

Study on the legal system of transgenic biotechnology safety protection

Songfei Chen*

Hunan City University, Yiyang, Hunan Province 413000, China

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In this study, we aim to comprehensively analyze the transgenic biotechnology as well as expound its characteristics and harms, thus to make a contribution to the safety protection of transgenic biotechnology in China. Referring to the relevant concepts of biotechnological safety, this study also put forward the concept of transgenic biotechnology safety. Although transgenic organisms can cause irreparable losses on the environment, the regulation on transgenic organisms using legal means still needs corresponding reasons. Therefore, this study discussed about the necessity of the legal system of transgenic biotechnology safety protection from the aspects of economy and legal principles, which came to a conclusion that the legal system of transgenic biotechnology safety protection was an important institution to keep the development of current transgenic biotechnology. Moreover, it could balance the fear of people caused by insecure factors of transgenic biotechnology. At last, this study analyzed loopholes and deficiencies of the legal system of transgenic biotechnology safety protection and relevant improvement links were specially set up, such as legislative selection, institution selection and legislative principles. Besides, suggestions for improvement of specific institution of the legal system of transgenic biotechnology safety protection were put forward.

Keywords: transgenesis; biotechnology; legal institution; prevention.

*Corresponding author: Songfei Chen, Hunan City University, NO.518, Yingbin East Road, Yiyang, Hunan, 413000, China. E-mail: songfei0725@sina.com .

Introduction

Transgenic biotechnology, one of the modern science and technology, has brought a new life to people but also has caused certain practical or potential threats on human society at the same time [1]. At present, the transgenic biotechnology is widely applied to various fields like agriculture, medicine, resources, industry and material, etc. [2]. As transgenic marketization occurs, people have begun to suspect the transgenic technology.

The transgenic biotechnology can change genetic constitutions of the original natural biology through modifying original biogens or

introducing foreign genes to the noumenon, which may cause various potential safety hazards as well as pose a threat to the environment and human health [3-4].

In recent years, as the reports related to the transgenic maize event [5], monarch butterfly event [6], laboratory mice cancer event [7] and Hunan golden rice event [8] were released, the public begin to pay more attentions to safety problems of the transgenic biotechnology. The technological development should not be halted, thus the risks caused by technological uncertainties should be predicted and regulated by legal means to guarantee the healthy and ordered operation of the ecological

environment. Safety problems of transgenic organisms are mainly related to human health, environmental safety and biological diversities [9]. Considering the uncertainty, large scale, abruptness and irreversibility of transgenic organism risks, once the safety problems occur, they can lead to global disasters [10]. Legal regulations in the field of transgenic science and technology in China are not sound and the legal hierarchy mainly focuses on low hierarchies. In the meantime, legal regulations lay the emphasis on beforehand preventing and there is no complementary legal institution.

The legal regulation of the transgenic biotechnological safety is taken as the research object in this study. Relevant laws and international agreements [11-12] on transgenic regulations in foreign developed countries are studied to analyze the attitudes, legal regulations and contents of different countries to the transgenic biotechnology. Based on the Chinese social reality, relevant suggestions for transgenic regulations in China are put forward, hoping to find an equilibrium point between the benign development of biotechnology and industry and environmental safety and human health.

Analysis of the legal system of transgenic biotechnology

Definition of transgenic biotechnology and its laws

Transgenic biotechnology refers to introducing gene segments that can express certain characters to target organisms through modern technologies, thus to add new functional characters to the recipient organisms to obtain new organisms. In early stage of the development, such technology transfers and integrates genes of one or multiple kinds of organisms into another organism, which provides new exogenous genes for the genetic system of the organism. In the later period of development, organisms can be successfully modified even without the intervention of

exogenous genes, such as gene processing and gene knockout, etc., which maintains advantageous characters as well as changes intrinsic hereditary characters.

However, as transgenic biotechnology develops, its safety problems have become the international concern. Thus international organizations are established and international conventions are carried out to coordinate interests among countries as well as normalize and guide genetically modified food. For example, the Convention on Biological Diversity includes stipulations of controlling potential risks of living biotechnology modified organisms during application or release. Such kind of risks includes the negative influence on environmental production as well as human health. Moreover, the Cartagena protocol on Biosafety stipulates that the transgenic biosafety detection in every country should include following procedures as shown in figure 1.

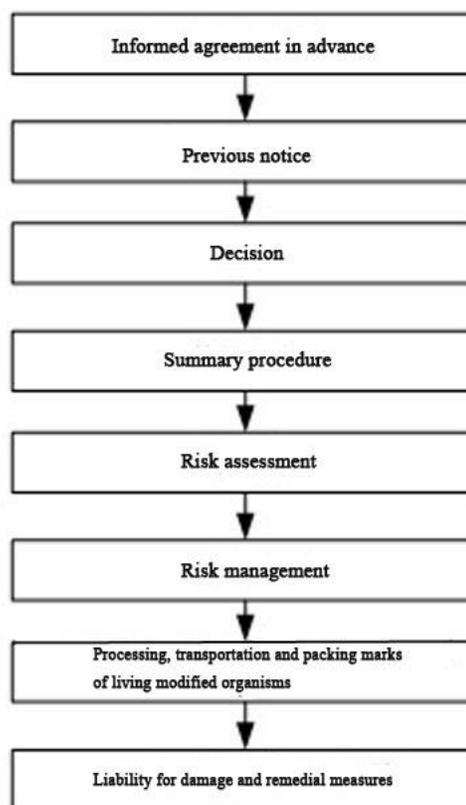


Figure 1. Procedures of transgenic biosafety detection stipulated by the protocol

In addition, its stipulations on the risk management of genetically modified organisms are as follows [13]. First of all, the contracting party should formulate and keep appropriate mechanisms, measures and strategies according to the article 8 stipulation of The Convention, thus to restrict, manage and control risks caused by the usage, processing and trans-boundary movement of living modified organisms. Secondly, within a necessary range, measures that are based on risk assessment results must be taken, thus to prevent the negative influence of living modified organisms on the biodiversity and sustainable development of the territory as well as human health. Thirdly, every contracting party should take appropriate measures to avoid accidental trans-boundary movement of living modified organisms. Before the first release of a kind of trans-boundary movement of living modified organism, measures like risk assessment should be taken.

Analysis of the legal system of transgenic biotechnology based on economics

The market itself has a kind of mechanism, which can apply such as the price mechanism, etc., to coordinate human economic life [14]. However, the mechanism also has its own limits and disadvantages, such as lack of perfect competition and its externality. The market is also characterized by spontaneity and blindness. An efficient market may lead to fairness problems [15].

Therefore, with no specific market mechanism, the main market players will think and make beneficial choices according to their own benefits. However, economic activities not only require the input of main market players, but also the sacrifice of environmental values. If there is no strict legal restrictions, the main market players will unconsciously transfer social costs either to other people or the future or the nature, thus to maximize their benefits.

The market efficiency is determined by its externality. When a market has no externality, it is efficient. On the contrary, the institutional

arrangement of government is efficient. Market failures can result in its inefficiency, which requires the government to cure these diseases [16]. Important economic mechanisms of the legal system of transgenic biotechnology safety prevention are as follows [17]: market mechanisms have a natural tendency to transfer ecological environment costs to the society; profit-driven transgenic biotechnology enterprises may pose a threat to the environment, which requires the intervention and correction from the government to regulate behaviors of the main market players. Therefore, taking the main market players as the main part and the macro-control of government as the auxiliary part, the improved legal system of transgenic biotechnology safety prevention should be established, which is the core content of safety prevention law of transgenic biotechnology.

Analysis of the legal system of transgenic biotechnology based on value conflict balance

For the development of science and the stability of society, like a proverb that says, you can't have your cake and eat it too. Science and technology has no thought, while the users of scientific and technological achievements are conscious, thus the users are the main determinant. The transgenic technology not only improves biological breeds and enriches biological diversities, but also improves the living quality of human. In the meantime, it significantly improves the utilization of biological resources. However, due to the insufficient recognition of people and their pursuit of benefits, the transgenic biotechnology also has enormous potential risks. It can result in disorder of the ecological system as well as have irreversible damage on the environment.

The safety law of transgenic biotechnology not only includes the value of order and free value, etc., but also contains the processing method of value relations. The purpose of perfecting the safety law of transgenic biotechnology is to better process the relationship between benefit value and safety value. In reality, transgenic laws

can guarantee the balance between benefit value and safety value. Therefore, law regulations can not only guarantee the benefits brought by transgenic technology, but also protect the environment. Moreover, they can have risk evaluation for the transgenic technology beforehand to guarantee its safety [18].

The legal system of transgenic biotechnology prevention safety in foreign countries

Safety of the transgenic biotechnology is the focus of the whole world, and its safety prevention also acquires great attentions. At present, there are Convention on Biological Diversity and Cartagena Protocol on Biosafety [19] in the world used for prevention of transgenic technology.

Comparison of the legal system of transgenic biotechnology safety in America and European Union

In principle, America takes the substantial equivalence principle on safety control of transgenic organisms. As the biggest exporting country of genetically modified organisms, America treats transgenic products as normal products without discrimination. The European Union takes the principle of cautious prevention and differential treatment [20]. Although transgenic organisms are not under embargo, they are strictly monitored by unique supervision mode and separated from normal crop products, thus to minimize the potential risks. In respect of the identification of transgenic organism products, America adopts voluntary identification and mainly refers to the Federal Food, Drug, and Cosmetic Act. Article 403 of the Act stipulates contents of food labeling and the labeling range involves all food instead of genetically modified food only; moreover, only when the genetically modified food is significantly different from corresponding traditional food and applied for special purposes, or it has special effect and contains allergens, it belongs to special labeling management. The

European Union takes strict identification policy. In 2003, the European Union put forward Genetically Modified Food and Feed Regulations (article 1829/2003) which stipulates the labeling of genetically modified food that is finally consumed by consumers and popular catering industries. Food that contains more than 0.9% of genetically modified organisms should be clearly labeled with Transgenic Product. Moreover, the specific contained transgenic ingredients, its differences in nutrients and allergens from traditional biological products and what kind of people does it suit to should all be noted. From the aspect of supervision organizations, America does not have specific organizations; according to stipulations of its Coordination Framework, the detection, evaluation and supervision of genetically modified organisms are accomplished by three apartments: Ministry of Agriculture, Environmental Protection Administration and Food and Drug Administration. The European Union has established the European Food Safety Authority and European Commission to evaluate the safety of new biological products as well as determine whether they can enter the European Union market.

As shown in table 1, the reasons why these differences exist are that, the transgenic technology in America is developed; America can protect its economic overlord status by transgenic organisms because transgenic organisms have low costs. On the other hand, genetically modified organisms are stronger than normal crops in resisting natural disasters, thus their costs are significantly reduced. The European Union is always in weak state in the respect of transgenic organism products export; thus in order to protect its crop economics, the European Union takes an against attitude. Natural conditions in America are poor, thus transgenic organisms can survive better than traditional creatures.

Experience and inspiration of foreign legal system to China

Table 1. Different attitudes of America and European Union to genetically modified organisms.

	America	European Union
Principle	Substantial equivalence	Cautious prevention and discriminatory
Product identification	Voluntary identification	Strict identification
Supervision institution	Coordinated supervision of Ministry of Agriculture, Environmental Protection Administration and Food and Drug Administration	European Food and Drug Administration and European Commission

The legal systems of transgenic organism safety in European and American countries are formulated according to their own development situations. A complete legal system can provide a blueprint for the marketization of transgenic organisms. Therefore, the construction of the legal system of transgenic organism safety in China should select the essence and discard the dross.

As shown in table 2, being lack of perfect laws and regulations, China should use the laws and regulations of genetically modified organisms of America and European Union for reference. Besides, China is lack of resources of biosafety supervision and the potential safety hazards are significant. Therefore, we should learn from other good supervising modes and experience from foreign countries as well as optimize supervising resources according to national conditions, thus to enhance people's awareness to the transgenic technology.

The current situation and analysis of the transgenic biotechnology safety prevention in China

The system of transgenic biotechnology safety prevention in China

China is the biggest rice production and consumption country. According to data provided by National Bureau of Statistics in 2015, the seeded area of rice was 30.213 million hectares; the average per unit yield was 6.89

ton/ hectare, accounting for about one third of national grain total output. As the national population increases continually, using the transgenic technology to increase the rice yield has become a key point. Currently, insect-resistant, disease-resistant, herbicide-resistant, stress-resistant and nutrition-improved transgenic rice has been bred. However, the influence of such kind of rice on human health is controversial. Therefore, China has passed a series of laws and established relevant systems of transgenic biotechnology safety [21]. These systems include inter-ministry co-presence conference system, transgenic biosafety evaluation system, transgenic administrative licensing system, transgenic identification management system, transgenic import safety approval system, transgenic safety monitoring and checking system and transgenic organism damage compensation system, etc. These systems not only guarantee the social stability and biological diversity, but also accelerate the development of transgenic biotechnology.

The inter-ministry co-presence conference is constituted by principals of each department related to transgenic biotechnology, which is mainly responsible for solving significant problems. The transgenic organism safety system refers to dividing the threat of transgenic organisms to the environment into different levels, and different prevention measures are used for different levels. The administrative licensing system of agricultural transgenic organisms refers to every link of agricultural

Table 2. Inspirations from America and European Union on China

	America	European Union
Soundness of laws and regulations	Genetically modified organisms and traditional food are supervised uniformly and specifically stipulated and monitored in other relevant laws.	<i>“Control Regulations of Genetically Modified Food and Fodder and Control Regulations of Tracking and Identification of Genetically Modified Food, Fodder and Food”</i> are specifically enacted to monitor genetically modified organisms
Independent operation of supervision organizations	Specific biotechnology scientific harmony committee is constructed and characterized by independent status, specific responsibilities and complementary functions	Environmental safety committee is constructed to supervise and manage the hazards of genetically modified organisms
Control of legal system resources	Human resources of genetically modified organisms supervision are arranged in multiple layers, thus to control environmental risks from the source and guarantee the living rights of the public	

transgenic organism products should be approved by the administrative director. The transgenic identification system is used to regulate sales of transgenic organisms, as well as protect the right of customers to be informed of transgenic products. Transgenic import safety approval system refers to safety approval of imported transgenic organisms. Transgenic safety monitoring and checking system refers to the national administrative department in charge of agriculture testing approved transgenic organisms, including field releasing experiment, experimental production and laboratory test, etc. Transgenic organism damage compensation system refers to a neutral damage compensation system that guarantees victims to obtain compensations immediately.

Problems in the safety prevention laws of transgenic biotechnology in China

Up till now, the safety prevention laws of transgenic biotechnology in China are becoming more and more improved. However, there are still some problems. For example, corns produced from the Altay Prefecture which locates in northern Xinjiang were found to be a transformed variety from a foreign country, thus

they belonged to transgenic organism invasion. Such kind of incidence was due to that, the prevention system of transgenic organism invasion is not perfect and relevant regulations and laws are in low level. Compared with America and European Union, although China has the Ministry of Agriculture of the State Council as well as the county level and above agricultural and hygiene departments to supervise genetically modified organisms, the management system is not transparent enough for the public to acquire relevant information of genetically modified organisms in time. Moreover, current transgenic organism management system is not reasonable and the transgenic identification system does not come into play fully; the safety evaluation system is missing; public damage compensation system is lack of specific stipulations.

Improvement of the safety prevention laws of transgenic biotechnology in China

Due to the mismatching of safety laws of the transgenic organisms in China and the current development status of biotechnology, the

development of biotechnology is significantly restricted. Therefore, it is urgent to improve and perfect current safety laws of transgenic organisms. Legislation models of safety prevention of transgenic biotechnology in China include two types: integrating current transgenic organism prevention legal system and bringing the transgenic biotechnology safety prevention legal system into new laws.

The basic principle of laws is the theoretical basis of the whole legal system as well as the reflection of legal core spirit. It determines basic properties, contents and value orientation of the legal system. This study believed that the safety prevention legal system of the transgenic biotechnology should include following principles: risk prevention principle, entire supervision principle, public participation principle, international cooperation principle, environmental protection principle and polluter pays principle.

The legal regulation of the transgenic biotechnology safety prevention requires a complete supervision system. The current legal supervision in China has lots of loopholes. The legislation of China's transgenic biotechnology safety should take example by ripe experience from developed countries. In order to improve the legal system of transgenic biotechnology safety prevention in China, this study put forward some suggestions:

1. improving risk evaluation system;
2. predicting adverse effects from research and development, experiment, production and sale, etc., of transgenic organisms;
3. improving transgenic organism identification system;
4. strictly protecting the right of information and the right of selection of customers;
5. fully implementing damage compensation system;
6. establishing relevant emergency processing systems to prevent faults and accidents;
7. perfecting public participation system;
8. improving people's level of understanding, thus to create a social atmosphere that is

beneficial for transgenic organism safety management.

Conclusion

The development of transgenic biotechnology is an important step in biotechnology. The development and application of transgenic biotechnology has posed a threat to biological diversity and stability of ecological environment. The legal regulation of the transgenic organism safety in China aims at the balance between biotechnology development and ecological safety. With the interaction between the basic principle and the basis system of transgenic organism safety laws, and referring to advantages of foreign transgenic laws as well as combing with the national conditions of China, the disadvantages in transgenic technology in China are improved and overcome, thus to reduce risks to the minimum. Therefore, the safety of transgenic biotechnology can be guaranteed, the biological diversity is maintained and human health is protected; besides, the ecological environment safety can be maintained, thus to accelerate the healthy development of transgenic technology. The addition of these systems and principles can provide the safety prevention of transgenic biotechnology in China with more guarantees as well as accelerate the legislation of China's biosafety.

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