; supervision and management system; safety legislation.

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Introduction

Ever since it first came out, genetically modified food (GMF) has developed irresistibly all around the world owing to its superiority [1]. However, its security has been questioned constantly for its potential and unpredictable harm to human health and the environment [2]. According to the report of commercialized development trend of GM crops given by International Service for the Acquisition of Agri-Biotech Applications (ISAAA) in 2013, a total of 27 countries grew GM crops [3]. As to GMF, the concerns about its security problems have been intensified [4]. It was pointed out that the fundamental feature of GMF was that human beings enabled genes to transfer between different species with the aid of genetically modified technology [5]. Based on the evolution of safety management system of GMF in China, Zhang XF [6] suggested that a definite and clear judgment of the development trend of GMF safety was in urgent need. Li GD et al. [7] stated that the perfectness in form was the only standard to judge the completeness of transgenosis regulation system.

While the planting area for genetically modified crops is expanding and commercialized genetically modified crops are prevailing, it is urgent to protect the legitimate rights and

interests of the public. In China, quite a few laws and regulations have been established to regulate safety of GMF. However, there are still deficiencies which might harm the legitimate rights and interests of the public [8].

Overview of genetically modified food safety

Genetically modified technology refers to the process of isolating an exogenous gene from animals, plants or microbes and transferring it into another organism; by integrating the exogenous gene to the host genome, the features, phenotypes, nutrition and resistance of the gene can be optimized to meet human requirements.

With the application of genetically modified technology, the resistance of crops to toxicity or phosphinothricin can be improved [9]; meanwhile, the yield of crops is increased, which helps relieve food crisis [10]. At present, the control over genetically modified technology is still in the primary stage. It is generally considered that with regard to genetically modified foods, there were certain risks which are inconclusive yet [11-13]. In other words, although there is no evidence that GMF causes harm to human health, it cannot be proved that it is not harmful. Academically, genetically modified products are regarded to be harmful to food safety, ecological environment, economy and society.

In 2015, the planting area of genetically modified (GM) crops in China covered more than 3.7 million hectares, including 3.7 million hectares of GM cotton and 7,000 hectares of papaya. The Chinese government has paid at least 3 billion dollars to research institutions and domestic companies for the development of domestic GM seeds; in addition, the government is considering accelerating the examination and approval of GM crops.

Synthetic CryIA (b) and CryIA (c) insecticidal genes are successfully imported into the main cotton cultivar, which reduces the loss caused by pests and cuts down the use of chemical pesticides. In addition, by importing animal keratin genes into cotton fiber, the GM cotton is featured by good luster, softness, good elasticity and warmth retention property (Figure 1).

Figure 1. GM cotton.

Papaya ring spot virus is a kind of RNA virus with high variability. Chinese scientists have independently developed GM papaya (Figure 2) which is resistant to domestic strain of papaya ring spot virus.

Figure 2. GM papaya.

The potentiality of the harm of GMF determines that the legal system should be more focused on risk prevention and control. Moreover, a whole-process (pre-event, on-event and post-event) monitoring mechanism can be established. This mechanism should contain beforehand, thing, after the whole process [14]. In the aspect of

legislation, a strict and reasonable legal protection system of GMF safety is supposed to be established.

The status and problems of the legal system of genetically modified food safety in China

Current legislation situation of genetically modified technology in China

In China, the basic policy on GMF is "active and cautious". Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (GMOs) stipulates the assessment requirements for genetically modified animals, plants and microorganisms from laboratory research stage to application safety evaluation certificate stage. According to the regulations regarding the import of agricultural GM crops, if the genetically modified organisms (GMO) are not guaranteed with safety assessment and approval from relevant national organizations, they will be returned or destroyed.

In 2015, the Chinese Ministry of Agriculture (MOA) proposed amendments to the Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (GMOs). Agricultural GMO safety certificate is issued only when the GMO is up to standard of the safety assessment of National Agricultural GMO Safety Committee and approved by the MOA. In the case of importing agricultural GMO or exporting agricultural GMO to China, the required safety assessment materials have to be submitted; in addition, the GMO samples, reference samples and testing methods have to be provided along with the application for safety certificate. The companies engaged in agricultural GMO test and production should be supervised and inspected by the Agricultural Administrative Department.

GMO Labeling and Management Measures stipulates that the main raw materials containing genetically modified ingredients should be labeled [15]. In addition, the products which fail to meet the specifications are forbidden from selling [16].

Problems and reasons of the legal system of GMF safety in China

Low legislative level

Currently, without a complete legal system, the normative documents on GM are mostly departmental rules and regulations. In the shortage of legal documents issued by the National People's Congress or the State Council, comprehensive and integrated regulation on GMF safety cannot be implemented [17]. Due to the defects in laws and regulations, it is difficult to solve the problems regarding GMF safety on a legal basis. In addition, the regulation force is unsatisfactory.

Imperfect management system

In China, with regard to GMF safety management, a regulation link is under the supervision of a department, which generates disadvantages such as poor supervision and formalism [18]. On the other hand, local governments are more concerned about their own interests instead of the public and long-term interests. Some departments are utilitarian and arbitrary in formulating regulations and rules. Generally, only when problems arise will they take measures, let alone preventive measures.

Unclear legislative concept

In the assessment of GMF safety, the evaluation method is unclear. As the evaluation of GMF safety is under classified management, different evaluation criteria are applied to the departments with different level. As to the division of risk level, the law does not provide any objective standard. In the current laws and regulations relating to GMF, there are few regulations regarding the evaluation on the risk and harm of GMF to human health.

Defective labeling system

Owing to the demand of consumers as well as the appeal of relevant organizations, labeling system of GMF has become an effective method

to normalize GMF [19]. In China, labeling system of GMF has not been fully understood by consumers yet. At present, relevant management measures for GMF labeling have been formulated with a cautious management mode. However, the compulsory labeling system did not bring any significant effect, which indicates that the labeling system of GMF in China is still imperfect.

Unreasonable genetically modified detection system

Currently, the detection organizations are entrusted by the Ministry of Agriculture, and there is no independent detection organization yet. In China, there are 17 universal detection standards which are formulated or recommended by industry associations or ministries and commissions. In terms of test methods, they are subject to testing standards and environment, which makes testing standards less authoritative.

Legal systems of genetically modified food safety in foreign countries

Legislation of genetically modified food safety in the European Union

As to the selection of legislation mode, the EU adopts "legislation based on manufacturing method" and adheres to precautionary principle which is applied to the laws and regulations of GMF safety [20]. Taking into account the potential risks of GMF in advance, the EU can perform risk management. In addition to the concern about the safety of GMF, the EU believes that there is potential safety hazard in the production process. Therefore, the EU applies a stringent management mode on GMF. Compared with the legal system of GMF safety in the US, the legal system in the EU is more complete and clear with a larger adjustment scope. However, strict and rigid legal rules will increase production and operating costs; moreover, there will be disputes on technical barriers.

Legislation of GMF safety in the US

Basically, the US is open-minded with GMF as well as the related laws and regulations. The legislative mode "based on products" and "reliable scientific principles" are adhered to in the US. Based on the legislation mode and supervision method, the US implements a relatively loose regulatory policy on GMF safety [21]. In the US, people generally hold positive attitudes towards GMF and support relevant policies to some extent; according, a relatively open system of GMF safety is implemented in the US on account that the policy can bring considerable benefits to the US economy and GMF is more acceptable to the public in the US.

Legislation of GMF safety in Japan

Considering its limited arable land, Japan is densely populated. Therefore, high-yield GMF is popular in Japan. The Japanese government has always taken the supervision of GMF safety seriously [22]. The supervision manner of labor division helps strengthen collaboration between departments and reduce conflicts between regulators, thus to improve unhindered implementation of legal system and reduce the cost of legislation [23]. Similar to Japan, China is faced with the contradiction of dense population and inadequate arable land; moreover, the legislative mode is also similar. Therefore, we can learn from Japan in legislation of GMF safety and establish a scientific and reasonable legal system of GMF safety that adapts to China's national conditions.

Improvement of the legal system of GMF safety in China

Basic principles of the legal system of GMF safety in China

Precautionary principle

This paper mainly discusses the risk of GMF to human health. Since there is no actual case proving the harm of GMF, laws protect humans and ecological environment from damage mainly based on prevention [24]. However, it does not mean that the damage will never happen.

Therefore, we must be vigilant and cautious about the potential risks which may transform into actual damage; in the formulation of related laws and regulations, the terms on relief should be worked out ahead of time.

Public participation principle

No law can be implemented or supervised without the participation of the public. However, as to the legislation for GMF, there is no stipulation on public participation and supervision. Citizens have the rights to know with regard to the whole process from research to after-sales tracking; moreover, they have the option in purchasing GMF. Entitled to safeguard their legitimate rights and interests, citizens can supervise the whole process and reflect the conditions after consuming GMF.

Informed choice principle

Informed choice principle is contributive to the related legislation in safeguarding the rights and interests of consumers as well as protecting consumers' informed choice rights. When formulating the relevant legislation of GMF, legislators should fully consider the consumers' informed choice right. In addition, the protection principal of intellectual property is also significant to promoting the healthy and rapid development of genetically modified technology.

Improvement of legislation of genetically modified food safety in China

GMF being a kind of new resource food, its potential risk is still unpredictable. Therefore, protecting the safety of GMF is undoubtedly the most important purpose of GMF safety legislation. Specifically, GMF safety legislation is aimed at reducing the risk and protecting consumers' rights to health and life.

When selecting the legislative mode for GMF safety in China, we must take comprehensive consideration of various factors. Despite that the genetically modified technology of China is in a leading position in the world, enterprises are short of corresponding credit systems. Consequently, a laissez-faire attitude towards GMF will give rise to risks. The legislation mode of the EU is relatively conservative for its regulation on GMF safety is rigorous. Assuming that such legislation mode is adopted in China, the development of GMF industry and technical researches will be hindered; moreover, it is inconducive to solving the problems of poverty and food safety in China. Instead, we suggest a more compromised and appropriate legislation mode similar to that of Japan. With strict control over the production process of GMF and specification on the sales process, the rights of consumers can be truly guaranteed.

Perfection of GMF safety system in China

On the premise of respecting ecological ethics

There are still debates on the existing or potential harm of GMOs, which mainly focus on the harm on human health, ecological environment and violation of ecological ethics. The third aspect is the most important concern. As nature has its development rule and law, artificial modification on nature might bring short-term explosive damage or long-term latent damage to the whole natural system. Therefore, while receiving convenience and benefits from transgenic technology, we must carry out thorough researches on the laws of nature and ecological ethics, thus to avoid devastating or permanent catastrophe.

Perfection of the regulation system of GMF

Whole-process supervision involves the process from research to after sales. Whole-process monitoring is implemented by recording information. Regulators can establish user profiles of GMF consumers for real-time tracking and timely feedback. Names and addresses of GMF manufacturers are recorded. In addition, the information of GMF names, production dates, expiration dates and information of sales personnel is also recorded.

Establishing and perfecting GMF safety guarantee mechanism

GMF safety guarantee mechanism is an important barrier to the protection of GMF

safety. The existing safety mechanism, such as detection system of GMF, risk assessment system and safety assessment system, should be perfected. Moreover, it is of positive practical significance to establish the missing systems in the safety mechanism, such as public participation mechanism.

Emphasis on decision-making mechanism and encouragement on innovation talents

GM technology should be incorporated into the national major science and technology project plan, aiming to encourage independent innovation. The national major decision-making procedure can be improved; a standard consulting and decision-making mechanism is expected to be established; reformation on science and technology evaluation system is also required. The evaluation on science and technology project is supposed to accord with the principles of fairness, justice, openness and encouragement of innovation; especially, to create opportunities for talents. When establishing transgenic regulation policies, we should consider our national conditions to make reasonable decisions and cultivate innovative talents.

To establish high-efficiency safety regulation system of GMF

Safety regulation of GMF is supposed to involve the development of GM technology, the application of GMO, production, processing and marketing of GMF. In the safety regulation process, the relationship between safety control and technology development needs to be balanced. Excessively strict control is inappropriate as it might hinder the research and development of transgenic biotechnology; on the other hand, a loose safety regulation system is irrational as it could endanger human health and ecological environment.

Citizen participation system for GMF safety

The content and forms of citizen participation system include the following aspects. Firstly, formulating relevant laws and regulations, the legislation departments should consider the opinions of the public. Secondly, the public can participate in the whole-process supervision on GMF safety. The establishment of the mechanism involves the guidance on citizens' legal consciousness and participation consciousness. Meanwhile, citizen participation can be combined with the government management and expert researches to determine its importance in the laws related to genetically modified food.

Conclusion

The development of genetically modified technology in China is in a relatively high level; however, the legislation of GMF safety is obviously falling behind. Therefore, it is essential to perfect the legal system for GMF safety so that the risk of genetically modified food will be controlled within a certain range, which will make consumers more willing to accept genetically modified food. By implementing strict legal regulation, the problems of food safety will be solved; furthermore, it is likely that higher-quality food will be developed to improve our life quality. In brief, this study provides a favorable approach to the development of GMF industry and the economy.

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