

China's Legal Issues in the Access and Benefit-sharing of the Genetic Resources*

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Abstract

In China, genetic resources is a relatively new legal term, and the system of access and benefit-sharing of biological genetic resources is also an important task of the leading group of legislative work led by the Ministry of Environment in recent years. The genetic resources are of significant economic and strategic importance to China. China urgently needs to establish an access and benefit-sharing system for genetic resources and related traditional knowledge, and then devote itself to the development and protection of biological genetic resources. This article introduces the overall legislative model and status quo of China's genetic resources, and discuss the legal issues in China's current access and benefit-sharing of genetic resources.

KEY WORDS: Nagoya Protocol, Access and Benefit-Sharing, Biological Genetic Resources, China, Legal Issues

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I. Introduction

In recent years, with the continuous development of genetic sciences and bio-related technologies, the economic value of genetic resources has been increasingly recognized by countries all over the world, and large-scale commercial development and utilization have begun.¹⁾ China is one of

1) Qin Tianbao, Wang Luquan, Zhao Fuwei, *Review of the EU Regulation on Access to Genetic Resources and Benefit-Sharing and its Implications for China*, 43(23) ENVIRONMENTAL

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the countries with the most abundant biodiversity in the world, but over-exploitation and loss of genetic resources is serious. It is necessary for China to establish a legal system to protect genetic resources.

For a long time, China has been the main target of developed countries to access genetic resources while protection of genetic resources has not gained much attention as it should. Foreign institutions and individuals have obtained a large number of China's abundant biological genetic resources through various improper means. The amount and value of the resulting loss are difficult to estimate. The situation is very severe. The problem of biopiracy in China has always been serious and China urgently needs to establish a legal system to stop it.

The benefit-sharing system originated from international treaties such as the Convention on Biological Diversity, the Bonn Guidelines and the Nagoya Protocol. More than 50 countries have established relevant domestic regulations. The system of benefit-sharing in China is basically blank while many resource-rich countries have established their own benefit-sharing systems.²⁾ There is no systematic and operable system in China yet. Thus, there is an urgent need to establish a benefit-sharing system for genetic resources and related traditional knowledge in China.

II. China's Laws, Regulations, Policies, and Status Quo Related to Biological Genetic Resources

Article 9 and Article 26 of China's Constitution stipulate that the state guarantees the rational use of natural resources and protects precious plants and animals and prohibits any organization or individual from using any means to invade or destroy natural resources. The crime of destroying environmental resources has also been added to the Criminal Law.

Since the 1980s, China has successively formulated and revised many branch laws, statutes, administrative regulations and policy documents on the protection of biological resources, and has made considerable progress.

PROTECTION 69, 72 (2015) (*in Chinese*).

2) QIN TIANBAO, Research on Legal Issues of Access to Genetic Resources and Benefit Sharing (Ph.D. Thesis, Wuhan University) 4 (2005) (*in Chinese*).

These laws are mainly about the protection, management, and utilization of biological resources in traditional knowledge, and they respectively cover the protection of various types of crops, wild animals, wild plants, domestic animals, and new plant varieties. Such laws include the Environmental Protection Law, the Marine Environmental Protection Law, the Forest Law, the Grassland Law, the Fisheries Law, the Wildlife Conservation Law, the Soil and Water Conservation Law, the Seed Law and other laws. China has also adopted more than 20 administrative regulations, including the Nature Reserve Regulations, the Wild Plant Protection Regulations, and the Regulations for the Management of Species of Livestock and Poultry. The promulgation and implementation of these laws and regulations have played an important role in promoting the collection, preservation, exchange, and utilization of genetic resources in China, and are traditionally related to biological resources.

In the field of biological genetic resources, China has initially recognized the importance of genetic resource management. However, due to the lack of sufficient research and understanding, a complete set of theories, methods and technical systems of the ecosystem approach has not yet been established and neither the establishment of a complete series of policies and specific implementation measures.

At the same time, the issue of access and benefit sharing of biological genetic resources in existing laws and regulations in China has not received much attention. In China's existing laws and regulations, the issue of access and benefit-sharing of genetic resources has not been taken seriously. So far, there is barely any laws and regulations in this field except the "Interim Measures for the Management of Human Genetic Resources"³⁾ jointly issued by the Ministry of Science and Technology and the Ministry of Health in 1998 and the "Livestock Husbandry Law"⁴⁾ passed in 2005.

3) The concept of "human genetic resources" defined in Article 2 of the Interim Measures for the Administration of Human Genetic Resources which is "The term 'human genetic resources' as mentioned in the present Measures refers to organs, tissues, cells, blood, preparations containing human genomes, genes, and their products, materials, and genetic material and related information for recombinant DNA constructs."

4) The concept of "livestock and poultry genetic resources" defined in Article 2 of the Measures of the People's Republic of China for the Examination and Approval of Entry & Exit and the Foreign Cooperative Research on the Application of Genetic Resources of Livestock

China's legal system is basically blank in the field of the access to genetic resources and benefit-sharing.

In 2017, China has already formulated the draft of Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources, and has completed the procedure of soliciting comments from the public. However, till present, the ordinance is still in the draft stage and cannot be used as the basis for the enforcement of China's biological genetic resources system.

As far as biological genetic resources are concerned, China has not yet developed specific legislation on the protection, management and utilization of genetic resources. However, China has initially formed a legal framework for the protection, management and utilization of environmental protection and genetic and biological resources:

1. General Laws and Regulations Rocusing on Biodiversity Protection

China has initially formed a legal system for environmental protection with the "Environmental Protection Law" as the center, the single-line environmental laws and regulations as the main body, and other branch laws and regulations including international environmental regulations, environmental standards, environmental protection department regulations, local environmental regulations as supporting supplement.

As to the protection of biological species diversity, the Environmental Protection Law, the Wildlife Protection Law, the Marine Environmental Protection Law, the Forest Law, the Grassland Law, the Fisheries Law, the Wildlife Protection Law, the Water and Soil Conservation Law, and the "Seed Law" stipulate in principle the protection, development and utilization of species resources.

Administrative regulations such as the Nature Reserve Regulations, Regulations on the Protection of Wild Plants and Regulations on the Management of Livestock and Poultry have formed an ecological protection regulation system that is coordinated with development and

and Poultry is" The term 'genetic resources of livestock and poultry' refers to livestock and poultry as well as their generic materials such as germ cells (eggs), embryo, semen and gene substance".

protection. Local governments have successively introduced local environmental protection laws and regulations. The promulgation and implementation of these laws and regulations have further enriched the ecological environmental protection laws and regulations system.

2. Provisions of Regulations and Normative Documents

Based on biological resource types, China's relevant laws provide industry-wide legal protection to different types of resources by adopting the method of classified protection. Some laws and regulations relating to environmental protection, such as the Environmental Protection Law and the Natural Resources Law, contain provisions about the collection, production and processing, trading, import and export, and other management activities of genetic resources. Legal requirements applicable to the issuance of licenses for different activities have been established, including procedures and requirements about the application, review and approval of such licenses. China has also formulated and promulgated a series of national, industry, and local standards for the protection of biodiversity, so that laws and regulations for the protection and use of biodiversity can be continuously improved. However, the foregoing does not involve the specific elements on genetic resources.

Although China currently has legal limbos in the access and benefit-sharing of biological genetic resources, the government has started to implement specific institutional arrangements in terms of legislation and policies. In 2004, the General Office of the State Council issued the Notice on Strengthening the Protection and Management of Biological Species Resources,⁵⁾ requiring the formulation of laws and regulations on the protection of biological species resources, the improvement of the external export approval system for biological species resources, and the strengthening of external cooperation management of biological species resources. In 2007, the EPA issued and implemented the National Outline

5) Guan yu jia qiang sheng wu wu zhong zi yuan bao hu he guan li de tong zhi (关于加强生物物种资源保护和管理的通知) [Notice on Implementing the " Notice on Strengthening the Protection and Management of Biological Species Resources "] Apr. 27 2004, at 25, http://sts.mep.gov.cn/swwzzybh/200404/t20040427_90807.shtml, (last visited May 5, 2018).

for the Conservation and Utilization of Biological Species Resources.⁶⁾ In 2010, China's National Commission on Biodiversity Conservation⁷⁾ reviewed and adopted the China Biodiversity Conservation Strategy and Action Plan (2011-2030).⁸⁾ Afterwards, a series of policies including the United Nations Biodiversity Decade China Action Plan⁹⁾ and Strengthening the National Work Program for the Management of Biological Genetic Resources (2014-2020)¹⁰⁾ were successively adopted, which promoted the rational utilization and benefit-sharing of biological genetic resources and related traditional knowledge, and established a series of immigration inspection and examination of biological genetic resources as a priority

6) Guan yu yin fa quan guo sheng wu wu zhong zi yuan bao hu yu li yong gui hua gang yao (关于印发全国生物物种资源保护与利用规划纲要) [Notice on Printing and Distributing the "National Outline for the Conservation and Utilization of Biological Species Resources"], Oct 24, 2007, at 163, http://www.mee.gov.cn/gkml/zj/wj/200910/t20091022_172479.htm (last visited May 5, 2018).

7) In 2010, the UN General Assembly designated 2011-2020 as the "UN Decade of Biodiversity," and the State Council of China established the "2010 International Year of Biodiversity China National Committee." The meeting convened and approved the International Year of Biodiversity China Action Plan, and "China Biodiversity Conservation Strategy and Action Plan (2011-2030)". In June 2011, the State Council of China decided to rename the "2010 International Year of Biodiversity China" as the "National Committee for the Conservation of China's Biodiversity" to coordinate national biodiversity conservation work and guide the "United Nations Biodiversity Decade China Initiative."

8) Guan yu yin fa zhong guo sheng wu duo yang xing bao hu zhan lue yu xing dong ji hua 2011-2030 nian de tong zhi (关于印发中国生物多样性保护战略与行动计划2011-2030年的通知) [Notice on Printing and Distributing China Biodiversity Conservation Strategy and Action Plan (2011-2030)], Sep. 17, 2010, at 106, http://www.mee.gov.cn/gkml/hbb/bwj/201009/t20100921_194841.htm (last visited May 5, 2018).

9) Guan yu yin fa zhong guo sheng wu duo yang xing bao hu zhan lue yu xing dong ji hua 2011-2030 nian de ren wu fen gong he lian he guo sheng wu duo yang xing shi nian zhong guo xing dong fang an de tong zhi (关于印发《关于实施〈中国生物多样性保护战略与行动计划(2011-2030年)〉的任务分工》和《联合国生物多样性十年中国行动方案》的通知) [Notice on Printing and Distributing the "Mission Division of the Implementation of the China Biodiversity Conservation Strategy and Action Plan (2011-2030)" and the "United Nations Biodiversity Decade China Action Plan"] Jun. 13, 2012, at 68, http://www.mee.gov.cn/gkml/hbb/bwj/201606/t20160601_352974.htm (last visited May 5, 2018).

10) guan yu yin fa jia qiang sheng wu yi chuan zi yuan guan li guo jia gong zuo fang an (2014-2020 nian) (关于印发《加强生物遗传资源管理国家工作方案(2014-2020年)》的通知) [Notice on the issuance of the "National Work Program for Strengthening the Management of Biological Genetic Resources (2014-2020)"]", Dec. 24, 2014, at 193, http://www.mee.gov.cn/gkml/hbb/bwj/201606/t20160601_352975.htm, (last visited May 5, 2018).

action.

This series of documents and policies clearly sets out China's policy objectives in the area of biological genetic resources systems which includes: to improve the protection, development, and utilization of genetic resources; to prevent loss and unregulated use of genetic resources; to coordinate the interests of the protection, development and utilization of genetic resources; to establish a reasonable access and benefit-sharing mechanism for genetic resources; and to ensure the right of informed consent of genetic resource providers.¹¹⁾

These policies are also being continuously implemented to guide legislation. In 2014, the Central National Security Council and the State Council listed the "Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources" as a part of National Security Legislation Plan and the relevant legislation work plan. In 2015, the Ministry of Environment took the lead to establish a leading group for legislation work and formulated a work plan. In 2017, the Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources (draft) has been formed, and the work for solicitation of public opinions has been completed.

In the next step, the Ministry of Environmental Protection will revise and perfect the Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources (draft) based on feedback of public opinions. At present, this work has not yet been finished. Therefore, the current regulations are still in draft and cannot be used as law enforcement basis for the genetic resources system in China. This is another substantive step taken by China to promote the protection, supervision and utilization of biological genetic resources after China officially became a party to the Nagoya Protocol on Genetic Resources on September 6, 2016. The Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources will regulate the access, benefit-sharing, and entry-exit management of biological genetic resources to ensure the safety of China's

11) Zhong guo lv xing sheng wu duo yang xing gong yue di san ci guo jia bao gao (中国履行生物多样性公约第三次国家报告) [China's fulfillment of the third national report of the Convention on Biological Diversity], Sep. 15, 2005, <http://www.mee.gov.cn/home/ztbd/swdxyx/2010sdn/bhbj/201001/P020100118435848590748.pdf>(last visited Mar. 20, 2018).

resources and safeguard national interests.

3. *Other Branch Laws*

Basically, the development of the concept of biological genetic resources in the legal system is closely related to the further development of the Patent Law. At present, China's Patent Law also contains provisions on general biological genetic resources, which promotes the convergence of related systems such as the patent system and the protection of genetic resources. However, it does not provide support for implementation systems or explicit benefit-sharing.

The Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources has specifically stipulated the issue of disclosure of origin, which can effectively protect China's rights and interests. At the same time, it can also work in conjunction with the relevant provisions of the Patent Law.

Based on a careful study of the existing international and domestic legal systems, the Chinese government plans to make the revision of the Patent Law and its detailed implementation rules in favor of safeguarding the interests of intellectual property rights holders as well as the interests of the public. Such action will also help to protect the ecological environment and achieve the goal of sustainable development of the country.

4. *International Cooperation Mechanism*

At the international level, China signed the Convention on Biological Diversity in 1992 and established the Access and Benefit-Sharing (abbreviated as ABS) system for genetic resources so as to maintain China's possession of its sovereign rights over its genetic resources, which means genetic resources are no longer governed by legal stipulations about the common heritage of mankind and the principle of free access. Such matters shall be regulated in accordance with relevant laws. This step is not only a follow-up to the relevant contract law. It also involves a series of public and political issues such as national science and technology, economy, health, environment and food security.

China has not yet established a legal mechanism for the access and

benefit-sharing of genetic resources. This is an important reason of the serious loss of genetic resources in China. In order to achieve the objectives of the Convention on Biological Diversity in relation to equitable benefit-sharing, China has conducted a number of studies on the access and benefit-sharing of genetic resources and related traditional knowledge in the past 20 years.

The National Science and Technology Support Program of the 12th and 13th Five-Year Plan of the Ministry of Science and Technology has listed the ABS issue as a research topic. The development of efficient development, utilization, and protection of resources is an important component of the development of a technical system that guarantees national security and strategic interests.¹²⁾ The Ministry of Environmental Protection has also listed the ABS issue as one of its key items in the implementation of the National Survey of Key Species Resources and the Special Project on Biodiversity.¹³⁾

In order to implement the provisions of the Convention on Biological Diversity relating to access and benefit-sharing of genetic resources, the Convention Secretariat convened an intergovernmental meeting to discuss and decide on a plan to develop international guidelines on access and benefit-sharing of genetic resources. The Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilization was reached in Bonn, Germany, in 2001. The Bonn Guidelines are based on voluntary principles and are not legally binding.¹⁴⁾

In addition, in order to integrate with the Nagoya Protocol, the Ministry of Environmental Protection has also led other relevant agencies to conduct

12) Shi san wu guo jia ke ji chuang xin gui hua (十三五国家科技创新规划) [The State Council of China, The "Thirteenth Five-Year National Science and Technology Innovation Plan"], Jul. 28, 2016, http://www.gov.cn/zhengce/content/2016-08/08/content_5098072.htm (last visited March 20, 2018).

13) Guan yu yin fa quan guo sheng wu wu zhong zi yuan bao hu yu li yong gui hua gang yao (关于印发全国生物物种资源保护与利用规划纲要) [Notice on Printing and Distributing the "National Outline for the Conservation and Utilization of Biological Species Resources"], Oct. 24, 2007, at 163, http://www.mee.gov.cn/gkml/zj/wj/200910/t20091022_172479.htm (last visited May 5, 2018).

14) See Xue Dayuan, *Access and Benefit Sharing of Genetic Resources: Background, Progress and Challenges*, 15(5) BIODIVERSITY SCIENCE, 563, 563-568 (2007) (in Chinese with English abstract).

research on the national regulatory system for the access and benefit-sharing of genetic resources and related traditional knowledge.¹⁵⁾ In the China Biodiversity Conservation Strategy and Action Plan approved by the State Council in 2010, the protection and benefit-sharing of genetic resources and related traditional knowledge was listed as a strategic task and priority action.¹⁶⁾

China has acceded to the 1992 Convention on Biological Diversity (CBD), the 2002 Bonn Guidelines, and the 2010 Nagoya Protocol, and gradually established three principles concerning genetic resources, i.e. state sovereignty principle, final consent principle and benefit sharing principle. These treaties do not have international enforcement mechanisms as the TRIPS does, but these treaties set out the basic principles for obtaining equal access to the world's genetic resources.¹⁷⁾

III. Legal Challenges for the Development in the Access and Benefit-Sharing of the Genetic Resources in China

1. The Lack of International Cooperation Mechanisms

On June 8, 2016, the Chinese Government submitted to the Secretariat of the Convention on Biological Diversity the instrument of accession to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. On September 6, the Protocol entered into force for China and China became the 78th contracting party. Therefore, China needs to transform the international

15) Xue Dayuan, Wu Jianyong, Zhao Fuwei, *Action, Progress and Prospects in Implementation of the Convention on Biological Diversity during the Past 20 Years in China*, 20 BIODIVERSITY SCIENCE 623, 631 (2012) (in Chinese with English abstract).

16) Guan yu yin fa zhong guo sheng wu duo yang xing bao hu zhan lue yu xing dong ji hua 2011-2030 nian de tong zhi (关于印发中国生物多样性保护战略与行动计划 2011-2030 年的通知) [Notice on Printing and Distributing China Biodiversity Conservation Strategy and Action Plan (2011-2030)], Sep. 17, 2010, at 106, http://www.mee.gov.cn/gkml/hbb/bwj/201009/t20100921_194841.htm (last visited May 5, 2018).

17) Wang Huaiyu, *China Urgently needs to Establish a Benefit Sharing System for Genetic Resources*, CHINA ECONOMIC TIMES, Dec. 18, 2015(in Chinese) at 5.

regulations into national laws, and it is necessary to establish a comprehensive access and benefit-sharing system at the national level to effectively implement the principles and the regulations of the Convention on Biological Diversity, the Bonn Guidelines and the Nagoya Protocol.¹⁸⁾

The regulation of biological genetic resources will be the target of the increasingly standardized rule of law. These treaties establish basic principles for the equitable sharing of world genetic resources, and the parties need to establish a national institutional framework that is in line with the Protocol. These treaties are not as internationally enforceable as the TRIPS. TRIPS does not support the benefit sharing system for the time being, which has hindered the realization of benefit sharing in the world. These treaties have laid down the basic principles for the equitable sharing of the world's genetic resources. Parties need to establish a national institutional framework that aligns with the Protocol. The entry into force of these treaties poses a challenge to China's current legal system and regulatory regime for genetic resources.

On one hand, as a developing country, China is a country with rich genetic resources and related traditional knowledge. For a long time, China will maintain its role as a resource provider. But on the other hand, China's current biotechnology progresses rapidly. China's bio-industry is developing rapidly and is potential to become a resource user in the future. Taking the global multilateral benefit-sharing mechanism as an example, China should pay more attention to topics such as the preservation of the off-site resources, the genetic resources acquired before the entry into force of the Convention on Biological Diversity and the Nagoya Protocol, and the traditional knowledge in the public domain. This protocol will have a far-reaching impact on other relevant international forums.

As the leading agency for the implementation of the Convention on Biological Diversity in China, the Ministry of Environmental Protection needs to coordinate with management departments such as departments of commerce, intellectual property, agriculture, forestry, and Chinese medicine so that the claims that cannot be resolved by the ABS protocol can be resolved under the WTO, WIPO and other international

18) Ma Jianquan, & Liu Zhongliang, *The Improvement of China's Legal Protection System for Genetic Resources*. 1 LEGAL SYSTEM and SOCIETY 683, 683 (2007) (in Chinese).

organizations and international conventions.¹⁹⁾

China is a country with rich traditional knowledge. Many traditional Chinese medicine knowledge in China has been publicly published in history. Japan, South Korea, etc. have developed many new drugs based on these traditional knowledge (Hanfangs) and obtained relevant patents. Since these Hanfangs have entered the public domain, how can China obtain benefits from them? There are a large number of raw materials and intermediate products traded between pharmaceutical companies in China, Japan and South Korea. China exports a large amount of medicinal raw materials and primary extracts (derivatives) at relatively low prices, while foreign pharmaceutical companies in Japan and South Korea use patents to obtain large profits. The unfair trade does not reflect fair benefit-sharing and sometimes even exacerbates China's domestic biodiversity destruction.

China also needs to consider how to make use of domestic laws and policies to make up for the inadequacies of the protocol and to achieve the protection and benefit-sharing of Chinese traditional medicine and traditional knowledge of ethnic medicine. In general, China needs to take into account the characteristics of its own national conditions, i.e. the dual role of both providers and users of biological genetic resources. In the future, we will continue to study and formulate the positions and tactics that we should hold in the negotiation of different issues.²⁰⁾

2. Defects in the Legislative System

According to the foregoing, we can see that in China's existing laws and regulations, the issue of access and benefit-sharing of genetic resources and even biological genetic resources has not received enough attention. Therefore, China's existing legal framework for the environment is imperfect, and there are flaws and imperfections. In China, there are neither substantive nor procedural legal provisions that clearly and comprehensively

19) See Xue Dayuan, *A New Milestone in the Convention on Biological Diversity: The Nagoya ABS Protocol*, 24 ENVIRONMENTAL PROTECTION 76, 76-78 (2010) (in Chinese).

20) Wang Luquan, Zhao Fuwei, Zang Chunxin, *The Challenges and Countermeasures of China's Implementation of the Nagoya Protocol – – Also on the Impact of Access to and Utilization of Agricultural Genetic Resources*, 16(4) JOURNAL OF AGRICULTURE AND FORESTRY ECONOMIC MANAGEMENT 550, 551 (2017).

regulate the acquisition of genetic resources, and only classified management of different types of genetic resources has been carried out. At present, it mainly focuses on biological resources such as animals and plants, and especially focuses on the protection of wild precious plants and animals. The protection of genetic resources is limited and the protection of the genetic resources is a legal blank.

On the overall perception of legislative system of genetic resources, there is no such independent system. There are provisions scattered in some traditional natural resources law or environmental law system. At the same time, the existing legislation cannot meet the requirements of China's implementation of the international conventions on the protection of biodiversity and genetic resources. It has not yet been linked to international conventions that China has concluded or participated in. The concepts and principles established in the international conventions on the conservation of biodiversity and genetic resources have not yet been clarified. The concept of genetic resources has not yet been explained in domestic laws and regulations. It can be said that China's current legislation about genetic resources is comparatively in principle, lacking details of rights and obligations. It is not so much a law as a declaration of policy.

The Nagoya Protocol stipulates that "providing countries should increase the legal certainty, clarity and transparency of relevant national legislative and regulatory requirements, establish fair and non-Arbitrary access to approval rules and procedures, the provision of rules and procedures for the establishment of mutually agreed terms, and the disclosure of such information to the acquirer," which raises higher requirements for the participating country's national legislation and systems for the provision of genetic resources. However, there are deficiencies in China's existing legal system, management system and system design. Judging from the current legislation, although laws and regulations such as the Livestock Husbandry Law, the Wildlife Conservation Law, and the Regulations on the Protection of Traditional Chinese Medicine are related to biological genetic resources and related traditional knowledge, the provisions on access to genetic resources are not comprehensive and systematic. The provisions for benefit-sharing are particularly lacking.

In addition, China's existing laws are actually legislation concerning

animal and plant biological resources instead of genetic resources, and can be extended to animal and plant genetic resources through theoretical explanations. However, microbial genetic resources obviously lack legal basis. The newly revised Livestock Law and Seeds Law have incorporated content related with benefit-sharing of livestock and poultry genetic resources and crop germplasm resources . It is required that the foreign-related use of genetic resources should propose a scheme for countries to share benefits. However, on the whole, there is no existing law or regulation that regulates the access and benefit-sharing system for biological genetic resources. There is a gap in legislation. Although the Patent Law stipulates that “the patent right shall not be granted for inventions and creations that acquire or use genetic resources in violation of laws and administrative regulations and rely on the genetic resources,” there is currently no link between laws and administrative regulations.

3. Defects in management system

The situation of loss of genetic resources in China is very serious. The level of development and utilization of genetic resources is low and the strength of basic research and management capacity are insufficient. It is impossible to participate in the utilization of biological and genetic resources by foreign companies in a substantive way. The lack of development and utilization of biological adequate capital and advanced technology needed for genetic resources is serious. As a developing country, China lacks genetic resources and associated traditional knowledge including basic research and management. China faces a main problem that the resources of the nationwide survey of the bottom has not been achieved and the development and utilization level is relatively low, with management techniques and tools to be improved.

China is still incomplete in management of access to genetic resources. IT lacks specific legislation on access and benefit-sharing of genetic resources and associated traditional knowledge, and lacks policies, standards, guidelines and technical specifications. China has a legal policy that is being developed specifically for the access and benefit-sharing of genetic resources and associated traditional knowledge. This area involves multiple jurisdictions, the cross-cutting and overlapping of legislative

mandates for individual resources, impact of genetic resource management and long headless management. Due to the interests of different departments, the relevant departments still have considerable controversy at the national legislative level, making the coordination among departments more difficult.

First of all, the legal status and ownership provisions of genetic resources in China are not clear. The current legislation only stipulates that the state enjoys ownership of wildlife and plant resources. The ownership of other resources is not specified. The provisions on the collection of fishery genetic resources do not distinguish with the purpose of collecting relevant genetic resources, nor do they establish different legal requirements for different purposes of the collection activities. From the user's point of view, there will be no distinction between genetic resources and natural resources.

Secondly, the current legislation does not provide a unified collection and licensing system covering all types of genetic resources. The regulations concerning the management of the import and export of genetic resources only use the examination and approval of the competent administrative department as the main means for implementing management. There is no provision for issues concerning intellectual property rights such as conditions for provision, participation in research, technology transfer, transfer to third parties, etc. The current law manages different systems for different types of genetic resources, lacks the necessary communication and coordination, and may create problems of repeated protection or omission in protection.²¹⁾

In addition, the current legislation does not establish the necessary link between the collection of genetic resources and the use of genetic resources, and it cuts off the close relationship between the collection of genetic resources and commercial use.²²⁾It is impossible to monitor and track the utilization of the collected genetic resources. The current legislation does not explicitly address the issue of the distribution of benefits arising from

21) Zhang Xiaoyong , *Research on the Legislation of Access and Benefit Sharing of Genetic Resources in China*, 25(1) JOURNAL OF NORTHWEST UNIVERSITY OF POLITICAL SCIENCE AND LAW 142, 143 (2007) (in Chinese with English abstract).

22) Id. At 145.

the use of genetic resources, nor does it provide clear rules on how important users and providers can analyze benefits. The current legislation does not clearly understand the relationship between the use and protection of genetic resources and does not regard utilization as an important means of providing financial and technical support for the protection of genetic resources. Therefore, there is no mention of the feedback on the benefits arising from the use of genetic resources.

China has not yet established a comprehensive legal system on access and benefit-sharing of genetic resources, leaving the access, exchange, international exchange, import, export, and utilization of genetic resources in China largely unregulated by law. In the practice of law enforcement, the enforcement of environmental laws is more rigid while the enforcement of laws against damages to natural resources is relatively weak. Local governments are in a hurry to develop the allocation of local resources to the economic use of resources, which leads to the mismatch between practice and legislation and the lack of coordination.²³⁾ In practice, most public institutions of government play a major role in the protection of genetic resources, and there is a phenomenon of inaction.

IV. Improvement measures

According to the understanding of China's current legislation, we can recognize that there is still considerable space for improvement in China's legal system for the acquisition and benefit-sharing of genetic resources. There is considerable space for improvement in transferring the framework's provisions to the operative regulatory requirements.

China also needs to assume the responsibility as a big country. It should actively learn from international advanced experience to promote the domestic construction of China's access to genetic resources and benefit-sharing mechanisms, and to promote relevant international legislation so as to better safeguard national rights and interests and to promote biodiversity

23) Liu Xueting, *On the Improvement of China's Legal System of Access to Genetic Resources and Benefit Sharing*, 12 LEGAL SYSTEM and ECONOMY 58, 58 (2017) (in Chinese).

conservation.²⁴⁾ We need to solve the problem of the shortage of biological resources in China's legislative system, including domestic legislation, as well as the transfer of relevant international treaties into domestic laws and then implementation in accordance with domestic laws.

The relevant legislation also requires special legislation on genetic resources that are different from traditional resources, i.e. the design of the part involving intellectual property in the acquisition phase of genetic resources. China needs to adopt a collection license system for genetic resources, to refine the requirements for acquisition in different situations, to determine the approval bodies and processes for different genetic resources, and to achieve effective control.

1. Sort out the Domestic Legal System and Promote Relevant Legislation

This requires a comprehensive consideration of China's richness of biological resources, China's status in the exchange of genetic resources, the status of China's biological development, the implementation capabilities of China's institutions and other factors. The existing laws and regulations relating to genetic resources in China are mostly provisions on the traditional use of resources and cannot be coordinated with emerging technology research and development activities. There are few regulations on the mechanisms for the access and benefit-sharing of genetic resources.

We need to develop a comprehensive law that covers access and benefit-sharing mechanisms for genetic resources, in line with international law. In order to curb the loss of genetic resources in a timely manner, we can first formulate specific administrative regulations. When the time is right, we shall formulate a nationwide comprehensive law and improve the mechanism.²⁵⁾ At present, there is only a draft of the Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources and relevant legislation must be accelerated.

24) Xue Dayuan, *The Main Content and Implementation Strategy of China Biodiversity Conservation Strategy and Action Plan*, 19(4) BIODIVERSITY SCIENCE 387, 387 (2011) (in Chinese).

25) Qin Tianbao, *The Legislative Model of Foreign Genetic Resources and Benefit-Sharing and its Implications for China*, 18(1) CHINA POPULATION, RESOURCES and ENVIRONMENT 202, 203 (2008) (in Chinese with English abstract).

The draft clearly stipulates the purpose of the specific legislation on access and benefit-sharing for biological genetic resources, namely “Strengthening the management of access and benefit-sharing of genetic resources, conservation and sustainable use of biological diversity, performing Nagoya Protocol on Biodiversity Convention on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of Their Utilization, safeguarding national interests.” There are seven chapters and forty-eight articles in the draft. The draft has specific provisions on the competent authorities’ management responsibilities for biological genetic resources, methods to be adopted by China and foreign parties for accessing biological genetic resources, benefit-sharing and outbound management of biological genetic resources, and penalties to be imposed by the competent authorities.²⁶⁾

Article 2 of the draft stipulates that the draft is applicable to the areas under the jurisdiction of China and the acquisition and benefit-sharing activities related to biological genetic resources and related traditional knowledge in other sea areas. The current draft has already embodied the construction of the overall framework and the convergence of other relevant legislation. It is an accepted principle of international law that the state enjoys economic sovereignty over the genetic resources within its territory. Even if the genetic resources within a country are not identified as specific right, it can be regarded as a country’s natural resources. Therefore, the national sovereignty of genetic resources should be clearly defined in China’s genetic resources protection legislation. The draft adheres to the principle of national sovereignty over biological genetic resources. Any institution or individual that obtains and utilizes China’s biological genetic resources should respect China’s sovereignty and abide by Chinese laws and regulations.

Article 11 of the draft stipulates that China’s biological genetic resources are mainly regulated by environmental protection departments, and that

26) Sheng wu yi chuan zi yuan huo qu yu hui yi fen xiang guan li tiao li (cao an) zheng qiu yi jian gao (《生物遗传资源获取与惠益分享管理条例(草案)》(征求意见稿)) [Drafting Instructions for the Regulations on the Administration of Biogenetic Resources Access and Benefit Sharing (Draft) (Draft for Soliciting Opinions)], Mar. 23, 2017, http://sts.mee.gov.cn/swdyx_1/swdyxxz/201703/W020170323537476188359.pdf (last visited Mar. 17, 2018).

other relevant departments including agricultural, forestry, construction, sanitation, marine, Chinese medicine, and so on will implement the regulation in their respective competencies. The Nagoya Protocol on Genetic Resources requires that Parties establish inspection agencies to monitor and inspect the domestic and international performance of ABS. The draft is closely linked with the Nagoya Protocol on Genetic Resources.

Under the unified supervision of environmental protection departments, all departments cooperate with each other according to their respective competencies. Each department reviews the compliance of the acquisition, utilization and exit of biological genetic resources, and shares relevant information about the record with the competent department of environmental protection under the State Council through the established information exchange mechanism. Environmental protection departments are responsible for receiving and processing relevant information through the information exchange mechanism, effectively tracking and monitoring the acquisition, cross-border transfer, utilization, and benefit-sharing of biological genetic resources in China.

At present, China's biosafety management system has attached great importance to the utilization of biological resources, neglecting the corresponding supervision of resources and dispersing management responsibilities of various departments, with the result of lacking unified and effective leadership. It is necessary to establish a framework for the supervision system. The access and benefit-sharing system of genetic resources is an important part of ecological security and sustainable development. China needs to learn from the United States and other developed countries to fully understand the importance of biological genetic resources.

Safeguarding the sovereignty and security of China's resources shall not be delayed. It requires continuous follow-up of high-tech and intellectual property rights. In accordance with the different stages of development and utilization of genetic resources, different specific institutional designs shall be conducted to establish a unified regulatory mechanism for the acquisition and benefit-sharing of genetic resources. The responsibilities of different government departments should be clearly divided to ensure legal access to genetic resources and equitable benefit-sharing. A major foundation for the effective control of genetic resources is to strengthen

scientific research and to carry out basic research work such as the collection and organization of biological genetic resources as well as to improve the development, utilization, and management of genetic resources in China.

However, the problem here is that coordination between departments may be complicated in practice. Take the current rules as an example: the Management Measures for Human Genetic Resources clarifies that the competent department of science and technology and the competent health authorities shall jointly lead to establish a single management body which is the Human Genetic Resources Management Office, serving the corresponding management functions. Its management functions include the application and approval of the corresponding activities, the organization of professional expert committees or academic committees to evaluate the content of the management, as well as to update of times which can be further clarified.²⁷⁾

Article 18 of the draft stipulates that the acquisition of biological genetic resources requires, in principle, the consent of the holder of the biological genetic resources and an agreement on access and benefit-sharing to be signed. The draft will use ABS agreements as the statutory basis for benefit-sharing activities and require the country to set up a protection and benefit-sharing fund of biological genetic resources specifically for the conservation and sustainable use of biological genetic resources. The concept of holders in this article remains questionable and is related to the broad interpretation of the concept for consistency in our laws in Article 2 of the draft. Such interpretation includes the definition of “traditional knowledge” and “derived biological resources.” There are many unclear definitions of “materials” and “and the information they produce.” The definition of this draft is very broad and covers almost any knowledge related to genetic resources, resulting in many legal uncertainties.

Article 25 of the draft provides for an international certificate system for biological genetic resources that can be used as a legitimate document for the protection of intellectual property rights and the departure of biological

27) Zhu shida, *Suggestions on the Regulations on the Management of Access to Biological Benefits and Benefit-sharing (Draft) (Draft for Comments)*, <http://www.cbcdgdf.org/NewsShow/4936/1962.html> (last visited August 20, 2018).

genetic resources and other related aspects of biological genetic resources. This is a proof of publicity. The international certification system for biological genetic resources is a practical need to implement the Nagoya Protocol on Genetic Resources and to track and monitor the trans-boundary movement and utilization of biological genetic resources.

Article 33 of the draft stipulates the protection and benefit-sharing fund for biological genetic resources, which means the country establishes a biological genetic resources protection and benefit-sharing fund which is to be incorporated into financial budget management. The acquirer shall pay annually, as a national benefit, 0.5 to 10% of the profits from the acquisition and use of biological genetic resources as direct contributions to the Biogenetic Resources Conservation and Benefit-sharing Fund.²⁸⁾ However, it needs to be noted that the rate of change of the fund's ratio is too high, and the executive authorities can rely on internal discretionary administrative discretion. We suggest that in the next step it can further refine the fund ratios based on different types of genetic resources, such as genetic resources, terrestrial plants, terrestrial animals, and other types of biological genetic resources. Such ratios can be decided on the basis of their maintenance costs and technical requirements.

By determining the multiplication of genetic resources and traditional resources, investors can determine costs and encourage investors to actively invest in the protection and utilization of biological genetic resources with the latest technologies. However, the problem here is that due to the insufficient protection of intellectual property rights, breeding enterprises lack the enthusiasm for breeding. If the same fiscal and taxation standards are adopted, the implementation of this draft may further dispel their research and development motivation, which may be detrimental to the development of Chinese seed industry. Therefore, the specific implementation standards need to be considered according to the cost of specific industry breeding, and the relevant provisions of the draft and patent regulations must be properly connected.

The draft is still in a draft state and the relevant provisions are currently in dispute. There is doubt about its legislative purpose and value

28) Zhao Fuwei, Xue Dayong, Wu Jianyong, *Negotiation Focus and Countermeasures after the Entry into Force of the Nagoya Protocol*, 16(4) BIODIVERSITY SCIENCE 550, 551 (2015).

orientation. For example, the key content of the regulation is to control the loss of domestic genetic resources and achieve benefit-sharing among different interest groups, or in terms of legislation, whether the emphasis should be on ecological security and the protection of biological diversity through legal systems, . There are also specific questions about how to determine the proportion of funds in practice. In general, China still has no direct legal basis in the field of biological genetic resources supervision. Implementation of the draft is imperative.

2. Sort out Administrative Supervision Procedures and Establish a Regulatory Coordination Mechanism for Access and Benefit-Sharing of Genetic Resources.

The regulation of biological genetic resources involves many sectors such as agriculture, forestry, environmental protection, urban construction, etc. Each department needs to strengthen cooperation and cooperation, to establish a legislative working mechanism, to accelerate the legislative process of promoting special regulations on access and benefit-sharing of biological genetic resources, and to promptly amend existing laws and regulations so as to meet the regulatory needs and compliance requirements of China's biological genetic resources and related traditional knowledge.

Although the ABS issue involves multiple departments, the establishment of a integrated leading unit of management is critical to coordinate other administrations and to establish a sound inter-departmental coordination mechanism. The existing compliance mechanism for the China Convention on Biological Diversity is consist of three main agencies, i.e. China's implementation of the "Biodiversity" work coordination group (which is active in the early implementation of the Convention), National Inter-ministerial Conference on the Conservation of Biological Resources (which focuses on inter-departmental coordination), and China National Committee for Biodiversity Conservation (the highest decision-making and coordination body in the field of biodiversity conservation).

To further implement the protocol in the future, a working group for the Nagoya Protocol can be established under the existing mechanisms of the Biodiversity Conservation Department cascade meeting and the China

National Committee for Biodiversity Conservation. Or it may be considered to combine these two mechanisms and establish a subject-oriented branch coordination mechanism as required. ²⁹⁾Negotiations on relevant conventions can also invite relevant persons involving with the convention to co-organize delegations to participate in the negotiation of international conventions on important issues.

3. Develop a National Action Plan for Access to Genetic Resources and Benefit Sharing

The State has issued and implemented the 12th Five-Year Plan for National Environmental Protection, Outline of the National Intellectual Property Strategy, and China Biodiversity Conservation Strategy and Action Plan (2011-2030), requiring to establish a legal system for the access and benefit-sharing of biological genetic resources. At present, the Chinese government must implement these national strategies, and plans, and urgently needs to formulate a national action plan for the access and benefit-sharing of biological genetic resources and related traditional knowledge to coordinate and plan in the long run to guide local governments and departments at all levels to promote building of access and benefit-sharing capacity .

From a technical perspective, we can take into consideration measures such as establishing a database and information platform for the utilization and benefit-sharing of biological genetic resources, strengthening the construction of professionals and management talents, and providing talent reserves and technical support for scientific management.

All agencies need to exchange information in a timely manner. The international conventions of relevant conventions only need to communicate promptly with the domestic implementation actions and achievements. They should communicate and provide early warning of the experiences gained in the negotiation and implementation of the conventions and problems that have already emerged, so that other agencies can avoid the same questions. In response to this issue, it may

²⁹⁾ Xue Dayuan, *National Coordination Strategy for the Implementation of International Conventions on Biodiversity Conservation*, 23(05) BIODIVERSITY SCIENCE 673, 678-679 (2015).

consider to adopt a collaborative contracting agency to summarize the progress of each convention in the current year and publish it in the form of an annual report.

It's important to further strengthen the dynamic investigation and monitoring of genetic resources. The mastery of the introduction, elicitation, and loss of genetic resources is not only the basis for China's participation in international discussions, but also an important supporting data for determining how the country will conduct genetic resource monitoring.

4. Strengthen the Ability to Respond to International Exchange Disputes

In the period to come, China still needs to strengthen national strategy research on the follow-up negotiations of the protocol, and conduct in-depth research on hot topics, including but not limited to traditional knowledge, global multilateral benefit-sharing, compliance mechanisms, international certificate systems, and participation of indigenous and local communities, coordination of the development of negotiation strategies for international laws related to biological genetic resources and traditional knowledge under the framework of the World Intellectual Property Organization, the UN Food and Agriculture Organization of the United Nations, the World Trade Organization, UNESCO, etc., promotion of the synergies of various negotiation processes; exploration of cooperation mechanisms in the field of access and benefit-sharing with countries of great biodiversity such as Europe, the United States as well as neighboring countries such as Japan, and South Korea to promote reciprocal cooperation in the access and benefit-sharing of biological genetic resources and related traditional knowledge.

China is still a developing country and a provider of biological resources. At the same time, it has the potential to meet the needs of resource users. This dual role determines that China shall continue to study and formulate its own positions and strategies in negotiations on different issues in the future.³⁰⁾ The choice will be focused on the need to improve the ability to

30) Wang Luquan & Zhao Fuwei, Zang Chunxin, *The Challenges and Countermeasures of China's Implementation of the Nagoya Protocol – Also on the Impact of Access to and Utilization of*

use international rules in order to deal with possible international disputes and litigation, and to maximize the protection of our interests.

V. Conclusion

The improvement of national legislation and system and realization of international cooperation is conducive to the protection of China's biodiversity and to the fair sharing of the benefits of China as well as to the protection and transmission of China's rich national culture and traditional knowledge, for the demonstration of access and benefit sharing. At the same time It also brings many opportunities and challenges for the protection and management of biological genetic resources in China.

It also poses a challenge to China's current legal system and the regulatory system of genetic resources. Up to now, China has attached great importance to the legal issues in biodiversity conservation and access to genetic resources and benefit-sharing, and has taken a series of measures to actively implement the Convention on Biological Diversity.

A draft of the Regulations on the Management of Access and Benefit-sharing of Biological Genetic Resources has been formed in 2017, taking substantial steps to advance the conservation, regulation and use of biological genetic resources. It is still in a draft state and there is no direct legal basis for the regulation of biological genetic resources in China. The formulation of this regulation is a necessary measure to fulfill the obligations of international law, and it is also an urgent need to meet the supervision of domestic biological genetic resources.

