

# China's Legal and Policy Frameworks for Access to Genetic Resources and Benefit-Sharing from their Use

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*Access to genetic resources and benefit-sharing has been an issue heatedly debated and negotiated in the past decade, at both national and international levels. While most of the international negotiations are slowly dragging on, countries have begun to turn to national legislation or policy making to safeguard their interests. As one of the countries rich in genetic resources, China's responses under these circumstances are important in shaping the final outcomes of the international negotiations, but also the future implementation of relevant international instruments, if any. This article captures important access and benefit-sharing-related provisions or elements in China's key related laws and policies, in particular the most recent ones, with a view to identifying existing gaps and future challenges.*

## INTRODUCTION

With the development of modern biotechnology, the value of genetic resources has exploded, which has been proven in many relevant research efforts, developments and applications. Understandably many countries as providers of genetic resources have been trying various ways and means to protect their interests and ensure that they will benefit from the use of the genetic resources they own, including through international treaty-making and domestic legislation and policy making.

Internationally, under the Convention on Biological Diversity (CBD),<sup>1</sup> countries have been negotiating an

international regime on access to and benefit-sharing from use of genetic resources (ABS) to achieve one of the Convention's three objectives, which is the fair and equitable sharing of benefits arising from utilization of genetic resources, including by appropriate access to genetic resources. However, this process has been an uphill exercise, though some light of hope turned up after a recent CBD Conference of the Parties (COP) meeting in Bonn, Germany (COP-9, 19–31 May 2008) adopted a roadmap to conclude the negotiation by 2010.<sup>2</sup> One important, parallel development is that the Commission on Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization (FAO) had been negotiating since 1991 an international undertaking, and an international treaty<sup>3</sup> later on to address issues related to ABS of plant genetic resources for food and agriculture. The negotiation under the FAO was also a very difficult process, though final agreement was reached on this international treaty in 2001, which entered into force in 2004. In addition, the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have also discussed in their respective bodies<sup>4</sup>

<sup>2</sup> See CBD COP Decision IX/12, Access and Benefit Sharing (30 May 2008), available at <<https://www.cbd.int/decisions/?m=cop-09>>.

<sup>3</sup> International Treaty on Plant Genetic Resources for Food and Agriculture (Rome, 3 November 2001). For more information, see the ITPGRFA website, available at <<http://www.planttreaty.org/>>.

<sup>4</sup> The General Assembly of the World Intellectual Property Organization established an Intergovernmental Committee (IGC) on Traditional Knowledge, Folklore and Genetic Resources in 2000 to address intellectual property rights-related issues concerning genetic resources and traditional knowledge (see Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WO/GA/26/6, 2000)) and the mandate of this IGC was renewed in 2003 through a decision adopted by the thirtieth (sixteenth ordinary) session of the General Assembly of WIPO (22 September–1 October 2003): *Report of the Thirtieth (16<sup>th</sup> Ordinary) Session of the WIPO General Assembly (WO/GC/30/8, 1 October 2003)*. In response to a request from the WTO Doha Declaration in 2001 (WTO Doha Ministerial 2001: Ministerial Declaration (WT/MIN (01)/DEC/1, 14 November 2001), the WTO TRIPS Council has been looking at the relationship between the TRIPS Agreement (Agreement Establishing the WTO (Marrakesh, 15 April 1994), Annex 1C) and the CBD and the protection of traditional knowledge and folklore, and most recently proposals about disclosing the source of biological material and associated traditional knowledge (see *Report on Issues Related to the Extension of the Protection of Geographical*

<sup>1</sup> Convention on Biological Diversity (Rio de Janeiro, 5 June 1992) (CBD). Under the CBD, an Ad Hoc Working Group on ABS was established in 2000 (mandated by CBD COP Decision VI/26, Access to Genetic Resources (26 May 2000), available at <<https://www.cbd.int/decisions/cop/?m=cop=05>>) to develop the guidelines and other approaches on ABS, and later on (mandated by COP Decision VII/19, Access and Benefit-Sharing as related to Genetic Resources (27 February 2004), Article 15, available at <<https://www.cbd.int/decisions/cop/?m=cop=07>>) to elaborate and negotiate an international regime on ABS, in response to a call from the World Summit on Sustainable Development held in 2002 in Johannesburg, South Africa (see Johannesburg Plan of Implementation (UN Doc. A/CONF.199/20, 4 September 2002), Resolution I, Annex, available at <[http://www.un.org/esa/sustdev/documents/WSSD\\_POI\\_PD/English/POIToc.htm](http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/POIToc.htm)>.

relevant issues related to genetic resources, however, so far not much progress has been achieved.

Clearly international negotiations on ABS-related issues, no matter where they are held, have been very difficult and slow, due to, among other reasons, the complexity of the issues involved and the great difficulty in finding points of balance between providers and users. While international negotiations or discussions are slowly dragging on, many countries have begun to resort to national legislation and policy making to regulate access and provide benefit-sharing arrangements.

Basically through all these instruments, though their scope may vary, providers of genetic resources wish to see that provisions or procedures (such as prior informed consent or a material transfer agreement) will be implemented to ensure that they will share benefits arising from the use of the genetic resources they provide, while users wish to see that the least barriers possible will be placed, so as not to impede their access to genetic resources. Users also argue that providers or provider countries should facilitate access to genetic resources in order to allow them to share benefits from use of genetic resources.

The positions and measures taken by countries like China, a country rich in genetic resources and primarily as a provider of genetic resources,<sup>5</sup> are certainly noteworthy because they are important in shaping the outcomes of international negotiations, but also to the future implementation of relevant international instruments. This article will capture China's key legal and policy frameworks for ABS arrangements, focusing on the most recent important developments in this regard. Based on this, the article also provides a brief analysis of existing gaps and future challenges ahead.

## LEGAL FRAMEWORKS<sup>6</sup>

In the past two decades, China has developed and adopted a considerable number of laws and regulations related to conservation of species and natural resources; however, most of these pieces of legislation provide principles and rules for domestic management

of these resources, which barely touch on the collection and trade of genetic resources, and even less on sharing of benefits from their use. Only the Husbandry Law of the People's Republic of China<sup>7</sup> (adopted on 29 December 2005), for the first time, includes an article (Article 16) particularly focused on sharing of benefits from use of livestock genetic resources. A noteworthy recent development in this regard was the adoption in September 2008 of a Regulation Concerning Approval of Import and Export of Livestock Genetic Resources and International Collaborative Research Using Livestock Genetic Resources of the People's Republic of China.<sup>8</sup> Another important sign is an amendment to the revised Patent Law,<sup>9</sup> which requires patent applicants to disclose the source of genetic resources used in inventions or innovations. Details about these two will be presented below, together with relevant provisions in relevant laws and regulations adopted earlier.

It should be noted that the laws and regulations presented below fall into three categories. The first category consists of national laws (adopted by the National People's Congress of China). These include the Husbandry Law, Seed Law, Wild Animals Protection Law and the revised Patent Law.<sup>10</sup> The second category consists of the regulations (usually proposed by one or several sectoral or cross-sectoral government departments and approved by the State Council). These include the Wild Plants Protection Regulation,<sup>11</sup> Regulation Concerning Trade in Endangered Species<sup>12</sup> and Regulation Concerning Approval of Import and Export of Livestock Genetic Resources and International Collaborative Research Using Livestock Genetic

<sup>7</sup> Husbandry Law of the People's Republic of China, adopted on 29 December 2005, through the President Order No 45. The text of this law can be accessed at <[http://www.gov.cn/flfg/2005-12/29/content\\_141833.htm](http://www.gov.cn/flfg/2005-12/29/content_141833.htm)>.

<sup>8</sup> Regulation Concerning Approval of Import and Export of Livestock Genetic Resources and International Collaborative Research Using Livestock Genetic Resources', promulgated by the State Council of China through its Order No 533 on 26 August 2008, and available at <[http://www.gov.cn/flfg/2008-09/04/content\\_1087639.htm](http://www.gov.cn/flfg/2008-09/04/content_1087639.htm)>.

<sup>9</sup> Revised Patent Law of the People's Republic of China, adopted by the National People's Congress on 27 December 2008 and issued by the President Order No 8, and available at <[http://www.gov.cn/flfg/2008-12/28/content\\_1189755.htm](http://www.gov.cn/flfg/2008-12/28/content_1189755.htm)>.

<sup>10</sup> For the Husbandry Law and the revised Patent Law, see nn. 7 and 9. The revised Seed Law was adopted on 28 August 2004 and issued by President Order 26, available at <[http://www.gov.cn/flfg/2005-06/22/content\\_8537.htm](http://www.gov.cn/flfg/2005-06/22/content_8537.htm)>. The Wild Life Protection Law was adopted on 8 November 1988 and revised on 28 August 2004 and issued by President Order No 24, available at <[http://www.gov.cn/flfg/2005-06/27/content\\_9693.htm](http://www.gov.cn/flfg/2005-06/27/content_9693.htm)>.

<sup>11</sup> Wild Plants Protection Regulation, promulgated by the State Council of China through its Order No 204 and enacted on 1 January 1997. The text of this regulation is available at <[http://www.mep.gov.cn/law/fg/xzhg/200701/t20070109\\_99402.htm](http://www.mep.gov.cn/law/fg/xzhg/200701/t20070109_99402.htm)>.

<sup>12</sup> Regulation Concerning Trade in Endangered Species, promulgated by the State Council of China on 12 April 2006 through its Order No 465 and enacted from 1 September 2006. The text of this regulation is available at <[http://www.gov.cn/zwgk/2006-05/17/content\\_282856.htm](http://www.gov.cn/zwgk/2006-05/17/content_282856.htm)>.

*Indications Provided for in Article 23 of the TRIPS Agreement to Products other than Wines and Spirits and those Related to the Relationship between the TRIPS Agreement and the Convention on Biological Diversity* (TN/C/W/50, 9 June 2008); and *Appropriate Action to be Taken/Decided by the General Council on TRIPS and CBD* (TN/C/W/49, 28 May 2008).

<sup>5</sup> Generally, countries are categorized as provider and user countries. In reality, there are some countries that could be both. China considers itself primarily as a provider of genetic resources.

<sup>6</sup> There is no official English translation of all the laws and regulations discussed in this article. All the translations here are provided by the authors.

Resources. The third category consists of administrative rules promulgated by one or several government departments, such as the Rules for Management of Germplasm Resources of Agricultural Crops,<sup>13</sup> which was issued by the Ministry of Agriculture on 26 June 2003 and enacted on 1 October 2003.

## **REQUIREMENTS FOR DISCLOSING SOURCES OF GENETIC RESOURCES IN PATENT APPLICATIONS IN THE REVISED PATENT LAW**

The revised Patent Law, which will be enacted on 1 October 2009, will have important new provisions concerning patenting of inventions or innovations using genetic resources. First, under Article 5 of its general provisions, there will be an important addition that reads:

Inventions or innovations using genetic resources in a way violating laws or regulations related to access to and use of genetic resources shall not be granted patents.

Second, a new paragraph has been added under Article 26 to require patent applicants to disclose the origin of genetic resources used in inventions or innovations. Paragraph 5 of Article 26 will read:

Patent applicants of those inventions or innovations using genetic resources shall disclose in their application documents the direct source or origin of genetic resources used. If they fail to do so, applicants must provide reason(s).

By incorporating such a disclosure requirement in its revised Patent Law, China has taken a very important, practical step towards the protection of genetic resources and benefit-sharing from their use, though further provisions are yet to be developed as to how benefits should be shared. This development is noteworthy because such a disclosure requirement is still being negotiated and no consensus has been reached at the international level, particularly at the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPs) Council. Meanwhile, it should also be noted that China is following a model set by India, Brazil and some northern European countries that have included such a requirement in their patent laws. Besides international influence, domestic awareness in China of relevant issues and the urgency to address them is also increasing. While circulating this draft revised law for public comments, the National People's Congress and the State Intellectual Property Administration jointly

issued a press release,<sup>14</sup> which highlighted cases of the loss of genetic resources and the reasons behind the losses. Among others, according to the press release, the most important reason is unregulated access by many foreign institutions and organizations without benefit-sharing arrangements. The press release also cited incomplete and ambiguous legislation or policies and lack of effective mechanisms for protection of genetic resources and benefit-sharing. As some Chinese legal experts involved in the revision of the Patent Law explained at the press conference announcing the revision, the proposed addition aims to prevent biopiracy of genetic resources from China and ensure sharing of benefits from their use with relevant communities and stakeholders in China.

## **REGULATION CONCERNING APPROVAL OF EXPORT AND IMPORT OF LIVESTOCK GENETIC RESOURCES AND INTERNATIONAL COLLABORATIVE RESEARCH USING LIVESTOCK GENETIC RESOURCES**

The other important development is the issuance of a set of rules for regulating the import and export of genetic resources of livestock and international cooperation in research which has been in effect since 1 October 2008. These rules were developed in accordance with the Husbandry Law and provide details concerning how access to livestock genetic resources and sharing of benefits from their use should be regulated. The key provisions of these rules are as follow:

Article 6: The export of livestock genetic resources included in the protection list shall be allowed when it meets the following conditions: (a) clear indication of their intended use; (b) consistency with the goals and objectives set in the national programme for conservation and use of livestock genetic resources; (c) posing no threat to domestic husbandry production and export of livestock products; and (d) putting in place a reasonable arrangement for benefit-sharing.

Article 7: Any institution or organization that intends to export livestock genetic resources included in the protection list shall submit an application to the provincial or province-level municipal authorities responsible for husbandry and veterinarian management, together with the following documents: (a) contracts or grant agreements that may be signed for such export; and (b) documents that contain detailed benefit-sharing arrangements provided by the importer.

<sup>13</sup> Rules for Management of Germplasm Resources of Agricultural Crops, issued by the Ministry of Agriculture on 26 June 2003 through its Order No 30, available at <[http://www.agri.gov.cn/blgg/blt20030717\\_101577.htm](http://www.agri.gov.cn/blgg/blt20030717_101577.htm)>.

<sup>14</sup> J. Sun, 'Revision of Patent Law Addresses Genetic Piracy', *China Legal Daily* (31 August 2008) (covering the details of the press release), and made available on 4 September 2008 on the website of China's National People Congress, available at <[http://www.npc.gov.cn/npc/xinwen/lfgz/2008-09/04/content\\_1448126.htm](http://www.npc.gov.cn/npc/xinwen/lfgz/2008-09/04/content_1448126.htm)>.

Article 8: Cooperation within or outside China with foreign institutions and/or individuals in research using livestock genetic resources included in the protection list shall meet the following conditions: (a) objectives, scope and period of cooperation must be clear and specific; (b) collaboration must be consistent with the goals and objectives set in the national programme for conservation and use of livestock genetic resources; (c) the ownership of intellectual property rights must be clear and arrangements for sharing of research results must be reasonable; (d) collaboration will not pose a threat to domestic livestock genetic resources and national ecological security; and (e) proposals for benefit-sharing must be rational.

The domestic institutions to collaborate with foreign institutions and/or individuals on research using livestock genetic resources should be educational and research institutions, and solely-invested Chinese enterprises (those companies or enterprises wholly invested by Chinese investors – they do not include joint ventures between Chinese and foreign companies) with the status of a legal person.

Article 9: In submitting an application, the Chinese institutions and/or individuals shall present the following documents: (a) a project feasibility study report; (b) a contract for collaborative research; and (c) benefit-sharing options agreed with foreign collaborator(s).

Article 10: Collaboration in research will not be allowed using unique, newly discovered but yet to be determined livestock genetic resources in China or those banned for export by the national authorities for husbandry and veterinarian management.

Article 16: A new application shall be submitted according to required procedures if the objectives and scope of research, period of collaboration, ownership of intellectual property rights, and options for sharing of research results or other benefits have to be changed in the process of undertaking collaborative research activities.<sup>15</sup>

Clearly from these provisions, putting in place benefit-sharing arrangements is a common condition that must be met for exporting livestock genetic resources from China and undertaking international collaborative research using livestock genetic resources. These rules are intended to complement relevant provisions in the Husbandry Law, with specific procedures and requirements in place for benefit-sharing.

## **HUSBANDRY LAW**

In December 2005, China adopted the Husbandry Law (in effect since 1 July 2006) of which Chapter II is particularly devoted to the protection of livestock genetic resources. This law builds on an earlier regulation concerning management of livestock and, notably, for the first time, provides provisions for sharing of benefits from use of livestock genetic resources. For example, Article 16 stipulates that:

Institutions and/or individuals that wish to export livestock genetic resources or undertake international collaboration in research with foreign institutions and/or individuals using livestock genetic resources included in the protection list shall submit an application to the provincial authority responsible for husbandry and veterinarian management, together with a proposal for benefit-sharing. The newly discovered livestock genetic resources shall not be exported or used in international collaborative research activities before they are identified by the National Committee on Livestock Genetic Resources.

In addition, the Husbandry Law particularly in its Articles 11 and 12 requires that protection be accorded to livestock genetic resources through the development of a list of protected livestock genetic resources and a national programme for conservation and use of livestock genetic resources, particularly those endemic and endangered species in China.

## **SEED LAW**

In the Seed Law (promulgated in July 2000), there is one paragraph under its Chapter II devoted to 'conservation and use of germplasm resources'.<sup>16</sup>

More importantly, the Seed Law incorporates a principle of national sovereignty over genetic resources within the jurisdiction of China. Article 10 clearly stipulates that:

The State will exercise national sovereignty over genetic resources, therefore any institution and/or individual that wishes to provide germplasm resources to foreign institutions and/or individuals must obtain approval from the national authorities responsible for agriculture and forestry.

For access to germplasm resources, Article 8 of the Seed Law also requires that any institution and/or individual shall not possess or destroy germplasm resources, and the collection or farming of natural germplasm resources will not be allowed. In cases of the collection or farming for scientific research or other special needs, approval must be obtained from the national or provincial authorities responsible for agriculture and forestry.

## **RULES CONCERNING MANAGEMENT OF GERmplasm RESOURCES OF AGRICULTURAL CROPS**

To enforce the Seed Law, the Ministry of Agriculture issued in June 2003 the Rules for Management of Germplasm Resources of Agricultural Crops to regulate the collection, storage and information management of agricultural germplasm resources.

<sup>15</sup> Authors' own translation. See n. 6 above.

<sup>16</sup> Germplasm resources in the Seed Law refer to 'crop varieties' and 'wild relatives of varieties'.

For collection of agricultural germplasm resources, the regulation bans the collection of wild species and relatives and endangered species included in the national list of protected plants, as well as of those in protected areas and germplasm gardens. Approvals must be obtained for collection of such germplasm resources for scientific research and other special needs. Without approval, a foreign institution and/or individual will not be allowed to collect agricultural germplasm resources within the territory of China. Approvals must be obtained for carrying agricultural germplasm resources out of the country and using agricultural germplasm resources in international collaborative projects. In addition, those institutions and/or individuals that hold germplasm resources not yet registered by relevant national departments are obliged to submit them for storage by the designated national institutions (see Article 14 of the Rules).

This regulation also stresses the principle of national sovereignty over agricultural germplasm resources; therefore, it requires any institution and/or group that wishes to provide germplasm resources to foreign institutions and/or individuals to obtain approval from the Ministry of Agriculture through the provincial authority responsible for agriculture. The management of agricultural germplasm resources allowed to be provided to foreign institutions and/or individuals shall adopt a classification system and the list of such germplasm resources shall be developed and updated by the Ministry of Agriculture on a regular basis (see Article 28 of the Rules).

## **WILD ANIMALS PROTECTION LAW**

In the Wild Animals Protection Law (adopted in November 1988 and in effect since 1 March 1989, and amended on 28 August 2004),<sup>17</sup> the State ownership of wild animal resources was established, while institutions and individuals continue to enjoy the rights of cultivation, reproduction, hunting and harvesting. A licensing and quota system was established for use of wild animal resources, including a licensing system for trade in wild animals. A special licensing system was also established by this law for access to wild animal resources by foreigners (see Article 26).

For international trade in protected wild animals and their products, in accordance with Article 24 of this law, approvals must be obtained from the relevant national authority responsible for management of wild animal resources and a trade permit issued by the national body to approve international trade in endangered species. Relevant provisions and rules of the Convention on International Trade in Endangered

Species (CITES)<sup>18</sup> also apply in this case, if wild animals for export are listed in CITES for trade bans or limitations<sup>19</sup> (see Article 24).

## **REGULATION CONCERNING PROTECTION OF WILD PLANTS**

In the Regulation Concerning Protection of Wild Plants (adopted in January 1997), a ban was put on the collection of Category I nationally protected wild plants listed in the appendix to this regulation.<sup>20</sup> For collection of such wild plants for use for scientific research, artificial cultivation or other purposes, approval must be obtained from relevant provincial or province-level municipal government departments and a collection permit from the national authority responsible for wild plants management or their authorized bodies. In addition, the regulation further stipulates that any institution and/or individual to undertake such collection must follow the categories, quantity, site, length of time and methods of collection specified in the collection permit (see Article 17).

For international trade in protected wild plants, approval must be obtained from the provincial and national authorities responsible for management of wild plant resources. Customs authorities can allow the export only with the permit issued by the relevant authorities. The export of valuable wild plants that are newly discovered or yet to be identified is banned. It should be noted that foreigners are not allowed to collect or purchase protected wild animals within the territory of China (see Article 21).

## **REGULATION CONCERNING TRADE IN ENDANGERED WILD ANIMALS AND PLANTS**

The Regulation Concerning Trade in Endangered Wild Animals and Plants (adopted in April 2006 and in effect since 1 September 2006) further endorsed the principles and rules mentioned above for trade in wild animals and plants. For example, Article 6 clearly establishes a ban on trade in endangered species for commercial purposes. The import and export of endangered species for scientific research, cultivation, cultural exchange and other purposes must be approved by the national authority for the management of wild

<sup>18</sup> Convention on International Trade in Endangered Species of Wild Fauna and Flora (Washington, 3 March 1973).

<sup>19</sup> *Ibid.*, Appendices I and II, available at <<http://www.cites.org/eng/app/E-Jul01.pdf>>.

<sup>20</sup> See appendix to the Regulation Concerning Protection of Wild Plants, which contains a list of nationally protected wild plants. In that list wild plants are divided into Categories I and II for protection. Category I is a group of wild plants that are given the highest level of protection.

<sup>17</sup> Issued by President Order 24. The amended version is available at <[http://new.xinhuanet.com/zhengfu/2004-08/30/content\\_1925402.htm](http://new.xinhuanet.com/zhengfu/2004-08/30/content_1925402.htm)>.

animals and plants. This also applies to those species listed under CITES for trade bans or limitations. Article 9 provides conditions for export of endangered wild animals and plants and their products, which include that (a) trade must meet eco-security requirements and public interests; (b) the sources of products must be legal; (c) the documents provided by applicants must be valid; (d) the species and products for export are not included in the national ban list;<sup>21</sup> and (e) trade must meet other conditions published by relevant national authorities. Article 10 of the Regulation also requires applicants to submit (a) contract(s) for import or export; (b) details concerning the name, category, quantity and intended use of endangered animals and plants and their products; (c) materials concerning the equipment for transporting living endangered animals; and (d) other documents required by relevant national authorities.

## POLICY FRAMEWORKS

Meanwhile, China has also adopted a number of policy frameworks related to access to genetic resources and sharing of benefits from their use. In December 2005, the State Council promulgated a Decision on Strengthening Environmental Protection and Implementing Scientific Development Vision,<sup>22</sup> in which it was recommended that the enactment of legislation concerning ecological conservation and the protection of genetic resources should be accelerated in order to prevent further loss of biodiversity and ecological degradation. The Decision also required that mechanisms for sharing of benefits from use of genetic resources and eco-compensation should be established as soon as possible to prevent loss of genetic resources. Institutionally, China has established an inter-ministerial committee<sup>23</sup> for protection and management of biological resources, which is headed and coordinated by the

Ministry of Environmental Protection and involves almost all the relevant departments and sectors, including agriculture, forestry, science and technology, development and reform, finance and commerce (international trade), among others. The main role of this committee is to coordinate the development and implementation of laws, regulations and policies related to conservation and management of genetic resources as the management of different kinds of genetic resources falls under the responsibilities of different departments.

### STATE COUNCIL NOTICE ON STRENGTHENING PROTECTION AND MANAGEMENT OF BIOLOGICAL RESOURCES

In March 2004, the State Council issued a Notification<sup>24</sup> on Strengthening Protection and Management of Biological Resources.<sup>25</sup> It was emphasized in this landmark document that biological and genetic resources are an important basis for human survival and national ecological security and provide important resources for sustainable development. The Notice identified 15 specific policies and actions, a number of which are closely related to ABS.

#### Improve the Mechanisms and Rules for Approving Export of Biological Resources

A responsibility and accountability system will be established to ensure that responsibilities will be fulfilled and failure to do so will be punished. The management and supervision of export of biological resources will be strengthened. A national network will be established to share relevant information among other departments and governments of different levels. Access by foreign institutions and/or individuals to biological resources within China must be approved by relevant government departments, with all the relevant information or data copied to the national environment department (see paragraph 6 of the Notice).

#### Establish a System to Examine and Test the Imported and Exported Biological Resources

This system is set up to strengthen the supervision of the import and export of biological resources. Approvals must be obtained from relevant national authorities for carrying, mailing and transporting biological resources out of the country. Export of protected and/or endangered species must be permitted by the national bodies for approving international trade in endangered species (see paragraph 7 of the Notice).

<sup>21</sup> This list of wild plants and animals banned for export is developed and updated by the State Forestry Administration with the approval of the State Council of China. The list was released by the State Forestry Administration of China on 1 August 2000 through its order No 7 and made available on its website at <<http://www.forestry.gov.cn/sub/FstList.aspx?id=zrbh.4000>>.

<sup>22</sup> The State Council Decision on Strengthening Environmental Protection and Implementing Scientific Development Vision, issued by the State Council of China on 13 December 2005 through the State Council Notification No 39 (2005), available at <[http://www.gov.cn/zwgg/2005-12/13/content\\_125680.htm](http://www.gov.cn/zwgg/2005-12/13/content_125680.htm)>.

<sup>23</sup> This committee was established in accordance with a Notification on Strengthening Protection and Management of Biological Resources issued by the State Council on 31 March 2004 through State Council Notification No 25 (2004), available at <[http://www.mep.gov.cn/natu/swdyx/swwzzybh/200403/t20040331\\_61215.htm](http://www.mep.gov.cn/natu/swdyx/swwzzybh/200403/t20040331_61215.htm)>. The working modalities, institutional arrangements and composition of this committee are contained in a Notification on Establishing an Inter-ministerial Mechanism for Protecting Biological Resources, issued by the State Environmental Protection Administration on 18 August 2003, available at <[http://www.mep.gov.cn/natu/swdyx/swwzzybh/200308/t20030818\\_90790.htm](http://www.mep.gov.cn/natu/swdyx/swwzzybh/200308/t20030818_90790.htm)>.

<sup>24</sup> A notification issued by the State Council of China is not a law in nature, but a type of administrative rule that is implemented at national and local levels.

<sup>25</sup> See n. 21 above.

### **Strengthen the Management of International Cooperation using Biological Resources**

Agreements must be signed for undertaking international cooperation projects using biological resources or providing biological resources to foreign institutions and/or individuals, with responsibilities, rights and obligations of each side specified. Sharing of benefits from collaboration and participation of research institutions and personnel from China must be ensured. Research activities will be undertaken primarily within China (see paragraph 8 of the Notice).

### **Improve Relevant Laws and Regulations**

Efforts will be stepped up to improve the existing laws and regulations or to develop new laws or regulations if necessary to regulate the collection of and trade or exchange in biological resources, and research and development activities using biological resources. Direct use of wild biological resources for commercialization will be strictly controlled, and use of cultivated or farmed resources will be encouraged (see paragraph 13 of the Notice).

## **CHINA'S INTELLECTUAL PROPERTY RIGHTS PROTECTION STRATEGY (CIPRPS)<sup>26</sup>**

In June 2008, China launched a Strategy for Intellectual Property Rights, which puts a special focus on intellectual property rights (IPR) issues related to genetic resources and associated traditional knowledge. Two important goals related to genetic resources have been included in this strategy. One is to improve the system of protection, development and use of genetic resources in order to prevent loss and disorderly use of genetic resources. To this end, the relationship between conservers, developers and users of genetic resources will be coordinated with a view to establishing rational mechanisms for access to genetic resources and sharing of benefits from their use. The providers' right to be informed must be guaranteed. The other is to establish a system for traditional knowledge protection. To this end, support will be provided to ensure documentation, inheritance and further development of traditional knowledge. Management and protection of intellectual property rights over traditional medicine will be improved. Protection, development and use of traditional practices will be also strengthened. This strategy recommended that the Patent Law, Copyright Law and Trademark Law should be revised in time<sup>27</sup>

<sup>26</sup> China Intellectual Property Rights Protection Strategy, issued on 5 June 2008 through State Council Notification No 18 (2008), available at <<http://www.chinanews.com.cn/gn/news/2008/06-10/1277555.shtml>>.

<sup>27</sup> In response to this recommendation, the National People's Congress of China has amended and adopted the Patent Law on 27 December 2008.

and new laws or regulations developed when necessary to protect genetic resources and associated traditional knowledge (see paragraph 8 under 'Strategic Priorities' in the CIPRPS).

## **CHINA'S NATIONAL PROGRAMME ON CONSERVATION AND USE OF BIOLOGICAL RESOURCES<sup>28</sup>**

The State Environmental Protection Administration (now called the Ministry of Environmental Protection) launched in November 2007 a national programme on conservation and use of biological resources based on a two-year nationwide survey of biological resources. This is by far the most comprehensive document China has ever developed to address the challenges faced by conservation and use of various biological resources at a species and genetic level, by identifying goals of various phases, measures and priority actions to address these problems and challenges. Many goals, measures and priority actions therein are related to genetic resources. Priority action 6 particularly addresses access to genetic resources and benefit-sharing, with the following measures or projects to be implemented in the next decade:

- Develop a system of intellectual property rights protection for biological resources and associated traditional knowledge.
- Establish a regime in which patent applicants are required to disclose their source of genetic resources and present a certificate of origin or legal provenance.
- Establish bodies and a clearing-house mechanism to process and harbour information concerning access to genetic resources and associated traditional knowledge.
- Inventory genetic resources and traditional knowledge and establish databases to support their protection.

## **CHINA'S DRAFT NATIONAL BIODIVERSITY STRATEGY AND UPDATED ACTION PLAN (2008–2020)<sup>29</sup>**

China is also developing a national biodiversity strategy and updating its biodiversity action plan in which

<sup>28</sup> National Program on Conservation and Use of Biological Resources, launched by the State Environmental Protection Administration of China on 24 October 2007, available at <[http://www.mep.gov.cn/natu/stbh/js/200712/t20071204\\_113760.htm](http://www.mep.gov.cn/natu/stbh/js/200712/t20071204_113760.htm)>.

<sup>29</sup> The China National Biodiversity Strategy and Action Plan (NBSAP) is being drafted, so it is not possible to quote from it. However, it is important to mention this strategic document because it includes, for the first time, a number of important ABS-related goals and actions. China's NBSAP is expected to be finalized in the first half of 2009.

'achieving equitable and fair sharing of benefits from use of genetic resources and associated traditional knowledge' has been identified as one of the major goals. The draft strategy proposes that a relatively complete legal system and relevant mechanisms will be established to achieve this goal in the next five years, and practical actions will be taken in the next decade to enforce these laws and mechanisms. Key actions identified at this stage include:

- Establish a system to store genetic resources.
- Establish a system including bodies for managing and regulating access to genetic resources and benefit-sharing.
- Establish a system to control the import and export of genetic resources.

## GAPS AND CHALLENGES

Obviously, from the above, in the past two decades China has adopted or promulgated a considerable number of laws, regulations and policies governing protection and management of biological and genetic resources. These policies, laws and regulations did play an important role in regulating the collection, storage, exchange, development and use of genetic resources in some areas, however, it is also clear that gaps are there and tremendous work is needed for improving relevant legislation or policy making, and even more for their enforcement and implementation.

Despite this, it is clear that China has been improving its relevant legal and policy frameworks to ensure that access to its genetic resources will be regulated and use of genetic resources, if any, shall benefit relevant stakeholders involved, though more details need to be worked out. From this it can be inferred that China may be inclined to see an international regime on ABS focus more on benefit-sharing while regulating access. An international legal framework like this will provide a very good basis for China to improve further its laws, regulations and policies in this regard.

### LEGAL SYSTEM IS INCOMPLETE

Most of the existing laws and regulations only address management of a single category of natural resources, while a comprehensive law is lacking to address issues related to conservation and use of all natural resources or various biodiversity components, including genetic diversity. More importantly most of these laws and regulations are inconsistent, making their enforcement difficult. In addition, genetic resources of some important natural resources such as fisheries have not been covered by any existing legislation. Neither have conservation and use of micro-organisms been addressed by any law or regulation, though some

discussions have been undertaken over years. So there is an urgent need to develop a comprehensive law to govern all the biological resources, including access to them and benefit-sharing from their use. While developing and adopting such a comprehensive law involves a long process, one option could be to improve the existing laws and regulations to address gaps identified.

### ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING ARE BARELY TOUCHED ON IN MANY EXISTING LAWS AND REGULATIONS

Most of these laws and regulations cover protection and management of natural resources, while barely touching on rules and procedures for access to these resources, and even less on benefit-sharing. Although most of them contain protection measures, they are limited to the establishment of protected areas and gene banks or germplasm storage facilities or control measures for import and export of these resources. After China ratified the CBD in 1993, some laws or regulations have incorporated some important principles of the CBD. For example, the Seed Law of 2000 has incorporated the principle of 'national sovereignty over germplasm resources'. However, the concept of benefit-sharing was not incorporated in any laws until the Husbandry Law was adopted in 2005, which has for the first time generally touched on the concept, without specific measures provided to ensure that benefits will be shared. Therefore, there is a big gap to fill in this regard, though some practical steps have been taken, such as revising the Patent Law and issuing a regulation concerning access to and benefit-sharing from use of livestock genetic resources.

### THERE IS NO EFFECTIVE MANAGEMENT SYSTEM OR BODIES IN PLACE

Although an inter-ministerial committee has been established for coordination among relevant departments and sectors, members of this committee are primarily ministers or vice ministers who could only coordinate major policy making. Due to its high-level representation and only as a coordinating mechanism, the committee's role is limited and cannot function as a body to handle day-to-day management of access to genetic resources and benefit-sharing. Therefore, there is an urgent need for China to establish bodies at various levels to take care of specific work related to access to genetic resources and benefit-sharing. Furthermore, the existing mechanisms or bodies should be better coordinated.

## **AWARENESS AT VARIOUS LEVELS IS LOW AND ENFORCEMENT CAPACITIES ARE WEAK**

The awareness of the public and local governments of the importance of genetic resources and the need to protect them is still low. Many local communities are not aware that they should share benefits from use of genetic resources and associated traditional knowledge they own. Local government regulations and effective mechanisms at the local level are still lacking. Relevant tools for benefit-sharing may be even unheard of at the local level, such as model agreements for transfer of materials or prior informed consent for access. Even with these tools, few local governments and communities have been trained to use them to safeguard their interests. In addition, technical or technological means and capacities to enforce measures like import and export control are still very limited, particularly of bodies like customs, quarantine and border control. All these pose great challenges for the enforcement of relevant laws and policies, both national and local. In addition, many local governments are also short of financial resources to support their enforcement activities. Allocations from central government are also very inadequate to meet local needs, despite some increases in recent years. Many of the resource-rich provinces or areas

are also economically poor ones. More importantly, many local governments do not have the political will to enforce these laws and regulations for a number of reasons. One is the shortage of political and economic incentives. The other is that they are preoccupied with other priorities.

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