XUE Dayuan

College of Life and Environmental Science, Minzu University of China and Nanjing Institute of Environmental Science, Ministry of Environmental Protection of China

Nov. 15, 2013

Topics

- Main points on ABS (access and benefit-sharing) in CBD and Nagoya Protocol
- China's GR and TK
- ABS policies in China
- Issues for ABS regulation

CBD's main points on Genetic Resources and associated TK

1、Three objectives of the CBD

(1) Conservation of biological diversity

(2) Sustainable use of the components of biodiversity

(3) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources (and associated traditional knowledge)

CBD's main points on Genetic Resources and associated TK

2、Article 15 of the Convention

- (1) Sovereign rights principle (the authority to determine access to genetic resources rests with the national governments and is subject to national legislation)
- (2) Prior Informed Consent (PIC)
- (3) Mutually agreed terms (MAT)
- (4) Benefit Sharing (BS)
- (5) Endeavour to develop and carry out scientific research in the Contracting Party providing genetic resources
- (6) Cope with the relationship between IP and the access and benefit-sharing of genetic resources

Main Points in CBD & NP CBD's main points on Genetic Resources and associated TK

3. Article 8, (j) of CBD

 Each Contracting Party shall, as far as possible and as appropriate: Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

- NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ONBIOLOGICAL DIVERSITY
- SCOPE (Article 3)
- This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

NAGOYA PROTOCOL

• USE OF TERMS (Article 2)

- (a) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;
- (b) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;
- (c) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity

- NAGOYA PROTOCOL
- TK forms (Preamble)
- Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity.

NAGOYA PROTOCOL

- FAIR AND EQUITABLE BENEFIT-SHARING (Article 5)
- Para.2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.
- Para.5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

NAGOYA PROTOCOL

- ACCESS TO GENETIC RESOURCES (Article 6)
- Para 6. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

China's Rich GR & TK

1. Genetic resources

- China has known 34,984 species of higher plants, ranking the third in the world, with 51% species are originated in China.
- China also has 6,445 vertebrate animal species, accounting for 13.7% of the total in the world. The fungi species proven in China are about 10,000, making up 14% of the total in the world.
- China has rich genetic resources and is a country of origin of many important agricultural crops such as rice and soybean, as well as a key center of origin of wild and cultivated fruit trees.

China's Rich GR & TK

2. Traditional Knowledge

- China has a long history over 5000 years. During the living and agricultural activities, Chinese people has created a great deal of traditional knowledge, renovations and practices.
- China has 56 ethnic groups for its population. Many of these ethnic groups now still keep their traditional living and cultivation styles.
- Based on a wide work in investigation and documentation of TK in China during the past years, a classification system for 5 TK categories is proposed.

- 1. China is a Party of CBD
- China became the Party of Convention on Biological Diversity (CBD) in early 1993, is one of the earliest countries for CBD ratification.
- China approved Cartagena Protocol on Biosafety (CPB) in 2005.
- China is underway to approve Nagoya Protocol and Nagoya-Kuala Lumpur Supplementary Protocol to CPB
- China has actively participated in all the activities under CBD

2. Coordinating Mechanisms for Biodiversity

- Immediately after approval of CBD, Chinese government established the National Coordination Committee for CBD Implementation in 1993 with 25 sectors, headed by Ministry of Environmental Protection (MEP).
- To correspond ABS issue, the State Council set up the Joint-Ministerial Meeting for Genetic Resources, headed by MEP and joined by other 16 ministries.
- To correspond UN Biodiversity Decade, China established a National Biodiversity Conservation Commission in 2011, headed by Premier Li Keqiang and joined by 25 ministers (or vice ministers)
- An office to serve the above three coordination mechanism of CBD Coordinating Committee, Joint-Ministerial Meeting for ABS and National Biodiversity Commission for high level decisionmaking, was set up in Dept of Natural Conservation and Ecological Protection, under Ministry of Environmental Protection (MEP) of China.

2. Coordinating Mechanisms for Biodiversity

- In March 2004, the State Council issued "Announcement to Enhance Protection and Management for Species Resource (Genetic Resources)".
- This document put forward 15 policies and tasks, including survey, inventory, protection plan, legislation, policy, coordinating mechanism, inspection for import and export goods.
- The document designed Ministry of Environmental Protection (MEP) as the national competent authority for biodiversity conservation and ABS issue

- **3. Policies Related to ABS Issue** (1) The Outline of the National IP Strategy
- On June 5, 2008, the State Council issued "the Outline of the National Intellectual Property Strategy", and genetic resources and traditional knowledge have been incorporated into the strategy Objectives and the strategy tasks in the Outline.

3. Policies Related to ABS Issue

- (1) The Outline of the National IP Strategy
 - 1) Improve the protection, exploration and utilization of genetic resources, preventing the loss and abuse of genetic resources. Coordinating the relationship of the protection, exploration and utilization of Genetic Resources, and establishing a reasonable mechanism of Access to Genetic Resources and Benefit Sharing. Guarantee the rights of awareness and consent of the providers of Genetic Resources.

3. Policies Related to ABS Issue

(1) The Outline of the National IP Strategy

2) Construct a comprehensive IP system. Support the compilation and passing-down of traditional knowledge, and promote the development of TK. Improve the coordinative mechanism of the management, protection and utilization of traditional pharmaceutical intellectual property, and strengthen the protection, development and utilization of traditional arts and crafts.

3. Policies Related to ABS

(2) China National Biodiversity Strategy and Action Plan (2011-2030) approved by the State Council on Sept 15, 2010

Strategy Tasks

- 6) Improve benefit sharing of biological and genetic resources and associated traditional knowledge. China will
- Rescue, protect and inherit related traditional knowledge by improving the protection system of traditional knowledge.
- Explore the establishment of a system for access to and benefit sharing of biological and genetic resources and associated traditional knowledge, and coordinate the interests between the protectors, developers and users of biological and genetic resources and associated traditional knowledge to ensure that the interests of all stakeholders will be protected.

3. Policies Related to ABS

(2) China National Biodiversity Strategy and Action Plan Action Plan

- Action 7 Carry out baseline surveys on biological resources and ecosystems
- Carry out comprehensive baseline surveys in the priority areas of biodiversity conservation.
- Carry out surveys on key species and in key areas.
- Establish baseline database of species surveyed at both national and local levels.
- Regularly organize nationwide surveys on wild flora and fauna and establish archives and catalogues of these resources.
- Carry out baseline and diversity surveys on aquatic species of rivers and wetlands.
- Establish national biodiversity information management system.

3. Policies Related to ABS

(2) China National Biodiversity Strategy and Action Plan Action Plan

- Action 8 Survey and catalogue genetic resources and related traditional knowledge
- Survey, collect and classify local crops, domesticated animals, wild edible and medical plants and animals and fungi with focus on remote and minority-inhabited regions and store the accessions in the national germplasm resource bank.
- Focus on the survey of germplasm resources of major timbers, wild flowers, medicinal species and aquatic species, and collect, store, catalogue these resources and establish databases.
- Survey traditional knowledge, innovation and practices related to genetic resources in the ethnic minority-inhabited areas and establish databases and undertake studies and demonstration projects concerning benefit sharing.

3. Policies Related to ABS

(2) China National Biodiversity Strategy and Action Plan Action Plan

Action 21: Establish rules and mechanisms of conservation, access to and benefit sharing of genetic resources and related traditional knowledge

- Develop policies of and regulations on access to and benefit sharing of genetic resources and related traditional knowledge.
- Improve regulations on disclosure of origin of genetic resources in patent applications and establish procedures of mutually agreed terms and prior informed consent for access to and benefit sharing of genetic resources and related traditional knowledge, and ensure that inspection of the import & export of biological resources will be operating effectively.
- Establish administration mechanisms, administrative agencies and technical supporting systems for access to and benefit sharing of genetic resources and improve related information exchange mechanisms.

3. Policies Related to ABS

(2) China National Biodiversity Strategy and Action Plan Action Plan

- Action 22 Establish a system of examination and inspection of import and export of genetic resources
- Establish a system for examination and inspection of import & export of genetic resources, coordinate domestic management and import & export law enforcement, and develop effective penalties and strengthen supervision on import & export.
- Develop an administrative list of import and export of genetic resources and strengthen professional training for customs and quarantine and inspection staff to improve the accuracy of examination and inspection.
- Undertake research on rapid inspection and identification methods and equip advanced examination and inspection facilities at major ports of passengers and international mail processing centers as well as establish and complete related laboratories.
- Raise the awareness of departing passengers especially scientific and research professionals and foreign service personnel of protection of genetic resources through various educational programs

4. Legislation

(1) The laws existed for access to genetic resources

- China has issued a series of laws concerning access to biological species and genetic resources, e.g.
- Wild Animal Protection Law (aim to nationally protected animal species
- Regulation on Protection of Wild Plants (aim to nationally protected plant species)
- Seed Law (Principally, it declaims the state sovereignty on crop germplasm)
- Regulation on the Management of Trade in Endangered Wild Animals and Plants
- Regulation on the Protection of Wild Medicine Resources.
- However, all above legislation are short of Benefit-sharing, though some regulatory articles for access.

- 2. New legislation reflecting ABS
 - (1) Newly revised Patent Law (Entered into force on Oct 1, 2009)
- Article 5: inventions violating laws, social morals, and damaging public interest will not be granted a patent right. Inventions created on the genetic resources illegally acquired or utilized will not be granted a patent right.

- 2. New legislation reflecting ABS
 - (1) Newly revised Patent Law (Entered into force on Oct 1, 2009)
- Article 26: for inventions and creations made on genetic resources to apply patents, the applicant shall disclosure the direct resources and origin of the genetic resources; if the applicant cannot clarify the origin, an explain shall be provided.

2. New legislation reflecting ABS

- (2) Animal Husbandry law (enacted on Dec. 2005), Put forward the concept of benefit sharing for the first time
- Article 16: for export and cooperation with foreign organizations, the utilization of animal and poultry resources in the protection name list, the user shall apply husbandry administration department at the provincial level, and provide a measure of benefit sharing at the same time.
- The animal and poultry resources newly found is prohibited to provide to foreign companies before identification by the state authority.

- 2. New legislation reflecting ABS
 - (3) 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 and Poultry (Entered into force on Oct 1, 2008) .
 - It prescribed the conditions for access to livestock genetic resources and the contents of benefit sharing more specifically

- 2. New legislation reflecting ABS
 - (4) The Law of Cultural Heritage for Intangible Goods) (Enforced on June 1, 2011)
- It provided that the culture sector is responsible to protection, investigation, preservation, identification and databases for intangible goods. It is also in charge of review and approval for application of foreigners' investigation work.
- But, many kinds of TK can be incorporated into this law for protection.

- 3. New legislation underway on ABS The follow legislation is underway for drafting with linkage with the Nagoya Protocol.
- (1) Law of Traditional Chinese Medicines
- (2) Regulation on Access and Benefit Sharing for Genetic Resources and Associated Traditional Knowledge.

1. Scope

Genetic resources (excluding food and agricultural GRs under ITPGRFA; expansion of the Annex 1; GRs beyond country's jurisdictions (polar regions, high seas)

Derivatives

exporting raw materials, extractives for traditional medicine products)?

Traditional knowledge

definitions? category; documented TK?

2. Access

- processing procedures for various situations Access from *in situ*
- Access from ex situ collections
- Access from indigenous and local communities
- Access by domestic users (research or commercial)
- Access by joint venture?
- Access by foreigner for science and exhibition?
- Who will receive the access applications and who can issue the internationally-recognized certificates?

3. Benefit-sharing

- Who are beneficiaries for *ex situ* collections? Who are beneficiaries for TK or documented TK? Who can represent ILCs for signing contracts? How to share the benefits from the new uses of the collections accessed before CBD? How to share the benefits for the exported extracts (derivatives)?
- How to share the benefits for border species (more than one origin)

- 4. Compliance, monitoring and capacity-building
 - How to identify the origins;
 - Multi-lateral benefit-sharing (border species and third user)?
 - How to trace and monitor the use in foreign countries and transfer to the other users?
 - Where are check points?
 - Institutional arrangement in central and local?
 - The capacity of negotiation for ILCs?
 - How to deal with the ABS with non-Parties of NP?

谢谢!

Thank you for your attention !