

### Research on Access and Benefit-Sharing Regimes for Agricultural Genetic Resources in India

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Abstract: India is one of the richest providers of genetic resources in the world and it advocates that the sovereignty of genetic resources belongs to the state to realize the equitable sharing of the benefits of genetic resources. The study shows that India has built a relatively complete legal system for access to genetic resources and benefit-sharing. This system revolves around three major laws and regulations, with clear management regulations for domestic and foreign access to genetic resources, a definite form and proportion of benefit-sharing, and a clear management method for the distribution of benefits after acquisition. India's achievements in institutional construction can act as a great reference for the management of access to genetic resources and benefit-sharing in China.

Keywords: India; Access to genetic resources; Benefit-sharing systems; Biodiversity

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#### **1. Introduction**

Developed countries frequently snatch agricultural genetic resources from developing countries through "biopiracy," use advanced biotechnology to create new products, and then make huge profits in the form of intellectual property protection. As a country with abundant genetic resources, China has always been an important place for Western countries to plunder biological resources <sup>[1]</sup>. At present, there is still a lack of complete, specific, and operational implementation regulations and management methods for the protection of genetic resources and fair benefit-sharing in China.

#### 2. Access to genetic resources and benefit-sharing legal system in India

#### 2.1. Perfect laws and regulations on access to genetic resources

The Protection of Plant Varieties and Farmers' Rights Act (PPVFRA) of 2001 added unique benefit-sharing provisions and supported providers of genetic material to make benefit-sharing requests to breeders of new varieties. Before 2002, the Indian government's protection of genetic resources was mostly limited to laws and regulations on administrative protection of biological resources, such as the Indian Constitution, Wildlife

Protection Law, Forest Protection Law, Environmental Protection Law, and Foreign Trade Development and Management Law. India has pioneered adopting the most important law on genetic resources, the Biodiversity Act, in 2002, which has established specific national laws on genetic resource management. Articles 25 and 64 of the Patent Law amended in 2002 require patent applicants who obtain biological resources and related traditional knowledge to fully disclose relevant information, otherwise, the patent will be invalid. The Biological Diversity Regulation, enacted in 2004, refines the provisions of the Biological Diversity Act and sets out the basic operational rules for the management of genetic resources. In 2014, India implemented the "Guidelines on Rules for Access to Biological Resources and Related Traditional Knowledge," which provide more specific basic guidelines for the use and management of genetic resources. The laws and regulations related to genetic resource cargoes in India were demarcated in 2002 <sup>[2]</sup>.

#### 2.2. Laws and regulations on benefit-sharing of genetic resources with strong guidance

Article 21 of the Biodiversity Act states that national authorities shall ensure that domestic interests share the benefits equitably as agreed when approving acquisition or transfer. Examples of benefit-sharing models that could be considered include the inclusion of Indian authorities or other beneficiaries as co-owners of intellectual property, transfer of technology, local research and development, joint research with Indian researchers or stakeholders, and the establishment of venture funds to finance stakeholders. Article 21 also states that the monetary benefits agreed upon in the agreement between the parties shall be administered exclusively by the National Biodiversity Authority (NBA). If the acquired biological resources or related knowledge are derived from specific persons, groups, or organizations, the national biodiversity authority allocates the proceeds to such subjects in an appropriate manner <sup>[3]</sup>.

The revised provisions of the Patent Law require patent applicants who obtain biological resources and related traditional knowledge to fully disclose relevant information, otherwise the patent will be invalid. In 2001, PPVFRA added a unique benefit-sharing clause, which was reviewed by the administrative authorities and entered into the National Biodiversity Fund account. On one hand, these provisions gave certain economic compensation to genetic resource providers, and more importantly, recognized "farmers' rights" through legal forms. Article 20 of the Biodiversity Regulation sets out the criteria for equitable sharing of benefits, which may include monetary benefits or other forms, such as copyright royalties, collaborative research, and development, technology transfer, product development, educational and public awareness-raising activities, institutional capacity building or venture funds, which may vary from case to case.

"The Guidelines on Rules for the Acquisition of Biological Resources and Related Traditional Knowledge" specify that the determination of benefits should take into account the commercial value of biological resources, the stage of research, the potential market for research results, the investment in research and development, the nature of the applied technology, the time from research to product production, and the risk of product commercialization. Whether the final product contains one or more biological resources, the amount of benefits should remain the same. Benefits can be divided into monetary benefits and non-monetary benefits. Monetary benefits include sample acquisition (collection) costs, prepaid costs, commercialization license fees, research funding fees, etc. Non-monetary benefits mainly include the transfer of research technology, participation in research and development, personnel training, etc <sup>[4]</sup>.

#### 3. Access to genetic resources and benefit-sharing management system in India

Perfect laws and regulations provide legal system guarantee, India has set up administrative agencies and protection management agencies at all levels, and clarified the relationship and responsibilities among various

agencies, thus building a good management system.

#### **3.1.** Genetic resources management system in India

According to the provisions of the Biological Diversity Act, India has set up three administrative bodies: the National Biodiversity Directorate, the State Biodiversity Board, and the local Biodiversity Management Committee (BMC). The main agencies for the conservation and management of Genetic Resources in India are the National Bureau of Animal Genetic Resources, the National Bureau of Fish Genetic Resources, and the National Bureau of Plant Genetic Resources (NBPGR). These three authorities are part of The Indian Council of Agricultural Research (ICAR), the largest network of agricultural research and education institutions in the world.

India has adopted a top-down vertical management approach among the various agencies for genetic resources management. The Plant Genetic Resources Agency of India consists of six integrated management bodies: the Institutional Management Committee, the Research Advisory Committee, the Institutional Research Council, the Germplasm Resources Advisory Committee, the Institutional Joint Staff Council, and the Appeals Department. These management bodies are responsible for the day-to-day management of its headquarters and 10 local sites. The Bureau is responsible for the overall planning, organization, coordination, and implementation of the development and protection of genetic resources. This includes managing international and domestic exchanges of genetic resources, conducting inspections and quarantines, as well as defining, evaluating, archiving, and safeguarding crop genetic resources.

#### 3.2. India's benefit-sharing and distribution management system for genetic resources

The Indian Biodiversity Act stipulates that the NBA is responsible for the coordination and management of benefit sharing, and puts forward several management suggestions.

(1) The benefit-sharing model

The NBA should guide the formulation of benefit-sharing models. Benefits can come in the form of both monetary and non-monetary. This includes copyright royalties, co-ops, technology transfer, product development, educational and public awareness campaigns, R&D capacity building in Indian research institutions, and venture capital funds. The NBA may place additional conditions on any person's request for access to, transfer of, or application for intellectual property rights or transfer to a third party to ensure a fair and equitable sharing of benefits.

(2) The amount of benefits

The amount of benefits should be negotiated between the applicant and the provider of the genetic resource use and reviewed and approved by the NBA. The NBA could invite local organizations and beneficiaries to join the discussion before making decisions.

(3) The implementation period of benefits

The NBA recommends that the benefits of each acquisition agreement be divided into three phases: short, medium, and long-term. Due to the relatively long cycle of genetic resource utilization and subsequent research and development, short-term benefit agreements are more unfavorable to resource providers. Therefore, when signing genetic resource benefit agreements, the NBA should propose benefit-sharing implementation plans for different periods on a case-to-case basis.

#### 4. The reference significance of India's access to genetic resources and benefitsharing management for China

The Chinese Patent Law implemented in 2009 applies the disclosure system to genetic resources for the first time. China's Biosecurity Law was passed in 2020, making it clear that the state has sovereignty over human genetic and biological resources. National economic sovereignty is one of the basis of international law for the protection of genetic resources and traditional knowledge, and the protection of genetic resources and traditional knowledge, and the protection of genetic resources and traditional knowledge is the inevitable conclusion of recognizing national economic sovereignty. However, similar to many developing countries, there is still no national law on biodiversity or genetic resources in China, and awareness of genetic resource protection is lacking. The existing Seed Law contains only basic provisions related to seed export. The management of genetic resources is also relatively lacking, and the country does not have a sound management system for the acquisition of genetic resources <sup>[5]</sup>. To enhance genetic resources management in China, it is recommended to take inspiration from India's practices and progressively make improvements in three main aspects.

## 4.1. Establishing a sound management system for access to genetic resources and benefit sharing

In terms of management systems, unitary multi-polarization management should be adopted to avoid power conflicts among competing agencies. All agencies involved in biodiversity should be integrated. The responsibilities and objectives of each agency should be well-defined to avoid repetitive work and conflict of responsibilities. Both national and local management agencies should oversee the approval and management of genetic resources acquisition, with the licensing system ensuring supervision over subsequent development, utilization, and the transformation of scientific and technological achievements and intellectual property rights. In terms of benefit-sharing, there are no relevant national laws and regulations for the form, proportion, distribution, and redistribution of benefit-sharing. There are limited studies on the value assessment of genetic resources, which is not conducive to the determination of the form and proportion of benefit distribution in international cooperation. It is essential for states to establish comprehensive benefit-sharing management methods at all levels, with clear contractual guidance models to delineate benefit distribution schemes <sup>[6]</sup>.

When the benefit contract is signed, the legality and rationality of the contract are reviewed. Due to the long period of biotechnology research and development and the greater risk of uncertainty, it is not possible to make excessively detailed provisions on the type of benefits and future use, etc. Instead, the contract may include conditions for subsequent negotiations, allowing for adjustments in the future. This can be achieved by establishing short-, medium-, and long-term benefit mechanisms, incorporating provisions for technology transfer, and specifying participation in research and development.

#### 4.2. Creating incentives for resource conservation and local authorities

In a top-down genetic resources management system, provinces, cities, districts, and counties possess comprehensive knowledge of local genetic resources information. They also have geographical advantages for registering and consolidating information related to accessing genetic resources and sharing benefits. However, it is difficult to ensure the quality of management due to the many departments involved in the process. The implementation of incentive measures is one of the ways to ensure the efficiency of management <sup>[7]</sup>.

To enhance the initiative of protection, genetic resource protection service providers should receive compensation, and the income of protectors needs to surpass the opportunity cost associated with other commercial activities. This approach ensures that the income derived from protection efforts is sufficiently attractive to incentivize effective genetic resource conservation <sup>[6]</sup>. To strengthen the management efficiency of local administrative institutions, economic incentives can be given through financial subsidies, tax incentives, and other ways.

# 4.3. Enhancing the awareness of genetic resources protection and improving the action capacity of genetic resources protection.

China's awareness of genetic resource protection is gradually growing, and there is an increasing focus on related publicity and training initiatives. For instance, the second international training on forest tree genetic resources in 2017 delved into the experience of protecting and preserving forest tree genetic resources, emphasizing variety exchange and sharing. In the same year, a training course on the protection of livestock and poultry genetic resources in Sichuan Province drew participation from technicians representing 38 national and provincial livestock and poultry genetic resource conservation facilities, along with personnel from local municipal, prefecture, and county competent departments.

However, at present, the publicity and training of genetic resources protection in China is mainly aimed at the staff in charge of conservation fields (districts) and national parks at all levels, with less training available for potential owners of genetic resources. One of the responsibilities of the Chinese National Committee of the International Biodiversity Program is to popularize science and enhance public awareness of biodiversity conservation. Efforts to enhance awareness of genetic resource protection extend to counties, towns, and villages where genetic resources are concentrated. These initiatives target potential owners and protectors, including farmers and herders, by disseminating fundamental knowledge of genetic resources, intensifying publicity, and enhancing the capacity for action in genetic resources protection.

#### **5.** Conclusion

India has perfect laws and regulations related to access to genetic resources and benefit-sharing, clear regulations, and procedures for the management of access to genetic resources abroad and at home. After the benefits are obtained, there are also reasonable and clear distribution and management methods, and the government and various institutions or organizations actively respond to the encroachment of their own genetic resources <sup>[8]</sup>. China is also rich in genetic resources, but it is lacking in terms of resource management and benefit-sharing regulations.

Despite the regulation of access to genetic resources and benefit-sharing within the framework of global conventions, the implementation situation remains challenging. China should proactively explore the establishment of a management system for access to genetic resources and benefit-sharing, enhance laws and regulations, create an effective management system, conduct in-depth studies on the value assessment of genetic resources, actively engage in international and national negotiations, sign agreements on benefit-sharing cooperation, and significantly boost the motivation for genetic resource providers to protect genetic resources. These measures ensure the long-term development of biodiversity in China.

#### **Disclosure statement**

The authors declare no conflict of interest.

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