

Access and benefit-sharing of genetic resources and associated traditional knowledge

XUE Dayuan

College of Life and Environmental Science, Minzu University of China (MUC)

Nanjing Institute of Environmental Science (NIES), Ministry of Environmental Protection of China (MEP)

xuedayuan@hotmail.com
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I. Objectives and hot issues of the CBD

1. Three objectives of the CBD

- (1) Conservation of biological diversity
- (2) Sustainable use of its components
- (3) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources (and associated traditional knowledge)

2. Two implementing methods:

Access to genetic resources + transferring technology

I. Objectives and hot issues of the CBD

3. Hot issues of the CBD

- (1) Conservation (forest ecosystem, agricultural biodiversity, marine, wetlands, dry and sub-humid lands biodiversity, protected areas scheme, etc.)
- (2) Sustainable usage of biological resources + technology transfer
- (3) GMOs biosafety
- (4) Invasive alien species
- (5) Access and benefit-sharing of the genetic resources
- (6) Access and benefit-sharing of the traditional knowledge
- (7) Climate change and bioenergy

II. Access and benefit-sharing of genetic resources in CBD

1. Principles and important regulations of the access of genetic resources

Article 15, 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

II. Access and benefit-sharing of genetic resources in CBD

2. Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits

- Identification of the rights and responsibilities of the relationships between Contracting Parties and stakeholders, providers and users of the genetic resources;
- Enriching the process and requirements of the "Prior Informed Consent";
- Specializing the "Mutually Agreed Terms" in Article 15, paragraph 7, of the CBD
- Bringing forward the National monitoring and reporting system
- Identification of the relationship between the Guidelines and relevant international systems;
- Elements for Material Transfer Agreements (MTA) ;
- However, as voluntary guidelines, difficult to be implemented till now.

II. Access and benefit-sharing of genetic resources in CBD

3. International Regime for access and benefit sharing of genetic resources, ABS

- The World Summit on Sustainable Development (South Africa, 2002) called for negotiation on establishing an international system of enhancing benefit sharing of genetic resources equitably and fairly under the framework of the CBD;
- Reiterated in the Fifty-Seventh Session of the U.N. General Assembly (December, 2002, New York), World Summit of the UN (September, 2005, New York) and following UN General Assemblies.

II. Access and benefit-sharing of genetic resources in CBD

3. International Regime for access and benefit sharing of genetic resources, ABS

COP 7 Decision VII/19, 2004

- Decides to mandate the Ad Hoc Open-ended Working Group on ABS to elaborate and negotiate an international regime on ABS, and adopting an outline of negotiation work, including the process, nature, scope and elements of the international regime.
- Followed by two Ad Hoc Open-ended Working Groups on ABS negotiating on the objective, nature, scope and elements of the international regime on ABS, with little improvement.

II. Access and benefit-sharing of genetic resources in CBD

3. International Regime for access and benefit sharing of genetic resources, ABS

COP8 (March 20 – 31, 2006, Curitiba of Brazil) :

- The Ad Hoc Open-ended Working Group on ABS needs to continue the drafting and negotiating work on the international regime on ABS, and is required to complete above-mentioned work before COP 10 (2010). COP 8 also requires two working groups before the COP 9.
- COP 8 decides “to establish a regionally balanced ad hoc technical expert group to elaborate possible options for an international certificate of origin, source and legal provenance”. Meeting of the Group of Technical Experts on an Internationally Recognized Certificate of Origin/Source/Legal Provenance was held in January, 2007, in Lima, Peru, adopting the concept of “**certificate of compliance**”.

II. Access and benefit-sharing of genetic resources in CBD

3. International Regime for access and benefit sharing of genetic resources, ABS

■ ABS-WG-5 (October, 2007, Montreal, Canada)

No improvement on the text framework of the international regime, but providing an opportunity for the contracting parties and stakeholders to express their opinions and see the divergences among them.

■ ABS-WG-6 (January, 2008, Geneva, Switzerland) with breakthroughs:

- Bring out the “roadmap” of to complete the work before the COP 10 of 2010, or to submit the draft process decision on the following work of negotiating the international regime to the COP 9, **which reminds the real start of the negotiation on the ABS international regime.**
- Adoption on one annex to the draft decision above, including different opinions on the objective, scope and nature of the international regime, which provides the main components of the international regime.

II. Access and benefit-sharing of genetic resources in CBD

3. International Regime for access and benefit sharing of genetic resources, ABS

- COP-9 (May, 2008, Germany)
- Adoption on the roadmap of the negotiation work:
 1. Continue to negotiate the ABS international regime based on the Geneva text, complete the work before the COP 10 in 2010 and report to the COP 10.
 2. Three ABS working group meetings (ABS WG-7, 8, 9) before the COP 10 in 2010.
 3. Establish three technical expert groups and hold three workshops (terms of reference, compliance, relationship with traditional knowledge).
 4. Agreement on the working outlines of the above technical expert groups.

II. Access and benefit-sharing of genetic resources in CBD

3. International Regime for access and benefit sharing of genetic resources, ABS

- ABS WG-7 held in April, 2009, in Paris, without important improvement because of great divergences.
- ABS WG-8 held in November, 2009, in Montreal, Canada;
- ABS WG-9 held in March 2010, in Cali, Columbia and the resumed meeting will be held in Montreal, July 10-16, 2010
- Three technical experts working groups held in December, 2008 (Namibia), January, 2009 (Tokyo, Japan) and June, 2009 (Hyderabad, India) with a little help in the negotiation of the international regime.
- ABS Friends of the Co-Chairs meeting held in Montreal from 26-29 January 2010 and Co-chairs Inter-regional Informal Consultations held in Cali, Colombia, March 16-18, 2010.
- Reports of the above three working group meetings will be submitted to the COP-10 to be held in October, 2010, in Nagoya, Japan.

II. Access and benefit-sharing of genetic resources in CBD

3 . International Regime for access and benefit sharing of genetic resources, ABS

Main elements and divergences:

- Objective
- Scope
- Compliance
- Equitable benefit sharing
- Access of genetic resources
- Nature of the international regime
- Capacity building

II. Access and benefit-sharing of genetic resources in CBD

3 . International Regime for access and benefit sharing of genetic resources, ABS

Main stakeholders and opinions:

- Like-Minded Mega-biodiversity Countries (LMMC): Legal-binding international regime, emphasis on the authority of the genetic resources provided country, equitable benefit sharing based on Prior Informed Consent and Mutually Agreed Terms;
- Similar opinions: African Group, GROLAC (South American and Caribbean Group);
- EU and the JUSCANZ Group: Access and benefit-sharing of genetic resources based on contracts, IP protection;
- Switzerland and Norway: agree to disclose the origin of genetic resources, reservation on Prior Informed Consent and the manner of benefit-sharing.

II. Access and benefit-sharing of genetic resources in CBD

4. Position of the Chinese Government

- China is the contracting party of the CBD
- As the member of LMMC, China has great biodiversity and rich genetic resources.
- As the important provider of genetic resources, China supports to establish a regime on the access and benefit sharing of genetic resources in the international level so as to improve the benefit sharing of genetic resources.
- China is also the important user of genetic resources with rapid-developing bio-technology and growing bio-industry.

III. Access and benefit-sharing of traditional knowledge in CBD

1. Negotiation on traditional knowledge in CBD

- (1) Relevant articles in the Convention Article 8 (j)
- (2) COP-7 Decision (VII/16) : to establish *sui generis* systems for traditional knowledge protection.
- (3) Special experts group on traditional knowledge issues (six working group meetings held)
- (4) Close connected to the indigenous and local community, with political connections
- (5) Bound with genetic resources: traditional knowledge, innovation and method embodying the culture and life of the indigenous and local communities related to the genetic resources;
- (6) Related to IP (related to the WTO and the WIPO)

III. Access and benefit-sharing of traditional knowledge in CBD

1. Negotiation on traditional knowledge in CBD

Article 8, (j), 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;

III. Access and benefit-sharing of traditional knowledge in CBD

1. Negotiation on traditional knowledge in CBD

- Most Developing Countries: as it is difficult to fully protect the traditional knowledge through existing IP system, we should call for *sui generis* systems for the protection of traditional knowledge based on common law and traditional methods under the framework of the CBD other than the WIPO.
- Developed Countries: it is necessary to protect traditional knowledge, but we should abide international laws like the TRIPs and relevant agreements of WTO, with consideration of the three standards of patent, and strengthen the cooperation with the IGC of WIPO to avoid repetitive work.

PROPOSED BASIC ELEMENTS OF SUI GENERIS SYSTEMS FOR THE PROTECTION OF THE KNOWLEDGE, INNOVATIONS AND PRACTICES OF INDIGENOUS AND LOCAL COMMUNITIES

- (a) Statement of purpose, objectives and scope;
- (b) Clarity with regard to ownership of traditional knowledge associated with biological and genetic resources;
- (c) Set of relevant definitions;
- (f) Rights of traditional knowledge holders and conditions for the grant of rights.
- (g) The rights conferred;
- (h) A system for the registration of indigenous/local knowledge/Systems for the protection and preservation of indigenous/local knowledge;
- (i) The competent authority to manage relevant procedural/administrative matters with regard to the protection of traditional knowledge and benefit-sharing arrangements;
- (j) Provisions regarding enforcement and remedies;
- (k) Relationship to other laws, including international law;
- (l) Extra-territorial protections;

III. Access and benefit-sharing of traditional knowledge in CBD

2. International patent cases of genetic resources and traditional knowledge

“Bio-piracy” cases

- (1) Basmati rice
- (2) Wild Soybean
- (3) Thai Jasmine rice
- (4) Mexico High Oil Corn
- (5) Indian Medical plant

Curcuma Longa; Azedarach; Ayahuasca; Hoodia Cactus

III. CBD Traditional Knowledge Protection and Benefit Sharing

3. Traditional Knowledge and Its Protection in Ethnic minority areas of China

China has numerous ethnic minorities and various traditional knowledge

- (1) Traditional genetic resources of crops and livestock and poultry species and traditional knowledge of breeding these resources
- (2) Ethical traditional medicine knowledge
- (3) Traditional technology and traditional way of production and traditional lifestyle
- (4) Traditional cultural related to the protection and sustainable use of bio-diversity
- (5) Traditional geographical indicators for biological products

IV. The Works of Other Related International Treaties/Conventions

Relevant background

- Related to ABS Other Than CBD
- The fulfillment of other related international conventions should also be taken into consideration
- All the conventions should be coordinated at the international level
- The fulfillment of related conventions that China participates in should be coordinated at the national level
 - The coordination among different authorities is inadequate
 - Research should also be coordinated
 - Overall strategy and measures should be developed at the Inter-Ministerial Joint Conference in China

IV. The Work of Other Related International Treaties/Conventions

1. Relationship with FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

- This multi-lateral system applies for 64 species (genus) of plants and forage grasses. And could be deemed as the specific implementation of the principle in Article 15 of CBD on plant genetic resources for food and agriculture ruled by multi-lateral system.
- There are some similarities between MTA (material transfer agreement) of FAO and MAT (mutually agreed terms) of CBD.
- Benefit sharing includes the payment of monetary and non-monetary benefits, exchange of information, access and transfer of technology and capacity building.

IV. The Work of Other Related International Treaties/Conventions

2. Relationship with TRIPS

- According to TRIPS Article 27 3(b), Members may also exclude from patentability: plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. So Members may decide the patentability of plants, animals and biological processes.
- Should the origin of genetic resource and related traditional knowledge be disclosed during the process of patent application? Should the disclosure of genetic resources and related traditional knowledge be developed as an independent requirement? Should we solve the problem of disclosure by the revision of Patent Cooperation Treaty administered by WIPO.
- 11 countries including Brazil and China propose to amend Article 27 of TRIPS that is to disclose the origins of genetic resources and related traditional knowledge in patent application. This proposal is supported by 50 odds countries.

IV. The Work of Other Related International Treaties/Conventions

3. Relationship with Conventions and Treaties administered by WIPO

- The General Assembly of WIPO established the Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, and make it the forum of debate and dialogue on the relationship of Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions. These themes are believed to go beyond the traditional branch of Intellectual Property Law and can't be administered by other bodies of WIPO. Till now, IGC has held 16 sessions.
- However, some Members indicate that issues related to Access and Benefit Sharing such as the disclose origins of genetic resources and related traditional knowledge should be resolved under the framework of the reform of *Patent Cooperation Treaty* and development of *Substantive Patent Law Treaty*.

IV. The Work of Other Related International Treaties/Conventions

4. Relationship with International Convention on Plant Variety Protection of UPOV

- The Convention provides a specific format of IP protection for the process of plant reproduction, with the purpose of encouraging the breed of new plant varieties by breeders. The rights of breeders are limited by two essential exceptions (Article 15). The first exception is called "Breeders' Privilege" that is the reproduction material could be used without prior informed consent if it is used for the purpose of breeding other varieties. "Breeders Privilege" guarantees obtaining of seeds of all the breeders, thus optimizes the evolution of varieties.

IV. The Work of Other Related International Treaties/Conventions

5. Relationship with United Nations Convention on the Law of the Sea (UNCLOS)

- The part XIII of the Convention establishes the system of marine scientific research, admitting that all States and competent international organizations have the rights to conduct marine scientific research in the marine environment including the areas administered by the Convention. The UNCLOS and CBD are mutual complement and supportive on the regulation of conservation and sustainable utilization of marine and coastal biodiversity, but there is a major legal gap concerning the commercial activities of genetic resources in the areas administered by UNCLOS. There is no regulation on bio-prospecting in UNCLOS. The genetic resources outside national sovereignties also go beyond the domain formulated by Article 15 of CBD.

IV. The Work of Other Related International Treaties/Conventions

6. Relationship with Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

- CITES requires that the export /import of any specimen of a species shall require the prior grant and presentation of an export/import permit, thus to control the international trade in wild fauna and flora, including the export, import and re-export of any specimen of any species and their recognizable part or derivative thereof.
- General thought is that experiences could be drawn from the “permit system” established by CITES to manage species close to extinction when conceiving the possibility and influence of the development of a certification for international origin/source/legal provenance

IV. The Work of Other Related International Treaties/Conventions

7. Relationship with the Antarctica Treaty

- The Scientific Committee on Antarctica Research thinks that the Antarctica Treaty needs to be revised so as to include the management of bio-prospecting. Meanwhile the Committee suggests the Antarctica Treaty and CBD be reviewed to facilitate the formulation of methods to resolve the exploration of Antarctica life-forms.

IV. The Work of Other Related International Treaties/Conventions

8. Four Regional Agreements:

- Andean Pact decision 391 on the Common Regime on Access to Genetic Resources;
- The draft Central American agreement on access to genetic resources and bio-chemical resources and related traditional knowledge;
- The draft ASEAN Framework Agreement on access to biological and genetic resources;
- The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, for the Regulation of Access to Biological Resources.

IV. The Work of Other Related International Treaties/Conventions

9. National Laws

- The main contents of national laws: national competent authorities, prior awareness and consent, terms of mutual consent including benefit sharing, IP rights and compliance measures, etc.
- According to case study carried out in Pacific Rim countries, among the 41 Parties of CBD, only 9 of them have developed national laws and policies on benefit sharing (22%), 26 of them are working on it (63%), while 6 of them have not involved in any process aiming at the establishment of such a framework (15%).

V. What China has done and needs to do

1. Policies Related

(1) The Outline of the National IP Strategy (promulgated by the State Council on June 5, 2008), put forward the following specific tasks:

- 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.
- 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) Strengthen the protection of folklore, and promote its development. Fully explore the value of folklore works, establish a mechanism of reasonable benefit sharing between the keepers and developers, and guarantee the legal rights of relevant person and group.

V. What China has done and needs to do

1. policies related

(2) 《The Outline of National Biological Species Resources Conservation and Utilization Plan 》 (Approved by the state council on Oct. 2007)

Priority action 6: establish legal system on the acquirement and benefit sharing of biological genetic resources and relevant TK.

- Priority project 1: study the definition of TK, formulate protection list of important TK, and establish the protection system of biological resources and TK.
- Priority project 2: study and establish a system of requiring the disclosure of the origin of genetic resources in patent application
- Priority project 3: establish organizations on processing biological genetic resources and associated TKs, and a mechanism of information exchange.
- Priority project 4: Study on the construction of protection database of biological genetic resources and TK, formulate protection list of genetic resources and relevant TK.

V. What China has done and needs to do

1. Policies Related

(3) 《National bio-diversity protection strategy and action plan 》 (to be enacted in 2010)

- Strengthen the studies on the genetic resources administration system at the national level, establish relevant policies that are in conformity with national conditions; besides the requirement of origin disclosure in patent application, there is also the requirement to follow the principle of prior informed agreement, so that the benefit can be shared on commonly determined articles, guarantee the benefit the resources providers, and protect the interest of the vulnerable groups like local communities and minorities.
- At the same time, we should study on establishing special laws of biological resources, introduce the system of certificate of the origin of biological resources. Strengthen the enforcement and custom inspections, combat illegal activities like smuggling of species, biological piracy, etc.

V. What China has done and needs to do

1. Policies Related

(3) 《National bio-diversity protection strategy and action plan》 (to be enacted in 2010)

4.2 Strategic Guidelines

- The strategic guidelines for biodiversity conservation in China are: Conservation first, sustainable use, public participation, benefit sharing.
- To establish ABS regime for genetic resources and traditional knowledge in country level, in order to a benefit balance between providers and users, in particular, to protect the benefits of developing countries, including the benefits of indigenous and local communities.

V. What China has done and needs to do

1. Policies Related

(3) 《National bio-diversity protection strategy and action plan》 (to be enacted in 2010)

Strategic guidelines

4.4.5 To realize the third objective of benefit sharing under CBD

- (1) To establish national ABS legislation and polity system
 - Including the main elements: to disclosure the sources and origin of genetic resources and associated TK; to follow PIC procedure for access to GR and TK; to share the benefits fair and equitably with providers based on MAT (mutually agreed terms).
- (2) To protect and promote the transit of TK associated biodiversity
 - To enhance the survey, organizing, documentation and database establishing for TK, to study the *sui generis* for TK protection and start to demonstrate in local level.

V. What China has done and needs to do

1. Policies Related

- (3) 《National bio-diversity protection strategy and action plan》 (to be enacted in 2010)

Priority Actions

Priority field 3

Action 8 To conduct the program for survey, organizing and inventory for GR and TK

- (1) To conduct a systematical survey, registration and collection for genetic resources, especially for the local crop varieties and animal breeding in remote areas and minority areas;
- (2) To focus on the survey, inventory and database of economic species of trees, wild flowers, medicinal herbs, etc.
- (3) To investigate and document the knowledge, innovation and practices associated biodiversity kept in minority areas by indigenous and local communities.

V. What China has done and needs to do

1. Policies Related

- (3) 《National bio-diversity protection strategy and action plan》 (to be enacted in 2010)

Priority Actions

Priority 6: To promote the access, use and benefit sharing of genetic resources and associated traditional knowledge.

Action 21 To establish a national ABS regime for GR and TK

- (1) To formulate national policy system on ABS of GR and TK;
- (2) To establish regulation system including disclosure of source and origin of GR and associated TK for patent application; follow PIC and MAT; set up check points in patent application and import & export;
- (3) To build the administrating mechanism, competent authority and technical supporting systems, such as CHM on ABS.

V. What China has done and needs to do

1. Policies Related

- (3) 《National bio-diversity protection strategy and action plan》 (to be enacted in 2010)

Priority

Priority field 6: Promote the access and benefit sharing,

Action 22, To establish a check system for imports and exports of genetic resources and associated TK

- (1) Identify a list of species or genetic resources for checking imports and exports;
- (2) Propaganda of ABS regime by network, in order to improve awareness of researchers, local community and public;
- (3) Establish a system for checking the genetic resources from imports and exports.
- (4) Study a quick identification methodology and enhance the capacity in inspection, facility and laboratory.
- (5) Build capacity of officials by training.

V. What China has done and needs to do

2. Relevant laws and regulations

- (1) newly revised 《Patent Law》 (approved by NPC on Dec. 27, 2008)

- 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.
- Article 26: for inventions and creations made on genetic resources to apply patents, the applicant shall clarify the direct resources and origin of the genetic resources; if the applicant cannot clarify the origin, an explain shall be provided.

V. What China has done and needs to do

2. Relevant laws and regulations

- (2) 《Animal husbandry law》 (enacted on Dec. 2005) , Put forward the concept of benefit sharing for the first time.

Article 16: for private 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.

- (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》 (approved on Aug.20, implemented on Oct.1) 。

The measure prescribed the contents of benefit sharing more specifically.

V. What China has done and needs to do

3. Related Administration and Coordination

- (1) Inter-Ministerial Joint Conference for the protection of species resource
- (2) Coordination mechanism on the fulfillment of CBD.
- (3) Coordination of implementing the commitments on joining relevant international conventions.
- (4) Related management and operating organizations
- (5) Related research institutions
- (6) other organizations and institutions

V. What China has done and needs to do

4. Work needs to be enhanced

- (1) The theoretical and practical research on the sovereignty, ownership and the right to use of genetic resources and IP.
- (2) The investigation, collection, documentation and database construction of genetic resources and associated traditional knowledge
- (3) Pilot demonstration on Access and Benefit Sharing.
- (4) Format and pilot case studies on genetic material **transfer agreement**
- (5) **Empirical research on western and major developing countries.**

V. What China has done and needs to do

4. Work needs to be enhanced

- (7) **Formulation of national management rules on access to biological genetic resources and benefit sharing. The work is underway.**
 - Chapter 1 General Principles
 - Chapter 2 Supervising
 - Chapter 3 Protection of GR and associated TK
 - Chapter 4 Access to genetic resources
 - Chapter 5 Benefit-sharing of GR for use
 - Chapter 6 GR' transportation and importing & exporting
 - Chapter 7 Legal obligation
 - Chapter 8 Supplementary articles

V. What China has done and needs to do

4. Work needs to be enhanced

(8) Research and develop the *sui generis* on traditional knowledge (TK) at national and local level.

- Some regulations are underway for formulation, such as the Regulation for protection of immaterial cultural heritage, and the regulation for protection of IP for traditional Chinese medicines.
- Local legislation in some provinces have been done or underway, such as in Guizhou province and Yunnan province.

谢谢！

Thanks !