

Implementing the Nagoya Protocol on Access and Benefit-Sharing in China: the Emerging Legal Issues

Author: Nan Xia, PhD Candidate in Faculty of Business and Law

In Queensland Technology of University (QUT)

Address: 2 George St, Brisbane City QLD 4000

Abstract:

This Article critically examines the implementation of the Nagoya Protocol on Access and Benefit Sharing under the Convention on Biological Diversity (CBD) by the Chinese Legal system. While referring to the major provisions of the Nagoya Protocol, the Article seeks to investigate how far the Draft Regulation (2017) in China is meeting the requirements of the Nagoya Protocol and what needs to be done in giving full effect to the obligations of the Protocol.

Key words: Access and benefit sharing; Nagoya Protocol; China; Benefit-Sharing

A Introduction

China entered into the *Nagoya Protocol*¹ in September 2016 and was always an active party in the negotiations.² Against this backdrop, the central thrust of China's active endeavors has always arisen from the State's growing concerns over the misappropriation of genetic resources and associated TMK.³ China enjoys a great wealth of genetic resources and associated TMK,⁴ thus becoming an ongoing target of biopiracy, primarily perpetrated by multinational companies from developed countries. The absence of binding ABS-related instruments in China facilitates the continuing misappropriation and biopiracy.⁵ Therefore, China's State Council set out a National Biodiversity Conservation Strategy and Action Plan (2011-2030) in 2010. In this Strategy, the imperative for a comprehensive ABS framework is highlighted.⁶ Upon its accession to *the Nagoya Protocol*, China's Ministry of Ecology and Environment developed the legislative approaches, namely the *Draft Regulations* for the implementation of the *Protocol*.⁷

The *Draft Regulation* represents the first attempt by the Chinese government to establish overarching regulatory ABS mechanisms governing the entire use of genetic resources and associated TK. It has a total of seven Articles and forty-eight Provisions with objectives of promoting the ABS principles of the CBD, contributing to the conservation and sustainable use of biodiversity, and fulfilling the obligations of the Nagoya Protocol.⁸ This article aims to give an overview of the key aspects of the *Draft Regulation*, analyse its conformity with the Nagoya Protocol, identify its normative gaps and figure out the need to revamp the legislative framework under three main headings: Access, Benefit-sharing, and Compliance.

B The Regulation of Access to Genetic Resources and Associated Traditional Knowledge

Article 3 is the main provision of the *Draft Regulation* for dealing with access to genetic resources and associated TK. It lays out procedures for access to genetic resources and associated TK in order to provide legal certainties and clarities required by Article 6 and 7 of the Nagoya Protocol. Although these provisions do not define the concept of access, the procedures on accessing the genetic resource and associated TK are quite specific. Those wishing to access genetic resources and associated TK are subject to various

¹ Conference of the Parties to the Convention on Biological Diversity, Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity UNEP/CBD/COP/10/27 (2010) [103] and Annex (Decision X/1, Annex 1, 89–109) (Nagoya Protocol).

² Secretariat of the Convention on Biological Diversity, 'Parties to the Nagoya Protocol', (*Convention on Biological Diversity*) <<https://www.cbd.int/abs/nagoya-protocol/signatories/>>

³ 《生物遗传资源获取与惠益分享管理条例起草说明》 [Access and benefit-sharing regulation drafting explanation] (People's Republic of China) Ministry of Environmental Protection, 23 March 2017

⁴ Ibid

⁵ Ibid3

⁶ 《中国生物多样性保护战略与行动计划》 (2011-2030) [National Biodiversity Conservation Strategy and Action Plan (2011-2030)] (People's Republic of China) Ministry of Environmental Protection, 17 September 2010

⁷ Ibid3

⁸ Ibid3

requirements and procedures depending on the type of user, at the time of access.⁹ Notably, an important distinction is made between domestic and foreign users.¹⁰ In order to access the genetic resources and associated TK in China, foreign users are required to partner with China's domestic institutions.¹¹ Article 3.20 of the *Draft Regulation* stresses that "any foreign users' applications and acts relating to the genetic resources and associated TK in China must be conducted in China and with the substantial participation of Chinese personnel." Mandatorily, the provision also calls for foreign users to obtain the prior informed consent (PIC) of, and to negotiate benefit-sharing arrangements (known as mutually agreed terms or MAT) with the provider of the genetic resources and associated TK at all times regardless of commercial or non-commercial nature of the use.¹² What's more, while the domestic users are required to obtain another mandatory approval from the provincial level competent authority, the foreign counterparts need to obtain approval from the National Authority under the State Council prior to accessing the genetic resources and associated TK.¹³ In comparison, domestic users seeking access to genetic resources and associated TK are subject to a lighter procedure.¹⁴ According to Article 3.19 of the *Draft Regulation*, the domestic users' access to the genetic resources and associated TK for academic research purposes is exempt from PIC and MATs requirements. Nevertheless, the access to the genetic resources and associated TK for the utilization with commercial purposes is subject to PIC and MATs from the relevant resources and knowledge holders/custodians.¹⁵ It should be noted that the *Draft Regulation* also obliges those wishing to access genetic resources and associated TK to apply for a new PIC, establish new MATs and regain the government approval when their intent of access changes.¹⁶ This arrangement is consistent with one of the recommendatory requirements of the *Nagoya Protocol* addressing in particular the issue of change of intent.¹⁷

Furthermore, Article 8(b) and (c) of the Nagoya Protocol requires States to devise their national ABS legislation in a way that "pays due regards to cases of present or imminent emergencies that threaten or damage human, animal or plant health"¹⁸ and "consider the importance of genetic resources for food and agriculture and their special role for food security"¹⁹. However, the extent or form of such requirements is not further provided. These ambiguities have prompted specific provisions in the Draft Regulation that introduce legal certainty and clarity concerning these special considerations. To be specific, in response to Article 8(b) of the Nagoya Protocol, Article 3(30) of the Draft Regulation provides expeditious access to the genetic resources used for the development of vaccine and medicine in the case of a pandemic outbreak or

⁹ *The Draft Regulation* art 3.

¹⁰ *The Draft Regulation* art 3(19) and 3(20).

¹¹ *The Draft Regulation* art 3(20)

¹² *Ibid*

¹³ *Ibid*

¹⁴ *The Draft Regulation* art 3(19)

¹⁵ *Ibid*

¹⁶ *The Draft Regulation* art 3(26)

¹⁷ *The Nagoya Protocol* art 6(3) and art 8(a).

¹⁸ *The Nagoya Protocol* art 8(b).

¹⁹ *The Nagoya Protocol* art 8(c).

other emergencies, and creates the regulatory room to guarantee that general ABS procedures do not disturb health-related emergencies by giving the access applicant more time and flexibilities to go through the access procedure.²⁰ The COVID-19 crisis has demonstrated the crucial significance of rapid access to genetic resources such as pathogen samples, and genetic sequence data to quickly identify the causative agent and develop therapeutics, antiviral treatments, and vaccines.²¹ In addition, in order to address the uncertainties embedded in the Article 8(c) of the Protocol, the *Draft Regulation* makes a distinction between access to genetic resources for food and agriculture from other genetic resources in order to not interfere with certain standard uses of resources by farmers, herders and, fishermen.²² The mandatory access requirements such as obtaining PIC and establishing MATs are exempted for these standard uses.²³

To the author, these concrete access measures should be welcomed as a significant indication of the willingness of the Chinese Government to comply with access requirements provided by the Protocol in an effective way. Most provisions in *the Draft Regulation* for dealing with access to genetic resources and associated TK are written in a straightforward and simple manner, and theoretically provide for “legal certainty, clarity and transparency”, “fair and non-arbitrary rules and procedures” required under Article 6 of the Nagoya Protocol. Nevertheless, there are still some gaps where the Nagoya Protocol obligations are not sufficiently met by current laws, which will bring enormous difficulties and challenges to the stakeholders. First, in *the Protocol*, the indigenous and local communities are made beneficiaries not only when traditional knowledge is concerned, but also when genetic resources are held by these communities. However, *the Draft Regulation* avoids the human rights-cognizant term ‘indigenous peoples and local communities.’, but adopts the politically neutral term ‘holders/custodians of genetic resources and associated TK’. This situation falls short of fulfilling the Protocol’s obligation to recognize the full range of rights that should be attributed to indigenous and local communities. In addition, given the intricacy of the task of identifying the holders/custodians of genetic resources and associated TK, the primary responsibility should lie with the state to determine the identification of relevant resources and knowledge holders/custodians. However, the *Draft Regulation* does not provide the mechanism to define and identify the holders/custodians of genetic resources and associated TK. These situations exemplify the insufficiencies of the *Draft Regulation*. Second, Article 8(a) of *the Protocol* provides a general obligation for States to create simplified measures to scientific research contributing to the conservation and sustainable use when implementing their domestic ABS regime. To fulfill this provision at the national level, the domestic users for academic research purposes are not subject to the same PIC and MATs requirements as the ones for commercial purposes in China’s *Draft Regulation*. Nevertheless, this situation introduces the additional challenges of further distinguishing the academic research for non-commercial purposes and research for commercialization. This is because these days, the distinction between commercial research and non-commercial research is increasingly vague with the emergence of new technologies driving changes in how the research can be

²⁰ *The Draft Regulation* art 3(30).

²¹ Michelle Rourke et al, 'Policy opportunities to enhance sharing for pandemic research' (May 2020) 368(6492) *Science* 716-718;

²² *Ibid*

²³ *Ibid*

conducted.²⁴ Recognizing this problem, the term “academic research” should be properly defined. Also, a further attempt should be made to make a clear distinction between “commercial” research (i.e. industrial or applied) from “non-commercial” (i.e. pure or basic) research. Third, the *Draft Regulation* requires the competent authorities at different government levels to make decisions concerning the access request and set the benefit-sharing agreements which will apply to the transaction.²⁵ Nevertheless, it does not clearly specify which competent authorities have the power to grant the permit of access at different government levels. It is also unclear what exact skills and expertise the relevant competent authorities should have in support of their decision-making. No procedure is developed to appeal or review decisions of the relevant competent authorities if the application for permits is rejected. These uncertainties and lack of clarity could lead to a substantial compliance burden on the parties wishing to obtain permits to access genetic resources and associated TK and discourage legitimate activities from using genetic resources and associated TK to develop useful products. Therefore, some amendments are likely to be eventually required to address these uncertainties.

C Fair and equitable benefit-sharing obligations and limitations

The *Nagoya Protocol* uses the term “fair and equitable benefit-sharing” as the main objective with anticipation that its implementation will help ensure the conservation of biological diversity and the sustainable use of its components.²⁶ Member States to the *Nagoya Protocol* are mandated to ensure a certain level of benefit-sharing through the various mechanisms.²⁷ Recognizing this obligation, the benefit-sharing obligations enshrined in Article 5 of the *Nagoya Protocol* are addressed in China’s domestic ABS measures. The main provision concerning the benefit-sharing arrangements can be captured in Article 4 of the *Draft Regulations*,²⁸ which requires a mandatory benefit-sharing agreement (referred to as Mutually Agreed Terms, or MAT for short) to be negotiated between the provider and the user prior to access.²⁹ The *protocol* has also created some best-endeavour measures for contracting members to implement the benefit-sharing obligations. These measures can be undertaken by the States establishing minimum contents of MATs and setting out the model contractual clauses for benefit-sharing agreements. As a response to this, Article 4(31) of the *Draft Regulation* provides that:

The terms on the intended use of genetic resources, the benefit types, proportions of benefits to be shared, specific benefit allocation arrangements, and the terms on changes of intent should be mutually agreed upon and reflected in the benefit-sharing agreement.

Ministry of Environmental Protection under the State Council has the responsibility to set out the benefit-sharing agreement templates in collaboration with other relevant competent authorities under the State Council.

Notably, the substantive and procedural standards with regards to the establishment of MATs are one of the most typically unaddressed issues highlighted by the *Nagoya Protocol* aiming to provide for fair and

²⁴ Sarah Laird et al, *Biodiversity Access and Benefit-Sharing Policies for Protected Areas* (UNU/IAS Report, 2003).

²⁵ *The Draft Regulation* art 3.

²⁶ *The Nagoya Protocol* art 1.

²⁷ *The Nagoya Protocol* art 5.

²⁸ *The Draft Regulation* art 4(31).

²⁹ *Ibid*

equitable benefit-sharing.³⁰ As a result, a wide range of implementing options are left to the discretion of the Member Parties. In the author's view, as a member party to the *Protocol*, China's attempts reflected in Article 4(31) of the *Draft Regulation* to provide substantive rules with regards to the establishment of MATs are very impressive, which contributes to providing both provider and user with a useful tool for achieving fairness and equity in benefit-sharing. More importantly, the arrangements being made through a contract containing the minimum contents of MATs and model clauses will contribute to providing a way of fostering certainty and predictability concerning the contracting parties' rights and obligations in ABS transactions. Given that these provisions of the *Draft Regulation* create one set of uniform rules for all the ABS transactions, cross-jurisdiction transactions can be facilitated. Nevertheless, these provisions still have room for improvement to ensure better compliance with the *Protocol*. For instance, the *Protocol* recommends that the minimum contents of MATs specified in the national ABS measures should at least include a dispute settlement clause and terms of subsequent third-party use,³¹ which are unfortunately not implemented in the *Draft Regulation*.

Fairness and equity are identified as two critical requirements relating to benefit-sharing in the international biodiversity law.³² However, neither the *Convention* nor the *Nagoya protocol* make clear the definition of fairness and equity, and provide any guidance on how fairness and equity can be achieved, thus leaving that to be determined by national legislation.³³ To realize fairness and equity, China's *Draft Regulation* entails the establishment of explicit mechanisms for benefit-sharing. On the one hand, it establishes a National Fund for Benefit-sharing into which equitable shares of monetary payments are made and from which the monetary benefit-sharing is operated in a fair and constructive manner.³⁴ To be specific, Article 4 (33) of Draft Regulations provides that:

The national government should establish the benefit-sharing funds, which should be incorporated into the government's financial budget.

The acquirers who commercialize a product innovation incorporating genetic resources and associated TK are obliged to make a payment of between 0.5%-10% of all sales of that product to the benefit-sharing funds.

The benefit-sharing fund should be dedicated to the conservation and sustainable use of the genetic resources and associated TK. The priority must go to encourage the social and economic development in the region where these resources and knowledge originated.

³⁰ Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity* (Brill, 2014)376.

³¹ *The Nagoya Protocol* art 6(3).

³² The international biodiversity law has been referred to the Convention on Biological Diversity (CBD) 1992, 1760 UNTS 79; the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization 2014, CBD Decision X/1 (2010) Annex I; the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) 2001, 2400 UNTS 303; CBD, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization, CBD Decision VI/24 (2002) Annex; Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity* (Brill, 2014)50.

³³ *The Nagoya Protocol* art 5(1) and art 5(3).

³⁴ *The Draft Regulation* art 4(33).

On the other hand, it calls upon to establish the collective management organizations (CMOs) that are responsible for collecting and distributing the benefits arising from the utilization of the traditional knowledge.³⁵ To be specific, Article 1 (7) of the *Draft Regulation* provides that:

The collective management organization (CMO) who is appointed by the Ministry of Environmental protection and other relevant competent authorities under the State Council is responsible for collective management of the registered traditional knowledge.

Article 4 (35) of the *Draft Regulation* provides that:

It is the responsibility of the representatives of the collective management organizations (CMO) to enter into the negotiation of a benefit-sharing agreement on behalf of the traditional knowledge holders. The collective management organization (CMO) is responsible for sharing the benefits after deducting the management fees with the registered traditional knowledge holders and disclosing the relevant information to the public. The unregistered traditional knowledge holders who have submitted the requests with county-level competent authorities, within six months following disclosing date, and have obtained the approval of provincial-level competent authorities are entitled to the benefit-sharing.

In the author's view, the form of benefit-sharing based on national benefit-sharing funds established by China's *Draft Regulations* is more consistent with the nature of the genetic resources and associated traditional knowledge than the bilateral benefit-sharing contract. This is because the values of the benefit are hard to determine during the negotiation of the terms of benefit-sharing agreements as long as the results of the utilization of genetic resources and associated traditional knowledge are unpredicted. Also, the benefit-sharing agreement is usually reached with private holders/custodians of the resources or knowledge. These particular persons are usually not willing to use the benefits to conserve the genetic resources and associated traditional knowledge. However, instead of addressing the complex issue concerning who is the provider of genetic resources and associated TK and how the specific value of these resources and knowledge contribute to the final products during the negotiation of the benefit-sharing agreement, the recipient is required to pay a fixed percentage of the value of all products developed from genetic resource and associated TK to the national benefit-sharing funds. These fixed benefits distributed to the public funds can be dedicated to the conservation and sustainable use of biodiversity. Moreover, it should be noted that the so-called user-pay principle has been incorporated into the *Draft Regulation* with the intention of internalizing the costs of environmental externalities.³⁶ In other words, the users of the genetic resources and associated TK with economic purposes must make contributions to the conservation and sustainable use of genetic resources and associated TK, rather than the costs being borne by the entire society.³⁷ This principle is notably reflected by Article 4 (33) of the *Draft Regulation*, which mandates the benefit-sharing funds to be dedicated for the conservation and sustainable use of the genetic resources and associated TK.³⁸ Nevertheless, despite the simplified and facilitating nature of the benefit-sharing fund, the controversy remains concerning how to

³⁵ *The Draft Regulation* art1(7) and art 4(35).

³⁶ JULIA NA SANTILLI 'Genetic Resources Common Pools in Brazil' in Evanson Chege Kamau and Gerd Winter (ed), *Common Pools of Genetic Resources* (2013) 110-111.

³⁷ *Ibid.*

³⁸ *Ibid*24

effectively implement such an approach. Given that the flow of payments accruing to the benefit-sharing fund is far from predictable, there is a need to identify regular and foreseeable sources of income for the benefit-sharing fund as well as further explore innovative strategies of raising payments flowing into the Benefit-sharing Fund. For instance, some studies suggest the upfront payments can be made to the benefit-sharing funds so as to cover initial costs and to encourage early commitments.³⁹ Contracting Parties could also be invited to make regular contributions to the Benefit-sharing Fund.⁴⁰ The implementation of these strategies would need amendments of the relevant provisions in *Draft Regulation* to alter the nature of the obligations of the payment.

There are uncertainties and controversies surrounding the question of who would manage and protect the TK, and who would ensure the holders of TK can share fair and equitable benefit if this occurs? According to WIPO, “it seems possible in law to establish mechanisms that vest rights in communities or in the State, the effectiveness of such provisions depends upon practical considerations.”⁴¹ Therefore, as a practical consideration, it is that collective management organizations (CMOs) proposed in the *Draft Regulation* could play a role in ensuring any benefits flow to the right holders of traditional knowledge in a fair and equitable way. The CMOs are originally used as a mechanism within China’s copyright system that allows copyright owners to exercise their rights by means of CMOs.⁴² This is because the licensing and use of copyright are often associated with extensively distributed works, the adoption of the CMOs representing various publishers can significantly reduce the administrative burdens of requesting permission from different copyright owners.⁴³ Nevertheless, to the author, the functioning of the CMOs is more coherent with the nature of TK. This is because the TK is generally recognized as the collective heritage and patrimony of indigenous and local communities.⁴⁴ This nature is consistent with CMOs as a system of collective rights administration. In addition, as noted by K Swiderska et al., “Collective resource management is a key feature of traditional economies ensuring maintenance of diverse bio-resources and survival in harsh environments.”⁴⁵ That being said, the management and conservation of TK can be greatly enhanced under collective management regimes, in that the collective management regimes can be operated in harmony with traditional forms of community organizations and in compliance with community policing and norms, including communities’ customs and traditions to accommodate the interests of marginalized TK holders and address the fair and equitable sharing of benefits. For example, it could help the traditional communities

³⁹ MS Suneetha and Balakrishna Pisupati, *Benefit sharing in ABS: Options and Elaborations* (UNU-IAS Report, 2009).

⁴⁰ CS Srinivasan, *Innovative Approaches For Enhancing The Flow Of Funds Into The Benefit Sharing Fund Of The International Treaty On Plant Genetic Resources For Food And Agriculture: An Evaluation Of Options* (Technical Report, 2014) 1.

⁴¹ WIPO, *Royal Commission into Trade Union Governance and Corruption* (Background Paper, 2003)

⁴² Liu, Wenqi, 'Model for Collective Management of Copyright from An International Perspective: Potential Changes for Enhancing Performance' (2012) 17 *Journal of Intellectual Property Rights* 46-54

⁴³ Christian Handke, 'Copyright for Librarians: The Essential Handbook' in Richard Watt (ed), *Handbook of The Economics of Copyright* (2013) 2

⁴⁴ *International Indigenous Forum on Biodiversity, Opening Statement – December 8, 2003, Item 7 Sub-Working Group II on Development of Elements of a Sui Generis System for the Protection of Traditional Knowledge, Innovations and Practices of Indigenous and Local Communities*, UNEP/CBD/WG8J/3/7 (2003).

⁴⁵ K Swiderska et al. (2006). *Protecting Community Rights over Traditional Knowledge: Implications of Customary Laws and Practices* (Interim Report)19. <https://pubs.iied.org/sites/default/files/pdfs/migrate/G01253.pdf>

with the negotiations of the benefit-sharing agreements, thus ensuring the outcome and the process behind the benefit-sharing negotiation must respect the ethical customs and norms in the communities.⁴⁶ Also, with regards to collecting and sharing the benefits, the CMOs can launch a process to mediate directly between the traditional communities and the companies, thereby reducing the conflicts between.⁴⁷ Therefore, to the author, the CMOs is a special creature in the creation of equity and fairness in the negotiation of benefit-sharing and the sustainable development of communities across the country. However, it is not free from controversies. In the author's view, the challenges faced in regulating collective management of copyright will also be reflected in regulating collective management of TK. For instance, the concerns include the lack of transparency and accountability in effective operations of CMOs;⁴⁸ the oversight of unregistered right holders;⁴⁹ CMOs' monopoly status leading to potential abuse of its dominant position.⁵⁰ Many of these challenges are interrelated and can't be tackled in isolation. Therefore, the introduction of CMOs is just the first step towards an effective mechanism to ensure the equitable and fair sharing of benefits arising from the TK. Institutional changes and law revision must then follow to produce the solutions to these practical challenges.

C Provisions and Mechanisms to Promote Compliance and Monitoring

1 Monitoring Measures

As a way to support and complement the compliance obligations required by the *Nagoya Protocol*, the *protocol* points out two means of monitoring and improving transparency concerning the utilization of genetic resources: one is to appoint checkpoints;⁵¹ the other is to develop an internationally recognized certificate of compliance.⁵² These obligations are primarily implemented through Article 2(14), 2(15), 2(16), and 3(25) of China's *Draft Regulation*. Notably, Article 2(14) of the *Draft Regulation* empowers all the government sectors which have potential contact with the use of genetic resources as the checkpoints for the monitoring of the compliance status.⁵³ These responsible government agencies include but are not limited to the Ministry of Agriculture and Rural Affairs, the State Forestry and Grassland Administration, the National Administration of Traditional Chinese Medicine and National Entry and Exit Supervision, and the Administration Authority.⁵⁴ These multiple agencies are required to collaborate and coordinate their efforts to verify compliance with the rules in ABS. Moreover, the relevant characteristics and functions of the designated checkpoints are set out in Article 2(15), which calls for the checkpoints to periodically review

⁴⁶ Peter Drahos 'INDIGENOUS KNOWLEDGE, INTELLECTUAL PROPERTY AND BIOPIRACY: IS A GLOBAL BIO_COLLECTING SOCIETY THE ANSWER' (2000) 22(6) *European Intellectual Property Review* 245-250

⁴⁷ Ibid.

⁴⁸ Lu, Haijun, 'Chinese collective management of copyright: the need for extensive changes' (2016) 6(2) *Queen Mary Journal of Intellectual Property* 175-206

⁴⁹ Jiang, Ye, 'CHANGING TIDES OF COLLECTIVE LICENSING IN CHINA' (2013) 21(3) *Michigan State International Law Review* 733-734;

⁵⁰ Fuxiao Jiang and Daniel Gervais 'Collective Management Organizations in China: Practice, Problems and Possible Solutions' (2012) 15(3) *The Journal of World Intellectual Property* 221-237

⁵¹ *The Nagoya Protocol* art 17(1).

⁵² *The Nagoya Protocol* art 17(2), 17(3) and 17(4).

⁵³ *The Draft Regulation* art 2(14).

⁵⁴ Ibid

and report the access and benefit-sharing related issues to the relevant national authorities and the ABS Clearing House.⁵⁵ According to Article 2(16), these checkpoints are also granted powers to conduct field inspections to determine on an ad-hoc basis whether China's ABS rules are complied with.⁵⁶ The concrete measures for the field inspections would include: check and verify the on-field compliance; access and copy the documents; make inquires with all people concerned.⁵⁷ To the author, despite the efforts made so far, the fragmented nature of the institutional arrangements is problematic. This is because the functions of the checkpoints are highly fragmented among many different government agencies. Also, the responsibilities of different government agencies are not clearly defined. Such a typical multi-agency governing system in China is coined as "fragmented authoritarianism" by Kenneth Lieberthal, which means the responsibilities and authorities are usually delegated among different State agencies with competing functions and duties.⁵⁸ Against this background, this fragmented institutional arrangement specified in the *Draft Regulation* ignores the fact that the interests of different governmental agencies may diverge sharply from each other, thus operating with poor coordination and probably creating more legal uncertainties. Therefore, a clearer line of authorities and decision-making process to monitor the utilization of genetic resources and associated TK is needed.

Additionally, the development of the internationally recognized certificates of compliance is well reflected in Article 3(25) of *Draft Regulation* to serve as evidence of due compliance with ABS obligations.⁵⁹ Such certificates are of voluntary nature and required to be published through a national ABS Clearing House, so as to enable not only providers but also third parties to contribute to monitoring the use of resources.⁶⁰ It is noteworthy that Article 13 of the *Nagoya Protocol* provides an explicit indication that such national ABS Clearing House should also play roles in ensuring liaison with the Protocol Secretariat, in addition to be an "information hub" at the national level, so that any changes could be timely made available to the international ABS Clearing House.⁶¹ However, such an external function for the national ABS Clearing House is not reflected in the *Draft Regulation*. To align with Article 17 (4) of the *Nagoya Protocol*, the *Draft Regulation* sets out the minimum information that must be included in the certificate. It provides that:⁶²

the internationally recognized certificates of compliance must include:

- (1). The government agencies from which the certificate is issued and the date the certificate is issued.
- (2). The subject matter of the certificate.
- (3). The government agencies by which the ABS agreement is approved, and the approval date.
- (4). The direct source and place of origin of the genetic resource and associated TK
- (5). The specifics about the providers of the genetic resources and associated TK

⁵⁵ *The Draft Regulation* art 2(15).

⁵⁶ *The Draft Regulation* art 2(16).

⁵⁷ *Ibid*.

⁵⁸ Kenneth G Lieberthal 'The "Fragmented Authoritarianism" Model and Its Limitations' in Kenneth G. Lieberthal and David M. Lampton (ed), *Bureaucracy, Politics, and Decision Making in Post-Mao China* (University of California Press, 1992) 11-25.

⁵⁹ *The Draft Regulation* art 3(25).

⁶⁰ *Ibid*

⁶¹ *The Nagoya Protocol* art 13.

⁶² *Ibid*38

- (6). The specifics about the users of the genetic resources and associated TK
- (7). The summary of the benefit-sharing agreement
- (8). The approved use of the genetic resource and associated TK
- (9). Terms on third party transfer
- (10). ABS situation regarding exporting and transfer of genetic resources and associated TK.
- (11). Other relevant issues

Despite the fact that the above-mentioned provisions were carefully crafted, there are some unresolved issues that should be addressed to ensure greater clarity and coherence. For instance, similar to the wording in the *Nagoya Protocol*, the internationally recognized certificate of compliance regulated in Article 3(25) of the *Draft Regulation* remains voluntary, not tied to any motivation or other desired incentives that could convince users of the related resources and knowledge to obtain such certificates that they would not otherwise consider. To be specific, Article 3(25) provides that “the relevant competent authorities may issue the internationally recognized certificates of compliance, depending to large extent, on whether users would like to apply for one or not.”⁶³ The recommendatory wording of Article 3(25) (“may”) and the expression “depending to large extent, on whether users would like to apply for one or not” leave little doubt of the voluntary nature of the internationally recognized certificate of compliance. However, the voluntary nature of the provision does not provide the desired motivation and gives the users of the genetic resources and associated TK sufficient reasons to comply with such voluntary measures. Therefore, although the implementation of the *Nagoya Protocol* is a step towards the right path, its success depends largely on the intention of States to further cooperate on ABS issues and to adopt effective domestic measures. The *Draft Regulation*, however, contains some unclarified issues concerning the provisions on monitoring measures, which urgently need to be fine-tuned in the future.

2 Compliance Measures

The most significant innovation of the *Protocol* is its series of provisions created to apply and ensure compliance with domestic ABS requirements. In the author’s view, at least two sets of compliance obligations are created for the Contracting parties, which include 1) an obligation to establish how breaches of domestic user-side measures on compliance with provider countries’ domestic ABS rules will be addressed and sanctioned.⁶⁴ 2) an obligation to enforce the domestic user-side measures to “provide for” the respect of provider countries’ national ABS rules.⁶⁵ Hence, to address situations of non-compliance and ensure compliance with the domestic ABS frameworks of the country of origin of the relevant genetic resource and associated TK, China’s *Draft Regulation* establishes a suite of rules on compliance measures to be taken in the context of ABS.

First, the *Draft Regulation* recommends that a system of “discredited judgment debtor list” and the already established nationwide social credit system should be applied to punish the non-compliance with China’s domestic ABS rules, whereby any breaches of national ABS rules or severe malfeasance by individuals,

⁶³ Ibid38

⁶⁴ *The Nagoya Protocol* art 15(2) and 16(2).

⁶⁵ *The Nagoya Protocol* art 15(1) and 16(1).

corporations, and governmental bodies across China will lead to being publicized as untrustworthy citizen or organizations through a nationwide social credit system, and being placed in the “discredited judgment debtor list” by the government agencies or other credit assessors.⁶⁶ To be specific, China’s social credit system is a type of national reputation system aiming at creating a unified record database to monitor the behaviours of individuals, corporations, and government agencies in China.⁶⁷ Blacklists and “red-lists” form two pillars of China’s Social Credit System.⁶⁸ Blacklists are used to punish “untrustworthy” behaviors while red-lists award positive ones.⁶⁹ Among various blacklist systems, the earliest and most widely used one is the “discredited judgment debtor list”, which uses disclosure as a stimulus and uses joint and cross-departmental sanctions as means of addressing difficulties in enforcing the law.⁷⁰ In the author’s view, these mechanisms represent the most prominent manifestation of the Chinese government's determination to promote compliance and punish non-compliance with all related ABS rules through the application of well-established nationwide schemes. The system of “discredited judgment debtor list” and the nationwide social credit system have already resolved many social and environmental problems, from violation of environmental protection standards⁷¹ to corporate malfeasance⁷² resulting from a lack of trust. No doubt such mechanisms would also be effective tools for stimulating mutual trust, reducing conflicts between providers and users of genetic resources and associated TK, and making the ABS regime functional. Nevertheless, in the author’s view point, there is still a lack of clarity concerning what exactly this system entails, which is the hidden cause for speculations and misunderstandings. These uncertainties have attracted intense criticisms over concerns that they may create threats to data privacy and lead to a dystopia of social surveillance.⁷³ Therefore, the authorities and the legislators should ensure transparency and fairness of these schemes, but the urgent priorities are providing greater clarity and details about how exactly the system will run.

Second, to ensure compliance with domestic ABS rules, the *Draft Regulations* also put in place strict national export control rules to prevent unauthorized export of domestic genetic resources.⁷⁴ Article 5 of the *Draft Regulation* requires those wishing to export China’s genetic resources to obtain an exporting license from relevant competent authorities. This provision specifically spells out the minimum procedural requirements for exporting China’s genetic resources including where and how to apply for valid exporting authorization.⁷⁵

⁶⁶ *The Draft Regulation* art 2(17).

⁶⁷ A Stevenson and P Mozur 'China Scores Businesses, and Low Grades Could Be a Trade-War Weapon', *The New York Times* (2019); Nicole Kobie 'The Complicated Truth About China's Social Credit System', *WIRED UK* (2019).

⁶⁸ Louise Matsakis 'How the West Got China's Social Credit System Wrong', *WIRED UK* (2019).

⁶⁹ *Ibid*

⁷⁰ Chuncheng Liu 'Multiple Social Credit Systems in China' (2019) 21(1) *Economic Sociology: The European Electronic Newsletter* 22-32

⁷¹ 《江苏省企业环保信用评价及信用管理暂行办法》 [Interim Measures for Environmental Protection Credit Evaluation and Credit Management of Enterprises in Jiangsu Province] (People’s Republic of China) Environmental Protection Bureau in Jiangsu Province; 《企业环境信用评价办法》 [Measures for Environmental Protection Credit Evaluation of Enterprises] (People’s Republic of China) Ministry of Environmental Protection(2013).

⁷² 《企业信息公示暂行条例》 [Interim Regulation on Enterprise Information Disclosure] (People’s Republic of China) State Administration for Industry and Commerce (2014).

⁷³ Tristan Claridge 'China’s Social Credit System: An ambitious attempt to build social capital', *Social Capital* (2020).

⁷⁴ *The Draft Regulation*, Art 5.

⁷⁵ *Ibid*

To the author, these provisions reflect China's continuing efforts to promote compliance with China's domestic ABS rules by strengthening the control over the export of genetic resources. However, the *Draft Regulation* ignores the fact that while a large collection of genetic resources continues to be critical for the new drugs and products discovery of the industries, more and more bioprospectors can access useful genetic materials without going to the field or importing a large collection of genetic resources from the providers' countries. Modern technology such as synthetic biology allows for genetic information to be sequenced in situ, uploaded online as digital data, and then transferred digitally to third countries with a low risk of detection.⁷⁶ It is impossible for the relevant competent authorities such as customs to effectively control the transfer and export of genetic information. Therefore, these limitations may be abused by unscrupulous users in order to circumvent their ABS obligations.

Nevertheless, despite the efforts made so far, the author finds that there is a serious loophole in the *Draft Regulation* with regard to the implementation of the compliance obligations under the *Nagoya Protocol*. According to the *Protocol*, the Member States can choose to adopt provider-country measures on ABS but must adopt user-country measures to ensure compliance in accordance with the provider country's legislation on ABS.⁷⁷ Such user-measure requirements are established as a result of long-term pressure from developing countries on developed countries to collaborate with each other in making the ABS system functional.⁷⁸ Therefore, the extent to which the user measure requirements have been implemented domestically will, therefore, be a key indicator of the success of the *Nagoya Protocol*.⁷⁹ However, such user-side measures are not reflected in the *Draft Regulation* at all. The compliance mechanisms adopted in the *Draft Regulation* are created purely from the provider perspective, which merely requires those wishing to access genetic resources and associated TK to do so with PIC of the national competent authority in China and based on MATs for benefit-sharing with domestic stakeholders in China.⁸⁰ Strangely, the Chinese Government reported to the CBD's ABS Clearing House that China is developing a specialized regulation on ABS, which will contain provisions to implement the compliance obligations under Nagoya Protocol.⁸¹ This situation arguably reflects the fact that the legislators and regulators in China may not be clear about the theoretical underpinnings of and rationale for the user measures envisaged in the *Nagoya Protocol*. Therefore, in this manner, apart from being able to impose existing compliance measures as provided in the *Draft Regulation*, the mandatory user-side compliance obligations should also be implemented by amending existing legislation to address the gaps or loopholes.

D Overall synthesis of implementation gaps and issues of the Draft ABS Regulations of China

⁷⁶ Margo Bagley 'Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology' (2015) *SSRN Electronic Journal* 7-17.

⁷⁷ *The Nagoya Protocol* art 15- art18.

⁷⁸ Christian Prip et al, 'The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: User-Country Measures and Implementation in India' (Technical Report 2016)19.

⁷⁹ *Ibid.*

⁸⁰ *The Draft Regulation* art 2 and art 6.

⁸¹ *China's Interim National Report on The Implementation of The Nagoya Protocol* (Interim Report, 2017).

The new ABS regulations have introduced into Chinese legislation a special measure to both open the doors for innovation and provide incentives for protecting the genetic resources and their associated TK. Although the *Draft Regulation* has not become effective yet, a good start has been made with the concrete implementation of obligations under the *Nagoya Protocol*. The objectives of this article are to identify and analyse the normative gaps in China's *Draft Regulation* and figure out the need to revamp the legislative framework in order to better implement its international obligation. Accordingly, the analysis revealed that there are gaps to be remedied as outlined hereunder.

China's *Draft Regulation* fails to adequately fulfill some critical obligations listed under the global norms. Some measures proposed by the *Draft Regulation* are even in conflict with China's international obligations required specifically by the *Nagoya Protocol*. Notably, it falls short of recognizing the rights that should be attributed to the indigenous and local communities (ILCs). By doing so, the significance of customary laws, community protocols, and ILCs' collective access to a fair and equitable share of benefits arising from their ancestral resources and knowledge is largely ignored. Moreover, China's *Draft Regulation* barely pays attention to its citizens and corporations using genetic resources and associated TK from other countries, or to China's role in complying with these countries' ABS regulations. In contrast, the compliance mechanisms established in the *Draft Regulation* are created purely from the provider perspective, which is in contradiction with users' compliance measures mandated by the *Nagoya Protocol*. Also, the breadth and the fragmentation of the decision-making arrangements of the bureaucracy are severe structural problems identified in the *Draft Regulation*, with serious implications for those wishing to access genetic resources and associated TK.

As a way forward, the above-mentioned shortcomings require a systemic approach and a consistent effort to address them. Concerning the overall consistency of China's *Draft Regulation* with the *Nagoya Protocol*, severe endeavours remain to be conducted towards revising and amending the *Draft Regulation* on ABS, as well as in China's domestic implementation to demonstrate an effective commitment to fairness and equity in benefit-sharing, transparency in the access to genetic resources and associated TK, towards ensuring full respect for human rights both domestically and abroad and providing for systematic user side compliance mechanisms for redressing the balance between providers and users.